# State of New Hampshire

### DEPARTMENT OF SAFETY
JAMES H. HAYES BLDG. 33 HAZEN DR.
CONCORD, N.H. 03305
(603) 271-2791

**ROBERT L. QUINN**
**COMMISSIONER**

**RICHARD C. BAILEY, JR.**
**ASSISTANT COMMISSIONER**

**EDDIE EDWARDS**
**ASSISTANT COMMISSIONER**

January 26, 2023

His Excellency, Governor Christopher T. Sununu
and the Honorable Council
State House
Concord, New Hampshire 03301

## REQUESTED ACTION

Authorize the Department of Safety, Division of State Police (NHSP) to enter into a **Sole Source** contract with Promega Corporation (VC# 169270), Madison, WI, in the amount of $176,000.00 for the purpose of validating and employing new chemistries and forensic instruments in the New Hampshire State Police Forensic Laboratory (NHSPFL), effective upon Governor and Council approval through December 31, 2023. 100% Federal Funds.

Funds are available in FY2023 and anticipated to be available in FY2024 upon the availability and continued appropriation, with the authority to adjust encumbrances between fiscal years within the price limitation through the Budget Office, if needed and justified

| | **SFY 2023** | **SFY 2024** |
|---|---|---|
| 02-23-23-234010-26540000 ARPA - Forensic Laboratory | | |
| 103-502664 Contracts for Operational Serv | $136,000.00 | $40,000.00 |
| | Total | $176,000.00 |

## EXPLANATION

This contract is **sole source** because Promega (through its GI Validation Services team) is the only company authorized to validate their proprietary equipment including the chemistries, equipment, and workflow. The New Hampshire State Police Forensic Laboratory is implementing new processes and instruments to markedly shorten analysis time within the Forensic Biology Unit, and decrease turnaround time for the NHSPFL's casework.

Before any new method or procedure may be employed in a forensic laboratory, an internal validation must be completed to show that the method and instruments perform as expected. Promega will complete this required validation of each new instrument and chemistry to establish that the final results are reliable and consistent. These experiments must demonstrate adherence with the FBI Quality Assurance Standards for DNA Casework Laboratories and ISO/IEC 17025 guidelines in accordance with the NHSPFL's accreditation requirements. With the assistance of Promega, this validation will be finished within six to eight months of contract award. These experiments and validations would take between two to three years to finish without the assistance of Promega, delaying the new procedures from being implemented.

In the event that Federal Funds become no longer available, General Funds will not be requested to support this program.

Respectfully submitted,
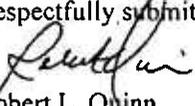
Robert L. Quinn
Commissioner of Safety

> Notice: This agreement and all of its attachments shall become public upon submission to Governor and Executive Council for approval. Any information that is private, confidential or proprietary must be clearly identified to the agency and agreed to in writing prior to signing the contract.

## AGREEMENT
The State of New Hampshire and the Contractor hereby mutually agree as follows:

## GENERAL PROVISIONS

### 1. IDENTIFICATION:

| 1.1 State Agency Name | 1.2 State Agency Address |
|---|---|
| Dept. of Safety, Division of State Police | 33 Hazen Drive, Concord, NH 03305 |

| 1.3 Contractor Name | 1.4 Contractor Address |
|---|---|
| Promega Corporation | 2800 Woods Hollow Dr. Madison, WI 53711 |

| 1.5 Contractor Phone Number | 1.6 Account Number | 1.7 Completion Date | 1.8 Price Limitation |
|---|---|---|---|
| 435-729-9209 | | December 31, 2023 | $176,000 Not to exceed |

| 1.9 Contracting Officer for State Agency | 1.10 State Agency Telephone Number |
|---|---|
| Jim Seeman | 603-223-3881 |

| 1.11 Contractor Signature | 1.12 Name and Title of Contractor Signatory |
|---|---|
| *Sharon C. Sheridan*   Date: 12/16/22 | Sharon C. Sheridan, Director, Genetic Identity |

| 1.13 State Agency Signature | 1.14 Name and Title of State Agency Signatory |
|---|---|
| [signature]   Date: 1/26/23 | Steven R. Lavoie, Director of Administration |

1.15 Approval by the N.H. Department of Administration, Division of Personnel *(if applicable)*

By:          Director, On:

1.16 Approval by the Attorney General (Form, Substance and Execution) *(if applicable)*

By: [signature]      On: 2/8/23

1.17 Approval by the Governor and Executive Council *(if applicable)*

G&C Item number:          G&C Meeting Date:

**2. SERVICES TO BE PERFORMED.** The State of New Hampshire, acting through the agency identified in block 1.1 ("State"), engages contractor identified in block 1.3 ("Contractor") to perform, and the Contractor shall perform, the work or sale of goods, or both, identified and more particularly described in the attached EXHIBIT B which is incorporated herein by reference ("Services").

## 3. EFFECTIVE DATE/COMPLETION OF SERVICES.
3.1 Notwithstanding any provision of this Agreement to the contrary, and subject to the approval of the Governor and Executive Council of the State of New Hampshire, if applicable, this Agreement, and all obligations of the parties hereunder, shall become effective on the date the Governor and Executive Council approve this Agreement as indicated in block 1.17, unless no such approval is required, in which case the Agreement shall become effective on the date the Agreement is signed by the State Agency as shown in block 1.13 ("Effective Date").
3.2 If the Contractor commences the Services prior to the Effective Date, all Services performed by the Contractor prior to the Effective Date shall be performed at the sole risk of the Contractor, and in the event that this Agreement does not become effective, the State shall have no liability to the Contractor, including without limitation, any obligation to pay the Contractor for any costs incurred or Services performed. Contractor must complete all Services by the Completion Date specified in block 1.7.

## 4. CONDITIONAL NATURE OF AGREEMENT.
Notwithstanding any provision of this Agreement to the contrary, all obligations of the State hereunder, including, without limitation, the continuance of payments hereunder, are contingent upon the availability and continued appropriation of funds affected by any state or federal legislative or executive action that reduces, eliminates or otherwise modifies the appropriation or availability of funding for this Agreement and the Scope for Services provided in EXHIBIT B, in whole or in part. In no event shall the State be liable for any payments hereunder in excess of such available appropriated funds. In the event of a reduction or termination of appropriated funds, the State shall have the right to withhold payment until such funds become available, if ever, and shall have the right to reduce or terminate the Services under this Agreement immediately upon giving the Contractor notice of such reduction or termination. The State shall not be required to transfer funds from any other account or source to the Account identified in block 1.6 in the event funds in that Account are reduced or unavailable.

## 5. CONTRACT PRICE/PRICE LIMITATION/ PAYMENT.
5.1 The contract price, method of payment, and terms of payment are identified and more particularly described in EXHIBIT C which is incorporated herein by reference.
5.2 The payment by the State of the contract price shall be the only and the complete reimbursement to the Contractor for all expenses, of whatever nature incurred by the Contractor in the performance hereof, and shall be the only and the complete compensation to the Contractor for the Services. The State shall have no liability to the Contractor other than the contract price.
5.3 The State reserves the right to offset from any amounts otherwise payable to the Contractor under this Agreement those liquidated amounts required or permitted by N.H. RSA 80:7 through RSA 80:7-c or any other provision of law.
5.4 Notwithstanding any provision in this Agreement to the contrary, and notwithstanding unexpected circumstances, in no event shall the total of all payments authorized, or actually made hereunder, exceed the Price Limitation set forth in block 1.8.

## 6. COMPLIANCE BY CONTRACTOR WITH LAWS AND REGULATIONS/ EQUAL EMPLOYMENT OPPORTUNITY.
6.1 In connection with the performance of the Services, the Contractor shall comply with all applicable statutes, laws, regulations, and orders of federal, state, county or municipal authorities which impose any obligation or duty upon the Contractor, including, but not limited to, civil rights and equal employment opportunity laws. In addition, if this Agreement is funded in any part by monies of the United States, the Contractor shall comply with all federal executive orders, rules, regulations and statutes, and with any rules, regulations and guidelines as the State or the United States issue to implement these regulations. The Contractor shall also comply with all applicable intellectual property laws.
6.2 During the term of this Agreement, the Contractor shall not discriminate against employees or applicants for employment because of race, color, religion, creed, age, sex, handicap, sexual orientation, or national origin and will take affirmative action to prevent such discrimination.
6.3. The Contractor agrees to permit the State or United States access to any of the Contractor's books, records and accounts for the purpose of ascertaining compliance with all rules, regulations and orders, and the covenants, terms and conditions of this Agreement.

## 7. PERSONNEL.
7.1 The Contractor shall at its own expense provide all personnel necessary to perform the Services. The Contractor warrants that all personnel engaged in the Services shall be qualified to perform the Services, and shall be properly licensed and otherwise authorized to do so under all applicable laws.
7.2 Unless otherwise authorized in writing, during the term of this Agreement, and for a period of six (6) months after the Completion Date in block 1.7, the Contractor shall not hire, and shall not permit any subcontractor or other person, firm or corporation with whom it is engaged in a combined effort to perform the Services to hire, any person who is a State employee or official, who is materially involved in the procurement, administration or performance of this Agreement. This provision shall survive termination of this Agreement.
7.3 The Contracting Officer specified in block 1.9, or his or her successor, shall be the State's representative. In the event of any dispute concerning the interpretation of this Agreement, the Contracting Officer's decision shall be final for the State.

Contractor Initials SCS
Date 12/16/22

## 8. EVENT OF DEFAULT/REMEDIES.

8.1 Any one or more of the following acts or omissions of the Contractor shall constitute an event of default hereunder ("Event of Default"):

8.1.1 failure to perform the Services satisfactorily or on schedule;

8.1.2 failure to submit any report required hereunder; and/or

8.1.3 failure to perform any other covenant, term or condition of this Agreement.

8.2 Upon the occurrence of any Event of Default, the State may take any one, or more, or all, of the following actions:

8.2.1 give the Contractor a written notice specifying the Event of Default and requiring it to be remedied within, in the absence of a greater or lesser specification of time, thirty (30) days from the date of the notice; and if the Event of Default is not timely cured, terminate this Agreement, effective two (2) days after giving the Contractor notice of termination;

8.2.2 give the Contractor a written notice specifying the Event of Default and suspending all payments to be made under this Agreement and ordering that the portion of the contract price which would otherwise accrue to the Contractor during the period from the date of such notice until such time as the State determines that the Contractor has cured the Event of Default shall never be paid to the Contractor;

8.2.3 give the Contractor a written notice specifying the Event of Default and set off against any other obligations the State may owe to the Contractor any damages the State suffers by reason of any Event of Default; and/or

8.2.4 give the Contractor a written notice specifying the Event of Default, treat the Agreement as breached, terminate the Agreement and pursue any of its remedies at law or in equity, or both.

8.3. No failure by the State to enforce any provisions hereof after any Event of Default shall be deemed a waiver of its rights with regard to that Event of Default, or any subsequent Event of Default. No express failure to enforce any Event of Default shall be deemed a waiver of the right of the State to enforce each and all of the provisions hereof upon any further or other Event of Default on the part of the Contractor.

## 9. TERMINATION.

9.1 Notwithstanding paragraph 8, the State may, at its sole discretion, terminate the Agreement for any reason, in whole or in part, by thirty (30) days written notice to the Contractor that the State is exercising its option to terminate the Agreement.

9.2 In the event of an early termination of this Agreement for any reason other than the completion of the Services, the Contractor shall, at the State's discretion, deliver to the Contracting Officer, not later than fifteen (15) days after the date of termination, a report ("Termination Report") describing in detail all Services performed, and the contract price earned, to and including the date of termination. The form, subject matter, content, and number of copies of the Termination Report shall be identical to those of any Final Report described in the attached EXHIBIT B. In addition, at the State's discretion, the Contractor

shall, within 15 days of notice of early termination, develop and submit to the State a Transition Plan for services under the Agreement.

## 10. DATA/ACCESS/CONFIDENTIALITY/PRESERVATION.

10.1 As used in this Agreement, the word "data" shall mean all information and things developed or obtained during the performance of, or acquired or developed by reason of, this Agreement, including, but not limited to, all studies, reports, files, formulae, surveys, maps, charts, sound recordings, video recordings, pictorial reproductions, drawings, analyses, graphic representations, computer programs, computer printouts, notes, letters, memoranda, papers, and documents, all whether finished or unfinished.

10.2 All data and any property which has been received from the State or purchased with funds provided for that purpose under this Agreement, shall be the property of the State, and shall be returned to the State upon demand or upon termination of this Agreement for any reason.

10.3 Confidentiality of data shall be governed by N.H. RSA chapter 91-A or other existing law. Disclosure of data requires prior written approval of the State.

## 11. CONTRACTOR'S RELATION TO THE STATE. In the performance of this Agreement the Contractor is in all respects an independent contractor, and is neither an agent nor an employee of the State. Neither the Contractor nor any of its officers, employees, agents or members shall have authority to bind the State or receive any benefits, workers' compensation or other emoluments provided by the State to its employees.

## 12. ASSIGNMENT/DELEGATION/SUBCONTRACTS.

12.1 The Contractor shall not assign, or otherwise transfer any interest in this Agreement without the prior written notice, which shall be provided to the State at least fifteen (15) days prior to the assignment, and a written consent of the State. For purposes of this paragraph, a Change of Control shall constitute assignment. "Change of Control" means (a) merger, consolidation, or a transaction or series of related transactions in which a third party, together with its affiliates, becomes the direct or indirect owner of fifty percent (50%) or more of the voting shares or similar equity interests, or combined voting power of the Contractor, or (b) the sale of all or substantially all of the assets of the Contractor.

12.2 None of the Services shall be subcontracted by the Contractor without prior written notice and consent of the State. The State is entitled to copies of all subcontracts and assignment agreements and shall not be bound by any provisions contained in a subcontract or an assignment agreement to which it is not a party.

## 13. INDEMNIFICATION. Unless otherwise exempted by law, the Contractor shall indemnify and hold harmless the State, its officers and employees, from and against any and all claims, liabilities and costs for any personal injury or property damages, patent or copyright infringement, or other claims asserted against

the State, its officers or employees, which arise out of (or which may be claimed to arise out of) the acts or omission of the Contractor, or subcontractors, including but not limited to the negligence, reckless or intentional conduct. The State shall not be liable for any costs incurred by the Contractor arising under this paragraph 13. Notwithstanding the foregoing, nothing herein contained shall be deemed to constitute a waiver of the sovereign immunity of the State, which immunity is hereby reserved to the State. This covenant in paragraph 13 shall survive the termination of this Agreement.

## 14. INSURANCE.
14.1 The Contractor shall, at its sole expense, obtain and continuously maintain in force, and shall require any subcontractor or assignee to obtain and maintain in force, the following insurance:

14.1.1 commercial general liability insurance against all claims of bodily injury, death or property damage, in amounts of not less than $1,000,000 per occurrence and $2,000,000 aggregate or excess; and

14.1.2 special cause of loss coverage form covering all property subject to subparagraph 10.2 herein, in an amount not less than 80% of the whole replacement value of the property.

14.2 The policies described in subparagraph 14.1 herein shall be on policy forms and endorsements approved for use in the State of New Hampshire by the N.H. Department of Insurance, and issued by insurers licensed in the State of New Hampshire.

14.3 The Contractor shall furnish to the Contracting Officer identified in block 1.9, or his or her successor, a certificate(s) of insurance for all insurance required under this Agreement. Contractor shall also furnish to the Contracting Officer identified in block 1.9, or his or her successor, certificate(s) of insurance for all renewal(s) of insurance required under this Agreement no later than ten (10) days prior to the expiration date of each insurance policy. The certificate(s) of insurance and any renewals thereof shall be attached and are incorporated herein by reference.

## 15. WORKERS' COMPENSATION.
15.1 By signing this agreement, the Contractor agrees, certifies and warrants that the Contractor is in compliance with or exempt from, the requirements of N.H. RSA chapter 281-A ("Workers' Compensation").

15.2 To the extent the Contractor is subject to the requirements of N.H. RSA chapter 281-A, Contractor shall maintain, and require any subcontractor or assignee to secure and maintain, payment of Workers' Compensation in connection with activities which the person proposes to undertake pursuant to this Agreement. The Contractor shall furnish the Contracting Officer identified in block 1.9, or his or her successor, proof of Workers' Compensation in the manner described in N.H. RSA chapter 281-A and any applicable renewal(s) thereof, which shall be attached and are incorporated herein by reference. The State shall not be responsible for payment of any Workers' Compensation premiums or for any other claim or benefit for Contractor, or any subcontractor or employee of Contractor, which might arise under applicable State of New Hampshire

Workers' Compensation laws in connection with the performance of the Services under this Agreement.

**16. NOTICE.** Any notice by a party hereto to the other party shall be deemed to have been duly delivered or given at the time of mailing by certified mail, postage prepaid, in a United States Post Office addressed to the parties at the addresses given in blocks 1.2 and 1.4, herein.

**17. AMENDMENT.** This Agreement may be amended, waived or discharged only by an instrument in writing signed by the parties hereto and only after approval of such amendment, waiver or discharge by the Governor and Executive Council of the State of New Hampshire unless no such approval is required under the circumstances pursuant to State law, rule or policy.

**18. CHOICE OF LAW AND FORUM.** This Agreement shall be governed, interpreted and construed in accordance with the laws of the State of New Hampshire, and is binding upon and inures to the benefit of the parties and their respective successors and assigns. The wording used in this Agreement is the wording chosen by the parties to express their mutual intent, and no rule of construction shall be applied against or in favor of any party. Any actions arising out of this Agreement shall be brought and maintained in New Hampshire Superior Court which shall have exclusive jurisdiction thereof.

**19. CONFLICTING TERMS.** In the event of a conflict between the terms of this P-37 form (as modified in EXHIBIT A) and/or attachments and amendment thereof, the terms of the P-37 (as modified in EXHIBIT A) shall control.

**20. THIRD PARTIES.** The parties hereto do not intend to benefit any third parties and this Agreement shall not be construed to confer any such benefit.

**21. HEADINGS.** The headings throughout the Agreement are for reference purposes only, and the words contained therein shall in no way be held to explain, modify, amplify or aid in the interpretation, construction or meaning of the provisions of this Agreement.

**22. SPECIAL PROVISIONS.** Additional or modifying provisions set forth in the attached EXHIBIT A are incorporated herein by reference.

**23. SEVERABILITY.** In the event any of the provisions of this Agreement are held by a court of competent jurisdiction to be contrary to any state or federal law, the remaining provisions of this Agreement will remain in full force and effect.

**24. ENTIRE AGREEMENT.** This Agreement, which may be executed in a number of counterparts, each of which shall be deemed an original, constitutes the entire agreement and understanding between the parties, and supersedes all prior agreements and understandings with respect to the subject matter hereof.

Contractor Initials <u>SCS</u>
Date <u>12/16/22</u>

# EXHIBIT A
## SPECIAL PROVISIONS

There are no special provisions.

# EXHIBIT B
## SCOPE OF SERVICES
## STATEMENT OF WORK (SOW) AND TECHNICAL REQUIREMENTS AND DELIVERABLES

The New Hampshire State Police Forensics Laboratory (NHSPFL; also referred to as the "Laboratory") is implementing the use of new chemistries and instruments in order to compress evidence analysis timelines and increase efficiencies to decrease turnaround time for casework. Before these new methods and instruments may be employed by a forensic laboratory, a validation must take place to show that the method(s) and equipment perform as expected. This validation must be conducted in adherence to FBI Quality Assurance Standards for DNA Casework Laboratories and ISO/IEC 17025 guidelines. These are part of NHSPFL's accreditation requirements.

## 1. CONTRACT TERM

The Contract shall begin on the Effective Date and extend until December 31, 2023. This completion date anticipates services will begin in February and is contingent upon efficient review of data and any decisions that the Laboratory and Contractor need to make.

## 2. STATEMENT OF WORK

Promega ("The Contractor") shall develop and execute a Validation Plan and post-validation training in support of the NHSPFL's new instrumentation (RSC 48 robots; QuantStudio5s; Spectrum Genetic Analyzers) and their associated chemistries. All validation experiments (detailed below, and as further described in The Attachments) must be reviewed and approved by the NHSPFL DNA Technical Leader prior to beginning work. The Contractor shall communicate the need for any samples to be provided by NHSPFL at least 30 days prior to the start of the validation in which they will be needed. All validation experiments must conform to the following standards:

### 2.1 Mandatory Standards
2.1.1 FBI Quality Assurance Standards for Forensic DNA Testing Laboratories (7/2020)(see Attachment 1.4)
2.1.2 FBI Quality Assurance Standards for Database Testing Laboratories (7/2020)(see Attachment 1.5)
2.1.3 ISO/IEC 17025:2017 for Testing and Calibration Laboratories
2.1.4 Scientific Working Group on DNA Analysis Methods (SWGDAM) Validation Guidelines, Section 3 (Developmental Validation) and Section 4 (Internal Validation).

### 2.2 Training

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The Contractor shall develop a training plan, and provide training for the NHSPFL staff consisting of:

    2.2.1   Presentation of method and validation data;

    2.2.2   Post-validation, 10 hours of virtual or in-person support for each internal validation method;

    2.2.3   Post-validation, provide up to 40 hours of virtual or in-person support for the developmental validation of PowerPlex 35GY on the Spectrum CE System.

    2.2.4   As part of the validation project for PowerPlex 35GY for direct amplification samples, a separate remote training will be conducted, as outlined in Section 3.9 of Exhibit B.

**2.3 Work Requirements:** Work will be performed on-site at the New Hampshire State Police Forensic Laboratory between the hours of 0800 and 1630. The Contractor shall communicate the need for any samples to be provided by the NHSPFL at least 30 days prior to the start of the validation in which they will be needed.

**2.4 Validation Plan/Validation of Instruments and Methods:**

    2.4.1   The validation plan will be reviewed and approved by the NHSPFL DNA Technical Leader prior to the commencement of work.

    2.4.2   The Contractor shall perform validation of the following instrumentation and methods, as set forth below and as detailed in Section 3 Technical Requirements:

        2.4.2.1.  Casework Direct System for the extraction of forensic samples to include known reference samples, mock sexual assault kit evidence samples, mock touch DNA type forensic evidence samples, and other forensic type samples, such as cigarette butts, bottles, etc.

        2.4.2.2.  Maxwell RSC 48 instrument with DNA IQ chemistry to purify genomic DNA from forensic type samples, to include known DNA reference samples, mock evidence samples, mock evidence samples resulting in mixtures, and casework direct extracts.

        2.4.2.3.  QuantStudio5 Real-Time PCR System with PowerQuant system for the quantification of genomic DNA forensic type samples.

        2.4.2.4.  PowerPlex 35GYon Spectrum CE System for casework samples

        2.4.2.5.  PowerPlex 35GY on Spectrum CE System for direct amplification of database samples.

        2.4.3.  Further guidance is contained in Attachment 1.3, PowerPlex 35GY Planning Table.

**3.    TECHNICAL REQUIREMENTS FOR VALIDATION OF CASEWORK/VALIDATION PROCESS**

All of the Quality Assurance and Mandatory Standards set forth in Section 2 of this contract are incorporated into this section as if fully set forth herein. The Quality Assurance and Mandatory Standards, along with the steps contained in each Test/Validation section below are further defined in the Attachments.

**3.1 Workflow Optimization of Casework Direct System**

    **3.1.1 Optimization:**

        3.1.1.1.  Swab cutting size evaluation

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3.1.1.2. Volume of Casework Direct Solution evaluation

3.1.1.3. Comparison of Casework Direct Lysates quantified with PowerQuant® to swabs screened with current serology method

*Note: The laboratory will perform the serology of the remaining swabs following their currently validated methods.*

3.1.1.4. Samples that will be tested will include a semen dilution on vaginal swabs and post coital swabs provided by the laboratory (or purchased by the Laboratory).

3.1.1.5. · A subset will be amplified (if desired by NHSPFL).

### 3.1.2. Optimization for Touch:

3.1.2.1. Swab cutting size evaluation

3.1.2.2. Volume of Casework Direct Solution evaluation

3.1.2.3. Comparison of Casework Direct Lysates quantified with PowerQuant® to swabs processed with current method

*Note: Th Laboratory will perform the extraction of the remaining swabs following their currently validated methods.*

3.1.2.4. Samples that will be tested will include gun swabs and swab types commonly encountered in the laboratory

3.1.2.5. A small sampling will be amplified (if desired).

## 3.2 Validation of Casework Direct System

### 3.2.1 Sensitivity

3.2.1.1 One donor of semen and one donor of saliva will be extracted in triplicate with Casework Direct System using the following input volumes: 10µl, 5µl, 1µl, 0.5µl, 0.25 µl, 0.1µl, 0.05µl and 0.01µl.

3.2.1.2 *The Laboratory* will perform extractions using their currently validated extraction method for comparison.

3.2.1.3. All extracts will be quantified using PowerQuant® and amplified.

3.2.1.4 *The Laboratory* will perform serology testing with the option to do differentials on any semen containing samples according to current protocol to correlate results to the Casework Direct System lysates.

3.2.1.5. All Casework Direct System lysates will be quantified and amplified.

### 3.2.2. Precision/Accuracy/Repeatability

3.2.2.1. One donor of semen will be extracted in triplicate using two different extraction sets.

3.2.2.2. Both extraction sets will be quantified.

3.2.2.3. Concentrations of DNA from different replicates will be compared within extraction sets and between extraction sets.

### 3.2.3. Known and Non-probative or Mock Evidence Samples

3.2.3.1. 1-3 known buccal swabs will be extracted with the Casework Direct System.

3.2.3.2. 15 non-probative or mock evidence samples (SAK type samples) will be extracted with the Casework Direct System for y-screening.

3.2.3.3. 15 non-probative or mock evidence samples (touch type samples) will be extracted with the Casework Direct System.

3.2.3.4. The Laboratory will perform serology testing with the option to do differentials on any semen containing samples according to current protocol to correlate results to the Casework Direct System lysates. The Laboratory will perform extractions following their current extraction method for comparison for touch samples.

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3.2.3.5. All extracts will be quantified using PowerQuant® and amplified.

3.2.3.6. Any sample showing signs of inhibition will be processed using the Maxwell® RSC 48.

**3.2.4. Male/Female Mixture Studies**

3.2.4.1. Semen will be extracted in triplicate with Casework Direct System using the following input volumes: 10µl, 5µl, 1µl, 0.5µl, 0.25 µl, 0.1µl, 0.05µl and 0.01µl spotted on vaginal swabs (volumes subject to change).

3.2.4.2. *The laboratory* will perform serology testing with the option to do differentials on any semen containing samples according to current protocol to correlate results to the Casework Direct System lysates.

3.2.4.3. All Casework Direct System lysates will be quantified using PowerQuant® and amplified.

**3.2.5. Contamination:** All negative controls will be evaluated for contamination

*Note:* a subset of samples processed with the Casework Direct System will be processed through the Maxwell® RSC 48 to show compatibility for any samples needing post extraction purification.

**3.3 Maxwell RSC 48 Instrument**

A full validation will be done on **one** Maxwell® RSC 48 instrument. A performance check will be performed on one additional instrument. The performance check will include precision (1 body fluid), sensitivity (1 donor), and contamination.

**3.3.1 Sensitivity**

3.3.1.1 Extractions will be performed using blood from 2 donors. Extractions for each sample will be done in triplicate. Volumes of blood extracted will include: 50µl, 10µl, 5µl, 1µl, 0.2µl, 0.04µl, and 0.008µl.

3.3.1.2. Samples will be quantified.

3.3.1.3. Data generated will include graphs/tables detailing:

a. Average and standard deviation of the quantification values for each target for each sample

b. Average total DNA yield summary

c. Linearity of the system

**3.3.2. Precision/Repeatability Study**

3.3.2.1. Three replicates of blood and semen from one donor will be extracted on two different Maxwell® runs.

3.3.2.2. Samples will be quantified.

3.3.2.3. Data generated will include graphs/tables detailing:

a. Average, standard deviation, and CV% of the quantification values for each target for each sample for within runs and between runs

**3.3.3. Known and Non-probative Evidence Samples or Mock Evidence Samples**

3.3.3.1. 15 known samples will be extracted.

3.3.3.2. 25 non-probative or mock evidence samples will be extracted.

3.3.3.3. Samples will be quantified.

3.3.3.4. All known and non-probative or mock samples will be manually normalized and amplified.

3.3.3.5. Data generated will include graphs/tables detailing:

a. Average DNA concentration for each sample for each target

Contractor Initials SCS

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b. Average peak height for each known sample

c. A table with the quantification results and STR results will be provided

### 3.3.4. Mixture Samples

3.3.4.1 One differential mixture set will be tested using the desired pre-Maxwell processing for cell separation (laboratory performs protocol).

a. 1:1, 1:5, 1:25, and 1:125 ratios will be tested with each mixture sample. Samples will be extracted in duplicate.

3.3.4.2. One non-differential mixture set will be tested.

a. 1:1, 1:5, 1:25, and 1:125 ratios will be tested with each mixture sample. Samples will be extracted in duplicate.

3.3.4.3. Samples will be quantified.

3.3.4.4. All mixture samples will be manually normalized and amplified.

3.3.4.5. Data generated will include graphs/tables detailing:

a. Average DNA concentration for each sample for each target

b. Average [Auto]/[Y] for each sample

c. Percent minor profile called for the non-differential samples

d. Genotype tables

### 3.3.5. Contamination Study

3.3.5.1. Multiple negative controls will be on each Maxwell® extraction run.

3.3.5.2 All negative control samples will be quantified.

3.3.5.3. Negative controls will be amplified if quantification values are observed.

### 3.3.6. Workflow

3.3.6.1. Samples will be pre-processed with the Casework Extraction Kit.

3.3.6.2. Extraction on Maxwell® RSC 48 with manual cartridge set-up of the Maxwell® FSC DNA IQ™ Casework Kit.

3.3.6.3. Manual quantification set up.

3.3.6.4. Manual amplification setup with previously determined optimal template.

3.3.6.5. Manual CE setup using one injection condition.

### 3.4. PowerQuant Validation

A full validation of PowerQuant® shall be done on *one* Applied Biosystems® QuantStudio™ 5. A performance check shall be performed on one additional instrument. The performance check will include precision, sensitivity, and contamination.

### 3.4.1. Precision/Reproducibility/Accuracy

3.4.1.1. Dilutions of the 50ng/μl PowerQuant® Male Genomic DNA Standard to 45ng/μl, 10ng/μl, 0.40ng/μl, and 0.016ng/μl will be tested.

3.4.1.2 Three replicates of the dilution series will be quantified on a single plate to demonstrate "intra-plate" reproducibility and precision.

3.4.1.3. Three replicates of the dilution series will be quantified on an additional plate to demonstrate "inter-plate" reproducibility and precision.

3.4.1.4. The average, standard deviation, and %CV of the autosomal, Y, degradation quantification values and IPC Cq values, [Auto]/[Y] ratios, and [Auto]/[Deg] ratios for each DNA concentration for "intra-plate" and "inter-plate" results will be determined.

### 3.4.2 Known and Non-Probative or Mock Evidence Samples

3.4.2.1 Fifteen known samples and 15 non-probative or mock evidence samples will be quantified in duplicate using PowerQuant®.

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3.4.2.2     The 15 known samples will be quantified by the laboratory with the current quantification system so that the new STR target can be mathematically calculated. The known samples used should have an [Auto]/[Y] ratio close to 1.

3.4.2.3.     Each of the 15 known samples and 15 non-probative or mock evidence samples will be amplified.

### 3.4.3.   Sensitivity and Stochastic Studies:

3.4.3.1     Dilutions of 0.025ng/µl, 0.005ng/µl, 0.001ng/µl, 0.0002ng/µl and 0.00004ng/µl using 3 male samples will be quantified in duplicate.

3.4.3.2.     The dilutions will be amplified for each donor in duplicate using max volume of the system.

### 3.4.4.   Male/Female Mixture Studies

3.4.4.1     Two sets of male/female mixtures with the following ratios will be created: 1:1, 1:3, 1:9, 1:15, 1:19, 1:25, 1:35, 1:50, and 1:100.

3.4.4.2     Each mixture series will be quantified in duplicate using PowerQuant® to determine the amount of DNA present in the samples, as well as the [Auto]/[Y] ratio.

3.4.4.3     The mixtures will be amplified in duplicate.

3.4.4.4.     The amplified results will be compared to [Auto]/[Y] ratios and autosomal and Y quantification values obtained from PowerQuant®.

### 3.4.5.   Degraded/Inhibited Samples

3.4.5.1.     One DNA sample will be used during these studies.

3.4.5.2.     The sample will be exposed to 0mJ, 50mJ, 100mJ, and 300mJ using a UV Stratalinker.

3.4.5.3.     Three humic acid concentrations will be tested.

3.4.5.4.     Three hematin concentrations will be tested.

3.4.5.5.     The amount of DNA present in the samples, the IPC cycle shift, as well as the [Auto]/[Deg] ratio values using PowerQuant® will be determined.

3.4.5.6.     The samples will be amplified in duplicate using optimal template or the max volume.

### 3.4.6.   Contamination: Multiple negative controls will be evaluated for contamination on each plate.

### 3.4.7.   Workflow

3.4.7.1.     Manual quantification set up.

3.4.7.2.     Manual amplification setup with previously determined optimal template.

3.4.7.3.     Manual CE setup using one injection condition.

### 3.4.8.   Conditions

3.4.8.1.     Default quantification conditions

       a.   20µL reaction volume (7µL Water, Amplification Grade, 10µL PowerQuant® 2X Master Mix, 1µL PowerQuant® 20X Primer/Probe/IPC Mix, and 2µL template).

### 3.5.   PowerPlex® Y-STR containing STR kit for Casework

A full validation of a PowerPlex® Y-STR containing kit will be done on one instrument. A performance check will be performed on Spectrum CE System for casework samples. The performance check will include precision, accuracy, sensitivity, and contamination assessment.

### 3.5.1.   Sensitivity, Analytical and Stochastic Threshold Study

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3.5.1.1     Sensitivity dilutions of extracted DNA (1.0ng, 500pg, 250pg, 125pg, 62.5pg, 31.25pg, 15.6pg, 7.8pg) will be amplified in triplicate using two different DNA samples. **Note**: these values may change depending on the optimal template of the chosen kit.

3.5.1.2.     Data generated will include graphs/tables detailing:

    a. Average peak heights of all samples
    b. Peak height ratios for all samples
    c. Calculated analytical threshold including noise distribution charts
    d. Assessment of dropout from dilution series and calculated stochastic threshold
    e. Linearity of the system

### 3.5.2. Accuracy Study

3.5.2.1.     Positive control samples (2800M) will be amplified on at least three different amplification plates.

3.5.2.2.     NIST 2391d samples will be amplified.

3.5.2.3.     Data generated will include the following graphs/tables:

    a. Genotype concordance table verifying reproducibility between amplification plates for 2800M.
    b. Average peak height table for 2800M.
    c. Concordance table verifying reproducibility for NIST 2391d samples as compared to NIST published profiles.

### 3.5.3. Known and Non-probative Evidence Samples or Mock Evidence Samples

3.5.3.1.     Fifteen known samples will be amplified and compared to previously obtained profiles.

3.5.3.2.     Fifteen non-probative evidence samples or mock evidence samples will be amplified.

3.5.3.3.     Data generated will include graphs/tables detailing:

    a. Genotypes concordance tables
    b. Average peak heights of all known single source samples
    c. Peak height ratios of all known single source samples

### 3.5.4. Mixture Samples

3.5.4.1.     Two-Person Mixture

    a. Two mixture sets will be tested using high quality DNA.
       i.    1:1, 2:1, 3:1, 5:1, 9:1, 15:1, 25:1 for mixture sets 1 and 2 (made from 4 different donors).
    b. One mixture set will be tested using DNA from degraded DNA
       i.    1:1, 2:1, 3:1, 5:1, 9:1, 15:1, 25:1 for mixture set 3.
    c. Each 2-person mixture sample will be amplified in duplicate at optimal template and a low template amount.
    d. Data generated will include graphs/tables detailing:
       i.    Percentage of unique minor alleles
       ii.    Percent contribution by peak height

3.5.4.2.     Three and Four-Person Mixture

    a. Three-person mixture set will be tested using high quality DNA.
       i.    1:1:1, 5:5:1, 5:1:1, 10:1:1, and 10:5:1 for mixture set.
    b. Four-person mixture sets will be tested using high quality DNA.
       i.    1:1:1:1, 10:5:2:1, 4:3:2:1, 10:10:1:1, 10:10:10:1, 10:1:1:1 for mixture set.

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c. Each 3 and 4-person mixture will be amplified in optimal template and a low template amount.
d. Total number of alleles present will be calculated for 3+ person mixtures.

### 3.5.5. Contamination Study
3.5.5.1.   Multiple negative controls will be on each plate.
3.5.5.2.   All negative controls will be assessed at the analytical threshold for contamination.

### 3.5.6 Workflow
3.5.6.1.   Amplification reactions will be set up in 96-well plates.
3.5.6.2.   Manual amplification setup.
3.5.6.3.   Manual CE setup.

### 3.5.7. Conditions
3.5.7.1.   Default amplification conditions.
    a. 25μL reaction volume.
    b. One cycle number option will be tested.
3.5.7.2.   Default injection conditions
    a. One injection time will be used.
3.5.7.3.   Samples analyzed with software version preferred by laboratory

## 3.6   Post Validation Training
The Contractor shall develop a training plan, and provide training for the NHSPFL staff as outlined more fully in Section 2.2 Training, in Exhibit B of this contract.

## 3.7   Timeline
**3.7.1. Pre-validation**: During this phase of the validation process, the Contractor and the Laboratory will discuss proposal, options for start dates, expectations of the materials that the Laboratory is expected to provide, and expectations from Promega during the validation process.

**3.7.2. Validation**
3.7.2.1   On-site laboratory work to be completed by Promega
3.7.2.2.   Off-site data analysis and write-up of report

**3.7.3. Post validation training**: Background presentation and validation review in addition to the training as set forth more fully in Section 2.2 Training, in Exhibit B of this contract.

## 3.8   PowerPlex 35GY Direct Amplification Validation
The Contractor will perform a full validation of PowerPlex on one capillary electrophoresis instrument with a performance check on a second Spectrum CE System.  This check will include precision, accuracy, sensitivity, and contamination assessment. All of the Quality Assurance and Mandatory Standards set forth in Exhibit B,Section 2 of this contract are incorporated into this section as if fully set forth herein.  The Quality Assurance and Mandatory Standards, along with the steps contained in each Test/Validation section below are further defined in the Attachments.

**3.8.1. Cycle Number Optimization**: Fourteen commonly used database-type samples will be amplified in duplicate using three cycle numbers.

**3.8.2. Known Sample Concordance Study**
3.8.2.1.   Forty known samples provided by the laboratory will be amplified in duplicate.
3.8.2.2.   Date generated will include graphs/tables detailing:

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a. Genotype concordance table.
b. Average peak height tables and graph.
c. Table provided with success rate.

### 3.8.3. Sensitivity, Analytical and Stochastic Threshold Study

3.8.3.1. Sensitivity dilutions of extracted DNA (20ng, 10ng, 5.0ng, 2.5ng, 1.0ng, 500pg, 400pg, 300pg, 200pg, 100pg) will be amplified in triplicate at the desired cycle number using two different DNA samples.

3.8.3.2. Data generated will include graphs/tables detailing:
a. Average peak heights of all samples.
b. Peak height ratios for all samples.
c. Calculated analytical threshold including noise distribution charts.
d. Assessment of dropout from dilution series and calculated stochastic threshold.
e. Linearity of the system.

### 3.8.4. Accuracy Study

3.8.4.1. Positive control sample (2800M) will be amplified on different amplification plates.

3.8.4.2. NIST 2391d sample(s) will be amplified in duplicate.

3.8.4.3. Date generated will include the following graphs/tables:
a. Genotype concordance table verifying reproducibility between amplification plates for 2800M.
b. Average peak height table for 2800M.
c. Concordance table verifying reproducibility for NIST 2391d samples as compared to NIST published profiles.

### 3.8.5. Contamination Study

3.8.5.1. Multiple negative controls will be on each plate.

3.8.5.2. All negative controls will be assessed at the analytical threshold for contamination.

### 3.8.6. Workflow

3.8.6.1. Amplification reactions will be set up in 96-well plates.

3.8.6.2. Manual CE setup.

### 3.8.7. Conditions

3.8.7.1. Default amplification conditions
a. AmpSolution will be added to reactions for appropriate sample types.
b. SwabSolution will be added to reactions for appropriate sample types.

3.8.7.2. Default injection conditions
a. One injection time will be used for full validation with the possible option of a reduced injection condition for saturated samples.

3.8.7.3. Samples analyzed with software version preferred by the Laboratory.

### 3.9 Post Validation Training

Training for the Internal Validation Experimental Design of PowerPlex 35GY for Direct Amplification Samples will be included as part of the validation. Training will be conducted remotely, and consist of a presentation with background on PowerPlex 35GY and the validation results.

## 4.0 DELIVERABLES, REVIEW, AND ACCEPTANCE

### 4.1 Delivery and Acceptance of Data, Validation Data, and Summaries

4.1.1 Validation data and summaries will be provided for each validation. The Contractor will work with the Laboratory to ensure that the summaries are acceptable for the

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Laboratory's standards and to address any concerns or need for additional information on any method.

4.1.2. The validation data and summaries will be reviewed and approved by NHSPFL's Technical Leader and Biology Unit Supervisor.

4.1.3. The contractor will provide the method protocols used for the validations to the laboratory.

4.1.4. Developmental validation report resulting from the experiments with the Spectrum instrument and PowerPlex 35GY kit shall be submitted to the FBI for NDIS approval within 7 days after review and approval of the write up by the Laboratory.

4.1.5. Should the validation of PowerPlex 35GY conducted at NHSPFL show levels of stutter and/or artifacts that deviate from the study conducted by the manufacturer, an additional study will be conducted by the vendor to establish NHSPFL laboratory specific stutter values and artifact determinations.

4.1.6. Should the validation of PowerPlex 35GY fail to produce results acceptable to the NHSPFL or receive the FBI's NDIS approval, a currently NDIS-approved PowerPlex STR and Y-STR kit will be validated for both casework and database samples by the vendor at no additional cost.

**4.2. Deliverables for Internal Validation of the Maxwell RSC 48 Instrument, Casework Direct System, PowerQuant System, and PowerPlex STR system (see Sections 3.1 to 3.5 in this Exhibit for further reference).**

4.2.1 Electronic copy of the validation report

4.2.2 All summary files for analyzed data (.xls)

4.2.3 All .eds files from throughout validation

4.2.4. All .HID files from throughout validation

4.2.5. .pdfs of electropherograms used during the validation

4.2.6. All testing notes related to validation project

**4.3. Deliverables for Internal Validation of the PowerPlex 35GY for Direct Amplification**

4.3.1. Electronic copy of the validation report

4.3.2 All summary files for analyzed data (.xls)

4.3.3 All .fsa files from throughout validation

4.3.4. .pdfs of electropherograms used during the validation

4.3.5. All testing notes related to validation project

**4.4 Conditional and Unconditional Acceptance**

By accepting a Deliverable, the State reserves the right to reject any and all deliverable in the event the State detects any Deficiency in the system or methods.

## 5.0 PROJECT MANAGEMENT & RQUIREMENTS

### 5.1. The Contractor's Key Staff

The Project requires the coordinated efforts of the NHSPFL ("the Laboratory") and Contractor personnel.

5.1.1. The Contractor's Contract Manager

The Contract Manager shall be responsible for all Contract authorization and administration:

Rachel Frieders
(608) 210-5999
rachel.frieders@promega.com

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5.1.2      The Contractor's Project Manager
The Project Manager must be qualified to perform or supervise the Contractor's
obligations under this agreement. The Project Manager shall have full authority to make
binding decisions under the Contract, and shall function as the Contractor's
representative for administrative and management matters.

Jonelle Thompson
435-729-9209
Jonelle.Thompson@promega.com

## 5.2      The State's Key Project Staff
5.2.1. .      The State Contract Manager
The Contract Manager shall function as the State's representative with regard to
Contract Administration:

Jim Seeman
603-223-3881
James.W.Seeman@dos.nh.gov

5.2.2.      The State's Project Manager
The State's Project Manager is:

Megan O'Donnell
603.223-8353
Megan.O.O'Donnell@dos.nh.gov

5.2.3      Additional Key State Personnel:

Katie Swango (DNA Technical Leader for NHSPFL)
603-223-3854
Katie.L.Swango@dos.nh.gov


## EXHIBIT C
## PRICING AND PAYMENT TERMS

## 1.  CONTRACT PRICE
This is a Not to Exceed Contract.  Notwithstanding any provision in the Contract to the contrary,
and notwithstanding unexpected circumstances, in no event shall the total of all payments made
by the State exceed the amount indicated in P-37 General Provisions – Block 1.8: Price Limitation.
The payment by the State of the total Contract price shall be the only, and the complete
reimbursement to the Contractor for all fees and expenses, of whatever nature, incurred by the
Contractor in the performance hereof.

## 2.  INVOICING
The Contractor shall submit correct invoices to the State for all amounts to be paid by the State.
The Contractor shall only submit invoices for Services or Deliverables as permitted by the Contract.

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Invoices should contain detailed information, to include (without limitation): itemization of each validation and date of satisfactory completion, and identification of the deliverable for which payment is being sought. Upon acceptance of a Deliverable, and a properly documented and undisputed invoice, the State will pay the correct and undisputed invoice within thirty (30) days of invoice receipt.

3. **INVOICE ADDRESS**

   Invoices must be sent to:

   Department of Safety
   accountspayable@dos.nh.gov

4. **PAYMENT ADDRESS**
   Payments shall be made via ACH. The Contractor must use the following links to enroll with the New Hampshire State Treasury for ACH payments:

   State of New Hampshire - Online Vendor Registration (nh.gov)

   Vendor-Application-and-W9.pdf (nh.gov)

   **4.1 Contract Pricing**

   4.1.1. Cost of Validation of Maxwell® RSC 48 with one performance check

   |  | Timeframe | Cost |
   |---|---|---|
   | GI On-Site Validation and Implementation (S1 1.1.1) | ~1 week | $12,500 |
   | GI Off-Site Validation and Implementation (S1112) | ~5 weeks | $37,500 |
   | GI Training (S1113) | As per Sec. 2.2 | $1,500 |
   | Discount | ~7% | -$3,500 |
   | Total | | $48,000 |

   4.1.2. . Cost of Validation of Casework Direct Kit

   |  | Timeframe | Cost |
   |---|---|---|
   | GI On-Site Validation and Implementation (S1.1.1.1) | ~2 weeks, | $25,000 |
   | GI Off-Site Validation and Implementation (S1112) | ~4 weeks | $30,000 |
   | GI On-Site Training (S1113) | As per Sec. 2.2 | $1,500 |
   | Discount* | 100% | -$56,500 |
   | Total | | $0 |

   *Discount based on commitment to the other projects contained in this contract

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### 4.1.3. Cost of Validation of PowerQuant

| | Timeframe | Cost |
|---|---|---|
| GI On-Site Validation and Implementation (S1111) | ~1 week | $12,500 |
| GI Off-Site Validation and Implementation (S1112) | ~5 week | $37,500 |
| GI On-Site Training (S1113) | As per Sec. 2.2 | $1,500 |
| Discount | ~14.5% | -$7,500 |
| Total | | $44,000 |

### 4.1.4 Cost of Validation of PowerPlex Y-STR containing STR Kit

| | Timeframe | Cost |
|---|---|---|
| GI On-Site Validation and Implementation (S1111) | ~1 week | $12,500 |
| GI Off-Site Validation and Implementation (S1112) | ~5.5 week | $41,250 |
| GI On-Site Training (S1113) | As per Sec. 2.2 | $1,500 |
| Discount | -20% | -$11,250 |
| Total | | $44,000 |

### 4.1.5. Cost of Validation for PowerPlex 35GY for Direct Amplification

| | Timeframe | Cost |
|---|---|---|
| GI On-Site Validation and Implementation (S1111) | ~1 week | $12,500 |
| GI Off-Site Validation and Implementation (S1112) | ~3.5 week | $26,250 |
| GI On-Site Training (S1113) | As per Sec. 3.9 | $1,250 |
| Total | | $40,000 |

## ATTACHMENTS

## 1. ATTACHMENTS

1.1 Contractor's Quote for Internal Validation of Maxwell RSC 48 Instrument, Casework Direct System, PowerQuant System, and PowerPlex System (includes proposed Scope of Work)

1.2 Contractor's Quote for Internal Validation Experimental Design of PowerPlex 35GY for Direct Amplification Samples (includes proposed Scope of Work)

1.3 PowerPlex 35GY DV Planning Table

1.4 FBI Databasing QAS 2020

1.5 FBI Forensic Testing QAS 2020

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# Scope of Work for Internal Validation of the Maxwell® RSC 48 Instrument, Casework Direct System, PowerQuant® System, and a PowerPlex® STR system.

## Contents

# 1. Introduction

Before an established method or procedure may be employed in a forensic laboratory, an internal validation must be completed to show that the method performs as expected. This proposal outlines a set of experiments that confers conformance with the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories, ISO/IEC 17025 standards, and the validation guidelines outlined by the Scientific Working Group on DNA Analysis Methods (SWGDAM). These experiments are designed to demonstrate the reliability of the Maxwell® RSC 48 instrument with DNA IQ™ chemistry to purify genomic DNA from forensic type samples. Also, these experiments are designed to demonstrate the sensitivity and reliability of the Casework Direct System, PowerQuant® system, and a PowerPlex® Y-STR containing STR kit. Upon completion of these experiments the laboratory will have sufficient data to develop a methodology to produce quality DNA extracts from casework samples and a methodology for the Maxwell® RSC 48, Casework Direct System, PowerQuant®, and a PowerPlex® Y-STR containing STR kit.

# 2. FBI Quality Assurance Standard

Standard 8.3.1: Internal validation studies shall include as applicable: known and non-probative evidence samples or mock evidence samples, precision and accuracy studies, sensitivity and stochastic studies, mixture studies, and contamination assessment studies.

## A. *Sensitivity*

Sensitivity studies are used to demonstrate the range of an assay. By testing a range of volumes of a body fluid, the laboratory can define the limits of the extraction method. By testing a lower range of DNA concentrations, the laboratory can determine the reliability of the [Auto]/[Y] and [Auto]/[Deg] ratios in the quantification reaction. By testing a range of DNA templates, the laboratory can define the analytical threshold, optimal target range, and stochastic threshold for the amplification kit.

## B. *Calculating Analytical and Stochastic Threshold (STR kit only)*

Signal-to-noise assessment of sensitivity data can help define an appropriate analytical threshold for the amplification system on the chosen CE instrument. The method described below is one of many scientific methods that can be used to analyze these data.

> The sensitivity sample profiles that contain minimal pull-up and are within the linear range of the CE instrument will be used to calculate the analytical threshold. The baseline will be examined for "noise" peaks—those that are not part of the profile, not stutter peaks and not known (or reproducible) artifacts of the system. To obtain peak height values for these low-level "noise" peaks, the calling threshold in your analytical software system will be set sufficiently low, such as 1RFU. Once the "noise" peaks are identified, the average peak height and standard deviation for these peaks will be calculated. The average peak height plus X standard deviations will define the analytical threshold, where X refers to the number of standard deviations needed to achieve the desired confidence level. Choose a confidence level that is appropriate for your laboratory. The laboratory will decide if one threshold is to be used for all dyes or if individual dye channels will have individual thresholds.

> A laboratory approved method will be used for calculating the stochastic threshold.

## C. *Known and Non-probative Evidence Samples or Mock Evidence Samples*

Extraction of known samples and non-probative or mock evidence samples allows the laboratory to provide evidence of suitability of the extraction, quantification, and amplification method for samples commonly tested in the laboratory. Non-probative evidence samples or mock evidence samples should include degraded and/or inhibited samples, if possible, to test the ability of the PowerQuant® system to detect degraded and inhibited DNA.

## D. *Precision and Accuracy*

The same sample will be extracted multiple times within a run and across runs to show the repeatability and precision of the method. The precision and accuracy of the quantification system can be evaluated by diluting the DNA standard to different concentrations and running replicates on different plates to determine the variance in the results as well as the % error from the expected concentration. The reproducibility of the standard curve will also be evaluated. The precision of the amplification system can be determined by examining multiple allelic ladders across multiple injections. The average base pair size and standard deviation will be calculated for each allele in the allelic ladder. Three times the standard deviation for

each allele should be less than 0.5bp. The accuracy of the amplification system will be determined by comparing the results of the NIST SRM 23491d genotypes to those published from NIST. In addition, the amplification kit will be tested by using the same positive control (2800M) amplified multiple times on the same plate and across different plates.

**E. Mixture Samples**

Mixture samples are commonly encountered in forensic casework samples. This study will provide information on the ability to extract DNA from multiple donors during extraction. This study will demonstrate the ability of the quantification kit to detect male/female mixtures at different ratios of contributors. In addition, these samples can be used by the laboratory when they are developing interpretation SOPs for determination of the number of contributors to the mixture, the ability of the amplification system to detect major and minor contributor profiles, and the ability to type mixtures of different contributor ratios.

**F. Contamination Assessment**

To ensure that the instrument sample-handling process minimizes the risk of contamination, negative controls will be examined for the presence of exogenous DNA in every extraction, quantification, and amplification plate throughout the validation process.

## 3. General Considerations

Prior to beginning any internal validation study, ensure that you have the required reagents and tools necessary to complete the study. Do not perform the experiments described within this guide using DNA derived from cell lines. Long-term storage and the storage conditions may affect the stability of genomic DNA and the ability to develop an STR profile.

## 4. Project Scope for Workflow Optimization of Casework Direct System

A. Optimization:
 1. Swab cutting size evaluation
 2. Volume of Casework Direct Solution evaluation
 3. Comparison of Casework Direct Lysates quantified with PowerQuant® to swabs screened with current serology method
 *Note: The laboratory will perform the serology of the remaining swabs following their currently validated methods.*
 4. Samples that will be tested will include a semen dilution on vaginal swabs and post coital swabs provided by the laboratory (or purchased by the laboratory).
 5. A subset will be amplified (if desired).
B. *Optimization for Touch:*
 1. Swab cutting size evaluation
 2. Volume of Casework Direct Solution evaluation
 3. Comparison of Casework Direct Lysates quantified with PowerQuant® to swabs processed with current method
 *Note: The laboratory will perform the extraction of the remaining swabs following their currently validated methods.*
 4. Samples that will be tested will include gun swabs and swab types commonly encountered in the laboratory
 5. A small sampling will be amplified (if desired).

## 5. Project Scope for Validation of Casework Direct System

A. Sensitivity
 1. One donor of semen and one donor of saliva will be extracted in triplicate with Casework Direct System using the following input volumes: 10µl, 5µl, 1µl, 0.5µl, 0.25 µl, 0.1µl, 0.05µl and 0.01µl.
 2. *The laboratory* will perform extractions using their currently validated extraction method for comparison.
 3. All extracts will be quantified using PowerQuant® and amplified.
 4. *The laboratory* will perform serology testing with the option to do differentials on any semen containing samples according to current protocol to correlate results to the Casework Direct System lysates.
 5. All Casework Direct System lysates will be quantified and amplified.
B. Precision/Accuracy/Repeatability
 1. One donor of semen will be extracted in triplicate using two different extraction sets.
 2. Both extraction sets will be quantified.
 3. Concentrations of DNA from different replicates will be compared within extraction sets and between extraction sets.

C. Known and Non-probative or Mock Evidence Samples
   1. 1-3 known buccal swabs will be extracted with the Casework Direct System.
   2. 15 non-probative or mock evidence samples (SAK type samples) will be extracted with the Casework Direct System for y-screening.
   3. 15 non-probative or mock evidence samples (touch type samples) will be extracted with the Casework Direct System.
   4. *The laboratory* will perform serology testing with the option to do differentials on any semen containing samples according to current protocol to correlate results to the Casework Direct System lysates. The laboratory will perform extractions following their current extraction method for comparison for touch samples.
   5. All extracts will be quantified using PowerQuant® and amplified.
   6. Any sample showing signs of inhibition will be processed using the Maxwell® RSC 48.
D. Male/Female Mixture Studies
   1. Semen will be extracted in triplicate with Casework Direct System using the following input volumes: 10µl, 5µl, 1µl, 0.5µl, 0.25 µl, 0.1µl, 0.05µl and 0.01µl spotted on vaginal swabs (volumes subject to change).
   2. *The laboratory* will perform serology testing with the option to do differentials on any semen containing samples according to current protocol to correlate results to the Casework Direct System lysates.
   3. All Casework Direct System lysates will be quantified using PowerQuant® and amplified.
E. Contamination
   1. All negative controls will be evaluated for contamination.

*Note*: a subset of samples processed with the Casework Direct System will be processed through the Maxwell® RSC 48 to show compatibility for any samples needing post extraction purification.

## 6. Project Scope for Maxwell® RSC 48 Instrument

A full validation will be done on one Maxwell® RSC 48 instrument. A performance check will be performed on one additional instrument. The performance check will include precision (1 body fluid), sensitivity (1 donor), and contamination.

A. Sensitivity
   1. Extractions will be performed using blood from 2 donors. Extractions for each sample will be done in triplicate. Volumes of blood extracted will include: 50µl, 10µl, 5µl, 1µl, 0.2µl, 0.04µl, and 0.008µl.
   2. Samples will be quantified.
   3. Data generated will include graphs/tables detailing:
      a. Average and standard deviation of the quantification values for each target for each sample
      b. Average total DNA yield summary
      c. Linearity of the system
B. Precision/Repeatability Study
   1. Three replicates of blood and semen from one donor will be extracted on two different Maxwell® runs.
   2. Samples will be quantified.
   3. Data generated will include graphs/tables detailing:
      a. Average, standard deviation, and CV% of the quantification values for each target for each sample for within runs and between runs
C. Known and Non-probative Evidence Samples or Mock Evidence Samples
   1. 15 known samples will be extracted.
   2. 25 non-probative or mock evidence samples will be extracted.
   3. Samples will be quantified.
   4. All known and non-probative or mock samples will be manually normalized and amplified.
   5. Data generated will include graphs/tables detailing:
      a. Average DNA concentration for each sample for each target
      b. Average peak height for each known sample
      c. A table with the quantification results and STR results will be provided
D. Mixture Samples
   1. One differential mixture set will be tested using the desired pre-Maxwell processing for cell separation (laboratory performs protocol).

       a. 1:1, 1:5, 1:25, and 1:125 ratios will be tested with each mixture sample. Samples will be extracted in duplicate.
2. One non-differential mixture set will be tested.
       a. 1:1, 1:5, 1:25, and 1:125 ratios will be tested with each mixture sample. Samples will be extracted in duplicate.
3. Samples will be quantified.
4. All mixture samples will be manually normalized and amplified.
5. Data generated will include graphs/tables detailing:
       a. Average DNA concentration for each sample for each target
       b. Average [Auto]/[Y] for each sample
       c. Percent minor profile called for the non-differential samples
       d. Genotype tables

E. Contamination Study
1. Multiple negative controls will be on each Maxwell® extraction run.
2. All negative control samples will be quantified.
3. Negative controls will be amplified if quantification values are observed.

F. Workflow
1. Samples will be pre-processed with the Casework Extraction Kit.
2. Extraction on Maxwell® RSC 48 with manual cartridge set-up of the Maxwell® FSC DNA IQ™ Casework Kit
3. Manual quantification set up.
4. Manual amplification setup with previously determined optimal template.
5. Manual CE setup using one injection condition.


## 7. Project Scope for PowerQuant® Validation

A full validation of PowerQuant® will be done on *one* Applied Biosystems® QuantStudio™ 5. A performance check will be performed on one additional instrument. The performance check will include precision, sensitivity, and contamination.

A. Precision/Reproducibility/Accuracy
1. Dilutions of the 50ng/µl PowerQuant® Male Genomic DNA Standard to 45ng/µl, 10ng/µl, 0.40ng/µl, and 0.016ng/µl will be tested.
2. Three replicates of the dilution series will be quantified on a single plate to demonstrate "intra-plate" reproducibility and precision.
3. Three replicates of the dilution series will be quantified on an additional plate to demonstrate "inter-plate" reproducibility and precision.
4. The average, standard deviation, and %CV of the autosomal, Y, degradation quantification values and IPC Cq values, [Auto]/[Y] ratios, and [Auto]/[Deg] ratios for each DNA concentration for "intra-plate" and "inter-plate" results will be determined.

B. Known and Non-Probative or Mock Evidence Samples
1. Fifteen known samples and 15 non-probative or mock evidence samples will be quantified in duplicate using PowerQuant®.
2. The 15 known samples will be quantified by the laboratory with the current quantification system so that the new STR target can be mathematically calculated. The known samples used should have an [Auto]/[Y] ratio close to 1.
3. Each of the 15 known samples and 15 non-probative or mock evidence samples will be amplified.

C. Sensitivity and Stochastic Studies:
1. Dilutions of 0.025ng/µl, 0.005ng/µl, 0.001ng/µl, 0.0002ng/µl and 0.00004ng/µl using 3 male samples will be quantified in duplicate.
2. The dilutions will be amplified for each donor in duplicate using max volume of the system.

D. Male/Female Mixture Studies
1. Two sets of male/female mixtures with the following ratios will be created: 1:1, 1:3, 1:9, 1:15, 1:19, 1:25, 1:35, 1:50, and 1:100.
2. Each mixture series will be quantified in duplicate using PowerQuant® to determine the amount of DNA present in the samples, as well as the [Auto]/[Y] ratio.
3. The mixtures will be amplified in duplicate.

4. The amplified results will be compared to [Auto]/[Y] ratios and autosomal and Y quantification values obtained from PowerQuant®.
E. Degraded/Inhibited Samples
    1. One DNA sample will be used during these studies.
    2. The sample will be exposed to 0mJ, 50mJ, 100mJ, and 300mJ using a UV Stratalinker.
    3. Three humic acid concentrations will be tested.
    4. Three hematin concentrations will be tested.
    5. The amount of DNA present in the samples, the IPC cycle shift, as well as the [Auto]/[Deg] ratio values using PowerQuant® will be determined.
    6. The samples will be amplified in duplicate using optimal template or the max volume.
F. Contamination
    1. Multiple negative controls will be evaluated for contamination on each plate.
G. Workflow ·
    1. Manual quantification set up.
    2. Manual amplification setup with previously determined optimal template.
    3. Manual CE setup using one injection condition.
H. Conditions
    1. Default quantification conditions
        a. 20μL reaction volume (7μL Water, Amplification Grade, 10μL PowerQuant® 2X Master Mix, 1μL PowerQuant® 20X Primer/Probe/IPC Mix, and 2μL template).

## 8. Project Scope for a PowerPlex® Y-STR containing STR kit for Casework

A full validation of a PowerPlex® Y-STR containing kit will be done on *one* instrument. A performance check will be performed on one additional instrument. The performance check will include precision, accuracy, sensitivity, and contamination.

A. Sensitivity, Analytical and Stochastic Threshold Study
    1. Sensitivity dilutions of extracted DNA (1.0ng, 500pg, 250pg, 125pg, 62.5pg, 31.25pg, 15.6pg, 7.8pg) will be amplified in triplicate using two different DNA samples. **Note:** these values may change depending on the optimal template of the chosen kit.
    2. Data generated will include graphs/tables detailing:
        a. Average peak heights of all samples
        b. Peak height ratios for all samples
        c. Calculated analytical threshold including noise distribution charts
        d. Assessment of dropout from dilution series and calculated stochastic threshold
        e. Linearity of the system
B. Accuracy Study
    1. Positive control samples (2800M) will be amplified on at least three different amplification plates.
    2. NIST 2391d samples will be amplified.
    3. Data generated will include the following graphs/tables:
        a. Genotype concordance table verifying reproducibility between amplification plates for 2800M.
        b. Average peak height table for 2800M.
        c. Concordance table verifying reproducibility for NIST 2391d samples as compared to NIST published profiles.
C. Known and Non-probative Evidence Samples or Mock Evidence Samples
    1. Fifteen known samples will be amplified and compared to previously obtained profiles.
    2. Fifteen non-probative evidence samples or mock evidence samples will be amplified.
    3. Data generated will include graphs/tables detailing:
        a. Genotypes concordance tables
        b. Average peak heights of all known single source samples
        c. Peak height ratios of all known single source samples

D. Mixture Samples
    1. Two-Person Mixture
        a. Two mixture sets will be tested using high quality DNA.
            1.  1:1, 2:1, 3:1, 5:1, 9:1, 15:1, 25:1 for mixture sets 1 and 2 (made from 4 different donors).
        b. One mixture set will be tested using DNA from degraded DNA
            1.  1:1, 2:1, 3:1, 5:1, 9:1, 15:1, 25:1 for mixture set 3.
        c. Each 2-person mixture sample will be amplified in duplicate at optimal template and a low template amount.
        d. Data generated will include graphs/tables detailing:
            1.  Percentage of unique minor alleles
            2.  Percent contribution by peak height
    2. Three and Four-Person Mixture
        a. Three-person mixture set will be tested using high quality DNA.
            1.  1:1:1, 5:5:1, 5:1:1, 10:1:1, and 10:5:1 for mixture set.
        b. Four-person mixture sets will be tested using high quality DNA.
            1.  1:1:1:1, 10:5:2:1, 4:3:2:1, 10:10:1:1, 10:10:10:1,10:1:1:1 for mixture set.
        c. Each 3 and 4-person mixture will be amplified in optimal template and a low template amount.
        d. Total number of alleles present will be calculated for 3+ person mixtures.
E. Contamination Study
    1.  Multiple negative controls will be on each plate.
    2.  All negative controls will be assessed at the analytical threshold for contamination.
F. Workflow
    1.  Amplification reactions will be set up in 96-well plates.
    2.  Manual amplification setup.
    3.  Manual CE setup.
G. Conditions
    1.  Default amplification conditions.
        a. 25µL reaction volume.
        b. **One** cycle number option will be tested.
    2.  Default injection conditions
        a. **One** injection time will be used.
    3.  Samples analyzed with software version preferred by laboratory.

## 9. Post Validation Training

A training will be included as part of the validation project. The training will consist of a presentation with the background of the kit and the validation results.

## 10. Timeline

A. Pre-validation: During this phase of the validation process, we will discuss proposal, options for start dates, expectations of the materials that the laboratory is expected to provide, and expectations from Promega during the validation process.

B. Validation
    1. On-site laboratory work to be completed by Promega
    2. Off-site data analysis and write-up of report

C. Post validation training: Background presentation and validation review.

## 11. Cost of Validation of Maxwell® RSC 48 with one performance check

| | Timeframe | Cost |
|---|---|---|
| GI On-Site Validation and Implementation (S1111) | ~1 week | $12,500 |
| GI Off-Site Validation and Implementation (S1112) | ~5 weeks | $37,500 |
| GI On-Site Training (S1113) | ½ day | $1,500 |
| Discount | ~7% | -$3,500 |
| Total | | $48,000 |

## 12. Cost of Validation of Casework Direct Kit

| | Timeframe | Cost |
|---|---|---|
| GI On-Site Validation and Implementation (S1111) | ~2 weeks | $25,000 |
| GI Off-Site Validation and Implementation (S1112) | ~4 weeks | $30,000 |
| GI On-Site Training (S1113) | ½ day | $1,500 |
| Discount* | 100% | -$56,500 |
| Total | | $0 |

*Discount in contingent upon commitment to other three project

## 13. Cost of Validation of PowerQuant® with one performance check

| | Timeframe | Cost |
|---|---|---|
| GI On-Site Validation and Implementation (S1111) | ~1 week | $12,500 |
| GI Off-Site Validation and Implementation (S1112) | ~5 week | $37,500 |
| GI On-Site Training (S1113) | ½ day | $1,500 |
| Discount | ~14.5% | -$7,500 |
| Total | | $44,000 |

## 14. Cost of Validation of PowerPlex® Y-STR containing STR kit with one performance check

| | Timeframe | Cost |
|---|---|---|
| GI On-Site Validation and Implementation (S1111) | ~1 week | $12,500 |
| GI Off-Site Validation and Implementation (S1112) | ~5.5 week | $41,250 |
| GI On-Site Training (S1113) | ½ day | $1,500 |
| Discount | -20% | -$11,250 |
| Total | | -$44,000 |

## 15. Deliverables

| |
|---|
| Electronic copy of the validation report |
| All summary files for analyzed data (.xls) |
| All .eds files from throughout validation |
| All .HID files from throughout validation |
| .pdfs of electropherograms used during the validation |
| All testing notes related to validation project |

## 16. Project Approval

It is the responsibility of the laboratory to make sure that all the experiments outlined are in accordance with the laboratory's regulatory requirements.

Approval signatures indicate that the approver has read, understands, and agrees with the content of this document.

| | Approver | Signature | Date |
|---|---|---|---|
| Name | | | |
| Organization | | | |
| Title | | | |
| Name | Jonelle Thompson | | |
| Organization | Promega | | |
| Title | Manager, Global Validation Services | | |

## 17. Personnel Contact

Manager, Global Validation Services (Primary Contact):
Jonelle Thompson
2800 Woods Hollow Dr, Madison WI 53711
Jonelle.Thompson@promega.com
1-435-729-9209

# Internal Validation Experimental Design of PowerPlex® 35GY for Direct Amplification Samples

## Contents

## 1. Introduction

Before an established method or procedure may be employed in a forensic laboratory, an internal validation must be completed to show that the method performs as expected. This proposal outlines a set of experiments that confers conformance with the FBI Quality Assurance Standards for DNA Database Laboratories, ISO/IEC 17025 standards, and the validation guidelines outlined by the Scientific Working Group on DNA Analysis Methods (SWGDAM). These experiments are designed to demonstrate the sensitivity and reliability of the amplification system. Upon completion of these experiments the laboratory will have sufficient data to develop a methodology for direct amplification of PowerPlex® 35GY.

## 2. FBI Quality Assurance Standard

8.3.1 (Database) Internal validation studies shall include as applicable: known database-type samples, precision and accuracy studies, sensitivity and stochastic studies, and contamination assessment studies.

### A. *Sensitivity and Stochastic Studies*

Sensitivity studies are used to demonstrate the limit of detection of an assay. By testing a range of DNA templates, the laboratory can define the analytical threshold, optimal target range, and stochastic threshold for the amplification kit.

### B. *Calculating Analytical and Stochastic Threshold*

Signal-to-noise assessment of sensitivity data can help define an appropriate analytical threshold for the amplification system on the chosen CE instrument. The method described below is one of many scientific methods that can be used to analyze these data.

The sensitivity sample profiles that contain minimal pull-up and are within the linear range of the CE instrument will be used to calculate the analytical threshold. The baseline will be examined for "noise" peaks—those that are not part of the profile, not stutter peaks and not known (or reproducible) artifacts of the system. To obtain peak height values for these low-level "noise" peaks, the calling threshold in your analytical software system will be set sufficiently low, such as 1RFU. Once the "noise" peaks are identified, the average peak height and standard deviation for these peaks will be calculated. The average peak height plus X standard deviations will define the analytical threshold, where X refers to the number of standard deviations needed to achieve the desired confidence level. Choose a confidence level that is appropriate for your laboratory. The laboratory will decide if one threshold is to be used for all dyes or if individual dye channels will have individual thresholds.

A laboratory approved method will be used for calculating the stochastic threshold.

### C. *Known/Database Samples*

Amplification of known samples allows the laboratory to provide evidence of concordance using the new amplification system or CE system.

### D. *Precision*

The precision of the amplification system can be determined by examining multiple allelic ladders across multiple injections. The average base pair size and standard deviation will be calculated for each allele in the allelic ladder. Three times the standard deviation for each allele should be less than 0.5bp.

### E. *Accuracy*

For the amplification kit, the NIST SRM 2391d genotypes obtained will be compared to those published from NIST. In addition, the amplification kit will be tested by using the same positive control (2800M) amplified different plates.

### F. *Contamination Assessment*

To ensure that the laboratory's sample-handling process minimizes the risk of contamination, negative controls will be examined for the presence of exogenous DNA in amplification set up throughout the validation process.

## 3. General Considerations

Prior to beginning any internal validation study, ensure that you have the required reagents and tools necessary to complete the study. Do not perform the experiments described within this guide using DNA derived from cell lines. Long-term storage and the storage conditions may affect the stability of genomic DNA and the ability to develop an STR profile. Installing fresh polymer, buffer, and a new capillary prior to performing validation experiments will provide optimal run conditions.

## 4. Project Scope for PowerPlex® 35GY Direct Amplification

A full validation of PowerPlex® will be done on *one* capillary electrophoresis instrument with a performance check on a second CE instrument.

A. *Cycle Number Optimization*
   1. Fourteen commonly used database-type samples will be amplified in duplicate using three cycle numbers.
B. *Known Sample Concordance Study*
   1. Forty known samples provided by the laboratory will be amplified in duplicate.
   2. Data generated will include graphs/tables detailing:
      a. Genotype concordance table
      b. Average peak height tables and graph
      c. Table provided with success rate
C. *Sensitivity, Analytical and Stochastic Threshold Study*
   1. Sensitivity dilutions of extracted DNA (20ng, 10ng, 5.0ng, 2.5ng, 1.0ng, 500pg, 400pg, 300pg, 200pg, 100pg ) will be amplified in triplicate at the desired cycle number using two different DNA samples.
   2. Data generated will include graphs/tables detailing:
      a. Average peak heights of all samples
      b. Peak height ratios for all samples
      c. Calculated analytical threshold including noise distribution charts
      d. Assessment of dropout from dilution series and calculated stochastic threshold
      e. Linearity of the system
D. *Accuracy Study*
   1. Positive control sample (2800M) will be amplified on different amplification plates.
   2. NIST 2391d sample(s) will be amplified in duplicate.
   3. Data generated will include the following graphs/tables:
      a. Genotype concordance table verifying reproducibility between amplification plates for 2800M.
      b. Average peak height table for 2800M.
      c. Concordance table verifying reproducibility for NIST 2391d samples as compared to NIST published profiles.
E. *Contamination Study*
   1. Multiple negative controls will be on each plate.
   2. All negative controls will be assessed at the analytical threshold for contamination.
F. *Workflow*
   1. Amplification reactions will be set up in 96-well plates.
   2. Manual CE setup
G. *Conditions*
   1. Default amplification conditions
      a. AmpSolution™ will be added to reactions for appropriate sample types
      b. SwabSolution™ will be added to reactions for appropriate sample types
   2. Default injection conditions
      a. One injection time will be used for full validation with the possible option of a reduced injection condition for saturated samples.
   3. Samples analyzed with software version preferred by laboratory.

## 5. Post Validation Training

A remote training will be included as part of the validation project for PowerPlex® 35GY. The training will consist of a presentation with background on PowerPlex® 35GY and the validation results.

## 6. Timeline

- **A.** Pre-validation: During this phase of the validation process we will discuss proposal, options for start dates, expectations of the materials that the laboratory is expected to provide, and expectations from Promega during the validation process.
- **B.** Validation
  1. On-site laboratory work performed by Promega
  2. Off-site data analysis and write-up of report by Promega
- **C.** Post validation training: One half day post validation training and validation review.

## 7. Cost of Validation for PowerPlex® 35GY For Direct Amplification

|  | Timeframe | Cost |
|---|---|---|
| GI On-site Validation and Implementation (S1111) | ~1 week | $12,500 |
| GI Off-site Validation and Implementation (S1112) | ~3.5 week | $26,250 |
| GI On-site Training (S1113) | 1/2 day | $1,250 |
| Total |  | $40,000 |

## 8. Deliverables

*Electronic copy of the validation reports*

*All summary files for analyzed data (.xls)*

*All .fsa files from throughout validation*

*.pdfs of electropherograms used during the validation*

*All testing notes related to validation project*

## 9. Project Approval

It is the responsibility of the laboratory to make sure that all the experiments outlined are in accordance with the laboratory's regulatory requirements.

Approval signatures indicate that the approver has read, understands, and agrees with the content of this document.

|  | Approver | Signature | Date |
|---|---|---|---|
| Name |  |  |  |
| Organization |  |  |  |
| Title |  |  |  |
| Name | Jonelle Thompson |  |  |
| Organization | Promega |  |  |
| Title | Manager, Global Validation Services |  |  |

## 10. Personnel Contact

Manager, Global Validation Services (Primary Contact):
Jonelle Thompson
2800 Woods Hollow Dr, Madison WI 53711
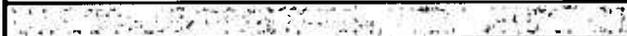Jonelle.Thompson@promega.com
1-435-729-9209

| SWGDAM Section from 2016 version (current) |
| --- |
| 3.1.1 Inheritance |
| 3.1.2 Mapping |
| 3.1.3 Detection |
| 3.1.4 Polymorphism |
| 3.2 Species Specificity |
| 3.3 Sensitivity Studies |
| 3.4 Stability Studies |
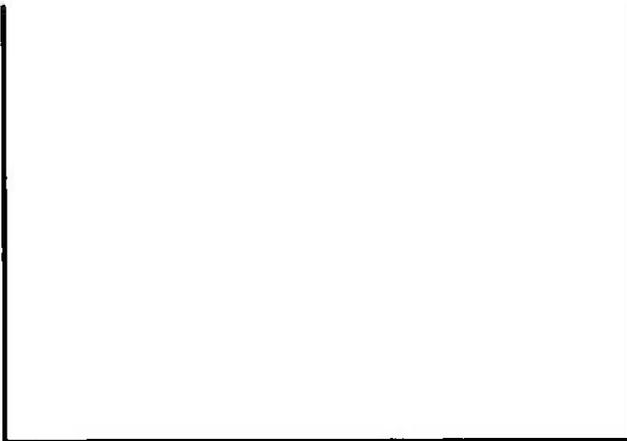
## 3.5 Precision and Accuracy

### 3.5.1 Repeatability

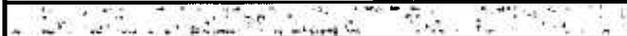### 3.5.2 Reproducibility

## 3.6 Case-type samples

## 3.7 Population Studies

## 3.8 Mixture Studies

## 3.9 PCR-based Studies

| Language |
|---|
| The mode of inheritance of DNA markers demonstrated through family studies. |
| The genomic location of the genetic marker. |
| Technological basis for identifying the genetic marker (e.g., capillary electrophoresis, DNA sequencing, hybridization assays, etc.). |
| Type of variation (e.g., sequence and/or length variants). |
| |
| The ability to detect genetic information from non-targeted species (e.g., detection of microbial DNA in a human assay) should be determined. The detection of genetic information from non-targeted species does not necessarily invalidate the use of the assay, but may help define the limits of the assay. |
| |
| The ability to obtain reliable results from a range of DNA quantities, to include the upper and lower limits of the assay, should be evaluated. |
| |
| The ability to obtain results from DNA recovered from biological samples deposited on various substrates and subjected to various environmental and chemical insults should be evaluated. In most instances, assessment of the effects of these factors on new forensic DNA procedures is not required. However, if substrates and/or environmental |

and/or chemical insults could potentially affect the analytical process, then the process should be
evaluated to determine the effects of such factors.

Precision and accuracy of results (e.g., quantitative and/or qualitative) of the same operator and/or detection instrument
should be evaluated.

Precision and accuracy of results (e.g., quantitative and/or qualitative) among different operators and/or detection instruments should be evaluated.

The ability to obtain reliable results should be evaluated using samples that are representative of those typically encountered by the
testing laboratory. Where appropriate, consistency of typing results should be
demonstrated by comparing results from the previous procedures to those
obtained using the new procedure.

The distribution of genetic markers in populations should be determined in relevant population groups. When appropriate, databases
should be tested for independence expectations.

The ability to obtain reliable results from mixed-source samples should be determined. These studies will assist the laboratory to
establish guidelines for mixture interpretation, which may include determination
of the number of contributors to the mixture, determination of the major and

3.9.1 Publication of the sequence of individual primers is not required in order to appropriately demonstrate the reliability and limitations of PCR-based technologies. However, availability of the primer sequences is encouraged in order to aid in the identification of potential primer binding site variants and troubleshooting.

3.9.2 The reaction conditions needed to provide the required degree of specificity and robustness should be determined. These include, but are not limited to, thermal cycling parameters, the concentration of primers, magnesium chloride, DNA polymerase, and other criticalreagents.

3.9.3 The potential for differential amplification among loci, preferential amplification of alleles in a locus, and stochastic amplification (i.e.,excessive allelic signal imbalances due to the random sampling and amplification of low template quantities) should be assessed.

3.9.4 The effects of multiplexing should be assessed.

3.9.5 Appropriate controls should be assessed.

3.9.6 Criteria for detection of amplified product should be determined based on the platform and/or method.

3.9.7 Appropriate measurement standards (qualitative and/or quantitative) for characterizing the alleles or resulting DNA product should be established.

| |
| --- |
| |
| |
| |
| |
| Balance and Stochastic |
| |
| Artifacts |
| |
| Stutter |

| PowerPlex 35GY | Promega | New Hampshire (Required) |
|---|---|---|
| Published papers | | |
| Published papers | | |
| Published papers | | |
| Published papers | | |
| Promega: 1-10ng of various species on hand, 29 cycles<br>Labs: run any samples that your laboratory has available | X | |
| Extracted DNA: 4ng, 2ng, 1ng, 500pg, 250pg, 125pg, 62.5pg, 31.25pg, 15.6pg, 7.8pg, NTC<br>2 males in replicates of 4 | X | X |
| Hematin (500, 750, 1000uM)<br>1 male in replicates of 4 and negative (no inhibitor) | X | |
| Humic Acid (100, 200, 300ng/ul)<br>1 male in replicates of 4 and negative (no inhibitor) | X | |

| | | |
|---|---|---|
| EDTA (4 concentrations also used in robustness (MgCL) section below | X | |
| Tannic Acid (100, 300, 400ng/ul)<br>1 male in replicates of 4 and negative (no inhibitor) | X | |
| Other possible inhibitors (coffee, spermicide, etc)<br>1 male in replicates of 4 and negative (no inhibitor) | X | |
| | | |
| Ladder Precision - multiple injections | X | X |
| Positive Control (2800M)/NIST 2391d | X | X |
| 2800M and Ladders done in multiple laboratories on different instruments | X | X |
| | | |
| 10-30 non-probative samples (body swabs, post-coital samples, P30+, sperm - samples, digital penetration, fingernails). Degraded, inhibited, multiperson mixtures, low level mixtures<br>Labs: run any appropriate samples that your laboratory has available | | X |
| | | |
| Already completed as these are not new loci | | |
| | | |
| Male:Female: 1:0; 19:1, 9:1, 5:1, 2:1, 1:1, 1:2, 1:5, 1:9, 1:19, 0:1<br>1 mixture in replicates of 4 | X | |
| Male:Male: Female 1:1:10, 1:1:20; 1ng Total<br>1mixture in replicates of 4 | X | |
| Other mixtures to test? | X | |
| Thermal Cycling Parameters | | |
| Reaction volume (µL): 25, 12.5; 6.25 | | |

| | | |
|---|:---:|---|
| Blood FTA: 1 x 1.2mm punch<br>3 males in replicates of 4 | X | |
| Buccal FTA: 1 x 1.2mm punches<br>3 males in replicates of 4 | X | |
| Extracted DNA: 1ng, 200pg, Neg<br>3 males in replicates of 4 | X | |
| **Cycle Number** | | |
| Extracted DNA - 1ng, 200pg, NTC<br>28, 29, 30 cycles; 2 male (QC2 and IQ) in replicates of 4 | X | |
| Blood FTA: 1 x 1.2mm punch<br>24,25, 26 cycles; 3 males in replicates of 4 | X | |
| Buccal FTA: 1 x 1.2mm punches<br>24, 25, 26 cycles; 3 males in replicates of 4 | X | |
| Bode Buccal with PunchSolution<br>24,25, 26 cycles; 3 males in replicates of 4 | X | |
| Buccal on OmniSwab with SwabSolution<br>24,25, 26 cycles; 3 males in replicates of 4 | X | |
| Blood on S&S 903 with PunchSolution<br>24,25, 26 cycles; 3 males in replicates of 4 | X | |
| Cotton swab with SwabSolution<br>24,25, 26 cycles; 3 males in replicates of 4 | X | |
| **Annealing temp. (°C) - 58, 60, 62** | | |
| Extracted DNA: 1ng , 200pg , NTC<br>2 males in replicates of 4 | X | |
| Blood FTA: 1 x 1.2mm punch<br>3 males in replicates of 4 | X | |
| Buccal FTA: 1 x1.2mm punches<br>3 males in replicates of 4 | X | |
| **PCR Reaction Components** | | |
| **Primer conc.: 0.8X, 1X, 1.2X Primer Pair Mix** | | |
| Extracted DNA: 1ng, 200pg, Neg<br>2 males in replicates of 4 | X | |
| Blood FTA: 1 x 1.2mm punch<br>2 males in in replicates of 4 | X | |
| Buccal FTA: 1 x1.2mm punches<br>2 males in replicates of 4 | X | |
| **MasterMix conc.: 0.8X, 1X, 1.2X Primer Pair Mix** | | |
| Extracted DNA: 1ng , 200pg , Neg<br>2 males in replicates of 4 | X | |
| Blood FTA: 1 x 1.2mm punch<br>2 males in in replicates of 4 | X | |
| Buccal FTA: 1 x1.2mm punches<br>2 males in replicates of 4 | X | |
| | | |
| Use sensitivity study data | X | |
| | | |
| Use the 1ng and NTC data from the sensitivity study | X | |
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| Completed as part of the concordance study | X | |

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# QUALITY ASSURANCE STANDARDS FOR DNA DATABASING LABORATORIES

## EFFECTIVE DATE:

These standards shall take effect July 1, 2020 and shall not be applied retroactively.

## 1. SCOPE AND APPLICABILITY

This document consists of definitions and standards. The standards are quality assurance measures that place specific requirements on the laboratory. Equivalent measures not outlined in this document may also meet the standard if determined sufficient through an accreditation process.

The term 'year' refers to calendar year in these standards. Also, when used in these standards, the terms 'review', 'approve', 'document', 'define', 'schedule', 'policy', 'procedure', 'program', 'appoint', 'notify', 'inform', 'authorize', or 'designate' are intended to require written documentation to demonstrate compliance. In order to demonstrate compliance with these standards for purposes of the audit and accreditation process, the laboratory shall have available objective proof of satisfying each standard.

The standards describe the quality assurance requirements that laboratories performing DNA testing on samples obtained from identified subject(s) for the purpose of entering DNA profile(s) into the Combined DNA Index System (CODIS) shall follow to ensure the quality and integrity of the data generated by the laboratory. As it pertains to these standards, DNA testing begins at sample extraction or direct amplification. If, in addition, the databasing laboratory is performing DNA analyses on known or casework reference samples considered as evidence by that laboratory, the databasing laboratory shall follow these standards including the additional requirements for known and casework reference samples in Standards 7.3.2.1 and 12.3.2. DNA databasing laboratories performing DNA testing on known or casework reference samples shall be audited to these standards only and not the Quality Assurance Standards for Forensic DNA Testing Laboratories.

These standards are applicable to DNA databasing laboratories using Rapid DNA instruments/Systems on database, known or casework reference samples. The use of Rapid DNA instruments/Systems is not approved for use on forensic samples.

These standards also apply to vendor laboratories that perform DNA testing in accordance with Standard 17. These standards do not preclude the participation of a laboratory, by itself or in collaboration with others, in research and development, on procedures that have not yet been validated.

## 2. DEFINITIONS

As used in these standards, the following terms shall have the meanings specified:

*Accreditation* is the formal recognition that a laboratory meets or exceeds a list of standards, including the FBI Director's Quality Assurance Standards, to perform specific tests. Accreditation is administered by a nonprofit professional association of persons actively involved in forensic science that is nationally recognized within the forensic science community in accordance with the provisions of the Federal DNA Identification Act (34 U.S.C. §12592) or subsequent laws.

*Accuracy* is the ability of a measurement to give results close to a true value.

*Administrative review* is an evaluation of the documentation for consistency with laboratory policies and for editorial correctness.

*Analyst* (or equivalent role, position, or title as designated by the laboratory) is an employee or contract employee, that has successfully completed the laboratory's training requirements for database analysis, passed a competency test, and has entered into a proficiency testing program according to these standards. This individual can conduct and/or direct the analysis of database, known or casework reference samples, interpret the resulting data from these samples and make conclusions.

*Analytical control* is a sample used to demonstrate that a method works correctly and to ensure the data are valid. See Positive amplification control, Positive sample control, Positive sequencing control, Negative amplification control, Negative sample control, Negative sequencing control, and Reagent blank control.

*Analytical documentation* is the documentation of procedural notes, controls, and instruments used; observations made; results of tests performed; and charts, graphs, photos, and other documentation generated which are used to support the analyst's conclusions.

*Analytical procedure* is an orderly, step-by-step process designed to ensure operational uniformity and to minimize analytical drift.

*Analytical threshold* is the minimum height requirement, determined through validation testing, at or above which detected peaks/signal can be reliably distinguished from background noise; peaks/signal at or above this threshold are generally not considered noise and are either artifacts or true alleles.

*Annual* is once per calendar year.

*Audit* is an on-site inspection used to evaluate, confirm, and/or determine the extent to which specified requirements are fulfilled.

*Audit team* is one or more individuals, including at least one auditor, that performs an inspection of a laboratory. At least one audit team member shall be or have been an analyst previously qualified in the laboratory's current DNA technologies and platforms.

*Auditor* is an individual who has successfully completed the FBI's DNA auditor training course.

*Biochemistry* is the study of the nature of biologically important molecules in living systems, DNA replication and protein synthesis, and the quantitative and qualitative aspects of cellular metabolism.

*Casework reference sample* is biological material (e.g., buccal swab, fingerprick, or blood draw) obtained directly from a known individual and used for purposes of comparison to forensic samples.

*Certified reference material* is a material for which values are obtained by a technically valid procedure and accompanied by, or traceable to, a certificate or other documentation which is issued by a certifying body (e.g., NIST).

*CODIS* is the Combined DNA Index System administered by the FBI. CODIS links DNA evidence obtained from crime scenes, thereby identifying serial criminals. CODIS also compares crime scene evidence to DNA profiles from offenders, thereby providing investigators with the identity of the putative perpetrator. In addition, CODIS contains profiles from missing persons, unidentified human remains, and relatives of missing persons. There are three levels of CODIS: the Local DNA Index System (LDIS), used by individual laboratories; the State DNA Index System (SDIS), used at the state level to serve as a state's DNA database containing DNA profiles from LDIS laboratories; and the National DNA Index System (NDIS), managed by the FBI as the nation's DNA database containing all DNA profiles uploaded by participating states. NDIS is the national and highest level index of CODIS containing the DNA records contributed from participating federal, state and local laboratories.

*CODIS administrator* (or equivalent role, position, or title as designated by the laboratory) is an employee of the laboratory responsible for administration and security of the laboratory's CODIS at a laboratory that owns the database and/or known samples. An alternate CODIS administrator must be designated by the laboratory as required by the NDIS operational procedures.

*CODIS user* is an employee or contract employee who has login access to the CODIS (i.e., State or Local) system and is authorized to read, add, modify and/or delete DNA records in CODIS.

*Competency testing* is a test or series of tests (practical, written, and/or oral) designed to establish that an individual has demonstrated achievement of technical skills and met minimum standards of knowledge necessary to perform DNA analysis.

*Competency* is the demonstration of technical skills and knowledge necessary to perform DNA analysis successfully.

*Contamination* is the unintentional introduction of exogenous DNA into a sample or analytical control during DNA testing.

*Continuing education* is an educational activity (such as a class, lecture series, conference, seminar, or short course) that is offered by a recognized organization or individual that brings participants up-to-date in their relevant area of knowledge.

*Contract employee* is an individual, not in the employ of the government or vendor laboratory, that performs DNA typing and/or analytical support services for a NDIS participating laboratory. The person performing these services must meet the relevant qualifications for the equivalent position in the NDIS participating laboratory. A contract employee cannot serve as a CODIS administrator or technical leader and cannot be counted as a full-time qualified analyst for purposes of satisfying the definition of a laboratory. Employment of a contract employee by multiple NDIS participating laboratories and/or vendor laboratories shall be disclosed to all employing laboratories and shall only be permitted subject to approval by the technical leader of the NDIS participating laboratory for which the contract employee is performing DNA typing and/or analytical services.

*Corrective action plan* evaluates and remediates a nonconformity with the goal to identify, correct, and/or prevent reoccurrence of the nonconformity, when possible.

*Coursework* is an academic class officially recognized and taught through a college or university program in which the participating student successfully completed and received one or more credit hours for the class.

*Critical equipment or instruments* are those equipment/instruments whose accurate functionality directly affects the results of the analysis and requires calibration, certification, or performance checks prior to use and periodically thereafter.

*Critical reagents* are those whose performance is vital to the success of the DNA testing and require testing on known samples before use on database or casework reference samples.

*Database* or *databasing* refers to the DNA analysis of database samples for entry into CODIS and, if eligible, for upload to the National DNA Index System (NDIS).

*Database sample* is a sample obtained from an individual who is legally required to provide a DNA sample for databasing purposes and whose identity is established at the time of collection of the sample.

*Developmental validation* - See Validation.

*Differential amplification* is the unequal amplification of one target region or locus over another during the polymerase chain reaction.

*Disposition of samples* is the documentation of the retention, return, or consumption of the samples upon completion of DNA testing.

*DNA record* is a database record that includes the DNA profile as well as data required to manage and operate NDIS, i.e., the Originating Agency Identifier, which serves to identify the submitting agency; the Specimen Identification Number; and DNA personnel associated with the DNA profile analyses.

*DNA type* (also known as a DNA profile) is the genetic constitution of an individual at one or more defined locations (also known as loci) in the DNA.

1)   A DNA type derived from nuclear DNA typically consists of one or two alleles at several loci (e.g., short tandem repeat loci).

2)   The DNA type derived from mitochondrial DNA is a specific sequence of nucleotides at a given mitochondrial region(s). In human DNA typing, the DNA type derived from mitochondrial DNA is described in relation to the revised Cambridge Reference Sequence (Nature Genetics [1999] 23:147).

*Electrophoresis detection system* is a platform that allows for the size separation of DNA molecules through a fluid or a gel under the influence of an electric field and the subsequent detection of the separated molecules by fluorescence or other means.

*Employee* is a person:

1)   In the service of the applicable federal, state, or local government, subject to the terms, conditions, and rules of federal, state, or local employment and eligible for the federal, state, or local benefits of service; or

2)   Formerly in the service of a federal, state, or local government who returns to service in the agency on a part-time or temporary basis.

3)   For purposes of a vendor laboratory, an employee is a person in the service of a vendor laboratory and subject to the applicable terms, conditions, and rules of employment of the vendor laboratory.

*Evidence* is an item submitted for DNA testing and/or a derivative of an item as defined by the laboratory that is subject to a chain of custody.

*Expert System* is a software program or set of software programs designed to interpret single source DNA data in accordance with laboratory defined quality assurance rules and identify DNA data not satisfying laboratory defined quality assurance rules, without human intervention.

*FBI* is the Federal Bureau of Investigation, the federal agency authorized by the DNA Identification Act of 1994 to issue quality assurance standards governing DNA testing laboratories and to establish and administer the National DNA Index System (NDIS).

*Forensic sample* is a biological sample originating from and associated with evidence from a crime scene. A sample associated with evidence from a crime scene may include a sample that has been carried away from the crime scene.

*Functional testing* is a process to confirm that a software performs the tasks as expected.

*Genetics* is the study of inherited traits, genotype/phenotype relationships, and population/species differences in allele and genotype frequencies.

*Guidelines* are a set of general principles used to provide direction and parameters for decision making.

*Integral component* is that portion of an academic course that is so significant and necessary to the understanding of the subject matter as a whole that the course would be considered incomplete without it.

*Internal validation* - See Validation.

*Interpretation software* is a tool to assist the analyst in assessing the analyzed data by applying quality assurance rules, performing mixture deconvolution, and/or evaluating comparisons. Interpretation software may include probabilistic genotyping software or Expert Systems.

*Known samples* are biological material whose identity or DNA type is established.

*Laboratory* is a facility
      1)    Employing at least two full-time employees who are qualified analysts; and
      2)    Having and maintaining the capability to perform the DNA analysis of database, known and/or casework reference samples at that facility.

*Laboratory support personnel* (or equivalent role, position, or title as designated by the laboratory) are employees or contract employees who perform laboratory support duties exclusive of analytical procedures on database, known or casework reference samples.

*Method* is a combination of procedural steps used to perform a specific technical process. The method includes the validated steps, reagents, and critical instruments needed to perform the process or portion of a process. The same method may be conducted using different equipment (automated vs manual) when appropriately validated.

*Methodology* refers to the categories of methods used to perform a stage of a DNA typing technology or technologies. For example, methodologies for STR technology can include extraction, quantification, amplification, and detection.

*Modified Rapid DNA analysis* is the semi-automated (hands-free) process of developing a CODIS acceptable STR profile from a database, known or casework reference sample. The "swab in – profile out" process consists of automated extraction, amplification, separation, ·

and detection without human intervention but requires an analyst to perform manual interpretation and technical review.

*Module* is an independent but interrelated part of software that performs a distinct function.

*Molecular biology* is the study of the theories, methods, and techniques used in the study and analysis of gene structure, organization, and function.

*Multi-laboratory system* is used to describe an organization that has more than one laboratory performing DNA analysis.

*Negative amplification control* is an analytical control that is used to detect DNA contamination of the amplification reagents. This analytical control consists of only amplification reagents without the intentional addition of template DNA.

*Negative sample control* is an analytical control that is used to detect DNA contamination in Rapid DNA reagents and consumables.

*Negative sequencing control* is an analytical control that is used to detect DNA contamination of the sequencing reagents. This analytical control consists of only sequencing reagents without the intentional addition of template DNA. The negative amplification control can be used as the negative sequencing control.

*NIST* is the National Institute of Standards and Technology.

*Nonconformity* is not meeting, implementing, maintaining, or complying with one or more of the requirements of these standards or a laboratory's procedures, policies, or other quality system documents.

*Offender* is an individual who is required by statute to submit a sample for DNA analysis and databasing. The term "offender" includes individuals who are convicted of or arrested for a crime or juveniles adjudicated delinquent for an offense and required by state or federal law to provide a DNA sample for analysis and databasing.

*On-site visit* is a scheduled or unscheduled visit to the vendor laboratory work site by one or more representatives of an NDIS participating laboratory.

*Outsourcing* is the utilization of a vendor laboratory to provide DNA services in which the NDIS participating laboratory takes or retains ownership of the DNA data. Outsourcing does not require the existence of a contractual agreement or the exchange of funds.

*Ownership* is the process by which the responsibility for the products of DNA analyses provided by a vendor laboratory may pass to an NDIS participating laboratory. It applies if any of the following will occur:

1)     The NDIS participating laboratory will use any samples, extracts or materials from the vendor laboratory for the purposes of DNA testing (e.g., a vendor laboratory prepares an extract that will be analyzed by the NDIS laboratory);
2)     The NDIS participating laboratory will interpret the DNA data generated by the vendor laboratory;
3)     The NDIS participating laboratory will issue a report describing or drawing conclusions on the results of the DNA analysis performed by the vendor laboratory; or
4)     The NDIS participating laboratory will enter or search a DNA profile in CODIS from data generated by the vendor laboratory.

*Ownership review* is the technical review of outsourced DNA data required by Standard 17. This review is to be distinguished from the technical and administrative reviews required by Standard 12. For outsourced DNA data, the vendor laboratory is responsible for conducting the technical and administrative reviews required by Standard 12.

*Performance check* is a quality assurance measure to assess the functionality of laboratory critical equipment and instruments.

*Platform* is the type of analytical system utilized to generate DNA profiles, such as capillary electrophoresis, real-time gel and end-point gel instruments or systems.

*Policy* is an organization's high level plan for a course of action or to address a requirement.

*Polymerase Chain Reaction* (PCR) is an enzymatic process by which a specific region of DNA is replicated during repetitive cycles, which consist of the following:
1)     Denaturation of the template;
2)     Annealing of primers to complementary sequences at an empirically determined temperature; and
3)     Extension of the bound primers by a DNA polymerase.

*Positive amplification control* is an analytical control that is used to determine if the PCR performed properly. This control consists of the amplification reagents and a known DNA sample.

*Positive sample control* is an analytical control that is used to determine if the Rapid DNA instrument/System is performing all steps of the process properly. This control consists of a known DNA sample.

*Positive sequencing control* is an analytical control that is used to determine if the sequencing performed properly. This control consists of the sequencing reagents and a known DNA sample. The positive amplification control can be used as the positive sequencing control.

*Precision* characterizes the degree of mutual agreement among a series of individual measurements, values, and/or results.

*Preferential amplification* is the unequal amplification of the two alleles present at a heterozygous locus during the polymerase chain reaction.

*Procedure* (protocol, standard operating procedure, or other equivalent) is a series of instructions to be followed in performing a specified task or under specific circumstances.

*Proficiency testing* is a quality assurance measure used to monitor performance and identify areas in which improvement may be needed. Proficiency tests may be classified as:
  1)  An internal proficiency test, which is produced by the agency undergoing the test.
  2)  An external proficiency test, which is a test obtained from a proficiency test provider accredited to the current applicable standard of the International Organization for Standardization and the applicable test is included on the proficiency test provider's scope of accreditation.

*Program* is a collection of policies, procedures, and/or instructions to fulfill a requirement.

*Qualified* is an adjective used to describe an individual who meets the requirements for the position, has successfully completed the laboratory's applicable training requirements, and is authorized to perform a specific task or role.

*Quality system* is the organizational structure, responsibilities, procedures, policies, and resources for implementing quality management.

*Quantitative PCR* is a method of determining the concentration of DNA in a sample by use of the polymerase chain reaction.

*Rapid DNA analysis* is the fully automated (hands-free) process of developing a CODIS acceptable STR profile from a database, known or casework reference sample. The "swab in – profile out" process consists of automated extraction, amplification, separation, detection and allele calling without human intervention.

*Rapid DNA cartridge* is a preassembled set of reagents and other analytical components (such as typing test kit) designed for use in a Rapid DNA instrument/System for the extraction, amplification and/or separation of DNA samples.

*Rapid DNA instrument* is an automated device that carries out Rapid DNA analysis or modified Rapid DNA analysis used to develop a CODIS acceptable STR profile from a database, known or casework reference sample.

*Rapid DNA System* is the collection of components that together performs a Rapid DNA analysis consisting of a Rapid DNA instrument, the PCR STR typing test kit/Rapid DNA cartridge, and an integrated Expert System used to develop a CODIS acceptable STR profile from a database, known or casework reference sample.

*Reagent* is a substance or mixture of substances used in the analysis process to detect, measure, produce, or interact with other substances.

*Reagent blank control* is an analytical control that is used to monitor contamination from extraction to DNA typing results and contains no intentionally added template DNA.

*Regression testing* is the process of testing an updated software program to confirm that modifications or new functionality do not unacceptably alter or terminate a desired functionality that behaved correctly before the change was implemented.

*Reliability testing* is the process of testing a software program beyond its functional aspects to ensure it works appropriately in the laboratory environment. This may include testing multi-user or multi-site scenarios, direct-access and network/server-access scenarios, and interaction with other software programs.

*Review* is an evaluation of documentation to check for consistency, accuracy, completeness, and compliance.

*Second agency* is an entity or organization external to and independent of the laboratory.

*Semi-annual* is used to describe an event that takes place two times during one calendar year, with the first event taking place in the first six months of that year and the second event taking place in the second six months of that year, and where the interval between the two events is at least four months and not more than eight months.

*Sensitivity studies* (for the purposes of Standard 8.3) are used to assess the ability to obtain reliable results from a range of DNA quantities, to include the upper and lower limits of the assay.

*Service* (for the purposes of Standard 10) is the performance of adjustments or specified procedures by the user, manufacturer, or other service personnel in order to ensure the intended performance of instruments and equipment.

*Specificity studies* (for the purposes of Standard 8.3) are used to assess the ability to detect genetic information from non-targeted species (e.g., detection of microbial DNA in a human assay). The detection of genetic information from non-targeted species does not necessarily invalidate the use of the assay, but may help define the limits of the assay.

*Stochastic threshold* is the peak height or signal magnitude value, determined through validation studies, below which it is reasonable to assume that, at a given locus, allelic dropout of a sister allele in a heterozygous pair may have occurred.

*Technical leader* (or equivalent role, position, or title as designated by the laboratory) is an employee who is accountable for the technical operations of the laboratory and who is authorized to initiate, suspend, and resume laboratory operations.

*Technical review* is an evaluation of notes, data, and other documents to ensure there is an appropriate and sufficient basis for the scientific conclusions.

*Technical reviewer* is an employee or contract employee who is a current or previously qualified analyst that performs a technical review of analytical documentation which he/she did not create.

*Technician* (or equivalent role, position, or title as designated by the laboratory) is an employee or contract employee who performs analytical procedures on database, known or casework reference samples under the direction of a qualified analyst. Technicians do not interpret data to reach conclusions on typing results or prepare final documents.

*Technology* is used to describe the type of DNA analysis performed in the laboratory, such as RFLP, STR, YSTR, XSTR, SNP, microhaplotypes or mitochondrial DNA.

*Test kit* is a preassembled set of reagents (or laboratory assembled equivalent) that allows the user to conduct a specific DNA extraction, quantification, or amplification method. A laboratory assembled equivalent may be referred to as a test system.

*Typing test kit* is a preassembled set of reagents (or laboratory assembled equivalent) that is used to generate a DNA type.

*Underlying scientific principle* is a rule concerning a natural phenomenon or function that is a part of the basis used to proceed to more detailed scientific functions.

*Uninterpretable* is a determination that DNA data cannot be interpreted (e.g., due to poor or limited data quality, data that fail to meet laboratory quality requirements).

*Validation* is a process by which a method is evaluated to determine its efficacy and reliability for DNA analysis and includes the following:
    1)    Developmental validation, which is the acquisition of test data and determination of conditions and limitations of a new or novel DNA method for use on database samples.
    2)    Internal validation, which is an accumulation of test data within the laboratory to demonstrate that established methods and procedures perform as expected in the laboratory.

*Vendor laboratory* is a governmental or private laboratory that provides DNA analysis services to another laboratory or agency and does not take ownership of the DNA data for purposes of entry into CODIS.

*Work product* is the material that is generated as a function of analysis, which may include extracts, amplified product and amplification tubes or plates as defined by the laboratory.

# 3. QUALITY ASSURANCE PROGRAM

STANDARD 3.1 The laboratory shall establish, follow, and maintain a documented quality system that is appropriate to the testing activities and is equivalent to, or more stringent than, what is required by these standards.

> 3.1.1 The quality system shall be documented in a manual that includes or references the following elements:
>
> > 3.1.1.1 Goals and objectives
> >
> > 3.1.1.2 Organization and management
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> > 3.1.1.3 Personnel
> >
> > 3.1.1.4 Training
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> > 3.1.1.5 Facilities and sample control
> >
> > 3.1.1.6 Validation
> >
> > 3.1.1.7 Analytical procedures
> >
> > 3.1.1.8 Equipment
> >
> > 3.1.1.9 Documentation
> >
> > 3.1.1.10 Review
> >
> > 3.1.1.11 Proficiency testing
> >
> > 3.1.1.12 Corrective action
> >
> > 3.1.1.13 Audits
> >
> > 3.1.1.14 Professional development
> >
> > 3.1.1.15 Outsourcing ownership
>
> 3.1.2 Any document referenced within the quality manual shall be available on-site or be readily accessible.

STANDARD 3.2 The laboratory shall have and follow a policy regarding document retention that specifically addresses proficiency tests, analytical results, sample receipt and processing records, sample retention, hit confirmation, corrective action, audits, training records, testimony, and continuing education.

STANDARD 3.3 The quality system as applicable to DNA shall be reviewed annually independent of the audit required by Standard 15. The review of the quality system shall be completed under the direction of the technical leader. The quality system review shall be approved by the technical leader.

STANDARD 3.4 The laboratory shall annually review sample processing records, determined by the technical leader to be representative of the samples tested. This review of the sample processing records shall be independent of an external audit conducted under Standard 15. The scope of the review shall be defined prior to each annual review and shall be approved by the technical leader.

## 4. ORGANIZATION AND MANAGEMENT

STANDARD 4.1 The laboratory shall:

> 4.1.1 Have a managerial staff with the authority and resources needed to discharge their duties and meet the requirements of the standards in this document.
>
> 4.1.2 Have a technical leader who is accountable for the technical operations. Multi-laboratory systems shall have at least one technical leader.
>
> 4.1.3 Have a CODIS administrator who is accountable for CODIS on-site at each individual laboratory facility utilizing CODIS.
>
> 4.1.4 Have at least two full-time employees who are qualified analysts.
>
> 4.1.5 Specify and document the responsibility, authority, and interrelation of all personnel who manage, perform, or verify work affecting the validity of the DNA analysis.
>
> 4.1.6 Have and follow a documented contingency plan that is approved by laboratory management if the technical leader position is vacated or if the number of qualified analysts falls below two full-time employees who are qualified analysts.

STANDARD 4.2 The laboratory shall have a policy that defines either the date of hire/appointment/promotion or the date of qualification to be used by the laboratory for determining the applicable version of the standard for education, experience and training requirements.

## 5. PERSONNEL

STANDARD 5.1 Laboratory personnel shall have the education, training, and experience commensurate with the examination and testimony provided.

5.1.1 The laboratory shall have a written job description for personnel, that may be augmented by additional documentation, which defines responsibilities, duties, and skills.

5.1.2 The laboratory shall maintain records on the relevant qualifications, training, skills, and experience of the technical personnel.

STANDARD 5.2 The technical leader shall be a full-time employee of the laboratory or multi-laboratory system and shall meet the following qualifications:

5.2.1 Minimum educational requirements: The technical leader of a laboratory shall have, at a minimum, a Master's degree in a biology-, chemistry-, or forensic science-related area and shall have successfully completed 12 semester or equivalent credit hours from a combination of undergraduate and graduate coursework covering the following subject areas: biochemistry, genetics, molecular biology, and statistics or population genetics.

> 5.2.1.1 The 12 semester or equivalent credit hours shall include at least one graduate level course registering three or more semester or equivalent credit hours.

> 5.2.1.2 The specific subject areas listed in Standard 5.2.1 shall constitute an integral component of any coursework used to demonstrate compliance with this standard.

> 5.2.1.3 Individuals who have completed coursework with titles other than those listed in Standard 5.2.1 shall demonstrate compliance with this standard through a combination of pertinent materials such as a syllabus, letter from the instructor, or other document that supports the course content.

> 5.2.1.4 If the degree requirements of Standard 5.2.1 were waived by the American Society of Crime Laboratory Directors (ASCLD) in accordance with criteria approved by the FBI Director, such a documented waiver shall be permanent and portable.

5.2.2 Minimum experience requirements: Any technical leader appointed prior to July 1, 2009, shall have three years of forensic, databasing or human identification DNA laboratory experience obtained at a laboratory where DNA testing was conducted for identification, databasing or forensic purposes. Any technical leader appointed on or after July 1, 2009, shall have a minimum of three years of human DNA (current or previous) experience as a qualified analyst on database or forensic samples.

5.2.3 Any technical leader appointed on or after July 1, 2020 shall be a currently or previously qualified analyst in each technology utilized in the laboratory, or have

documented training in each technology utilized in the laboratory within one year of appointment.

5.2.4 The technical leader shall have previously completed or will successfully complete the FBI's DNA auditor training course within one year of appointment.

5.2.5 The technical leader shall have the following authority and minimum responsibilities:

5.2.5.1 Oversee the technical operations of the laboratory.

5.2.5.2 Authority to initiate, suspend, and resume technical operations for the laboratory or an individual.

5.2.5.3 Evaluate and approve all validations and new or modified methods used by the laboratory.

5.2.5.4 Review the training records for newly qualified analysts, technicians and technical reviewers and approve their qualifications prior to independent database analysis. Review, verify, and approve the academic transcripts for newly qualified analysts and technical reviewers.

5.2.5.5 Approve the technical specifications for outsourcing agreements.

5.2.5.6 Review internal and external DNA Audit documents and, if applicable, approve corrective action(s).

5.2.5.7 Review, on an annual basis, the procedures of the laboratory.

5.2.5.8 Review and approve the training, quality assurance, and proficiency testing programs in the laboratory.

5.2.5.9 Review potential conflicts of interest when contract employees are employed by multiple NDIS participating and/or vendor laboratories.

5.2.6 The technical leader shall be accessible to the laboratory to provide on-site, telephone, or electronic consultation as needed. A multi-laboratory system may have one technical leader over a system of separate laboratory facilities. For multi-laboratory systems, the technical leader shall conduct and document a site visit to each laboratory at least semi-annually.

5.2.7 Newly appointed technical leaders shall be responsible for the review of the following within one year of appointment:

5.2.7.1 Validation studies and analytical procedures currently used by the laboratory; and

5.2.7.2 Educational and training records of currently qualified analysts and technical reviewers.

STANDARD 5.3 The CODIS administrator shall be an employee of the laboratory and meet the following qualifications:

5.3.1 Minimum educational requirements: The CODIS administrator shall meet the education requirements for an analyst as defined in Standard 5.4. A CODIS administrator appointed prior to July 1, 2020 shall be deemed to have satisfied the minimum educational requirements; satisfaction of these minimum educational requirements shall be applicable to the specific laboratory by which the CODIS administrator is employed by prior to July 1, 2020 and shall not be portable.

5.3.2 Minimum experience requirements: A CODIS administrator shall be a current or previously qualified forensic or database analyst as defined in Standard 5.4 with documented mixture interpretation training. A CODIS administrator appointed prior to July 1, 2009 who is not or has never been a qualified analyst (with documented training in mixture interpretation) shall be deemed to have satisfied the minimum experience requirements upon completion of FBI sponsored CODIS training; satisfaction of these minimum requirements shall be applicable to the specific laboratory the CODIS administrator is employed by prior to July 1, 2009 and shall not be portable.

5.3.3 Minimum CODIS training requirements: The CODIS administrator shall successfully complete the FBI-sponsored training in CODIS software within six months of assuming CODIS administrator duties if the administrator had not previously completed such training. The CODIS administrator shall successfully complete the FBI's DNA auditor training course within one year of assuming his/her administrator duties if the administrator had not previously completed such training.

5.3.4 The CODIS administrator shall have the following minimum responsibilities:

5.3.4.1 Administer the laboratory's CODIS network.

5.3.4.2 Schedule and document the CODIS computer training of database analysts.

5.3.4.3 Ensure that the security of data stored in CODIS is in accordance with state and/or federal law and NDIS operational procedures.

5.3.4.4 Ensure that the quality of data stored in CODIS is in accordance with state and/or federal law and NDIS operational procedures.

5.3.4.5 Ensure that matches are dispositioned in accordance with NDIS operational procedures.

5.3.5 The CODIS administrator shall be authorized to terminate participation in CODIS until the reliability and security of the computer data can be assured in the event an issue with the data is identified.

5.3.6 A laboratory shall not upload DNA profiles to NDIS in the event that the CODIS administrator position is unoccupied.

STANDARD 5.4 The analyst shall be an employee or contract employee of the laboratory and meet the following qualifications:

5.4.1 Minimum educational requirements: The analyst shall have a bachelor's (or its equivalent) or an advanced degree in a biology-, chemistry-, or forensic science-related area and shall have successfully completed coursework (graduate or undergraduate level) covering the following subject areas: biochemistry, genetics, and molecular biology. Any analyst hired/appointed/promoted or qualified (as defined by the laboratory per Standard 4.2) prior to July 1, 2020, shall have coursework and/or training in statistics and/or population genetics as it applies to forensic or databasing DNA analysis. Any analyst hired/appointed/promoted or qualified (as defined by the laboratory pursuant to Standard 4.2) on or after July 1, 2020, shall have successfully completed coursework covering statistics and/or population genetics.

5.4.1.1 The specific subject areas listed in Standard 5.4.1 shall be an integral component of any coursework for compliance with this standard.

5.4.1.2 Analysts appointed or hired on or after July 1, 2009 shall have a minimum of nine cumulative semester hours or equivalent that cover the required subject areas of biochemistry, genetics, and molecular biology.

5.4.1.3 Analysts who have completed coursework with titles other than those listed in 5.4.1 above shall demonstrate compliance with this standard through a combination of pertinent materials, such as a syllabus, letter from the instructor, or other document that supports the course content. The technical leader shall approve compliance with this standard.

5.4.2 Minimum experience requirements: The analyst shall have six months of human DNA laboratory experience with at least three months in a forensic or database DNA laboratory. If prior human DNA laboratory experience is accepted by a laboratory, the prior experience shall be documented and augmented by additional training, as needed. The analyst shall successfully complete the required training.

STANDARD 5.5 The technical reviewer shall be an employee or contract employee of the laboratory. The technical reviewer shall meet the education and experience requirements in Standard 5.4 and shall meet the following:

5.5.1 A current or previously qualified analyst.

5.5.2 Successful completion of documented training.

STANDARD 5.6 The technician shall be an employee or contract employee of the laboratory and shall successfully complete the laboratory's documented training program.

STANDARD 5.7 The technical leader shall verify and approve the education, to include a review of academic transcripts, of each analyst and technical reviewer.

## 6. TRAINING

STANDARD 6.1 The laboratory shall have a training program documented in a training manual for qualifying analysts and technicians. The training program shall:

6.1.1 Address all DNA analytical and interpretation procedures used in the laboratory.

6.1.2 Include practical exercises encompassing the examination of a range of samples routinely encountered in database analysis.

6.1.3 Teach and assess the technical skills and knowledge required to perform DNA analysis.

6.1.3.1 The training program for analysts shall include the skills and knowledge required to conduct a technical review.

6.1.4 Include an assessment of oral communication skills and/or a mock court exercise.

6.1.5 Include requirements for competency testing.

STANDARD 6.2 The technical leader shall approve any modifications to an analyst's, technical reviewer's, technician's, or laboratory support personnel's required training based on the documented assessment of the individual's previous training and experience.

STANDARD 6.3 All analyst/technician(s), regardless of previous experience, shall successfully complete competency testing covering the routine DNA methods and interpretation procedures that the analyst/technician will perform prior to participating in independent database analysis/processing.

6.3.1 Competency testing for a new analyst shall include a practical component, and written and/or oral components.

6.3.2 Competency testing for a new technician shall include a practical component.

STANDARD 6.4 For an analyst or technician, currently or previously qualified within the laboratory, to be qualified in a new or additional method, the laboratory shall teach and assess the technical skills and knowledge required to perform the additional method.

> 6.4.1 Before the use of a new or additional method on database, known or casework reference samples, the analyst and/or technician shall successfully complete competency testing to the extent of his/her participation in database analyses. The competency testing shall include a practical component.

STANDARD 6.5 For an analyst, currently or previously qualified within the laboratory, to be qualified to interpret data for a new or additional technology, typing test kit, platform, or interpretation software, the laboratory shall teach and assess the technical skills and knowledge required to interpret data using the additional technology, typing test kit, platform, or interpretation software.

> 6.5.1 Before the use of a new or additional technology, typing test kit, platform or interpretation software on database, known or casework reference samples, the analyst shall successfully complete competency testing using the additional technology, typing test kit, platform, or interpretation software to the extent of his/her participation in database analyses. The competency testing shall include a practical component.

STANDARD 6.6 A technical reviewer, who is not currently qualified as an analyst in the laboratory, shall receive training on processing records, data analysis and interpretation for any method, technology, typing test kit, platform, or interpretation software on which they will conduct reviews of data and/or records and for which they were not previously qualified as an analyst in the laboratory.

> 6.6.1 The technical reviewer shall successfully complete competency testing before completing a technical review of data and/or documentation using the additional method, technology, typing test kit, platform, or interpretation software used in database analyses.

>> 6.6.1.1 For a technical reviewer who is a contract employee conducting reviews for an NDIS participating laboratory, the competency testing shall be administered by the NDIS participating laboratory.

STANDARD 6.7 The technical leader shall review the training records for the analyst, technician, and/or technical reviewer and approve his/her qualifications prior to independent database responsibilities.

STANDARD 6.8 The analyst, technician, and/or technical reviewer shall be authorized to independently perform assigned job responsibilities and the date(s) shall be documented.

STANDARD 6.9 Laboratory support personnel shall have documented training specific to their job function(s).

STANDARD 6.10 The laboratory shall have and follow a policy for addressing retraining of personnel when necessary. The technical leader shall be responsible for evaluating the need for and assessing the extent of retraining. The retraining plan shall be documented and approved by the technical leader.

> 6.10.1 The individual shall successfully complete competency testing prior to his/her return to participation in database analyses. This competency testing shall include a practical component.

STANDARD 6.11 The laboratory shall maintain records on the training, including successful completion of competency testing, of the laboratory personnel.


# 7. FACILITIES AND SAMPLE CONTROL

STANDARD 7.1 The laboratory shall have a facility that is designed to ensure the integrity of the analyses and the samples.

> 7.1.1 The laboratory shall have secure, controlled access areas for sample storage.

> 7.1.2 Except as provided in Standard 7.1.3.1, techniques performed prior to PCR amplification such as sample accessioning, DNA extractions, and PCR setup shall be conducted at separate times or in separate spaces from each other.

> 7.1.3 Except as provided in Standard 7.1.3.1, amplified DNA product, including real time PCR, shall be generated, processed, and maintained in a room(s) separate from the sample accessioning, DNA extractions, and PCR setup areas. The doors between rooms containing amplified DNA and other areas shall remain closed except for passage.

> > 7.1.3.1 A Rapid DNA instrument/System used for processing database, known or casework reference samples shall be maintained in rooms outside of sample accessioning areas or those containing amplified DNA.

STANDARD 7.2 The laboratory shall have and follow procedures for laboratory security.

> 7.2.1 Access to the laboratory shall be controlled and limited in a manner to prevent access to the operational areas by unauthorized personnel. All exterior entrance/exit points require security controls that limit entry and access into the operational areas. The distribution of all keys, combinations, etc., shall be documented and limited to the personnel designated by laboratory management.

STANDARD 7.3 The laboratory shall have and follow a documented sample inventory control program to ensure the integrity of database, known and casework reference samples.

7.3.1 Database, known and casework reference samples shall be marked with a unique identifier. The laboratory shall clearly define what constitutes evidence and what constitutes work product. The laboratory shall have and follow a method to distinguish each sample throughout processing.

7.3.2 Documentation of sample identity, collection, receipt, storage, and disposition shall be maintained.

7.3.2.1 If the databasing laboratory is processing known or casework reference sample(s) as evidence, a chain of custody shall be documented and maintained in written, printed or electronic format. The chain of custody shall include the signature, initials, or electronic equivalent of each individual receiving or transferring the evidence, the corresponding date for each transfer, and the known or casework reference sample(s) transferred.

7.3.3 The laboratory shall have and follow procedures that address handling and preserving the integrity of samples and work product designed to minimize loss, contamination, and/or deleterious change.

7.3.3.1 The laboratory shall have and follow a policy or procedure for securing samples and work product in progress.

7.3.3.2 The laboratory shall have secure areas for sample storage including environmental control consistent with the form or nature of the sample.

STANDARD 7.4 The laboratory shall have a policy on sample consumption.

7.4.1. Where possible, the laboratory shall retain the database sample for retesting for quality assurance and sample confirmation purposes.


## 8. VALIDATION

STANDARD 8.1 The laboratory shall use validated methods for DNA analyses.

STANDARD 8.2 Developmental validation shall precede the implementation of any new methods used for DNA database analysis.

8.2.1 Developmental validation studies shall include, where applicable, characterization of the genetic marker, species specificity, sensitivity studies, stability studies, database-type samples, population studies, mixture studies, precision and accuracy studies, and PCR-based studies. PCR-based studies include reaction conditions, assessment of differential and preferential amplification, effects

of multiplexing, assessment of appropriate controls, and product detection studies. All validation studies shall be documented.

8.2.2 Peer-reviewed publication of the underlying scientific principle(s) of a method shall be required.

STANDARD 8.3 Except as provided in Standard 8.3.1.1, internal validation of all manual and robotic methods shall be conducted by each laboratory with the appropriate sample number and type to demonstrate the reliability and potential limitations of the method.

8.3.1 Internal validation studies shall include as applicable: known database-type samples, precision and accuracy studies, sensitivity and stochastic studies, and contamination assessment studies.

8.3.1.1 Internal validation data may be shared by all locations in a multi-laboratory system. The summary of the shared validation data shall be available at each site. Each laboratory in a multi-laboratory system shall complete, document and maintain applicable site-specific precision, sensitivity, and contamination assessment studies.

8.3.2 Internal validation shall define quality assurance parameters and interpretation guidelines.

8.3.3 Internal validation studies shall be conducted prior to implementing a change in platform instrument model or typing test kit.

8.3.4 Internal validation studies shall be documented and summarized. Internal validation shall be reviewed and approved by the technical leader prior to implementing a procedure for database applications.

STANDARD 8.4 Newly validated DNA methods (from amplification through characterization), typing test kit or platform instrument model shall be checked against an appropriate and available certified reference material (or sample made traceable to the certified reference material) prior to the implementation of the method for database analysis.

STANDARD 8.5 The performance of a modified procedure shall be evaluated by comparison to the original procedure using similar DNA samples and the evaluation documented. The evaluation shall be reviewed and approved by the technical leader prior to the implementation of the modified procedure into database applications.

STANDARD 8.6 An Expert System used to generate NDIS eligible DNA profiles shall be validated in accordance with Standard 8 and applicable NDIS operational procedures.

8.6.1    An Expert System shall be subject to recertification in accordance with NDIS operational procedures.

STANDARD 8.7 A Rapid DNA instrument used for modified Rapid DNA analysis on database, known or casework reference samples shall be validated in accordance with Standard 8.

STANDARD 8.8 An NDIS approved Rapid DNA System shall require a performance check prior to use on database, known or casework reference samples.

STANDARD 8.9 New software or new modules of existing software and modifications to software shall be evaluated to assess the suitability of the software for its intended use in the laboratory and to determine the necessity of validation studies or software testing. This evaluation shall include the determination of which studies will and will not be conducted and shall be documented.

8.9.1 New software or new modules of existing software that are used as a component of instrumentation, for the analysis and/or interpretation of DNA data, or statistical calculations shall be subject to developmental validation prior to implementation in DNA database analysis.

8.9.1.1 With the exception of legally protected information, the underlying scientific principle(s) utilized by software with an impact on the analytical process, interpretation, or statistical calculations shall be publicly available for review or published in a peer-reviewed scientific journal.

8.9.1.2 Developmental software validation studies for new software or new modules of existing software used as a component of instrumentation shall include at a minimum, functional testing and reliability testing.

8.9.1.3 Developmental software validation studies for new software or new modules of existing software for the analysis and/or interpretation of DNA data shall include at a minimum, functional testing, reliability testing, and as applicable, accuracy, precision, sensitivity, and specificity studies.

8.9.1.4 Developmental software validation studies for new software or new modules of existing software for statistical calculations shall include at a minimum, functional testing, reliability testing, and as applicable, accuracy, and precision studies.

8.9.2 New software or new modules of existing software that are used as a component of instrumentation, for the analysis and/or interpretation of DNA data, or for statistical calculations shall be subject to internal validation specific to the laboratory's intended use prior to implementation in DNA database analysis.

8.9.2.1 Internal software validation studies for new software or new modules of existing software used as a component of instrumentation shall include functional testing and reliability testing.

8.9.2.2 Internal software validation studies for new software or new modules of existing software for the analysis and/or interpretation of DNA data shall include functional testing, reliability testing, and, as applicable, precision and accuracy studies, sensitivity, and specificity studies.

8.9.2.3 Internal software validation studies for new software or new modules of existing software for statistical calculations shall include functional testing, reliability testing, and, as applicable, precision and accuracy studies.

8.9.2.4 Software that does not impact the analytical process, interpretation, or statistical calculations shall require at a minimum, a functional test.

8.9.3 Modifications to software as described in Standards 8.9.1 and 8.9.2 shall be evaluated to determine if the modifications result in major or minor revisions to the software.

8.9.3.1 A major revision to software used as a component of instrumentation shall require validation prior to implementation. Software validation studies shall include functional testing, reliability testing, and regression testing.

8.9.3.2 A major revision to software used for the analysis and/or interpretation of DNA data shall require validation prior to implementation. Software validation studies shall include functional testing, reliability testing, regression testing, and, as applicable, precision and accuracy studies, sensitivity, and specificity studies.

8.9.3.3 A major revision to software used for statistical calculations shall require validation prior to implementation. Software validation studies shall include functional testing, reliability testing, regression testing, and, as applicable, precision and accuracy studies.

8.9.3.4 A minor revision to software that does not impact the analytical process, interpretation, or statistical calculations shall require at a minimum, a functional test.

8.9.4 Software validation studies and software testing may be shared by all locations in a multi-laboratory system. The summary of the shared validation data shall be available at each site. Each laboratory in a multi-laboratory system shall complete, document and maintain applicable site-specific reliability testing.

8.9.5 Software validation and testing shall be documented. Software validation and testing shall be reviewed and approved by the technical leader prior to implementation.

STANDARD 8.10 Developmental validation studies, internal validation studies, modified procedure evaluations, and software testing, including the approval of the technical leader, shall be retained and available for review.

## 9. ANALYTICAL PROCEDURES

STANDARD 9.1 The laboratory shall have and follow analytical procedures supported by the internal validations and approved by the technical leader.

9.1.1 The laboratory shall have and follow a standard operating procedure for each analytical method used by the laboratory including the appropriate analytical controls required for DNA analysis and data interpretation.

STANDARD 9.2 The laboratory shall use reagents that are suitable for the methods employed.

9.2.1 The laboratory shall have procedures for documenting commercial reagents and for the formulation of in-house reagents.

9.2.2 Commercial reagents shall be labeled with the identity of the reagent and the expiration date as provided by the manufacturer or as determined by the laboratory.

9.2.3 In-house reagents shall be labeled with the identity of the reagent, the date of preparation and/or expiration, and the identity of the individual preparing the reagent.

STANDARD 9.3 The laboratory shall identify critical reagents and evaluate them prior to use in database sample processing. The following shall be identified as critical:

9.3.1 Test kits or systems for DNA quantification or amplification.

9.3.2 Thermostable DNA polymerase, primer sets and allelic ladders used for genetic analysis that are not tested as test kit components under Standard 9.3.1.

9.3.3 Rapid DNA cartridges.

9.3.4 Other laboratory defined critical reagents.

STANDARD 9.4 Except for Rapid DNA instruments/Systems used to analyze database, known or casework reference samples pursuant to Standards 9.6 and 9.7, the laboratory

shall monitor the analytical procedures using the following analytical controls and standards.

> 9.4.1 Reagent blank controls associated with each extraction set being analyzed shall be:

>> 9.4.1.1 Extracted concurrently and treated with the most sensitive conditions as the samples;

>> 9.4.1.2 Amplified utilizing the same typing test kit, instrument model, and sensitivity conditions as required by the sample(s) containing the least amount of DNA; and

>> 9.4.1.3 Typed utilizing the same instrument model, injection conditions and most sensitive volume conditions of the extraction set.

> 9.4.2 Where quantification is used, quantification standards shall be used. If a virtual or external standard curve is utilized, a calibrator must be run concurrently with the samples.

> 9.4.3 Positive and negative amplification controls associated with samples being typed shall be amplified concurrently using the same typing test kit on the same instrument as the samples.

>> 9.4.3.1 Except as provided in Standard 9.4.4.1, all samples typed shall also have the corresponding amplification controls typed.

> 9.4.4 For laboratories performing sequencing, the laboratory shall use positive and negative sequencing controls concurrently sequenced using the same typing test kit on the same instrument as the samples.

>> 9.4.4.1 If the positive amplification control is not used as the positive sequencing control, the laboratory shall have and follow procedures for the evaluation of the positive amplification control.

> 9.4.5 Allelic ladders and internal size standards for PCR-based systems, as applicable.

STANDARD 9.5 The laboratory shall have and follow written guidelines for the interpretation of data that are based on and supported by internal validation studies. An NDIS approved and internally validated Expert System may be used to complete the data interpretation process. The laboratory shall:

> 9.5.1 Have criteria to evaluate internal size standards, allelic ladders and analytical controls.

9.5.2 Have criteria for the interpretation of non-allelic peaks/signal.

9.5.3 Have criteria for the interpretation of allelic peaks/signal.

9.5.4 Define the thresholds used for interpretation. As appropriate to the interpretation model utilized, the laboratory shall establish the following thresholds:

9.5.4.1 Analytical Threshold

9.5.4.2 Stochastic Threshold

9.5.5 Define criteria for uninterpretable data.

STANDARD 9.6 For modified Rapid DNA analysis, a laboratory shall:

9.6.1 Have and follow written guidelines for the manual interpretation of data.

9.6.1.1 The laboratory shall verify that the internal size standard and allelic ladder results meet the laboratory's interpretation guidelines.

9.6.2 Have and follow procedures to address the use of positive sample controls and negative sample controls.

STANDARD 9.7 For Rapid DNA analysis, a laboratory shall have and follow procedures to address the use of positive sample controls and negative sample controls.

9.7.1 The Rapid DNA cartridge shall include an internal size standard with each sample.

STANDARD 9.8 The laboratory shall have and follow a procedure for the detection and control of contamination.

9.8.1 The laboratory shall have and follow procedures for cleaning and decontaminating facilities and equipment.

## 10. EQUIPMENT

STANDARD 10.1 The laboratory shall use equipment suitable for the methods employed.

STANDARD 10.2 The laboratory shall identify critical equipment or instruments and have and follow a program to ensure they are maintained.

10.2.1 At minimum, the following shall be identified as critical:

10.2.1.1 Handheld mechanical pipettes

10.2.1.2 A thermometer traceable to national or international standard(s)

10.2.1.3 Incubators/heat blocks used in analytical procedures

10.2.1.4 Robotic systems

10.2.1.5 Thermal cyclers, including quantitative PCR

10.2.1.6 Thermal cycler temperature verification systems

10.2.1.7 Electrophoresis detection systems, including Genetic Analyzers

10.2.1.8 Rapid DNA instruments/Systems

10.2.1.9 Any additional instruments or equipment that produces DNA typing results

STANDARD 10.3 The laboratory shall have procedures for conducting performance checks and evaluating results of critical equipment or instruments.

10.3.1 New critical equipment or instruments, not requiring validation, shall undergo a performance check before use in database analysis. Each additional critical instrument, of the same instrument model validated for use in the laboratory, shall require a performance check prior to use in database analysis.

10.3.2 The following critical equipment or instruments shall require annual performance checks:

10.3.2.1 Handheld mechanical pipettes

10.3.2.2 Incubators/heat blocks used in an analytical procedure

10.3.2.3 Robotic systems

10.3.2.4 Thermal cyclers, including quantitative-PCR

10.3.2.5 Thermal cycler temperature verification systems

10.3.2.6 Electrophoresis detection systems, including Genetic Analyzers

10.3.2.7 Any additional instruments or equipment that produces DNA typing results

10.3.2.8 Other critical equipment or instruments defined by laboratory

10.3.3 The following critical equipment or instruments shall require a performance check after repair or service:

    10.3.3.1 Robotic systems

    10.3.3.2 Thermal cyclers, including quantitative-PCR

    10.3.3.3 Electrophoresis detection systems, including Genetic Analyzers

    10.3.3.4 Rapid DNA instruments/Systems

    10.3.3.5 Any additional instruments or equipment that produces DNA typing results

    10.3.3.6 Other laboratory defined critical equipment or instruments

10.3.4 A Rapid DNA instrument/System shall require a performance check upon installation.

10.3.5 A Rapid DNA instrument/System shall undergo a performance check if the Rapid DNA instrument remains idle longer than the period recommended in the instrument specifications or as established by the laboratory.

STANDARD 10.4 The laboratory shall maintain documentation of maintenance, service, repair, and performance checks.

# 11. DOCUMENTATION

STANDARD 11.1 The laboratory shall have and follow procedures for maintaining documentation for database, known or casework reference samples. The laboratory shall maintain all analytical documentation generated by technicians and/or analysts related to database analyses. The laboratory shall retain, in written, printed, or electronic format, sufficient documentation for each technical analysis to support the profile data such that another qualified individual can evaluate what was done and interpret the data.

STANDARD 11.2 The laboratory shall have and follow a documented procedure for the resolution, verification and reporting/notification of database matches.

STANDARD 11.3 Except as otherwise provided by state or federal law, the information in DNA records and DNA databases shall be confidential.

    11.3.1 The laboratory shall have and follow policies and/or procedures for the release of DNA records and databases, in accordance with applicable state or federal law.

11.3.2 The laboratory shall have and follow policies and/or procedures for the release of personally identifiable information in accordance with applicable state and federal law.

11.3.2.1 The laboratory shall have and follow a procedure for the release of personally identifiable information in connection with a database hit.

## 12. REVIEW

STANDARD 12.1 The laboratory shall have and follow procedures for reviewing DNA records and database information, including the verification and resolution of database matches.

12.1.1 An individual conducting technical reviews shall be an analyst or technical reviewer qualified in the method, technology, typing test kit, platform and interpretation software being reviewed.

STANDARD 12.2 The laboratory shall perform a technical review of all DNA records, except when using an NDIS approved Rapid DNA System to analyze database, known or casework reference samples. Completion of the technical review shall be documented and the technical review of a DNA record shall include the following elements:

12.2.1 A review of all notes, all worksheets, and the electronic data (or printouts of such data) supporting the results.

12.2.2 A review of all analytical controls, internal size standards, and allelic ladders to verify that the expected results were obtained, except when using an NDIS approved and internally validated Expert System.

12.2.3 A review of all DNA types to verify that they are supported by the raw or analyzed data (electropherograms or images), except when using an NDIS approved and internally validated Expert System.

STANDARD 12.3 The release of personally identifiable information associated with a database hit shall require an administrative review of the official correspondence. Completion of the administrative review shall be documented and shall include the following elements, any or all of which may be included within the technical review:

12.3.1 A review of the supporting administrative documentation and the correspondence for clerical errors, accuracy of information and adherence to agency policy.

12.3.2 A review of chain of custody for known or casework reference samples processed as evidence.

12.3.3 A review of the individual's biographical data, qualifying offense, and DNA profile generated from reanalysis, as applicable.

STANDARD 12.4 The laboratory shall have and follow a policy and/or procedure to address unresolved discrepant interpretations or conclusions between analysts and reviewer(s).

STANDARD 12.5 The laboratory shall have a system in place to ensure that the correct CODIS specimen categories have been assigned.

## 13. PROFICIENCY TESTING

STANDARD 13.1 Analysts, technical reviewers, technicians, and other personnel designated by the technical leader, shall undergo semi-annual external proficiency testing.

13.1.1 Analysts qualified in more than one technology shall be proficiency tested in each technology at least once per calendar year.

13.1.1.1 Typing of all CODIS core loci or CODIS core sequence ranges shall be attempted for each technology at least once per calendar year.

13.1.2 Analysts qualified in more than one typing test kit shall be proficiency tested in each typing test kit at least once per calendar year.

13.1.2.1 Analysts qualified to perform modified Rapid DNA analysis shall be externally proficiency tested on the interpretation of data generated by each Rapid DNA instrument model for each PCR STR typing test kit at least once per calendar year.

13.1.3 Individuals that perform analytical procedures on database, known, or casework reference samples shall be proficiency tested on at least one method in each methodology at least once per calendar year.

13.1.4 Except as provided in Standard 13.1.4.1, each external proficiency test shall be assigned to and completed by one analyst.

13.1.4.1 Laboratories that employ technicians and/or use a team approach for database analysis may do so on external proficiency tests. However, each analyst shall be assigned a proficiency test to complete the interpretation and report the results.

13.1.5 Individuals whose sole responsibility is technical review[1] shall be proficiency tested in the technical review of each technology and typing test kit at least once per calendar year.

> 13.1.5.1 The proficiency testing shall cover the CODIS core loci or CODIS core sequence ranges attempted for each technology at least once per calendar year.

> 13.1.5.2 Technical reviewers qualified to review modified Rapid DNA analysis shall be externally proficiency tested on the technical review of data generated by each Rapid DNA instrument model for each PCR STR typing test kit at least once per calendar year.

> 13.1.5.3 If the technical reviewer is a contract employee conducting technical reviews for an NDIS participating laboratory the proficiency testing shall be administered by an NDIS participating laboratory and shall be reviewed and approved by the technical leader of the NDIS participating laboratory for which the technical reviewer is conducting reviews.

13.1.6 Newly qualified individuals shall undergo semi-annual external proficiency testing within eight months of the date of their authorization.

STANDARD 13.2 The laboratory shall use an external proficiency test provider that is accredited to the current applicable standard of the International Organization for Standardization and the applicable test is included on the proficiency test provider's scope of accreditation. External proficiency testing shall be an open proficiency testing program and shall be submitted to the proficiency testing provider in order to be included in the provider's published external summary report.

STANDARD 13.3 For purposes of tracking compliance with the proficiency testing requirements, the laboratory shall define and consistently use the date that the proficiency test is performed as the received date, assigned date, submitted date, or the due date.

STANDARD 13.4 The laboratory shall maintain the following records for proficiency tests:

13.4.1 The test set identifier;

13.4.2 Identity of the analyst, and other participants, if applicable;

13.4.3 Date of analysis and completion;

13.4.4 Copies of all data and notes supporting the interpretations or conclusions;

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[1] A qualified analyst proficiency-tested in the specific technology is qualified to serve as a technical reviewer without needing to take an additional proficiency test as a technical reviewer.

13.4.5 The proficiency test results;

13.4.6 Any discrepancies noted; and

13.4.7 Corrective actions taken.

STANDARD 13.5 The laboratory shall evaluate proficiency test results and shall include, at a minimum, the following criteria:

13.5.1 All reported genotypes, phenotypes, and/or sequences are correct or incorrect according to consensus results or are compliant with the laboratory's interpretation guidelines.

13.5.2 All reported uninterpretable results are compliant with written laboratory guidelines.

13.5.3 All final proficiency tests shall be evaluated as satisfactory or unsatisfactory.

13.5.3.1 All discrepancies or errors and subsequent corrective actions, as applicable, shall be documented.

STANDARD 13.6 The following shall be informed of the results of the proficiency test:

13.6.1 The proficiency test participant(s)

13.6.2 The technical leader

13.6.3 The CODIS administrator in the event of non-administrative discrepancies that affect the typing results.


## 14. CORRECTIVE ACTION

STANDARD 14.1 The laboratory shall have and follow a policy and/or procedure to address nonconformities detected in database analysis, proficiency tests, testimony, and audits. The laboratory policy and/or procedure shall define when a nonconformity requires documentation and/or a corrective action plan.

14.1.1 Corrective action plans shall be documented.

STANDARD 14.2 The laboratory's documented corrective action plan shall include the identification (when possible) of the cause(s) of the nonconformity, corrective actions taken with time frames (where applicable), and preventive measures taken (where applicable) to minimize its reoccurrence.

14.2.1 Corrective action plans shall be approved by the technical leader prior to implementation.

14.2.2 The CODIS administrator shall be notified when the nonconformity impacts DNA records entered into CODIS.

## 15. AUDITS

STANDARD 15.1 The laboratory shall be audited annually in accordance with these standards. The annual audits shall occur every calendar year and shall be at least six months and no more than 18 months apart.

STANDARD 15.2 At least once every two years, an external audit shall be conducted by one or more auditor(s) from a second agency(ies). At least one auditor shall be or have been an analyst previously qualified in the laboratory's current DNA technologies and platforms.

15.2.1 Each analyst, technical reviewer, CODIS administrator, and technical leader shall have his/her education, experience, and training qualifications evaluated and approved during two successive, separate external audits. Approval of an individual's education, experience, and training qualifications shall be documented in the Audit Document.

15.2.1.1 An analyst or technical reviewer that receives additional qualification in an additional technology(ies), typing test kit(s), or platform(s) shall have the additional training qualifications evaluated and approved during one external audit. Approval of additional training qualifications shall be documented in the Audit Document.

15.2.2 Each validation study shall be evaluated and approved during one external audit. Approved validation studies shall be documented in the Audit Document.

STANDARD 15.3 Internal audits shall be conducted by an audit team that includes at least one auditor. At least one team member shall be or have been an analyst previously qualified in the laboratory's current DNA technologies and platforms.

STANDARD 15.4 Internal and external audits shall be conducted utilizing the FBI *DNA Quality Assurance Standards* Audit Document in effect at the time of the audit.

STANDARD 15.5 Internal and external audit documentation and, if applicable, corrective action(s) shall be reviewed by the technical leader to ensure that findings, if any, were appropriately addressed and this review shall be documented.

15.5.1 Internal and external audit documentation, and if applicable, corrective action(s), shall be provided to the CODIS administrator.

15.5.2 For NDIS participating laboratories, all external audit documentation and laboratory responses shall be provided to the FBI within 30 days of laboratory receipt of the Audit Document or report.

STANDARD 15.6 Internal and external audit documentation shall be retained and available for inspection during subsequent audits.


## 16. PROFESSIONAL DEVELOPMENT

STANDARD 16.1 The laboratory shall have and follow a program to ensure technical qualifications are maintained through participation in continuing education.

16.1.1 The technical leader, CODIS administrator, analyst(s), and technical reviewers shall stay abreast of topics relevant to the field of forensic or databasing DNA analysis by attending seminars, courses, professional meetings, or other documented lectures or classes in relevant subject areas for a minimum of eight cumulative hours each calendar year.

16.1.1.1 The continuing education hours shall be documented. Attendance at a regional, national, or international conference with content including topics relevant to the field of forensic or databasing DNA analysis shall be deemed to provide a minimum of eight hours of continuing education.

16.1.1.2 The laboratory shall maintain documentation of attendance through a mechanism such as certificates, attendance list, or travel documentation.

16.1.1.3 With the exception of a regional, national, or international conference, the laboratory shall maintain documentation of content through a mechanism such as agenda/syllabus, record of presentation content, or the curriculum vitae of the presenter.

16.1.1.4 Continuing education based on multimedia or internet delivery shall be subject to the approval of the technical leader.

16.1.2 The laboratory shall have and follow a program approved by the technical leader for the annual review of scientific literature that documents the analysts' ongoing reading of scientific literature.

16.1.2.1 The laboratory shall maintain or have physical or electronic access to a collection of current books, reviewed journals, or other literature applicable to DNA analysis.

STANDARD 16.2 The laboratory shall have and follow a program that documents the annual review of the testimony of each analyst.

16.2.1 The program shall define elements and methods for testimony review.

16.2.2 The testimony review shall be documented and provided to the testifying. individual.

16.2.2.1 Any deficiency and subsequent corrective actions, as applicable, shall be documented.


## 17. OUTSOURCING OWNERSHIP

STANDARD 17.1 A vendor laboratory performing database DNA analysis shall comply with these standards and the accreditation requirements of federal law.

17.1.1 An NDIS participating laboratory that outsources to a vendor laboratory shall require the vendor laboratory to provide documentation of compliance with these standards and the accreditation requirements of federal law. The NDIS participating laboratory's technical leader shall review the vendor laboratory's compliance with these standards and the accreditation requirements of federal law.

17.1.2 A vendor laboratory performing Rapid DNA analysis using an NDIS approved Rapid DNA System shall have a system in place to ensure that the correct CODIS specimen categories have been assigned.

STANDARD 17.2 Except as provided in Standards 17.2.1 and 17.2.2, the NDIS participating laboratory's technical leader shall approve the technical specifications of the outsourcing agreement with the vendor laboratory before it is awarded.

17.2.1 A vendor laboratory that is performing DNA analysis on behalf of a law enforcement agency or other entity for the purposes of ownership by an NDIS participating laboratory, shall not initiate analysis until approval has been obtained from the appropriate NDIS participating laboratory's technical leader.

17.2.2 An NDIS participating laboratory shall not upload or accept DNA data for upload to CODIS from any vendor laboratory or agency without the prior approval of the technical specifications of the outsourcing agreement and/or approval of acceptance of ownership of the DNA data by the NDIS participating laboratory's technical leader.

STANDARD 17.3 An NDIS participating laboratory shall have and follow a procedure to verify the integrity of the DNA data received for the purposes of taking ownership of DNA data from a vendor laboratory.

17.3.1 The NDIS participating laboratory shall have and follow quality assurance procedures to verify the integrity of the DNA data received from a vendor laboratory including, but not limited to, the following:

17.3.1.1 Random reanalysis of database, known or casework reference samples; and

17.3.1.2 Inclusion of quality control samples.

17.3.2 Prior to the search of DNA data in SDIS, an analyst, CODIS administrator or technical reviewer employed by an NDIS participating laboratory shall review the DNA data to verify the correct specimen category for entry into CODIS.

17.3.3 Prior to the upload of DNA data to SDIS or the reporting of search results, an ownership review of a vendor laboratory's DNA data shall be performed by an analyst or technical reviewer employed by an NDIS participating laboratory who is qualified in the technology, platform and typing test kit used to generate the data and participates in an NDIS participating laboratory's proficiency testing program. A portion of this review may be accomplished through the use of an NDIS approved and internally validated Expert System.

17.3.3.1 If the proficiency testing is administered by another NDIS participating laboratory, the technical leader of the NDIS participating laboratory for which the reviewer is conducting ownership reviews shall review and approve the reviewer's participation in an NDIS participating laboratory's proficiency testing program.

17.3.4 Except as provided in Standard 17.3.5, the ownership review shall include the following elements:

17.3.4.1 A review of all DNA types that the NDIS participating laboratory will take ownership of to verify that they are supported by the raw and/or analyzed data (electropherograms or images).

17.3.4.2 A review of all associated analytical controls, internal size standards and allelic ladders to verify that the expected results were obtained.

17.3.4.3 For samples to be entered into CODIS, verification of the DNA types, eligibility, and the correct specimen category.

17.3.4.3.1 Verification of eligibility shall be performed by a current CODIS user.

17.3.5 For an NDIS participating laboratory that outsources to a vendor laboratory performing Rapid DNA analysis on database, known or casework reference samples using an NDIS approved Rapid DNA System, the ownership review for data generated by the Rapid DNA System shall include:

17.3.5.1 A review of the final report (if provided) to verify that the results are supported by the Rapid DNA System data.

17.3.5.2 For samples to be entered into CODIS, verification of the eligibility and the correct specimen category.

17.3.5.2.1 Verification of eligibility shall be performed by a current CODIS user.

17.3.5.3 A review of the data associated with applicable Rapid DNA System performance checks.

STANDARD 17.4 An NDIS participating laboratory or multi-laboratory system outsourcing DNA sample(s) to a vendor laboratory or accepting ownership of DNA data from a vendor laboratory shall have and follow a procedure to perform an on-site visit(s) of the vendor laboratory, provided, however, that an on-site visit shall not be required when only technical review services are being provided. The procedure to perform an on-site visit shall include, at a minimum, the following elements:

17.4.1 A documented initial on-site visit, to assess the vendor laboratory's ability to perform analysis on outsourced database samples, prior to the vendor laboratory's beginning of DNA analysis for the NDIS laboratory.

17.4.1.1 The on-site visit shall be performed by the technical leader, or a designated employee of an NDIS participating laboratory, who is a qualified or previously qualified analyst in the technology, platform and typing test kit used to generate the DNA data. Alternatively, the technical leader of the NDIS participating laboratory shall evaluate and approve an on-site visit coordinated by a designated FBI employee.

17.4.2 If the outsourcing agreement extends beyond one year, an annual on-site visit shall be required. Each annual on-site visit shall occur every calendar year and shall be at least six months and no more than 18 months apart.

17.4.2.1 An NDIS participating laboratory may accept an on-site visit conducted by another NDIS participating laboratory using the same technology, platform and typing test kit for the generation of the DNA data, or coordinated by a designated FBI employee, and shall document the review and approval of such on-site visit.

# QUALITY ASSURANCE STANDARDS FOR FORENSIC DNA TESTING LABORATORIES

## EFFECTIVE DATE:

These standards shall take effect July 1, 2020 and shall not be applied retroactively.

## 1. SCOPE AND APPLICABILITY

This document consists of definitions and standards. The standards are quality assurance measures that place specific requirements on the laboratory. Equivalent measures not outlined in this document may also meet the standard if determined sufficient through an accreditation process.

The term 'year' refers to calendar year in these standards. Also, when used in these standards, the terms 'review', 'approve', 'document', 'define', 'schedule', 'policy', 'procedure', 'program', 'appoint', 'notify', 'inform', 'authorize', or 'designate' are intended to require written documentation to demonstrate compliance. In order to demonstrate compliance with these standards for purposes of the audit and accreditation process, the laboratory shall have available objective proof of satisfying each standard.

The standards describe the quality assurance requirements that laboratories performing forensic DNA testing or utilizing the Combined DNA Index System (CODIS) shall follow to ensure the quality and integrity of the data generated by the laboratory. As it pertains to these standards, forensic DNA testing begins at sample extraction or direct amplification.

These standards are applicable to forensic DNA testing laboratories using Rapid DNA instruments/Systems on casework reference samples. The use of Rapid DNA instruments/Systems is not approved for use on forensic samples.

These standards also apply to vendor laboratories that perform forensic DNA testing in accordance with Standard 17. These standards do not preclude the participation of a laboratory, by itself or in collaboration with others, in research and development, on procedures that have not yet been validated.

## 2. DEFINITIONS

As used in these standards, the following terms shall have the meanings specified:

*Accreditation* is the formal recognition that a laboratory meets or exceeds a list of standards, including the FBI Director's Quality Assurance Standards, to perform specific tests. Accreditation is administered by a nonprofit professional association of persons actively involved in forensic science that is nationally recognized within the forensic science

community in accordance with the provisions of the Federal DNA Identification Act (34 U.S.C. §12592) or subsequent laws.

*Accuracy* is the ability of a measurement to give results close to a true value.

*Administrative review* is an evaluation of the report and supporting documentation for consistency with laboratory policies and for editorial correctness.

*Analyst* (or equivalent role, position, or title as designated by the laboratory) is an employee or contract employee, that has successfully completed the laboratory's training requirements for casework sample analysis, passed a competency test, and has entered into a proficiency testing program according to these standards. This individual can conduct and/or direct the analysis of forensic samples, interpret data, reach conclusions, and generate reports.

*Analytical control* is a sample used to demonstrate that a method works correctly and to ensure the data are valid. See Positive amplification control, Positive sample control, Positive sequencing control, Negative amplification control, Negative sample control, Negative sequencing control, and Reagent Blank Control.

*Analytical documentation* is the documentation of procedural notes, controls, and instruments used; observations made; results of tests performed; and charts, graphs, photos, and other documentation generated which are used to support the analyst's conclusions.

*Analytical procedure* is an orderly, step-by-step process designed to ensure operational uniformity and to minimize analytical drift.

*Analytical threshold* is the minimum height requirement, determined through validation testing, at or above which detected peaks/signal can be reliably distinguished from background noise; peaks/signal at or above this threshold are generally not considered noise and are either artifacts or true alleles.

*Annual* is once per calendar year.

*Audit* is an on-site inspection used to evaluate, confirm, and/or determine the extent to which specified requirements are fulfilled.

*Audit team* is one or more individuals, including at least one auditor, that performs an inspection of a laboratory. At least one audit team member shall be or have been an analyst previously qualified in the laboratory's current DNA technologies and platforms.

*Auditor* is an individual who has successfully completed the FBI's DNA auditor training course.

*Binary method* is an approach for which there are only two values (possible or not possible) for each decision.

*Biochemistry* is the study of the nature of biologically important molecules in living systems, DNA replication and protein synthesis, and the quantitative and qualitative aspects of cellular metabolism.

*Casework CODIS administrator* (or equivalent role, position, or title as designated by the laboratory) is an employee of the laboratory responsible for administration and security of the laboratory's CODIS at a laboratory performing DNA analysis on forensic and casework reference samples. An alternate casework CODIS administrator must be designated by the laboratory as required by the NDIS operational procedures.

*Casework reference sample* is biological material (e.g., buccal swab, fingerprick, or blood draw) obtained directly from a known individual and used for purposes of comparison to forensic samples.

*Certified reference material* is a material for which values are obtained by a technically valid procedure and accompanied by, or traceable to, a certificate or other documentation which is issued by a certifying body (e.g., NIST).

*CODIS* is the Combined DNA Index System administered by the FBI. CODIS links DNA evidence obtained from crime scenes, thereby identifying serial criminals. CODIS also compares crime scene evidence to DNA profiles from offenders, thereby providing investigators with the identity of the putative perpetrator. In addition, CODIS contains profiles from missing persons, unidentified human remains, and relatives of missing persons. There are three levels of CODIS: the Local DNA Index System (LDIS), used by individual laboratories; the State DNA Index System (SDIS), used at the state level to serve as a state's DNA database containing DNA profiles from LDIS laboratories; and the National DNA Index System (NDIS), managed by the FBI as the nation's DNA database containing all DNA profiles uploaded by participating states.

*CODIS user* is an employee or contract employee who has login access to the CODIS (i.e., State or Local) system and is authorized to read, add, modify and/or delete DNA records in CODIS.

*Competency testing* is a test or series of tests (practical, written, and/or oral) designed to establish that an individual has demonstrated achievement of technical skills and met minimum standards of knowledge necessary to perform forensic DNA analysis.

*Competency* is the demonstration of technical skills and knowledge necessary to perform forensic DNA analysis successfully.

*Contamination* is the unintentional introduction of exogenous DNA into a sample or analytical control during DNA testing.

*Continuing education* is an educational activity (such as a class, lecture series, conference, seminar, or short course) that is offered by a recognized organization or individual that brings participants up-to-date in their relevant area of knowledge.

*Contract employee* is an individual, not in the employ of the government or vendor laboratory, that performs DNA typing and/or analytical support services for a NDIS participating laboratory. The person performing these services must meet the relevant qualifications for the equivalent position in the NDIS participating laboratory. A contract employee cannot serve as a casework CODIS administrator or technical leader and cannot be counted as a full-time qualified analyst for purposes of satisfying the definition of a laboratory. Employment of a contract employee by multiple NDIS participating laboratories and/or vendor laboratories shall be disclosed to all employing laboratories and shall only be permitted subject to approval by the technical leader of the NDIS participating laboratory for which the contract employee is performing DNA typing and/or analytical services.

*Corrective action plan* evaluates and remediates a nonconformity with the goal to identify, correct, and/or prevent reoccurrence of the nonconformity, when possible.

*Coursework* is an academic class officially recognized and taught through a college or university program in which the participating student successfully completed and received one or more credit hours for the class.

*Critical equipment or instruments* are those equipment/instruments whose accurate functionality directly affects the results of the analysis and requires calibration, certification, or performance check prior to use and periodically thereafter.

*Critical reagents* are those whose performance is vital to the success of the DNA testing and require testing on known samples before use on forensic or casework reference samples.

*Developmental validation* - See Validation.

*Differential amplification* is the unequal amplification of one target region or locus over another during the polymerase chain reaction.

*Disposition of evidence* is the documentation of the retention, return, or consumption of the evidence item(s) upon completion of DNA testing.

*DNA record* is a database record that includes the DNA profile as well as data required to manage and operate NDIS, i.e., the Originating Agency Identifier, which serves to identify the submitting agency; the Specimen Identification Number; and DNA personnel associated with the DNA profile analyses.

*DNA type* (also known as a DNA profile) is the genetic constitution of an individual at one or more defined locations (also known as loci) in the DNA.
    1)    A DNA type derived from nuclear DNA typically consists of one or two alleles at several loci (e.g., short tandem repeat loci).
    2)    The DNA type derived from mitochondrial DNA is a specific sequence of nucleotides at a given mitochondrial region(s). In human DNA typing, the DNA type derived from mitochondrial DNA is described in relation to the revised

Cambridge Reference Sequence (Nature Genetics [1999] 23:147).

*Electrophoresis detection system* is a platform that allows for the size separation of DNA molecules through a fluid or a gel under the influence of an electric field and the subsequent detection of the separated molecules by fluorescence or other means.

*Employee* is a person:
>    1)    In the service of the applicable federal, state, or local government, subject to the terms, conditions, and rules of federal, state, or local employment and eligible for the federal, state, or local benefits of service; or
>    2)    Formerly in the service of a federal, state, or local government who returns to service in the agency on a part-time or temporary basis.
>    3)    For purposes of a vendor laboratory, an employee is a person in the service of a vendor laboratory and subject to the applicable terms, conditions, and rules of employment of the vendor laboratory.

*Evidence* is an item submitted for DNA testing and/or a derivative of an item as defined by the laboratory that is subject to a chain of custody.

*Expert System* is a software program or set of software programs designed to interpret single source DNA data in accordance with laboratory defined quality assurance rules and identify DNA data not satisfying laboratory defined quality assurance rules, without human intervention.

*FBI* is the Federal Bureau of Investigation, the federal agency authorized by the DNA Identification Act of 1994 to issue quality assurance standards governing forensic DNA testing laboratories and to establish and administer the National DNA Index System (NDIS).

*Forensic DNA analysis* (also referred to as Forensic DNA testing) is the process of isolation, detection, identification, and evaluation of biological evidence in criminal matters using DNA technologies.

*Forensic sample* is a biological sample originating from and associated with evidence from a crime scene. A sample associated with evidence from a crime scene may include a sample that has been carried away from the crime scene.

*Functional testing* is a process to confirm that a software performs the tasks as expected.

*Genetics* is the study of inherited traits, genotype/phenotype relationships, and population/species differences in allele and genotype frequencies.

*Guidelines* are a set of general principles used to provide direction and parameters for decision making.

*Inconclusive* is a determination that no inclusion or exclusion can be drawn from the comparison of a casework reference sample to a forensic sample. This could result from

statistical analyses that fail to provide sufficient support for an inclusion or exclusion. An inconclusive conclusion could be due to uninterpretable data or data determined by the laboratory as not suitable for comparisons.

*Integral component* is that portion of an academic course that is so significant and necessary to the understanding of the subject matter as a whole that the course would be considered incomplete without it.

*Internal validation* - See Validation.

*Interpretation Software* is a tool to assist the analyst in assessing the analyzed data by applying quality assurance rules, performing mixture deconvolution, and/or evaluating comparisons. Interpretation software may include probabilistic genotyping software or expert systems.

*Intimate sample* is a biological sample from an evidence item that is obtained directly from an individual's body; it is not unexpected to detect that individual's allele(s) in the DNA typing results.

*Known samples* are biological material whose identity or DNA type is established.

*Laboratory* is a facility
    1)    Employing at least two full-time employees who are qualified analysts; and
    2)    Having and maintaining the capability to perform the DNA analysis of forensic samples and/or casework reference samples at that facility.

*Laboratory support personnel* (or equivalent role, position, or title as designated by the laboratory) are employees or contract employees who perform laboratory support duties exclusive of analytical procedures on forensic or casework reference samples.

*Legacy* refers to a typing test kit, platform, or technology that is no longer in use by a laboratory.

*Legacy data* is data generated by a typing test kit, platform, or technology that is no longer in use by the laboratory that is used for the interpretation of DNA types.

*Method* is a combination of procedural steps used to perform a specific technical process. The method includes the validated steps, reagents, and critical instruments needed to perform the process or portion of a process. The same method may be conducted using different equipment (automated vs manual) when appropriately validated.

*Methodology* refers to the categories of methods used to perform a stage of a DNA typing technology or technologies. For example, methodologies for STR technology can include extraction, quantification, amplification, and detection.

*Modified Rapid DNA analysis* is the semi-automated (hands-free) process of developing a CODIS acceptable STR profile from a casework reference sample. The "swab in – profile out" process consists of automated extraction, amplification, separation, and detection without human intervention but requires an analyst to perform manual interpretation and technical review.

*Module* is an independent but interrelated part of software that performs a distinct function.

*Molecular biology* is the study of the theories, methods, and techniques used in the study and analysis of gene structure, organization, and function.

*Multi-laboratory system* is used to describe an organization that has more than one laboratory performing forensic DNA analysis.

*Negative amplification control* is an analytical control that is used to detect DNA contamination of the amplification reagents. This analytical control consists of only amplification reagents without the intentional addition of template DNA.

*Negative sample control* is an analytical control that is used to detect DNA contamination in Rapid DNA reagents and consumables.

*Negative sequencing control* is an analytical control that is used to detect DNA contamination of the sequencing reagents. This analytical control consists of only sequencing reagents without the intentional addition of template DNA. The negative amplification control can be used as the negative sequencing control.

*NIST* is the National Institute of Standards and Technology.

*Nonconformity* is not meeting, implementing, maintaining, or complying with one or more of the requirements of these standards or a laboratory's procedures, policies, or other quality system documents.

*On-site visit* is a scheduled or unscheduled visit to the vendor laboratory work site by one or more representatives of an NDIS participating laboratory.

*Outsourcing* is the utilization of a vendor laboratory to provide DNA services in which the NDIS participating laboratory takes or retains ownership of the DNA data. Outsourcing does not require the existence of a contractual agreement or the exchange of funds.

*Ownership* is the process by which the responsibility for the products of forensic DNA analyses provided by a vendor laboratory may pass to an NDIS participating laboratory. It applies if any of the following will occur:
> 1)     The NDIS participating laboratory will use any samples, extracts or materials from the vendor laboratory for the purposes of forensic DNA testing (e.g., a vendor laboratory prepares an extract that will be analyzed by the NDIS laboratory);

2) The NDIS participating laboratory will interpret the DNA data generated by the vendor laboratory;

3) The NDIS participating laboratory will issue a report describing or drawing conclusions on the results of the DNA analysis performed by the vendor laboratory; or

4) The NDIS participating laboratory will enter or search a DNA profile in CODIS from data generated by the vendor laboratory.

*Ownership review* is the technical review of outsourced DNA data required by Standard 17. This review is to be distinguished from the technical and administrative reviews required by Standard 12. For outsourced DNA data, the vendor laboratory is responsible for conducting the technical and administrative reviews required by Standard 12.

*Performance check* is a quality assurance measure to assess the functionality of laboratory critical equipment and instruments.

*Platform* is the type of analytical system utilized to generate DNA profiles, such as capillary electrophoresis, real-time gel and end-point gel instruments or systems.

*Policy* is an organization's high level plan for a course of action or to address a requirement.

*Polymerase Chain Reaction* (PCR) is an enzymatic process by which a specific region of DNA is replicated during repetitive cycles, which consist of the following:

1) Denaturation of the template;

2) Annealing of primers to complementary sequences at an empirically determined temperature; and

3) Extension of the bound primers by a DNA polymerase.

*Positive amplification control* is an analytical control that is used to determine if the PCR performed properly. This control consists of the amplification reagents and a known DNA sample.

*Positive sample control* is an analytical control that is used to determine if the Rapid DNA instrument/System is performing all steps of the process properly. This control consists of a known DNA sample.

*Positive sequencing control* is an analytical control that is used to determine if the sequencing performed properly. This control consists of the sequencing reagents and a known DNA sample. The positive amplification control can be used as the positive sequencing control.

*Precision* characterizes the degree of mutual agreement among a series of individual measurements, values, and/or results.

*Preferential amplification* is the unequal amplification of the two alleles present in a heterozygous locus during the polymerase chain reaction.

*Procedure* (protocol, standard operating procedure, or other equivalent) is a series of instructions to be followed in performing a specified task or under specific circumstances.

*Proficiency testing* is a quality assurance measure used to monitor performance and identify areas in which improvement may be needed. Proficiency tests may be classified as:
  1)   An internal proficiency test, which is produced by the agency undergoing the test.
  2)   An external proficiency test, which is a test obtained from a proficiency test provider accredited to the current applicable standard of the International Organization for Standardization and the applicable test is included on the proficiency test provider's scope of accreditation.

*Program* is a collection of policies, procedures, and/or instructions to fulfill a requirement.

*Qualified* is an adjective used to describe an individual who meets the requirements for the position, has successfully completed the laboratory's applicable training requirements, and is authorized to perform a specific task or role.

*Qualitative statement* is a description of the evidence (e.g., partial profile, mixture profile) or a conclusion of any comparisons that were performed without a statistical significance provided (e.g., source attribution, consistent with an intimate sample).

*Quality system* is the organizational structure, responsibilities, procedures, policies, and resources for implementing quality management.

*Quantitative PCR* is a method of determining the concentration of DNA in a sample by use of the polymerase chain reaction.

*Quantitative statement* is a conclusion that provides a statistical measure of the DNA profile (e.g., random match probability) or comparison performed (e.g., likelihood ratio).

*Rapid DNA analysis* is the fully automated (hands-free) process of developing a CODIS acceptable STR profile from a casework reference sample. The "swab in – profile out" process consists of automated extraction, amplification, separation, detection and allele calling without human intervention.

*Rapid DNA cartridge* is a preassembled set of reagents and other analytical components (such as typing test kit) designed for use in a Rapid DNA instrument/System for the extraction, amplification and/or separation of DNA samples.

*Rapid DNA instrument* is an automated device that carries out Rapid DNA analysis or modified Rapid DNA analysis used to develop a CODIS acceptable STR profile from a casework reference sample.

*Rapid DNA System* is the collection of components that together performs a Rapid DNA analysis consisting of a Rapid DNA instrument, the PCR STR typing test kit/Rapid DNA cartridge, and an integrated Expert System used to develop a CODIS acceptable STR profile from a casework reference sample.

*Reagent* is a substance or mixture of substances used in the analysis process to detect, measure, produce, or interact with other substances.

*Reagent blank control* is an analytical control that is used to monitor contamination from extraction to DNA typing results and contains no intentionally added template DNA.

*Regression testing* is the process of testing an updated software program to confirm that modifications or new functionality do not unacceptably alter or terminate a desired functionality that behaved correctly before the change was implemented.

*Reinterpretation* is the reassessment of legacy data that may change the previously documented results. This may be due to a reevaluation of any of the allele calls or genotype calls [to include potential allelic drop-out], removal of alleles (or entire loci) from statistical estimates, or a change in the assumptions.

*Reliability testing* is the process of testing a software program beyond its functional aspects to ensure it works appropriately in the laboratory environment. This may include testing multi-user or multi-site scenarios, direct-access and network/server-access scenarios, and interaction with other software programs.

*Review* is an evaluation of documentation to check for consistency, accuracy, completeness, and compliance.

*Second agency* is an entity or organization external to and independent of the laboratory.

*Semi-annual* is used to describe an event that takes place two times during one calendar year, with the first event taking place in the first six months of that year and the second event taking place in the second six months of that year, and where the interval between the two events is at least four months and not more than eight months.

*Sensitivity studies* (for the purposes of Standard 8.3) are used to assess the ability to obtain reliable results from a range of DNA quantities, to include the upper and lower limits of the assay.

*Sensitivity studies* (for the purposes of Standard 8.8) are used to assess the ability of the system to reliably determine the presence of a contributor's DNA over a broad variety of evidentiary typing results (to include mixtures and low-level DNA quantities).

*Service* (for the purposes of Standard 10) is the performance of adjustments or specified procedures by the user, manufacturer, or other service personnel in order to ensure the intended performance of instruments and equipment.

*Specificity studies* (for the purposes of Standard 8.3) are used to assess the ability to detect genetic information from non-targeted species (e.g., detection of microbial DNA in a human assay). The detection of genetic information from non-targeted species does not necessarily invalidate the use of the assay, but may help define the limits of the assay.

*Specificity studies* (for the purposes of Standard 8.8) are used to evaluate the ability of the system to provide reliable results over a broad variety of evidentiary typing results (to include mixtures and low-level DNA quantities).

*Stochastic threshold* is the peak height or signal magnitude value, determined through validation studies, below which it is reasonable to assume that, at a given locus, allelic dropout of a sister allele in a heterozygous pair may have occurred.

*Technical leader* (or equivalent role, position, or title as designated by the laboratory) is an employee who is accountable for the technical operations of the laboratory and who is authorized to initiate, suspend, and resume laboratory operations.

*Technical review* is an evaluation of reports, notes, data, and other documents to ensure there is an appropriate and sufficient basis for the scientific conclusions.

*Technical reviewer* is an employee or contract employee who is a current or previously qualified analyst that performs a technical review of, and is not an author of, the applicable report or its contents.

*Technician* (or equivalent role, position, or title as designated by the laboratory) is an employee or contract employee who performs analytical procedures on forensic samples or casework reference samples under the direction of a qualified analyst. Technicians do not interpret data to reach conclusions on typing results or prepare final reports.

*Technology* is used to describe the type of forensic DNA analysis performed in the laboratory, such as RFLP, STR, YSTR, XSTR, SNP, microhaplotypes or mitochondrial DNA.

*Test kit* is a preassembled set of reagents (or laboratory assembled equivalent) that allows the user to conduct a specific DNA extraction, quantification, or amplification method. A laboratory assembled equivalent may be referred to as a test system.

*Typing test kit* is a preassembled set of reagents (or laboratory assembled equivalent) that is used to generate a DNA type.

*Underlying scientific principle* is a rule concerning a natural phenomenon or function that is a part of the basis used to proceed to more detailed scientific functions.

*Uninterpretable* is a determination that DNA data cannot be interpreted (e.g., due to poor or limited data quality, data that fail to meet laboratory quality requirements). Uninterpretable data may result in an inconclusive conclusion.

*Validation* is a process by which a method is evaluated to determine its efficacy and reliability for forensic casework analysis and includes the following:
1)   Developmental validation, which is the acquisition of test data and determination of conditions and limitations of a new or novel DNA method for use on forensic samples.
2)   Internal validation, which is an accumulation of test data within the laboratory to demonstrate that established methods and procedures perform as expected in the laboratory.

*Vendor laboratory* is a governmental or private laboratory that provides DNA analysis services to another laboratory or agency and does not take ownership of the DNA data for purposes of entry into CODIS.

*Work product* is the material that is generated as a function of analysis that is not subject to a chain of custody.

## 3. QUALITY ASSURANCE PROGRAM

STANDARD 3.1 The laboratory shall establish, follow, and maintain a documented quality system that is appropriate to the testing activities and is equivalent to, or more stringent than, what is required by these standards.

3.1.1 The quality system shall be documented in a manual that includes or references the following elements:

3.1.1.1 Goals and objectives

3.1.1.2 Organization and management

3.1.1.3 Personnel

3.1.1.4 Training

3.1.1.5 Facilities and evidence control

3.1.1.6 Validation

3.1.1.7 Analytical procedures

3.1.1.8 Equipment

3.1.1.9 Reports

3.1.1.10 Review

3.1.1.11 Proficiency testing

3.1.1.12 Corrective action

3.1.1.13 Audits

3.1.1.14 Professional development

3.1.1.15 Outsourcing ownership

3.1.2 Any document referenced within the quality manual shall be available on-site or be readily accessible.

STANDARD 3.2 The laboratory shall have and follow a policy regarding document retention that specifically addresses proficiency tests, corrective action, audits, training records, continuing education, case files, and court testimony monitoring.

STANDARD 3.3 The quality system as applicable to DNA shall be reviewed annually independent of the audit required by Standard 15. The review of the quality system shall be completed under the direction of the technical leader. The quality system review shall be approved by the technical leader.

STANDARD 3.4 The laboratory shall annually review case files determined by the technical leader to be a representative sample of the cases worked. This review of case files shall be independent of an external audit conducted under Standard 15. The scope of the review shall be defined prior to each annual review and shall be approved by the technical leader.

## 4. ORGANIZATION AND MANAGEMENT

STANDARD 4.1 The laboratory shall:

4.1.1 Have a managerial staff with the authority and resources needed to discharge their duties and meet the requirements of the standards in this document.

4.1.2 Have a technical leader who is accountable for the technical operations. Multi-laboratory systems shall have at least one technical leader.

4.1.3 Have a casework CODIS administrator who is accountable for CODIS on-site at each individual laboratory facility utilizing CODIS.

4.1.4 Have at least two full-time employees who are qualified analysts.

4.1.5 Specify and document the responsibility, authority, and interrelation of all personnel who manage, perform, or verify work affecting the validity of the DNA analysis.

4.1.6 Have and follow a documented contingency plan that is approved by laboratory management if the technical leader position is vacated or if the number of qualified analysts falls below two full-time employees who are qualified analysts.

STANDARD 4.2 The laboratory shall have a policy that defines either the date of hire/appointment/promotion or the date of qualification to be used by the laboratory for determining the applicable version of the standards for education, experience and training requirements.


## 5. PERSONNEL

STANDARD 5.1 Laboratory personnel shall have the education, training, and experience commensurate with the examination and testimony provided.

5.1.1 The laboratory shall have a written job description for personnel, that may be augmented by additional documentation, which defines responsibilities, duties, and skills.

5.1.2 The laboratory shall maintain records on the relevant qualifications, training, skills, and experience of the technical personnel.

STANDARD 5.2 The technical leader shall be a full-time employee of the laboratory or multi-laboratory system and shall meet the following qualifications:

5.2.1 Minimum educational requirements: The technical leader of a laboratory shall have, at a minimum, a Master's degree in a biology-, chemistry-, or forensic science-related area and shall have successfully completed 12 semester or equivalent credit hours from a combination of undergraduate and graduate coursework covering the following subject areas: biochemistry, genetics, molecular biology, and statistics or population genetics.

5.2.1.1 The 12 semester or equivalent credit hours shall include at least one graduate level course registering three or more semester or equivalent credit hours.

5.2.1.2 The specific subject areas listed in Standard 5.2.1 shall constitute an integral component of any coursework used to demonstrate compliance with this standard.

5.2.1.3 Individuals who have completed coursework with titles other than those listed in Standard 5.2.1 shall demonstrate compliance with this standard through a combination of pertinent materials such as a syllabus, letter from the instructor, or other document that supports the course content.

5.2.1.4 If the degree requirements of Standard 5.2.1 were waived by the American Society of Crime Laboratory Directors (ASCLD) in accordance with criteria approved by the FBI Director, such a documented waiver shall be permanent and portable.

5.2.2 Minimum experience requirements: Any technical leader appointed prior to July 1, 2009, shall have three years of forensic DNA laboratory experience obtained at a laboratory where forensic DNA testing was conducted for the identification and evaluation of biological evidence in criminal matters. Any technical leader appointed on or after July 1, 2009, shall have a minimum of three years of human DNA (current or previous) experience as a qualified analyst on forensic samples.

5.2.3 Any technical leader appointed on or after July 1, 2020 shall be a currently or previously qualified analyst in each technology utilized in the laboratory, or have documented training in each technology utilized in the laboratory within one year of appointment.

5.2.4 The technical leader shall have previously completed or will successfully complete the FBI's DNA auditor training course within one year of appointment.

5.2.5 The technical leader shall have the following authority and minimum responsibilities:

5.2.5.1 Oversee the technical operations of the laboratory.

5.2.5.2 Authority to initiate, suspend, and resume technical operations for the laboratory or an individual.

5.2.5.3 Evaluate and approve all validations and new or modified methods used by the laboratory.

5.2.5.4 Review the training records for newly qualified analysts, technicians and technical reviewers and approve their qualifications prior to independent casework analysis. Review, verify, and approve the academic transcripts for newly qualified analysts and technical reviewers.

5.2.5.5 Approve the technical specifications for outsourcing agreements.

5.2.5.6 Review internal and external DNA Audit documents and, if applicable, approve corrective action(s).

5.2.5.7 Review, on an annual basis, the procedures of the laboratory.

5.2.5.8 Review and approve the training, quality assurance, and proficiency testing programs in the laboratory.

5.2.5.9 Review potential conflicts of interest when contract employees are employed by multiple NDIS participating and/or vendor laboratories.

5.2.6 The technical leader shall be accessible to the laboratory to provide on-site, telephone, or electronic consultation as needed. A multi-laboratory system may have one technical leader over a system of separate laboratory facilities. For multi-laboratory systems, the technical leader shall conduct and document a site visit to each laboratory at least semi-annually.

5.2.7 Newly appointed technical leaders shall be responsible for the review of the following within one year of appointment:

5.2.7.1 Validation studies and analytical procedures currently used by the laboratory; and

5.2.7.2 Educational and training records of currently qualified analysts and technical reviewers.

STANDARD 5.3 The casework CODIS administrator shall be an employee of the laboratory and meet the following qualifications:

5.3.1 Minimum educational requirements: The casework CODIS administrator shall meet the education requirements for an analyst as defined in Standard 5.4. A casework CODIS administrator appointed prior to July 1, 2020 shall be deemed to have satisfied the minimum educational requirements; satisfaction of these minimum educational requirements shall be applicable to the specific laboratory by which the casework CODIS administrator is employed by prior July 1, 2020 and shall not be portable.

5.3.2 Minimum experience requirements: A casework CODIS administrator shall be a current or previously qualified analyst as defined in Standard 5.4 with documented mixture interpretation training. A casework CODIS administrator appointed prior to July 1, 2009 who is not or has never been a qualified analyst (with documented training in mixture interpretation) shall be deemed to have satisfied the minimum experience requirements upon completion of FBI sponsored CODIS training; satisfaction of these minimum requirements shall be applicable to the specific laboratory the casework CODIS administrator is employed by prior to July 1, 2009 and shall not be portable.

5.3.3 Minimum CODIS training requirements: The casework CODIS administrator shall successfully complete the FBI-sponsored training in CODIS software within

six months of assuming CODIS casework administrator duties if the administrator had not previously completed such training. The casework CODIS administrator shall successfully complete the FBI's DNA auditor training course within one year of assuming his/her administrator duties if the administrator had not previously completed such training.

5.3.4 The casework CODIS administrator shall have the following minimum responsibilities:

> 5.3.4.1 Administer the laboratory's local CODIS network.
>
> 5.3.4.2 Schedule and document the CODIS computer training of casework analysts.
>
> 5.3.4.3 Ensure that the security of data stored in CODIS is in accordance with state and/or federal law and NDIS operational procedures.
>
> 5.3.4.4 Ensure that the quality of data stored in CODIS is in accordance with state and/or federal law and NDIS operational procedures.
>
> 5.3.4.5 Ensure that matches are dispositioned in accordance with NDIS operational procedures.

5.3.5 The casework CODIS administrator shall be authorized to terminate an analyst's or laboratory's participation in CODIS until the reliability and security of the computer data can be assured in the event an issue with the data is identified.

5.3.6 A laboratory shall not upload DNA profiles to NDIS in the event that the casework CODIS administrator position is unoccupied.

STANDARD 5.4 The analyst shall be an employee or contract employee of the laboratory and meet the following qualifications:

> 5.4.1 Minimum educational requirements: The analyst shall have a bachelor's (or its equivalent) or an advanced degree in a biology-, chemistry-, or forensic science-related area and shall have successfully completed coursework (graduate or undergraduate level) covering the following subject areas: biochemistry, genetics, and molecular biology. Any analyst hired/appointed/promoted or qualified (as defined by the laboratory per Standard 4.2) prior to July 1, 2020, shall have coursework and/or training in statistics and/or population genetics as it applies to forensic DNA analysis. Any analyst hired/appointed/promoted or qualified (as defined by the laboratory pursuant to Standard 4.2) on or after July 1, 2020, shall have successfully completed coursework covering statistics and/or population genetics.

5.4.1.1 The specific subject areas listed in Standard 5.4.1 shall be an integral component of any coursework for compliance with this standard.

5.4.1.2 Analysts appointed or hired on or after July 1, 2009 shall have a minimum of nine cumulative semester hours or equivalent that cover the required subject areas of biochemistry, genetics, and molecular biology.

5.4.1.3 Analysts who have completed coursework with titles other than those listed in 5.4.1 above shall demonstrate compliance with this standard through a combination of pertinent materials, such as a syllabus, letter from the instructor, or other document that supports the course content. The technical leader shall approve compliance with this standard.

5.4.2 Minimum experience requirements: The analyst shall have six months of forensic human DNA laboratory experience. If prior forensic human DNA laboratory experience is accepted by a laboratory, the prior experience shall be documented and augmented by additional training, as needed. The analyst shall successfully complete the required training.

STANDARD 5.5 The technical reviewer shall be an employee or contract employee of the laboratory. The technical reviewer shall meet the education and experience requirements in Standard 5.4 and shall meet the following:

5.5.1 A current or previously qualified analyst.

5.5.2 Successful completion of documented training.

STANDARD 5.6 The technician shall be an employee or contract employee of the laboratory and shall successfully complete the laboratory's documented training program.

STANDARD 5.7 The technical leader shall verify and approve the education, to include a review of academic transcripts, of each analyst and technical reviewer.

# 6. TRAINING

STANDARD 6.1 The laboratory shall have a training program documented in a training manual for qualifying analysts and technicians. The training program shall:

6.1.1 Address all DNA analytical, interpretation, and/or statistical procedures used in the laboratory.

6.1.2 Include practical exercises encompassing the examination of a range of samples routinely encountered in casework.

6.1.3 Teach and assess the technical skills and knowledge required to perform DNA analysis.

> 6.1.3.1 The training program for analysts shall include the skills and knowledge required to conduct a technical review.

6.1.4 Include an assessment of oral communication skills and/or a mock court exercise.

6.1.5 Include requirements for competency testing.

STANDARD 6.2 The technical leader shall approve any modifications to an analyst's, technical reviewer's, technician's, or laboratory support personnel's required training based on the documented assessment of the individual's previous training and experience.

STANDARD 6.3 All analyst/technician(s), regardless of previous experience, shall successfully complete competency testing covering the routine DNA methods, interpretation, and/or statistical procedures that the analyst/technician will perform prior to participating in independent casework.

> 6.3.1 Competency testing for a new analyst shall include a practical component, and written and/or oral components.

> 6.3.2 Competency testing for a new technician shall include a practical component.

STANDARD 6.4 For an analyst or technician, currently or previously qualified within the laboratory, to be qualified in a new or additional method, the laboratory shall teach and assess the technical skills and knowledge required to perform the additional method.

> 6.4.1 Before the use of a new or additional method on forensic samples or casework reference samples, the analyst and/or technician shall successfully complete competency testing to the extent of his/her participation in casework analyses. The competency testing shall include a practical component.

STANDARD 6.5 For an analyst, currently or previously qualified within the laboratory, to be qualified to interpret data and generate reports for a new or additional technology, typing test kit, platform, or interpretation software, the laboratory shall teach and assess the technical skills and knowledge required to interpret data, reach conclusions, and generate reports using the additional technology, typing test kit, platform, or interpretation software.

> 6.5.1 Before the use of a new or additional technology, typing test kit, platform or interpretation software on forensic samples or casework reference samples, the analyst shall successfully complete competency testing using the additional technology, typing test kit, platform or interpretation software to the extent of his/her participation in casework analyses. The competency testing shall include a practical component.

STANDARD 6.6 A technical reviewer, who is not currently qualified as an analyst in the laboratory, shall receive training on the case notes, data analysis, interpretation, and reporting criteria for any method, technology, typing test kit, platform, or interpretation software or the legacy technology, typing test kit, platform and/or interpretation software on which they were not previously qualified as an analyst in the laboratory.

> 6.6.1 The technical reviewer shall successfully complete competency testing before completing a technical review of data and/or reports using the additional method, technology, typing test kit, platform or interpretation software used in casework analyses.

>> 6.6.1.1 For a technical reviewer who is a contract employee conducting reviews for an NDIS participating laboratory, the competency testing shall be administered by the NDIS participating laboratory.

STANDARD 6.7 For an analyst to be qualified in reinterpretation of legacy data, for which they were not previously qualified within the laboratory, the analyst shall demonstrate the technical skills and knowledge required to interpret data, reach conclusions, and generate reports in the legacy technology, typing test kit, and/or platform.

> 6.7.1 The analyst shall successfully complete competency testing in the legacy technology, typing test kit, and/or platform to the extent of his/her participation in casework analyses. The competency testing shall include practical components of reinterpretation.

STANDARD 6.8 The laboratory shall have and follow procedures for maintaining or reestablishing the technical skills and knowledge of analysts and technical reviewers who reinterpret legacy data for which they are qualified or previously qualified and whose external proficiency testing does not include a legacy technology, typing test kit or platform.

> 6.8.1 The technical leader shall review the documentation of an analyst's or technical reviewer's maintenance or reestablishment of the technical skills and knowledge and authorize the analyst or technical reviewer to reinterpret legacy data for no more than a two year period.

STANDARD 6.9 The technical leader shall review the training records for the analyst, technician, and/or technical reviewer and approve his/her qualifications prior to independent casework responsibilities.

STANDARD 6.10 The analyst, technician, and/or technical reviewer shall be authorized to independently perform assigned job responsibilities and the date(s) shall be documented.

STANDARD 6.11 Laboratory support personnel shall have documented training specific to their job function(s).

STANDARD 6.12 The laboratory shall have and follow a policy for addressing retraining of personnel when necessary. The technical leader shall be responsible for evaluating the need for and assessing the extent of retraining. The retraining plan shall be approved by the technical leader.

> 6.12.1 The individual shall successfully complete competency testing prior to his/her return to participation in casework analyses. This competency testing shall include a practical component.

STANDARD 6.13 The laboratory shall maintain records on the training, including successful completion of competency testing, of the laboratory personnel.

## 7. FACILITIES AND EVIDENCE CONTROL

STANDARD 7.1 The laboratory shall have a facility that is designed to ensure the integrity of the analyses and the evidence.

> 7.1.1 The laboratory shall have secure, controlled access areas for evidence storage.

> 7.1.2 Except as provided in Standard 7.1.3.1, techniques performed prior to PCR amplification such as evidence examinations, DNA extractions, and PCR setup shall be conducted at separate times or in separate spaces from each other.

> 7.1.3 Except as provided in Standard 7.1.3.1, amplified DNA product, including real time PCR, shall be generated, processed, and maintained in a room(s) separate from the evidence examination, DNA extractions, and PCR setup areas. The doors between rooms containing amplified DNA and other areas shall remain closed except for passage.

>> 7.1.3.1 A Rapid DNA instrument/System used for processing casework reference samples shall be maintained in rooms outside of evidence examination areas or those containing amplified DNA.

STANDARD 7.2 The laboratory shall have and follow procedures for laboratory security.

> 7.2.1 Access to the laboratory shall be controlled and limited in a manner to prevent access to the operational areas by unauthorized personnel. All exterior entrance/exit points require security controls that limit entry and access into the operational areas. The distribution of all keys, combinations, etc., shall be documented and limited to the personnel designated by laboratory management.

STANDARD 7.3 The laboratory shall have and follow a documented evidence control program to ensure the integrity of physical evidence.

7.3.1 Evidence shall be marked with a unique identifier on the evidence package. The laboratory shall clearly define what constitutes evidence and what constitutes work product. The laboratory shall have and follow a method to distinguish each sample throughout processing.

7.3.2 Chain of custody for all evidence shall be documented and maintained in written, printed or electronic format. The chain of custody shall include the signature, initials, or electronic equivalent of each individual receiving or transferring the evidence, the corresponding date for each transfer, and the evidentiary item(s) transferred.

7.3.3 The laboratory shall have and follow procedures that address handling and preserving the integrity of evidence and work product designed to minimize loss, contamination, and/or deleterious change.

> 7.3.3.1 The laboratory shall have and follow a policy or procedure for securing evidence and work product in progress.

> 7.3.3.2 The laboratory shall have and follow a policy or procedure for properly sealing evidence.

STANDARD 7.4 The laboratory shall have a policy on sample consumption.

7.4.1 Where possible, the laboratory shall retain or return a portion of the evidence sample or extract.

STANDARD 7.5 The laboratory shall have and follow a policy for the disposition of evidence.


# 8. VALIDATION

STANDARD 8.1 The laboratory shall use validated methods for DNA analyses.

STANDARD 8.2 Developmental validation shall precede the implementation of any new methods used for forensic DNA analysis.

8.2.1 Developmental validation studies shall include, where applicable, characterization of the genetic marker, species specificity, sensitivity studies, stability studies, case-type samples, population studies, mixture studies, precision and accuracy studies, and PCR-based studies. PCR-based studies include reaction conditions, assessment of differential and preferential amplification, effects of multiplexing, assessment of appropriate controls, and product detection studies. All validation studies shall be documented.

8.2.2 Peer-reviewed publication of the underlying scientific principle(s) of a method shall be required.

STANDARD 8.3 Except as provided in Standard 8.3.1.1, internal validation of all manual and robotic methods shall be conducted by each laboratory with the appropriate sample number and type to demonstrate the reliability and potential limitations of the method.

8.3.1 Internal validation studies shall include as applicable: known and non-probative evidence samples or mock evidence samples, precision and accuracy studies, sensitivity and stochastic studies, mixture studies, and contamination assessment studies.

8.3.1.1 Internal validation data may be shared by all locations in a multi-laboratory system. The summary of the shared validation data shall be available at each site. Each laboratory in a multi-laboratory system shall complete, document and maintain applicable site-specific precision, sensitivity, and contamination assessment studies.

8.3.2 Internal validation shall define quality assurance parameters and interpretation guidelines, including, as applicable, guidelines for mixture interpretation and the application of appropriate statistical calculations.

8.3.2.1 Mixture interpretation validation studies shall include samples with a range of the number of contributors, template amounts, and mixture ratios expected to be interpreted in casework.

8.3.3 Internal validation studies shall be conducted prior to implementing a change in platform instrument model or typing test kit.

8.3.4 Internal validation studies shall be documented and summarized. Internal validation shall be reviewed and approved by the technical leader prior to implementing a procedure for forensic applications.

STANDARD 8.4 Newly validated DNA methods (from amplification through characterization), typing test kit, or platform instrument model shall be checked against an appropriate and available certified reference material (or sample made traceable to the certified reference material) prior to the implementation of the method for forensic analysis.

STANDARD 8.5 The performance of a modified procedure shall be evaluated by comparison to the original procedure using similar DNA samples and the evaluation documented. The evaluation shall be reviewed and approved by the technical leader prior to the implementation of the modified procedure into casework applications.

STANDARD 8.6 A Rapid DNA instrument used for modified Rapid DNA analysis on casework reference samples shall be validated in accordance with Standard 8.

STANDARD 8.7 An NDIS approved Rapid DNA System shall require a performance check prior to use on casework reference samples.

STANDARD 8.8 New software or new modules of existing software and modifications to software shall be evaluated to assess the suitability of the software for its intended use in the laboratory and to determine the necessity of validation studies or software testing. This evaluation shall include the determination of which studies will and will not be conducted and shall be documented.

> 8.8.1 New software or new modules of existing software that are used as a component of instrumentation, for the analysis and/or interpretation of DNA data, or for statistical calculations, shall be subject to developmental validation prior to implementation in forensic DNA analysis.
>
> > 8.8.1.1 With the exception of legally protected information, the underlying scientific principle(s) utilized by software with an impact on the analytical process, interpretation, or statistical calculations shall be publicly available for review or published in a peer-reviewed scientific journal.
> >
> > 8.8.1.2 Developmental software validation studies for new software or new modules of existing software used as a component of instrumentation shall include at a minimum, functional testing and reliability testing.
> >
> > 8.8.1.3 Developmental software validation studies for new software or new modules of existing software for the analysis and/or interpretation of DNA data shall include at a minimum, functional testing, reliability testing, and as applicable, accuracy, precision, sensitivity, and specificity studies.
> >
> > 8.8.1.4 Developmental software validation studies for new software or new modules of existing software for statistical calculations shall include at a minimum, functional testing, reliability testing, and as applicable, accuracy, and precision studies.
>
> 8.8.2 New software or new modules of existing software that are used as a component of instrumentation, for the analysis and/or interpretation of DNA data, or for statistical calculations shall be subject to internal validation specific to the laboratory's intended use prior to implementation in forensic DNA analysis.
>
> > 8.8.2.1 Internal software validation studies for new software or new modules of existing software used as a component of instrumentation shall include functional testing and reliability testing.

8.8.2.2 Internal software validation studies for new software or new modules of existing software for the analysis and/or interpretation of DNA data shall include functional testing, reliability testing, and, as applicable, precision and accuracy studies, sensitivity, and specificity studies.

8.8.2.3 Internal software validation studies for new software or new modules of existing software for statistical calculations shall include functional testing, reliability testing, and, as applicable, precision and accuracy studies.

8.8.2.4 Software that does not impact the analytical process, interpretation, or statistical calculations shall require at a minimum, a functional test.

8.8.3 Modifications to software as described in Standards 8.8.1 and 8.8.2 shall be evaluated to determine if the modifications result in major or minor revisions to the software.

8.8.3.1 A major revision to software used as a component of instrumentation shall require validation prior to implementation. Software validation studies shall include functional testing, reliability testing, and regression testing.

8.8.3.2 A major revision to software used for the analysis and/or interpretation of DNA data shall require validation prior to implementation. Software validation studies shall include functional testing, reliability testing, regression testing, and, as applicable, precision and accuracy studies, sensitivity, and specificity studies.

8.8.3.3 A major revision to software used for statistical calculations shall require validation prior to implementation. Software validation studies shall include functional testing, reliability testing, regression testing, and, as applicable, precision and accuracy studies.

8.8.3.4 A minor revision to software that does not impact the analytical process, interpretation, or statistical calculations shall require at a minimum, a functional test.

8.8.4 Software validation studies and software testing may be shared by all locations in a multi-laboratory system. The summary of the shared validation data shall be available at each site. Each laboratory in a multi-laboratory system shall complete, document and maintain applicable site-specific reliability testing.

8.8.5 Software validation and testing shall be documented. Software validation and testing shall be reviewed and approved by the technical leader prior to implementation.

STANDARD 8.9 Developmental validation studies, internal validation studies, modified procedure evaluations, and software testing, including the approval of the technical leader, shall be retained and available for review.

## 9. ANALYTICAL PROCEDURES

STANDARD 9.1 The laboratory shall have and follow analytical procedures supported by the internal validations and approved by the technical leader.

> 9.1.1 The laboratory shall have and follow a standard operating procedure for each analytical method used by the laboratory including the appropriate analytical controls required for DNA analysis and data interpretation.

STANDARD 9.2 The laboratory shall use reagents that are suitable for the methods employed.

> 9.2.1 The laboratory shall have procedures for documenting commercial reagents and for the formulation of in-house reagents.

> 9.2.2 Commercial reagents shall be labeled with the identity of the reagent and the expiration date as provided by the manufacturer or as determined by the laboratory.

> 9.2.3 In-house reagents shall be labeled with the identity of the reagent, the date of preparation and/or expiration, and the identity of the individual preparing the reagent.

STANDARD 9.3 The laboratory shall identify critical reagents and evaluate them prior to use in casework. The following shall be identified as critical:

> 9.3.1 Test kits or systems for DNA quantification or amplification.

> 9.3.2 Thermostable DNA polymerase, primer sets and allelic ladders used for genetic analysis that are not tested as test kit components under Standard 9.3.1.

> 9.3.3 Rapid DNA cartridges.

> 9.3.4 Other laboratory defined critical reagents.

STANDARD 9.4 Except as provided in Standard 9.4.1, the laboratory shall quantify or otherwise calculate the amount of human DNA in forensic samples prior to nuclear DNA amplification.

9.4.1 Quantification of human DNA for casework reference samples shall not be required if a laboratory has a validated system demonstrated to reliably yield successful DNA amplification and typing without prior quantification.

STANDARD 9.5 Except for Rapid DNA instruments/Systems used to analyze casework reference samples pursuant to Standards 9.7 and/or 9.8, the laboratory shall monitor the analytical procedures using the following analytical controls and standards.

9.5.1 Reagent blank controls associated with each extraction set being analyzed shall be:

9.5.1.1 Extracted concurrently and treated with the most sensitive conditions as the samples;

9.5.1.2 Amplified utilizing the same typing test kit, instrument model, and sensitivity conditions as required by the sample(s) containing the least amount of DNA; and

9.5.1.3 Typed utilizing the same instrument model, injection conditions and most sensitive volume conditions of the extraction set.

9.5.2 Where quantification is used, quantification standards shall be used. If a virtual or external standard curve is utilized, a calibrator must be run concurrently with the samples.

9.5.3 Positive and negative amplification controls associated with samples being typed shall be amplified concurrently using the same typing test kit on the same instrument as the samples.

9.5.3.1 Except as provided in 9.5.4.1, all samples typed shall also have the corresponding amplification controls typed.

9.5.4 For laboratories performing sequencing, the laboratory shall use positive and negative sequencing controls concurrently sequenced using the same typing test kit on the same instrument as the samples.

9.5.4.1 If the positive amplification control is not used as the positive sequencing control, the laboratory shall have and follow procedures for the evaluation of the positive amplification control.

9.5.5 Allelic ladders and internal size standards for PCR-based systems, as applicable.

STANDARD 9.6 The laboratory shall have and follow written guidelines for the interpretation of data that are based on and supported by internal validation studies. The laboratory shall:

9.6.1 Have criteria to evaluate quantification standards, internal size standards, allelic ladders and analytical controls.

9.6.2 Have criteria for the interpretation of non-allelic peaks/signal.

9.6.3 Have criteria for the interpretation of allelic peaks/signal.

9.6.4 Define the thresholds used for interpretation. As appropriate to the interpretation model utilized, the laboratory shall establish the following thresholds:

>9.6.4.1 Analytical Threshold

>9.6.4.2 Stochastic Threshold

9.6.5 Define criteria for uninterpretable data.

9.6.6 Have and follow procedures for mixture interpretation that address the following:

>9.6.6.1 The assessment of the number of contributors.

>9.6.6.2 The separation of contributors (e.g., major versus minor).

>9.6.6.3 The criteria for deducing potential contributors.

STANDARD 9.7 For modified Rapid DNA analysis, a laboratory shall:

9.7.1 Have and follow written guidelines for the manual interpretation of data.

>9.7.1.1 The laboratory shall verify that the internal size standard and allelic ladder results meet the laboratory's interpretation guidelines.

9.7.2 Have and follow procedures to address the use of positive sample controls and negative sample controls.

STANDARD 9.8 For Rapid DNA analysis, a laboratory shall have and follow procedures to address the use of positive sample controls and negative sample controls.

9.8.1 The Rapid DNA cartridge shall include an internal size standard with each sample.

STANDARD 9.9 The laboratory shall define criteria for the formulation of inclusionary, exclusionary, and inconclusive conclusions.

STANDARD 9.10 The laboratory shall have and follow procedures for statistical calculations and the reporting of results and conclusions that address the following:

9.10.1 The assumptions that can be made when formulating conclusions.

9.10.2 Performing statistical analysis in support of any inclusion that is determined to be relevant in the context of the case.

9.10.3 Documenting of the genetic loci and assumptions used for statistical calculations, at a minimum, in the case notes.

9.10.4 Not using uninterpretable data in statistical calculations.

9.10.5 The approaches to performing statistical calculations.

9.10.5.1 For autosomal STR typing, the procedure shall address homozygous and heterozygous typing results, multiple locus profiles, mixtures, minimum allele frequencies, and where appropriate, biological relationships.

9.10.5.2 For lineage marker testing, the procedure shall address parameters specific for the applicable lineage marker statistical calculations.

9.10.5.3 The laboratory shall use loci that are shown to be in Hardy-Weinberg equilibrium and statistically unlinked, when using the product rule for statistical calculations.

9.10.6 The source of the population database(s) used in any statistical calculations.

9.10.7 The criteria for source attribution declarations, when applicable.

STANDARD 9.11 The laboratory shall have and follow a procedure to address the reinterpretation of legacy data.

STANDARD 9.12 The laboratory shall have and follow a procedure for the detection and control of contamination.

9.12.1 The laboratory shall have and follow procedures for cleaning and decontaminating facilities and equipment.


## 10. EQUIPMENT

STANDARD 10.1 The laboratory shall use equipment suitable for the methods employed.

STANDARD 10.2 The laboratory shall identify critical equipment or instruments and have and follow a program to ensure they are maintained.

10.2.1 At minimum, the following shall be identified as critical:

10.2.1.1 Handheld mechanical pipettes

10.2.1.2 A thermometer traceable to national or international standard(s)

10.2.1.3 Incubators/heat blocks used in analytical procedures

10.2.1.4 Robotic systems

10.2.1.5 Thermal cyclers, including quantitative PCR

10.2.1.6 Thermal cycler temperature verification systems

10.2.1.7 Electrophoresis detection systems, including Genetic Analyzers

10.2.1.8 Rapid DNA instruments/Systems

10.2.1.9 Any additional instruments or equipment that produce DNA typing results

STANDARD 10.3 The laboratory shall have procedures for conducting performance checks and evaluating results of critical equipment or instruments.

10.3.1 New critical equipment or instruments, not requiring validation, shall undergo a performance check before use in casework analysis. Each additional critical instrument, of the same instrument model validated for use in the laboratory, shall require a performance check prior to use in casework analysis.

10.3.2 The following critical equipment or instruments shall require annual performance checks:

10.3.2.1 Handheld mechanical pipettes

10.3.2.2 Incubators/heat blocks used in an analytical procedure

10.3.2.3 Robotic systems

10.3.2.4 Thermal cyclers, including quantitative-PCR

10.3.2.5 Thermal cycler temperature verification systems

10.3.2.6 Electrophoresis detection systems, including Genetic Analyzers

10.3.2.7 Any additional instruments or equipment that produce DNA typing results

10.3.2.8 Other critical equipment or instruments defined by laboratory

10.3.3 The following critical equipment or instruments shall require a performance check after repair or service:

10.3.3.1 Robotic systems

10.3.3.2 Thermal cyclers, including quantitative-PCR

10.3.3.3 Electrophoresis detection systems, including Genetic Analyzers

10.3.3.4 Rapid DNA instruments/Systems

10.3.3.5 Any additional instruments or equipment that produce DNA typing results

10.3.3.6 Other laboratory defined critical equipment or instruments

10.3.4 A Rapid DNA instrument/System shall require a performance check upon installation.

10.3.5 A Rapid DNA instrument/System shall undergo a performance check if the Rapid DNA instrument remains idle longer than the period recommended in the instrument specifications or as established by the laboratory.

STANDARD 10.4 The laboratory shall maintain documentation of maintenance, service, repair, and performance checks.

## 11. REPORTS

STANDARD 11.1 The laboratory shall have and follow procedures for taking and maintaining casework notes to support the conclusions drawn in laboratory reports. The laboratory shall maintain all analytical documentation generated by technicians and/or analysts related to case analyses. The laboratory shall retain, in written, printed, or electronic format, sufficient documentation for each technical analysis to support the report conclusions such that another qualified individual can evaluate what was done and interpret the data.

STANDARD 11.2 Casework reports shall include the following elements:

11.2.1 Case identifier;

11.2.2 Description of evidence examined and identification of samples tested;

11.2.3 Technology used;

11.2.4 Loci, sequence region, or amplification system;

11.2.5 Results and/or conclusions for each forensic sample tested;

11.2.6 A quantitative or qualitative interpretative statement to support all inclusions;

11.2.7 Date of the report;

11.2.8 Disposition of evidence; and

11.2.9 A signature and title, or equivalent identification, of the person accepting responsibility for the content of the report.

STANDARD 11.3 Except as otherwise provided by state or federal law, reports, case files, DNA records, and databases shall be confidential.

11.3.1 The laboratory shall have and follow policies and/or procedures to ensure the privacy of the reports, case files, DNA records, and databases.

11.3.2 The laboratory shall have and follow policies and/or procedures for the release of reports, case files, DNA records, and databases, in accordance with applicable state or federal law.

11.3.3 The laboratory shall have and follow policies and/or procedures for the release of personally identifiable information in accordance with applicable state and federal law.

## 12. REVIEW

STANDARD 12.1 The laboratory shall have and follow a procedure to conduct and document technical and administrative reviews of all case files and reports to ensure conclusions and supporting data are reasonable and within the constraints of scientific knowledge.

12.1.1 An individual conducting technical reviews shall be an analyst or technical reviewer qualified in the method, technology, typing test kit, platform, and interpretation software being reviewed.

STANDARD 12.2 Completion of the technical review shall be documented and the technical review of forensic casework shall include the following elements:

12.2.1 A review of all case notes, all worksheets, and the electronic data (or printouts of such data) supporting the results and/or conclusions.

12.2.2 A review of all analytical controls, internal size standards, and allelic ladders to verify that the expected results were obtained, except when using an NDIS approved Rapid DNA System on casework reference samples.

12.2.3 A review of all DNA types to verify that they are supported by the raw or analyzed data (electropherograms or images), except when using an NDIS approved Rapid DNA System on casework reference samples.

12.2.4 A review of all data to verify conclusions (i.e., inclusions, exclusions, inconclusive) are in compliance with laboratory guidelines.

12.2.5 A review of statistical analysis, if applicable.

12.2.6 A review of the final report's content to verify compliance with Standard 11.2 and that the results and/or conclusions are supported by the data.

12.2.7 Verification that all profiles entered into CODIS are eligible, have the correct DNA types, and correct specimen category.

12.2.7.1 Prior to upload to SDIS, entry of a DNA profile into a searchable category of SDIS, or search of SDIS, verification of the following criteria by two concordant assessments by a qualified analyst or technical reviewer: eligibility for CODIS, correct DNA types, and appropriate specimen category.

STANDARD 12.3 Completion of the administrative review shall be documented and shall include the following elements, any or all of which may be included within the technical review:

12.3.1 A review of the case file and final report for clerical accuracy and compliance with Standard 11.2.

12.3.2 A review of chain of custody and disposition of evidence.

STANDARD 12.4 The laboratory shall have and follow a policy and/or procedure to address unresolved discrepant conclusions between analysts and reviewer(s).

STANDARD 12.5 The laboratory shall have and follow a procedure for the verification and resolution of database matches.

## 13. PROFICIENCY TESTING[1]

STANDARD 13.1 Analysts, technical reviewers, technicians, and other personnel designated by the technical leader, shall undergo semi-annual external proficiency testing.

13.1.1 Analysts qualified in more than one technology shall be proficiency tested in each technology at least once per calendar year.

13.1.1.1 Typing of all CODIS core loci or CODIS core sequence ranges shall be attempted for each technology at least once per calendar year.

13.1.2 Analysts qualified in more than one typing test kit shall be proficiency tested in each typing test kit at least once per calendar year.

13.1.2.1 Analysts qualified to perform modified Rapid DNA analysis shall be externally proficiency tested on the interpretation of data generated by each Rapid DNA instrument model for each PCR STR typing test kit at least once per calendar year.

13.1.3 Individuals that perform analytical procedures on forensic samples or casework reference samples shall be proficiency tested on at least one method in each methodology at least once per calendar year.

13.1.4 Except as provided in Standard 13.1.4.1, each external proficiency test shall be assigned to and completed by one analyst.

13.1.4.1 Laboratories that employ technicians and/or use a team approach for casework examination may do so on external proficiency tests. However, each analyst shall be assigned a proficiency test to complete the interpretation and report the results.

13.1.5 Individuals whose sole responsibility is technical review[2] shall be proficiency tested in the technical review of each technology and typing test kit at least once per calendar year.

13.1.5.1 The proficiency testing shall cover the CODIS core loci or CODIS core sequence ranges attempted for each technology at least once per calendar year.

13.1.5.2 Technical reviewers qualified to review modified Rapid DNA analysis shall be externally proficiency tested on the technical review of data

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[1] The testing of legacy technologies, typing test kits and platforms shall be governed by Standard 6.8.
[2] A qualified analyst proficiency tested in the specific technology is qualified to serve as a technical reviewer without needing to take an additional proficiency test as a technical reviewer.

generated by a Rapid DNA instrument model for each PCR STR typing test kit at least once per calendar year.

13.1.5.3 If the technical reviewer is a contract employee conducting technical reviews for an NDIS participating laboratory the proficiency testing shall be administered by an NDIS participating laboratory and shall be reviewed and approved by the technical leader of the NDIS participating laboratory for which the technical reviewer is conducting reviews.

13.1.6 Newly qualified individuals shall undergo semi-annual external proficiency testing within eight months of the date of their authorization.

STANDARD 13.2 The laboratory shall use an external proficiency test provider that is accredited to the current applicable standard of the International Organization for Standardization and the applicable test is included on the proficiency test provider's scope of accreditation. External proficiency testing shall be an open proficiency testing program and shall be submitted to the proficiency testing provider in order to be included in the provider's published external summary report.

STANDARD 13.3 For purposes of tracking compliance with the proficiency testing requirements, the laboratory shall define and consistently use the date that the proficiency test is performed as the received date, assigned date, submitted date, or the due date.

STANDARD 13.4 The laboratory shall maintain the following records for proficiency tests:

13.4.1 The test set identifier;

13.4.2 Identity of the analyst, and other participants, if applicable;

13.4.3 Date of analysis and completion;

13.4.4 Copies of all data and notes supporting the conclusions;

13.4.5 The proficiency test results;

13.4.6 Any discrepancies noted; and

13.4.7 Corrective actions taken.

STANDARD 13.5 The laboratory shall evaluate proficiency test results and shall include, at a minimum, the following criteria:

13.5.1 All reported genotypes, phenotypes, and/or sequences are correct or incorrect according to consensus results or are compliant with the laboratory's interpretation guidelines.

13.5.2 Inclusions and exclusions are correct or incorrect.

13.5.3 All reported uninterpretable results and/or inconclusive conclusions are compliant with written laboratory guidelines.

13.5.3.1 The technical leader shall review any inconclusive conclusion for compliance with laboratory guidelines.

13.5.4 All final proficiency tests shall be evaluated as satisfactory or unsatisfactory.

13.5.4.1 All discrepancies or errors and subsequent corrective actions, as applicable, shall be documented.

STANDARD 13.6 The following shall be informed of the results of the proficiency test:

13.6.1 The proficiency test participant(s)

13.6.2 The technical leader

13.6.3 The casework CODIS administrator in the event of non-administrative discrepancies that affect the typing results and/or conclusions.

## 14. CORRECTIVE ACTION

STANDARD 14.1 The laboratory shall have and follow a policy and/or procedure to address nonconformities detected in casework analysis, proficiency tests, testimony, and audits. The laboratory policy and/or procedure shall define when a nonconformity requires documentation and/or a corrective action plan.

14.1.1 Corrective action plans shall be documented.

STANDARD 14.2 The laboratory's documented corrective action plan shall include the identification (when possible) of the cause(s) of the nonconformity, corrective actions taken with time frames (where applicable), and preventive measures taken (where applicable) to minimize its reoccurrence.

14.2.1 Corrective action plans shall be approved by the technical leader prior to implementation.

14.2.2 The casework CODIS administrator shall be notified when the nonconformity impacts DNA records entered into CODIS.

# 15. AUDITS

STANDARD 15.1 The laboratory shall be audited annually in accordance with these standards. The annual audits shall occur every calendar year and shall be at least six months and no more than 18 months apart.

STANDARD 15.2 At least once every two years, an external audit shall be conducted by one or more auditor(s) from a second agency(ies). At least one auditor shall be or have been an analyst previously qualified in the laboratory's current DNA technologies and platforms.

> 15.2.1 Each analyst, technical reviewer, casework CODIS administrator, and technical leader shall have his/her education, experience, and training qualifications evaluated and approved during two successive, separate external audits. Approval of an individual's education, experience, and training qualifications shall be documented in the Audit Document.

> > 15.2.1.1 An analyst or technical reviewer that receives additional qualification in an additional technology(ies), typing test kit(s), or platform(s) shall have the additional training qualifications evaluated and approved during one external audit. Approval of additional training qualifications shall be documented in the Audit Document.

> 15.2.2 Each validation study shall be evaluated and approved during one external audit. Approved validation studies shall be documented in the Audit Document.

STANDARD 15.3 Internal audits shall be conducted by an audit team that includes at least one auditor. At least one audit team member shall be or have been an analyst previously qualified in the laboratory's current DNA technologies and platforms.

STANDARD 15.4 Internal and external audits shall be conducted utilizing the *FBI DNA Quality Assurance Standards* Audit Document in effect at the time of the audit.

STANDARD 15.5 Internal and external audit documentation and, if applicable, corrective action(s) shall be reviewed by the technical leader to ensure that findings, if any, were appropriately addressed and this review shall be documented.

> 15.5.1 Internal and external audit documentation, and if applicable, corrective action(s) shall be provided to the casework CODIS administrator.

> 15.5.2 For NDIS participating laboratories, all external audit documentation and laboratory responses shall be provided to the FBI within 30 days of laboratory receipt of the Audit Document or report.

STANDARD 15.6 Internal and external audit documentation shall be retained and available for inspection during subsequent audits.

## 16. PROFESSIONAL DEVELOPMENT

STANDARD 16.1 The laboratory shall have and follow a program to ensure technical qualifications are maintained through participation in continuing education.

16.1.1 The technical leader, casework CODIS administrator, analyst(s), and technical reviewers shall stay abreast of topics relevant to the field of forensic DNA analysis by attending seminars, courses, professional meetings, or other documented lectures or classes in relevant subject areas for a minimum of eight cumulative hours each calendar year.

16.1.1.1 The continuing education hours shall be documented. Attendance at a regional, national, or international conference with content including topics relevant to the field of forensic DNA analysis shall be deemed to provide a minimum of eight hours of continuing education.

16.1.1.2 The laboratory shall maintain documentation of attendance through a mechanism such as certificates, attendance lists, or travel documentation.

16.1.1.3 With the exception of a regional, national, or international conference, the laboratory shall maintain documentation of content through a mechanism such as agenda/syllabus, record of presentation content, or the curriculum vitae of the presenter.

16.1.1.4 Continuing education based on multimedia or internet delivery shall be subject to the approval of the technical leader.

16.1.2 The laboratory shall have and follow a program approved by the technical leader for the annual review of scientific literature that documents the analysts' ongoing reading of scientific literature.

16.1.2.1 The laboratory shall maintain or have physical or electronic access to a collection of current books, reviewed journals, or other literature applicable to DNA analysis.

STANDARD 16.2 The laboratory shall have and follow a program that documents the annual review of the testimony of each analyst.

16.2.1 The program shall define elements and mechanisms for testimony review.

16.2.2 The testimony review shall be documented and provided to the testifying individual.

16.2.2.1 Any deficiency and subsequent corrective actions, as applicable, shall be documented.

## 17. OUTSOURCING OWNERSHIP

STANDARD 17.1 A vendor laboratory performing forensic DNA analysis shall comply with these standards and the accreditation requirements of federal law.

> 17.1.1 An NDIS participating laboratory that outsources to a vendor laboratory shall require the vendor laboratory to provide documentation of compliance with these standards and the accreditation requirements of federal law. The NDIS participating laboratory's technical leader shall review the vendor laboratory's compliance with these standards and the accreditation requirements of federal law.

STANDARD 17.2 Except as provided in Standards 17.2.1 and 17.2.2, the NDIS participating laboratory's technical leader shall approve the technical specifications of the outsourcing agreement with the vendor laboratory before it is awarded.

> 17.2.1 A vendor laboratory that is performing forensic DNA analysis on behalf of a law enforcement agency or other entity for the purposes of ownership by an NDIS participating laboratory, shall not initiate analysis until approval has been obtained from the appropriate NDIS participating laboratory's technical leader.

> 17.2.2 For rare instances where the NDIS participating laboratory is requested to take ownership and no outsourcing agreement exists between either the law enforcement agency, the vendor laboratory or that NDIS participating laboratory, the requested NDIS participating laboratory's technical leader shall document the following prior to acceptance of ownership of product(s) of forensic DNA analyses from the vendor laboratory:

>> 17.2.2.1 Approval of the casework CODIS administrator and written permission from the NDIS Custodian for any scenario that involves CODIS entry or searching;

>> 17.2.2.2 Approval of the technical specifications of testing; and

>> 17.2.2.3 Review the documentation of or conduct an on-site visit of the vendor laboratory. The on-site visit shall have been within 18 months of the conducted analysis and in accordance with Standard 17.4.2.

STANDARD 17.3 An NDIS participating laboratory shall have and follow a procedure to verify the integrity of the DNA data received for the purposes of taking ownership of DNA data from a vendor laboratory.

> 17.3.1 Prior to the search of DNA data in SDIS, an analyst, casework CODIS administrator or technical reviewer employed by an NDIS participating laboratory

shall review the DNA data to verify specimen eligibility and the correct specimen category for entry into CODIS.

17.3.2 Prior to the upload of DNA data to SDIS or the reporting of search results, the ownership review of a vendor laboratory's DNA data shall be performed by an analyst or technical reviewer employed by an NDIS participating laboratory who is qualified in the technology, platform and typing test kit used to generate the data and participates in an NDIS participating laboratory's proficiency testing program.

17.3.2.1 If the proficiency testing is administered by another NDIS participating laboratory, the technical leader of the NDIS participating laboratory for which the reviewer is conducting ownership reviews shall review and approve the reviewer's participation in an NDIS participating laboratory's proficiency testing program.

17.3.3 Except as provided in Standard 17.3.4, the ownership review shall include the following elements:

17.3.3.1 A review of all DNA types that the NDIS participating laboratory will take ownership of to verify that they are supported by the raw and/or analyzed data (electropherograms or images).

17.3.3.2 A review of all associated analytical controls, internal size standards and allelic ladders to verify that the expected results were obtained.

17.3.3.3 A review of the final report (if provided) to verify that the results/conclusions are supported by the data.

17.3.3.4 For samples to be entered into CODIS, verification of the DNA types, eligibility, and the correct specimen category.

17.3.3.4.1 Verification of eligibility must be performed by a current CODIS user.

17.3.4 For an NDIS participating laboratory that outsources to a vendor laboratory performing Rapid DNA analysis on casework reference samples using an NDIS approved Rapid DNA System, the ownership review for data generated by the Rapid DNA System shall include:

17.3.4.1 A review of the final report (if provided) to verify that the results/conclusions are supported by the Rapid DNA System data.

17.3.4.2 For samples to be entered into CODIS, verification of the eligibility and the correct specimen category.

17.3.4.2.1 Verification of eligibility must be performed by a current CODIS user.

17.3.4.3 A review of the data associated with applicable Rapid DNA System performance checks.

STANDARD 17.4 An NDIS participating laboratory or multi-laboratory system outsourcing DNA sample(s) to a vendor laboratory or accepting ownership of DNA data from a vendor laboratory shall have and follow a procedure to perform an on-site visit(s) of the vendor laboratory, provided, however, that an on-site visit shall not be required when only technical review services are being provided. The procedure to perform an on-site visit shall include, at a minimum, the following elements:

17.4.1 A documented initial on-site visit, to assess the vendor laboratory's ability to perform analysis on outsourced casework, prior to the vendor laboratory's beginning of casework analysis for the NDIS laboratory.

17.4.1.1 The on-site visit shall be performed by the technical leader, or a designated employee of an NDIS participating laboratory, who is a qualified or previously qualified analyst in the technology, platform and typing test kit used to generate the DNA data. Alternatively, the technical leader of the NDIS participating laboratory shall evaluate and approve an on-site visit coordinated by a designated FBI employee.

17.4.2 If the outsourcing agreement extends beyond one year, an annual on-site visit shall be required. Each annual on-site visit shall occur every calendar year and shall be at least six months and no more than 18 months apart.

17.4.2.1 An NDIS participating laboratory may accept an on-site visit conducted by another NDIS participating laboratory using the same technology, platform and typing test kit for the generation of the DNA data, or coordinated by a designated FBI employee, and the technical leader shall review and approve such on-site visit.

# State of New Hampshire
# Department of State

## CERTIFICATE

I, David M. Scanlan, Secretary of State of the State of New Hampshire, do hereby certify that PROMEGA CORPORATION is a Wisconsin Profit Corporation registered to transact business in New Hampshire on November 30, 2007. I further certify that all fees and documents required by the Secretary of State's office have been received and is in good standing as far as this office is concerned.

Business ID: **588129**
Certificate Number: **0005899941**

IN TESTIMONY WHEREOF,
I hereto set my hand and cause to be affixed
the Seal of the State of New Hampshire,
this 22nd day of November A.D. 2022.

David M. Scanlan
Secretary of State

# CERTIFICATE OF AUTHORIZATION

Promega Corporation, a corporation formed and existing under the laws of the State of Wisconsin, and pursuant to the corporate Bylaws: Sharon Sheridan, Director of Genetic Identity, is authorized to execute contracts in the name of said corporation with the State of New Hampshire and any public entity thereof. Such execution of any contract or obligation with the State of New Hampshire and any public entity thereof in this corporation's name on its behalf by duly authorized individual shall be valid and including upon the corporation. Authority was approved by the Board of Directors on December 14, 2022.


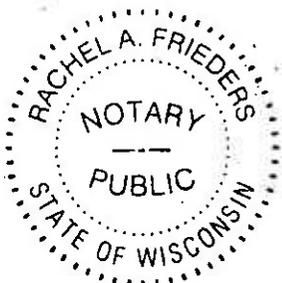William A. Linton
President & CEO
Date: December 16, 2022
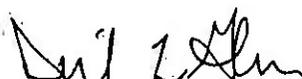
Daniel L. Ghoca
VP & Corporate Secretary
Date: December 16, 2022


State of Wisconsin        )
                          )
County of Dane        )

This document was signed before me on 16<sup>th</sup> of December, 2022 by Daniel L. Ghoca William A. Linton

(Seal)

Signature Rachel A. Frieders
Print Name: Rachel A. Frieders
Notary's expiration date: March 21, 2025

# ACORD® CERTIFICATE OF LIABILITY INSURANCE

**DATE(MM/DD/YYYY)** 11/28/2022

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

| PRODUCER | CONTACT NAME: | | |
|---|---|---|---|
| Aon Risk Services Central, Inc.<br>Milwaukee WI Office<br>10700 Research Drive<br>Suite 450<br>Milwaukee WI 53226 USA | PHONE (A/C, No, Ext): (414) 271-6420 | | FAX (A/C, No.): (414) 271-4103 |
| | E-MAIL ADDRESS: | | |

| | INSURER(S) AFFORDING COVERAGE | NAIC # |
|---|---|---|
| INSURER A: | The Charter Oak Fire Insurance Company | 25615 |
| INSURED | INSURER B: | Travelers Property Cas Co of America | 25674 |
| Promega Corporation<br>2800 Woods Hollow Road<br>Madison WI 53711 USA | INSURER C: | The Travelers Indemnity Co of CT | 25682 |
| | INSURER D: | |
| | INSURER E: | |
| | INSURER F: | |

## COVERAGES  CERTIFICATE NUMBER: 570096579400  REVISION NUMBER:

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

Limits shown are as requested

| INSR LTR | TYPE OF INSURANCE | ADDL INSD | SUBR WVD | POLICY NUMBER | POLICY EFF (MM/DD/YYYY) | POLICY EXP (MM/DD/YYYY) | LIMITS | |
|---|---|---|---|---|---|---|---|---|
| A | X COMMERCIAL GENERAL LIABILITY<br>CLAIMS-MADE X OCCUR | | | H6607E155531COF22 | 08/15/2022 | 08/15/2023 | EACH OCCURRENCE | $1,000,000 |
| | | | | | | | DAMAGE TO RENTED PREMISES (Ea occurrence) | $300,000 |
| | | | | | | | MED EXP (Any one person) | $10,000 |
| | | | | | | | PERSONAL & ADV INJURY | $1,000,000 |
| | GEN'L AGGREGATE LIMIT APPLIES PER:<br>X POLICY PRO-JECT LOC<br>OTHER: | | | | | | GENERAL AGGREGATE | $2,000,000 |
| | | | | | | | PRODUCTS - COMP/OP AGG | Excluded |
| B | AUTOMOBILE LIABILITY<br>X ANY AUTO<br>OWNED AUTOS ONLY SCHEDULED AUTOS<br>HIRED AUTOS ONLY NON-OWNED AUTOS ONLY | | | 810-3N117793-22-I2-G | 08/15/2022 | 08/15/2023 | COMBINED SINGLE LIMIT (Ea accident) | $1,000,000 |
| | | | | | | | BODILY INJURY (Per person) | |
| | | | | | | | BODILY INJURY (Per accident) | |
| | | | | | | | PROPERTY DAMAGE (Per accident) | |
| | | | | | | | Medical Payments Lia | $5,000 |
| B | X UMBRELLA LIAB X OCCUR<br>EXCESS LIAB CLAIMS-MADE<br>DED X RETENTION $10,000 | | | CUP2J73838522I2 | 08/15/2022 | 08/15/2023 | EACH OCCURRENCE | $5,000,000 |
| | | | | | | | AGGREGATE | $5,000,000 |
| C | WORKERS COMPENSATION AND EMPLOYERS' LIABILITY<br>ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? N N/A<br>(Mandatory in NH)<br>If yes, describe under DESCRIPTION OF OPERATIONS below | | | UB7K37698022I2E | 08/15/2022 | 08/15/2023 | X PER STATUTE OTH | |
| | | | | | | | E.L. EACH ACCIDENT | $500,000 |
| | | | | | | | E.L. DISEASE-EA EMPLOYEE | $500,000 |
| | | | | | | | E.L. DISEASE-POLICY LIMIT | $500,000 |
| B | E&O-Technology | | | ZPL71N4218A22I2<br>Cyber- Claims Made<br>SIR applies per policy terms & conditions | 08/15/2022 | 08/15/2023 | Limit<br>SIR | $5,000,000<br>$100,000 |

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

| CERTIFICATE HOLDER | CANCELLATION |
|---|---|
| New Hampshire State Police<br>33 Hazen Drive<br>Concord NH 03305 USA | SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.<br><br>AUTHORIZED REPRESENTATIVE<br>*Aon Risk Services Central, Inc.* |

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*Holder Identifier :*

*570096579400  Certificate No :*