**BLAST FAX 2020-91**

TO: CLIA Laboratories

FROM: Commissioner Deidre S. Gifford, MD, MPH

CC: Deputy Commissioner Heather Aaron, MPH, LNHA

Adelita Orefice, MPM, JD, CHC, Senior Advisor to the Commissioner

Barbara Cass, RN., Branch Chief, Healthcare Quality and Safety Branch

Donna Ortelle, Section Chief, Facility Licensing and Investigations Section

DATE: September 4, 2020

SUBJECT: Emergency Use Authorization re Yale’s SalivaDirect

For those labs who are interested in adopting Yale’s SalivaDirect, the following is needed per FDA/CMS (CLIA), and per the current letter of authorization from the FDA (to Yale) dated August 28, 2020 (<https://www.fda.gov/media/141194/download>).

* The FDA views this as an approved Emergency Use Authorization (EUA) protocol for Yale School of Public Health, Department of Epidemiology of Microbial Diseases and laboratories authorized by Yale.
* Contact Yale directly using the following link (<https://covidtrackerct.com/about-salivadirect/> ) and complete the External Lab Authorization Request Form. If approved, Yale will issue a letter of authorization.
* Authorized laboratories will collect information on the performance of SalivaDirect and report any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of SalivaDirect of which they become aware to (salivadirect@gmail.com) and Medwatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling 1-800-FDA-1088.
* If you obtain all the same reagents used by Yale, do the performance characteristics according to the package insert (Instruction for Use document) that Yale provided to you. The attached ASM document and CMS link below are reference materials on how to perform verification studies on EUA assays.
* This will be an EUA authorized assay that you are running in your laboratory. For state tracking purposes, complete the attached attestation form and return to DPH.FLISLab@ct.gov.

Here is an American Society for Microbiology (ASM) link.

<https://asm.org/Articles/2020/August/What-is-the-COVID-19-SalivaDirect-Test>

The following is a Centers for Medicare and Medicaid (CMS) link regarding EUA:

<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO18-19-CLIA.pdf>