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, 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

Laboratory Name: _____ NYS PFI: _____

Assay (Test) Name*: _____

Assay (Test) Identifier(s) (e.g., Test Code(s))*: _____

Assay (Test) Type: ☐ Laboratory Developed Assay (LDA) ☐ Investigational Use Only (IUO)
☐ Analyte Specific Reagent (ASR) ☐ Research Use Only (RUO)

For RUOs only, provide the manufacturer/kit used: _____

Target Population (if applicable): _____

Methodology (e.g., LC-MS/MS, HPLC): _____

Analyte(s) included (Cortisol, etc.): _____

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

Intended Use: _____

Permit Category (check all that apply): ☐ Andrology ☐ Bacteriology ☐ Clinical Chemistry ☐ Cytokines
☐ Endocrinology ☐ Fetal Defect Markers ☐ Genetic Testing - Biochemistry ☐ Hematology ☐ Histocompatibility
☐ Immunohematology ☐ Therapeutic Substance Monitoring/Quantitative Toxicology ☐ Transplant Monitoring

*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 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.

All submissions must include a “Risk Attestation Form” found on the CLEP Test Approval webpage.

If this submission is a modification of an FDA or NYS-approved assay, see the "Assay Modification Checklist" on the CLEP Test Approval webpage.

If this submission is for the addition of an assay under an approved exemption, see the "Add Test Under Exemption Checklist" on the CLEP Test Approval Webpage.

SECTION 2: INSTRUCTIONS FOR SUBMITTING A FULL VALIDATION 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. Refer to the New York State General System Standards and any relevant Specialty Standards in preparing your submissions. See https://www.wadsworth.org/regulatory/clep/clinical-labs/laboratory-standards.

Section 2.1: Standard Operating Procedure and Controls

Procedure manuals must contain all required elements as described in the **NYS General Systems Standards, Test Procedure Content Standard of Practice 1 (TPC S1): Test Procedure Content.**

File Name	
	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.

Section 2.2: Test Requisition and Reports

File Name	
	A sample requisition form containing all the required elements in **Test Request Standard of Practice 3 (TR S3): Test Request Form.**
	Examples of test reports containing all findings (e.g., positive, negative, indeterminate, inconclusive, etc.) with interpretive text, assay limitations and any disclaimers required by the federal government, such as for tests utilizing Analyte-Specific Reagents (ASRs) and in compliance with **Reporting Standard of Practice 2 (REP S2): Test Report Content**. If preliminary or presumptive positive results will be reported without confirmation, include examples of these reports containing the appropriate statements explaining the presumptive/preliminary nature of the results and recommendations for confirmation, if applicable.

Section 2.3: References

File Name	
	A list of relevant literature references that describe the scientific basis and clinical validity of the assay. Provide electronic copies of primary references only.
	Applicable package inserts

Section 2.4: Validation

File Name	Validation Studies
	NARRATIVE SUMMARY of the validation studies performed with results and conclusions must be submitted and must 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 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.

File Name	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.

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

Section 2.5: Quality Assurance

File Name	
	Proficiency Testing: A plan for proficiency testing including criteria for passing, the number of samples included in the proficiency panel, and the corrective actions that would be taken. The proficiency testing plan must be compliant with **Proficiency Testing Standards of Practice.** If there are no commercially available proficiency testing programs for the analyte(s), a detailed plan for an alternative to proficiency testing must be provided. This plan must be in compliance with **Proficiency Testing Standard of Practice 3 (PT S3): Alternative to Proficiency Testing.**
	Systems agreement: If different instruments or platforms will be used to perform the assay, demonstrate the assay's consistency across these variables.
	Quality Control Plan: 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.

Section 2.6: Test Design

The below list of questions **must** be answered for **ALL** validation submissions. NOTE: Any automated software, algorithm, statistical models, or simpler artificial intelligence (AI) methods MUST be locked. Unlocked algorithms will not be considered.

Does this assay use an automated software, algorithm, statistical models, or simpler AI methods (e.g., decision trees, logistic regression)? ☐ Yes ☐ No

If the above answer is yes, please complete the below section. Below, the term 'algorithm' refers to any automated software, algorithm, statistical models, or simpler AI methods**:**

Is the algorithm locked? ☐ Yes ☐ No

Was the algorithm developed in-house? ☐ Yes ☐ No

If developed in-house, please complete the below section:

File Name	
	NARRATIVE SUMMARY of the data used to train **and** validate the algorithm. If you refer to previously published information on the cohort, please provide the full reference. The **NARRATIVE SUMMARY** must include the following: • Sample size • Inclusion/exclusion criteria • Data quality control policy(ies) • Relevant patient characteristics (e.g., age, gender, ethnicity), as applicable • The software package(s) used • How the algorithm's features or variables were selected • Description of any algorithms, statistical models, or simpler AI methods implemented by the software • Indicate if advanced AI/ML, such as Natural Language Processing (NLP) was used in the development process • Where/how the training/validation data was generated (e.g., in-house, previously published)
	Provide the power or sample size calculations used to determine specimens or data points required for training/validation. Include justification for the calculations.
	What quality control processes do you have in place? Describe any pre-analytical (e.g., specimen rejection criteria) and analytical controls to monitor the software/algorithm/model output.
	Explain how the algorithm is locked from revisions during use.
	What information do you provide to clinicians that allows them to make an independent decision about the results? Include details on the data set, key variables or analytes, and error metrics such as accuracy, precision, recall, and any misclassification rates.