

SECTION I NOTIFICATION

Please submit the completed form (and attachments) by email, compact disc or postal mail, to: **Clinical Laboratory Evaluation Program, Wadsworth Center, New York State Department of Health, PO Box 509, Empire State Plaza, Albany, NY 12201-0509, Attn: Assay Validation Review.** Email: **CLEPVAL@health.state.ny.us**

Laboratory: _____ PFI: _____ Director: _____

Address: _____ Contact Person: _____

Date: _____ Phone: _____ Fax: _____ E-mail: _____

- TEST INFORMATION AND CATEGORIZATION

Organism: _____ Specimen Type(s) _____

Assay Name: _____ Manufacturer: _____

Method/Procedure Principle: _____

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

Assay Type: Indicate below the manufacturer's labeling of the reagents and submit a full validation package as described in Section II. For FDA-cleared or approved assays, complete the form "Notification to "Add or Delete Analyte(s)" DOH 3519:

Kit labeled for Investigational Use Only (IUO)

Kit labeled for Research Use Only (RUO)

Commercially distributed test, modified for intended use – reagents labeled as:

IVD RUO IUO Other _____

Laboratory developed test that utilizes Analyte Specific Reagents (ASRs)

Laboratory developed test not utilizing ASRs

- INTENDED USE

If the submission is for a change in intended use, indicate the changes made:

Specimen Type: _____

Target Population: _____

Type of analysis (e.g., qualitative vs. quantitative): _____

Purpose of Testing:

Diagnostic - identification of infected patients for treatment and management purposes.

Prognostic - the use of indicators to predict outcomes of disease, e.g. viral load assays.

Identification - identification and characterization of infectious agents in patients.

- PERFORMANCE EVALUATION

Describe the comparative method and/or identify the reference laboratory:

SECTION II ASSAY DESCRIPTION

Laboratories are required to submit the following documentation for in-house developed methods . Please organize enclosed items into attachments as indicated below. If an item is not included, indicate the reason. Include a complete SOPM and indicate the **page numbers** on which the items and/or attachments can be found.

- ATTACHMENT I: METHODS

- ___ 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.
- ___ Calculation of results and interpretation (amplification assays: describe product size and method used to confirm product and result, where applicable).
- ___ Assay interferences and limitations.

- ATTACHMENT II: REQUISITION AND REPORTING

- ___ A sample requisition form.
- ___ For genetic testing, provide the policy used to inform physicians of the requirement to obtain written informed consent from the patient prior to ordering a genetic test. The laboratory shall have available to the physician the information needed to provide informed consent. This information should include: a) A general description and statement of purpose for the test; b) a general description of the disease or condition related to the test; c) the level of certainty that a positive test result serves as a predictor of the disease; and, d) a statement that no tests other than those authorized will be performed on the biological sample and that the sample will be destroyed at the end of the testing process or not more than sixty days after the sample was taken, unless a longer period of retention is expressly authorized in the consent.
- ___ Sample reports (in the laboratory's official report format) for all applicable findings including interpretive text, assay limitations (both diagnostic and technical limitations), appropriate patient information and signature line for the qualified laboratory director or assistant director, when required and any disclaimer required by the federal government such as that required for ASRs. Genetic testing reports should include suggestions for additional or alternative testing, recommendations for referral to a genetic counselor, and the signature of the qualified person who reviewed, approved and/or diagnosed the case.

- ATTACHMENT III: REFERENCES

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

- ATTACHMENT IV: INITIAL VALIDATION PROTOCOL AND DATA

Describe the protocols used to validate the assay, including a description of the comparative method and the source and number of specimens. An overall narrative summary of the validation studies performed with results and conclusions must also be submitted. Data to demonstrate the following must be provided (please explain when data is not 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.

PRE-ANALYTIC PHASE

- ___ Analyte and matrix stability.
- ___ Specimen transport conditions.
- ___ Storage time and temperature.

ANALYTIC PHASE

- ___ Accuracy.
- ___ Precision / reproducibility.
- ___ Reportable range / linearity, if applicable.
- ___ Analytical sensitivity or limit of detection (how well the assay performs with known positive samples).
- ___ Analytical specificity, i.e., how well the assay performs with known negative samples, the existence of any cross-reactivity (for infectious disease testing) and any interferences (endogenous and exogenous).

Where clinical investigations are necessary to determine assay accuracy:

- ___ 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.

POST-ANALYTIC PHASE

- ___ Data reduction and interpretation.
- ___ Determination of the reference interval or assignment of cutoff value, if applicable. For molecular tests, provide high quality original results of a sample of validation data. Validation data for genetic tests should include heterozygous, homozygous normal, and if available, homozygous mutant specimens.
- ___ Clinical validity, data regarding the degree to which a result or variant predicts a disease state.

SPECIMEN RUNS

- ___ Provide actual instrument printouts, worksheets, or charts from a representative run, including all standards and quality control materials.
 - ___ For those methods using gels, blots and/or electrophoresis, submit high quality photographs.
 - ___ Include information to evaluate quality control.

- ATTACHMENT V: 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.
- ___ For assays where there is no available New York State proficiency test, describe the mechanism that will be put in place to verify the accuracy and reliability of test results at least twice yearly, as required in the NYS Quality Assurance Standards.
- ___ For forensic identity testing, describe the qualifying test that will be used to assess that staff have been adequately trained and can demonstrate competence in the new method prior to performing the assay and reporting actual results on real samples.