CLINICAL LABORATORY EVALUATION PROGRAM
BIGGS LABORATORY, WADSWORTH CENTER
NEW YORK STATE DEPARTMENT OF HEALTH
EMPIRE STATE PLAZA
ALBANY, NY 12237

RISK ATTESTATION FORM
For Laboratory Developed Tests

PFI:

Office Use Only: Project ID

LABORATORY NAME:

LDT TITLE:

Provide a summary (not more than 500 words) of the proposed test including:

- **Intended use to include target population if applicable**
- **Methodology and technology (e.g., sequencing by next generation sequencing)**
- **Specimen type(s)**

Respond to the following questions:

1. Does the intended use of the assay make clinical claims or direct reference to recognized diseases/ condition(s)? Note that any materials submitted to the Department may be shared with federal Centers for Medicare and Medicaid Services (CMS) CLIA Program. The intended use must be clearly stated above.

☐ Yes ☐ No

Enter relevant literature references here; full citations required. References must be available, upon request.

2. Is this test used only in a clinical trial? ☐ Yes ☐ No

2a. If yes, does the LDT as a device in the clinical trial have IRB APPROVAL?

☐ No ☐ Yes - Submit the following:

- validation summary
- sample reports for all possible outcomes

And submit at least one of the following:

- IRB Approval letter
- clinicaltrials.gov (NTC) identifier
- FDA letter stating LDT meets requirements as NSR device

2b. If used in a clinical trial, describe the intended use. (No more than 200 words)

3. Is this LDT a modification of an FDA cleared/approved/exempted IVD or of an existing LDT **in your laboratory** that is fully approved or conditionally approved by CLEP ?

☐ Yes – Provide CLEP Project number, PID ____ , or manufacturer and name of the FDA approved test
☐ *No*

3a. Describe exactly what is modified/changed in this test *(please check all that apply)*

☐ Specimen type or specimen handling procedure
☐ Reagents, probes, primers, antibodies, etc.
☐ Algorithm
☐ Instrumentation
☐ Clinical purpose, intended use, and/or targeted patient population
☐ Other

Detailed explanation of modification/change and any effect on assay performance:
(No more than 200 words)

4. Do you have any LDTs with this methodology that have received full CLEP approval?

☐ Yes ☐ No If yes, provide PIDs:

5. Does the LDT utilize methodology that is well-established **in your laboratory** and generally accepted by the field?

☐ Yes ☐ No

5a. If yes, do you have an exemption for this methodology in the permit category of testing?

☐ Yes ☐ No If yes, provide PID

If yes, please explain and provide supporting evidence by identifying available tests currently performed in your laboratory with the same methodology that either have full CLEP approval (include Project IDs) or are FDA approval/clearance/exempt. *(No more than 200 words)*

Describe methodology here:

Enter References here. Full citations, including titles, are required.

6. Was the intended clinical use or claim for the LDT established via literature, clinical trial/studies, or both? If via literature, provide the full citation of the reference and a brief description of its relevance. Supporting clinical or laboratory data and/or publications must be included in the submission package. (No more than 200 words)

Write Explanation here:

Enter References here. Full citations, including titles, are required.

7. Briefly explain which critical and/or essential information (i.e., key determinants), if any, is generated to 1) diagnose, and/or 2) indicate a greater likelihood of developing a disease or condition, and/or 3) establish eligibility for a specific treatment, and/or 4) provide prognostic information that influences patient management/treatment decisions, and/or 5) provide information on treatment adherence and/or drug abuse. (No more than 200 words)

8. Briefly describe the potential impact of an inaccurate test result and whether it is likely to increase the risk of significant morbidity or mortality. (No more than 200 words)