NEW YORK STATE | Department of Health | Wadsworth Center

FORENSIC IDENTITY ASSAY APPROVAL

Please submit all information as outlined below. Submit one hard copy of the entire package and one electronic copy (as a PDF file on a CD or flash drive) to:

US Postal Service: Clinical Laboratory Evaluation Program, Biggs Laboratory, Wadsworth Center, New York State Department of Health, Empire State Plaza, Albany, NY 12237; Attn: Assay Validation Review

UPS, FedEx, Courier: Clinical Laboratory Evaluation Program, Biggs Laboratory, Wadsworth Center, New York State Department of Health, Dock J - P1 Level, Empire State Plaza, Albany, NY 12237; Attn: Assay Validation Review

Materials submitted, including related data packages, cannot be returned to the laboratory. All materials are maintained under strict confidentiality. As relates to New York State's Freedom of Information Law (commonly called FOIL): The Department's Records Access Officer has advised Wadsworth Center that if documents are marked "proprietary"; "confidential"; or with any labeling indicative of the submitter's desire for an increased level of protection based on the submission content, such protection from immediate release based on a FOIL request is justified. Laboratories will be given an opportunity to block information release if a request for the material is filed under the FOIL, by presenting evidence that the materials contain trade secrets. Marking should minimally appear on the cover page of each unit of material. Documents not marked with such terms will not block release of the submission through a FOIL request.

Guidance for Forensic Identity Submissions:
The Forensic Identity Section views all analytical assays as "analytes." This includes: evidence screening procedures (i.e. alternate light source screening, serology methods); DNA extraction procedures; DNA quantitation (kit and platform); DNA amplification (kit and platform); and product detection platforms and analysis software.
The required studies to be performed are determined based on the status of the validation; internal versus developmental. Please refer to the Federal Bureau of Investigation Quality Assurance Standards (FBI QAS) for Forensic DNA Testing Laboratories and the Federal Bureau of Investigation Quality Assurance Standards for DNA Databasing Laboratories for the appropriate definitions of internal and developmental validations.
Additional studies / considerations are required by the New York State Forensic Identity Standards (NYS FI). Please be advised that when testing is performed at multiple sites or on multiple instruments (e.g. multiple units of the same detection platform), separate validations are required.
The criteria listed below incorporate the FBI QAS and NYS FI Standards as well as the applicable New York State Clinical Laboratory Standards of Practice. Based on the type of assay, not all criteria are applicable.
Please contact the Forensic Identity Section at ForensicID@health.ny.gov for clarification or further information.

SECTION 1: GENERAL INFORMATION

Lab Name: _____ PFI: _____ Contact Person: _____

Phone: _____ Fax: _____ Contact E-mail: _____

Assay (Test) Name (i.e. title of Standard Operating Procedure adopted through this validation):

_____

Methodology (e.g. evidence screening, DNA extraction, DNA amplification):

_____

Analyte(s) included (if different from Assay Name): _____

Validated Specimen Type(s) _____

Laboratory Director/Assistant Director (NYS Certificate of Qualification Holder for Forensic Identity)

CQ Code _____ Signature _____

Laboratory Director (if not the responsible CQ Holder for Forensic Identity)

CQ Code _____ Signature _____

SECTION 2: COMPLETE THIS ENTIRE SECTION AND PROVIDE ALL REQUIRED ATTACHMENTS

Please submit the following documentation, organized as numbered attachments as indicated below. If an item is not included, indicate the reason. Indicate the **page numbers and/or tabs where** the items and/or attachments can be found. **SUBMISSIONS THAT ARE NOT ORGANIZED AS DESCRIBED MAY BE RETURNED AND THE REVIEW SIGNIFICANTLY DELAYED.**

Section 2.1: Standard Operating Procedures

The standard operating procedures must contain all required elements as described in the **NYS General Systems Standards, Operating Procedures Sustaining Standard of Practice 2 (SOPM S2) content (a-q).**

Page/Tab	
	Specimen collection and handling and specimen rejection criteria, including a description of the mechanism to assure collection and transport requirements have been followed.
	A description of the assay and assay principle.
	Complete and detailed procedures for performing the assay, including algorithms and flowcharts as necessary and any safety considerations.
	List of equipment / instrumentation essential to the assay.
	Reagents: source, preparation, storage stability and handling (amplification assays: include a list of primers and sequences, when possible).
	Source and verification of standards / calibrators, quality control materials and the type, number, frequency and placement of the QC samples in an analytical run. Include QC evaluation / monitoring protocols.
	Calculation of results, interpretation guidelines and reporting guidelines (amplification assays: describe product size and method used to confirm the product and result, where applicable). Interpretation guidelines must include the consequence of the results on further testing (e.g. consequence of negative semen screening result on decision to perform differential extraction)
	For short tandem repeat fragment analysis on capillary electrophoresis instruments, include the determination of the RFU thresholds for reporting of single source and mixture samples.
	Assay interferences and limitations.
	Quality Assurance: Identify the critical steps, reagents and equipment in the test procedure and the quality control measures taken to control and monitor assay performance for consistent and reliable results.
	Quality Assurance: Policy and procedures to meet the **Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy**

Section 2.2: Requisition and Reporting

Page/Tab	
	A sample requisition form or equivalent Laboratory Information System (LIS) report compliant with **Requisition Sustaining Standard of Practice 4 (Requisition S4): Request Form**.
	Sample reports (in the laboratory's official report format) for all applicable findings including interpretive text, assay limitations (both diagnostic and technical limitations), appropriate client / case information and signature line for the qualified analyst(s), compliant with **Reporting Sustaining Standard of Practice 1 (Reporting S1): Report Content**, and any disclaimer required by the federal government such as that required for ASRs.

Section 2.3: References

Page/Tab	
	Copies of literature references that describe the scientific basis and support the validity of the assay.
	Test kit package insert if the test is commercially distributed, and/or package inserts for any commercially prepared reagents

Section 2.4: Validation Summary, Protocol And Representative Data

Page/Tab	
	NARRATIVE SUMMARY of the validation studies performed with results and conclusions must be submitted. **The summary must address how analytical performance characteristics were established and the source and number of specimens**.
	Documentation of validation approval by the NYS Certificate of Qualification Holder for Forensic Identity and the Technical Leader (FBI QAS 5.2.3.2.1 and 8.3).

Page/Tab	**INTERNAL VALIDATION STUDIES (required for all submissions)**
	Specimen storage time, temperature (FBI QAS 8.2.1.d)
	Accuracy (NYS Validation S5)
	Precision (both within (intra-) and between (inter-)runs for STR analysis assays (NYS Validation S5; FBI QAS 8.3.1.b.2)
	Reproducibility (reproducible result from sample tested more than once under identical conditions; FBI QAS 8.3.1.b.2)
	Analytical sensitivity (limit of detection and/or quantitation) (NYS FI 24; FBI QAS 8.3.1.b.3)
	Analytical specificity, address potential cross-reactivity and any interferences (endogenous and exogenous) (NYS Validation S5)
	For quantitative assays (e.g. Quantifiler® Human DNA Quantification Kit) define the reportable range
	For qualitative assays (e.g. acid phosphatase evidence screening) establish the basis for positive / negative results and how this will be reported.
	Analysis of known (identity or source is established) samples (FBI QAS 8.3.1.b.1)
	Analysis of casework-like samples (adjudicated or mock samples; describe any environmental insults to samples) (FBI QAS 8.3.1.b.1)
	Analysis of mixture samples, when appropriate (FBI QAS 8.3.1.b.4)
	Assessment of contamination (FBI QAS 8.1.3.1)
	Description of the qualifying/competency test for the assay and documentation of the completion of such test by technical personnel (NYS FI 24; FBI QAS 8.4)

Page/Tab	**ADDITIONAL STUDIES FOR DEVELOPMENTAL VALIDATION**
	Characterization of the genetic marker; or the biological or chemical target for evidence screening assays (NYS FI 24; FBI QAS 8.2.1.a)
	Species specificity (NYS Validation S5; FBI QAS 8.2.1.b)
	Population studies (FBI QAS 8.2.1.g)
	PCR-based studies must include: reaction conditions, assessment of differential and preferential amplification, effects of multiplexing, effects of sample volume, assessment of appropriate controls, and product detection studies. (FBI QAS 8.2.1.j)

Page/Tab	METHOD MODIFICATIONS
	Comparison with original procedures using similar samples (FBI QAS 8.5; for major modifications: e.g reaction volume change requires a full internal validation.)

Page/Tab	SOFTWARE
	New software or significant software changes (e.g. change to a new version, not an upgrade) require validation. (FBI QAS 8.7)
	Customized / in-house developed software requires validation. (NYS FI 26)