**BLAST FAX 2020-81**

TO: Laboratory Directors

FROM: Commissioner Deidre S. Gifford, MD, MPH

CC: Deputy Commissioner Heather Aaron, MPH, LNHA

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DATE: July 24, 2020

SUBJECT: **Thermo Fisher Scientific, Inc.: TaqPath COVID-19 Combo Kit**

Connecticut’s State Public Health Laboratory identified a flaw in one of the testing systems it uses to test for SARS-CoV-2, the virus that causes COVID-19. The flaw, which has been reported to both the manufacturer and the federal Food and Drug Administration (FDA), led to 90 of 144 people tested during June 15–July 17, 2020 receiving a false positive COVID test report. The Department of Public Health (DPH) has taken immediate steps to make sure the patients are notified. The errant testing results were from a widely-used laboratory testing platform that the state laboratory started using on June 15, the Thermo Fisher Scientific, Inc.: TaqPath COVID-19 Combo Kit (Thermo Fisher TaqPath).

On March 13, 2020 the FDA acknowledged receipt of an EUA request for the Thermo Fisher TaqPath.

Please be advised that on July 17, 2020, the Food and Drug Administration issued an acknowledgement indicating that Thermo Fisher Scientific, Inc. has updated the Instructions for Use (IFU) of the TaqPath COVID-19 Combo Kit. Please review the attached FDA acknowledgement letter and revised IFU.

The Department is strongly recommending and in accordance with state and federal laws and regulations regarding Analytic Systems and Quality Assurance, if you have been utilizing the Thermo Fisher Taqpath to test for SARS-CoV-2, an impact study should be conducted to validate test results.

If you are in the process of validating the Thermo Fisher Taqpath to test for SARS-CoV-2, please notify the Department at [DPH.FLISLab@ct.gov](mailto:DPH.FLISLab@ct.gov).

If you have any questions, please reach out to the DPH laboratory regulatory unit at: [DPH.FLISLab@ct.gov](mailto:DPH.FLISLab@ct.gov)