Guidance for Laboratory Testing Certification from CLIA and Approvals from DPH

Skilled Nursing Facilities/Assisted Living Facilities/congregate settings/healthcare providers/school system etc. interested in using FDA-EUA approved point of care devices (example: Quidel Sofia SARS Antigen FIA, Becton Dickson (BD) Veritor System, Abbott ID NOW system/Abbott BinaxNOW COVID-19 Ag Card Point of Care SARS-CoV-2 Diagnostic test etc.) for Rapid detection of SARS-COV-2 (COVID-19) testing test in-house, are required to have an active Clinical Laboratory Improvement Amendment (CLIA) Certificate of Waiver from CMS.

The process to follow for those facilities with an active CLIA certificate of Waiver:

a. Complete the **FDA-Emergency Use Authorization (EUA) attestation form** and return to DPH.FLISLab@ct.gov prior to testing patient samples.
b. Submit a copy of the patient test report/dummy patient chart/a narrative as to how the results are being recorded to the Dept. of Public Health's (DPH) along with the above attestation form.

The process to follow for those facilities with no CLIA certification:

a. Complete a CMS 116 Application form and return to DPH.FLISLab@ct.gov. Once entered into the CMS database, the department will notify the facility of their CLIA number immediately.
b. Follow steps a & b above.

All facilities are mandated by the FDA EUA to provide fact sheets to the healthcare provider and patients undergoing COVID 19 testing. The Department needs to know the way this is accomplished by the facility's preference (hard copy or electronic link).

Once you submit the required documents we will review and get back to you.

No patient testing for COVID-19 is allowed until you get such approval from DPH.

NOTE: COVID-19 is a reportable event to the state epidemiology section. Please contact DPH Informatics directly at: DPH.InformaticsLab@ct.gov for reporting instructions.

All COVID-19 test(s) must be ordered by a Licensed Medical Practitioner who must be available for evaluation/consultation of these patients.