**LABORATORIES UTILIZING MANUFACTURER ASSAYS GRANTED EMERGENCY USE AUTHORIZATION (EUA) BY THE FDA FOR CORONAVIRUS DISEASE-2019 DURING A PUBLIC HEALTH EMERGENCY**

This form must be completed and submitted to the CT Department of Public Health, Healthcare Quality and Safety Branch for all State of Connecticut licensed clinical laboratories that have validated manufacturer assays granted EUA from the FDA to perform COVID-19 testing on clinical specimens during a public health emergency.

Facility: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Town: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, CT Zip \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Telephone number:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

CLIA #\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ State License # \_\_\_\_\_\_\_\_\_\_\_\_\_

Laboratory Director Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Are you adding the subspecialty of virology: □ yes □ no

If yes, please submit Completed State of Connecticut 'Laboratory Personnel Report' for all regulatory positions. Note: If the laboratory (or technical staff) has not previously qualified for the subspecialty of virology, appropriate credentials (education and training; CVs are unacceptable) for the technical and testing personnel must be included. <https://portal.ct.gov/-/media/DPH/FLIS-Forms/CT-Laboratory-Personnel-List.pdf?la=en>

Testing Platform: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Kit Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Sensitivity of the test: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Estimated Test Volume: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Days & times testing performed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Testing population (i.e. Inpatient, Outpatient, Healthcare Workers etc.): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Turn around Time for testing: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Testing capacity:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Patient testing start date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**REPORTING**:

1. Please submit a sample test report along with this form.
2. SARS-CoV-2, the virus that causes COVID-19 is a reportable laboratory finding. Refer to the Public Health Commissioner’s correspondence titled ‘Change to the List of Reportable Laboratory Findings’. <https://portal.ct.gov/-/media/Departments-and-Agencies/DPH/Facility-Licensing--Investigations/Blast-Faxes/Change-to-the-List-of-Reportable-Laboratory-Findings.pdf?la=en>

**NOTE:** You are NOT required to submit COVID-19 validation data at this time. It will be reviewed at your next onsite inspection.

The Laboratory shall make provisions to maintain appropriate safety and infection control measures at all times.

The undersigned Laboratory Director or designee, duly authorized, responsible for the services performed in the Laboratory, attests that the Laboratory has sufficient staff, equipment, and provisions will be provided to ensure the health and safety needs of the laboratory according to both state and federal regulations.

This Attestation shall remain in effect until the Laboratory no longer requires this service or such use by the Laboratory is revoked by the Department upon a finding that the health, safety, or welfare of any staff or patient has been jeopardized.

The parties hereto have caused this Attestation to be executed by their respective officers and officials and will be effective as of the later of the two dates noted below

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Laboratory Representative

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Facility Licensing & Investigations Section, Laboratory Section

Healthcare Quality and Safety Branch

Please return this form along with the documentation to: shelley.olm@ct.gov