

# STATE OF CONNECTICUT

## DEPARTMENT OF PUBLIC HEALTH

Deidre S. Gifford, MD, MPH  
Acting Commissioner



Ned Lamont  
Governor  
Susan Bysiewicz  
Lt. Governor

### HEALTHCARE QUALITY AND SAFETY BRANCH

#### CLIA CERTIFICATE OF WAIVER 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 Clinical Laboratory Improvement Amendment (CLIA) certificate of waiver laboratories in Connecticut that utilize any manufacturer assay granted Emergency Use Authorization (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 #: \_\_\_\_\_

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

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: \_\_\_\_\_



Phone: (860) 509-7400 • Fax: (860) 509-7543  
Telecommunications Relay Service 7-1-1  
410 Capitol Avenue, P.O. Box 340308  
Hartford, Connecticut 06134-0308  
[www.ct.gov/dph](http://www.ct.gov/dph)  
Affirmative Action/Equal Opportunity Employer



## **REPORTING:**

1. Please submit a sample test report/dummy patient chart/a narrative as to how the results are being recorded 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>

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 the federal CLIA 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: [DPH.FLISLab@ct.gov](mailto:DPH.FLISLab@ct.gov)

8/19/20