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 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 #_____

CLIA Laboratory Director Name: _____

Testing Platform: _____

Kit Name: _____

Sensitivity of the test (refer to manufacturer package insert): _____

Estimated Test Volume: _____

Days & times testing performed: _____

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

Turn around Time for testing: _____

Testing capacity at your facility:_____

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

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. Indicate how are you providing the FDA mandated fact sheets to the health care provider(s) and patients? Check the appropriate box below.

   ☐ Hard copy ☐ Electronic link ☐ Other: (specify)……

3. 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

8/19/20