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:

- **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. Do you wish this test/assay to be considered for Lifestyle classification? If yes, you consent for the validation materials submitted for this assay to be forwarded to CMS for a determination that this test is not considered clinical (ie: lifestyle testing, 'wellness' testing)?

☐ Yes ☐ No

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 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 compliant with the relevant submission Checklist sample reports for all possible outcomes compliant with relevant submission Checklist

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 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.)