NEW YORK STATE | Department of Health | Wadsworth Center

GENERAL 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.

SECTION 1: GENERAL INFORMATION:

Lab Name: _____ PFI: _____

Contact Person: _____

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

Assay (Test) Name*: _____

Methodology (e.g., EIA, PCR; LC-MS/MS; RIA): _____

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

Validated Specimen Type(s) _____

Clinical Purpose: _____

Permit Category: (subject to final determination by CLEP) _____

Laboratory Director/Assistant Director (NYS Certificate of Qualification Holder for the appropriate Permit Category)

CQ Code _____ Signature _____

Laboratory Director (if not the responsible CQ Holder for the appropriate Permit Category)

CQ Code _____ Signature _____

*If the test comprises a number of individual assays that are combined into a panel and interpreted as such you must clearly describe the composition and application of the panel. Complete packages for each individual assay must be submitted. In addition to validation of each individual assay, the combined panel must also be validated in its combination. For example, if the end result consists of a risk/prediction factor, score or similar, it is this value that must be shown to be accurate, precise and reproducible, and meet all the other criteria described in the general requirements for assay validation.

SECTION 2: COMPLETE THIS PART ONLY FOR THOSE SUBMISSION TYPES LISTED BELOW. ALL OTHER SUBMISSIONS REQUIRE A COMPLETE PACKAGE AS DESCRIBED IN SECTION 3

☐ Research Use Only (RUO) kit or ☐ Investigational Use Only (IUO) kit:
Attach a summary of the establishment of, or verification of, performance characteristics; attach sample patient reports and copy of the package insert.

☐ Addition of an assay under an approved exemption:
Provide the Project ID from your original exemption approval letter, a description of the original exemption, the name of the assay to be added, a summary of the validation performed, and sample reports for all possible outcomes.

☐ Modified FDA or NYS-approved assay:
Indicate assay modification below and attach a summary of the study performed to validate the modification.
☐ Specimen Type ☐ Target Population ☐ Purpose of Testing ☐ Analysis (e.g., qualitative vs. quantitative)

NOTE: Section-specific guidelines and requirements supersede the instructions listed here.

SECTION 3: 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.** Refer to the New York State General System Standards and any relevant Specialty Standards in preparing your submissions.

SECTION 3.1: Standard Operating Procedure Manual (SOPM)

Procedure manuals 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	
	Practitioner and patient educational materials that include a description of assay limitations and, where applicable, other information as may be necessary for informed consent of test subjects.
	Clinical indications for testing, including, where appropriate, the prevalence and description of the medical condition.
	Test subject preparation, specimen collection and handling, specimen rejection criteria, including a description of the mechanism to assure collection and transport requirements have been followed.
	A description of the assay, assay principle and clinical validity. For molecular tests, a description of the structure of the gene(s) to be tested, if applicable, must be provided.
	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 list of primers and sequences).
	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 and interpretation (amplification assays: describe product size and method used to confirm product and result, where applicable).
	Assay interferences and limitations.

	Quality Assurance: Identify the critical steps 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 3.2: Requisition and Reporting

Page/Tab

	A sample requisition form containing all the required elements in **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), 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 3.3: References

Page/Tab

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

SECTION 3.4: Validation Summary, Protocol and Representative Data

Page/Tab	**Validation Studies**
	NARRATIVE SUMMARY of the validation studies performed with results and conclusions must be submitted and should be supported by providing the laboratory's validation protocols. **The summary must address how analytical and clinical performance characteristics were established and describe any comparative methods and the source and number of specimens**. Raw data must be provided using an appropriate number of samples across all representative specimen matrices and expected outcomes. Data should be summarized with clearly labeled tables, figures and photographs.
	Analyte and specimen matrix stability
	Specimen transport conditions
	Storage time and temperature
	Accuracy
	Precision (reproducibility, both within (intra-) and between (inter-)runs)
	Reportable range, where applicable (calibration of quantitative tests).
	Analytical sensitivity (limit of detection and/or quantitation)
	Analytical specificity, address potential cross-reactivity (for infectious disease testing) and any interferences (endogenous and exogenous)
	Clinical validity (sensitivity and specificity) establishment: • Describe the protocols used to determine the clinical status of test subjects • Describe the procedure used to blind the clinical status of specimens during testing • Describe the procedures used to resolve discrepant or equivocal test results

	• Present data used for the determination of clinical sensitivity, specificity and/or predictive values
	A description of studies performed to validate any data reduction and interpretation processes, including statistical or algorithmic calculations.
	A description of how reference intervals or assignment of cutoff values were determined, if applicable. For molecular tests, provide high quality original results of a sample of validation data.

Page/Tab	**Representative Specimen Run**
	Provide actual instrument printouts, worksheets, or charts from one representative run, including all calibration and quality control materials.
	For those methods using gels, blots and/or electrophoresis, submit high quality photographs.

Page/Tab	**Quality Control Data**
	Provide quantitative QC data and QC review format (e.g., Levey-Jennings charts) for 20-30 consecutive runs.