NEW YORK STATE | Department of Health | Wadsworth Center

Exemption Request from Comprehensive Laboratory Developed Test Submissions

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 StateDepartment 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 StateDepartment of Health, Dock J - P1 Level, Empire State Plaza, Albany, NY 12237; Attn: Assay Validation Review

Materials submitted, including related data packages, will not be returned to the laboratory. All materials are maintained under strict confidentiality. Materials are subject to New York State's Freedom of Information Law (commonly called FOIL). We suggest marking your documents as “proprietary” or “confidential”. If so marked, laboratories will be given an opportunity to block information release.

SECTION 1: GENERAL INFORMATION

TYPE OF REQUEST:
Initial ☐ Renewal ☐ For Renewal, enter Project ID of existing exemption: _____

NOTE: Renewals require a complete method validation submission for a representative assay, including the appropriate submission checklist for the category

Laboratory Name:_____ **NYS PFI**:_____

Provide information on the methodology(ies), which may include platform, and specimen types for exemption consideration.

Methodology(ies) (e.g., FISH, Sanger sequencing, LC-MS/MS, EIA):

_____

Detection Platform (optional): _____

Specimen Type(s) (e.g., serum, plasma, CSF): _____

Permit Category(ies): _____

Has your laboratory received approval for previously submitted LDT packages using this method(s) before in the requested permit category(ies)? If so, please list below:

Ex: PID 123456			

SECTION 2: INSTRUCTIONS FOR SUBMITTING A FULL EXEMPTION PACKAGE

The checklist below is a guide for items that must be included in the full validation submission packages. The information submitted must be organized as **numbered or uniquely named attachments**. If an item is not included, indicate the reason.

Section 2.1: Standard Operating Procedure and Controls

File Name	
	Standardized protocol for method validation in compliance with **Test Procedure Content Standard of Practice 1 (TPC S1): Test Procedure Content**, including: • a brief summary for method validation to include a description of the laboratory's principles and practices for assay development and initial validation. • acceptable specimen types and collection materials (i.e., tube types), specimen transport requirements (e.g., temperature, time to receipt) and specimen rejection criteria. • technical limitations of the methodology, potential sources of error, trouble-shooting protocols, and any other information relevant to performing the assay • the validation protocol must address all the criteria for method validation set forth in the relevant category-specific Submission Guidelines document, where one exists for the category of testing.
	Laboratory-specific protocols for on-going validation, including quality control procedures and quality assurance indicators in compliance with **Quality Control Standard of Practice 1 (QC S1): Minimum Quality Control Requirements** including: • quality control plan, which should include a lot to lot quality control plan • quality assurance guidelines in compliance with **Quality Management System Standard of Practice 3 (QMS S3): Quality Indicators** • proficiency testing plan in compliance with **Proficiency Testing Fundamental Standard of Practice (PT FS)**