ASSAY MODIFICATION SUBMISSION FORM

Please submit all information as outlined below. Submit one hard copy of the entire package and one electronic copy (as PDF files 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.

SECTION 1: GENERAL INFORMATION:

Lab Name: _____ PFI: _____

Contact Person: _____

Phone: _____ Contact E-mail: _____

Assay (Test) Name*: _____

*As indicated on the approval from the FDA or NYS.

NYS-approved Project ID, if applicable: _____

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

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

Validated Specimen Type(s): _____

Clinical Purpose/Intended Use: _____

Permit Category: _____

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

CQ Code _____ Signature _____ Date _____

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

CQ Code _____ Signature _____ Date _____

SECTION 2: Please submit the following documentation. Refer to the New York State General System Standards and any relevant Specialty Standards in preparing your submissions.

- **DESCRIPTION OF THE MODIFICATION** from either an FDA cleared/approved assay or NYS-approved assay, if the modification changes the intended use, including whether the modification changes the risk of the assay and how.
- **NARRATIVE SUMMARY** of the validation studies performed with results and conclusions must be submitted. **The summary must address how analytical and clinical performance characteristics were established and describe any comparative methods and the source and number of specimens**.
- Relevant Standard Operation Procedures (SOPs), if modified.
- Copies of pertinent references, if appropriate.
- Sample Test requisitions and reports, if changed.
- Informed Consent materials, if applicable.
- **Completed RISK ATTESTATION FORM.**