NEW YORK STATE | Department of Health | Wadsworth Center

## ADD TEST/ANALYTE UNDER EXEMPTION 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: _____ Fax: _____ Contact E-mail: _____

**Approved Exemption Project ID (PID)**: _____

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/Intended Use: _____

_____

Permit Category: _____

I attest that the validation of the analytes described above was performed in accordance with the protocol for method validation that was submitted to the Department in support of the laboratory's Exemption from Comprehensive Submission request. Any deviations from said protocol have been noted in the attached summary of validation.

Laboratory Director
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.

**NARRATIVE SUMMARY** describing the clinical purpose/intended use of the assay and the validation studies performed with results and conclusions.. The summary must address how analytical and clinical performance characteristics were established and describe any comparative methods and the source and number of specimens.

**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.