NEW YORK STATE DEPARTMENT OF HEALTH
WADSWORTH CENTER
CLINICAL LABORATORY EVALUATION PROGRAM
EMPIRE STATE PLAZA, PO BOX 509
ALBANY, NY 12201-0509

RISK ATTESTATION FORM
For Laboratory Developed Tests

PFI:

Office Use Only: Project ID

LABORATORYNAME:

LDT TITLE:

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

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

Respond to the following questions:

1. Did you receive a determination from CMS that this test is not considered clinical? Please include the CMS decision letter.

☐ No ☐ Yes

Please explain why you believe the test is not clinical? (No more than 200 words)

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

2. Is this test used in a clinical trial?

☐ No ☐ Yes

2a. If yes, does the trial have IRB APPROVAL?

☐ No ☐ Yes - Submit approval letter and clinicaltrials.gov number

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 that is fully approved by CLEP? ***(Note: check 'no' if conditional approval only)***

☐ Yes – Provide CLEP Project number, PID ☐, or manufacturer and name of the FDA approved test
☐ *No –Skip to question 4*

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?

☐ 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.)