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Commissioner

March 23, 2020

Dear Laboratory Director/Owners:

On March 16, 2020, the Food and Drug Administration (FDA) issued new guidance that describes two policies for accelerating the development of certain laboratory tests to detect SARS-CoV-2. The first policy requires an EUA submission to the FDA as described in the FDA Guidance Document. The second, a new policy, allows a state or territory to authorize clinical laboratories to develop and perform a test for SARS-CoV-2 within the state or territory. This policy does not require the clinical laboratory to submit an EUA request and SARS-CoV-2 test validation to the FDA.

Licensed clinical laboratories in New Jersey that intend to perform testing for SARS-CoV-2 in their laboratory must follow the Clinical Laboratory Improvement Services (CLIS) Clinical Laboratory Licensing procedure for adding a test to their license prior to performing patient testing.

1. **Laboratories that have Laboratory Developed Tests (LDTs) and are submitting EUA applications to FDA**

Each clinical laboratory director must submit a written request to add SARS-CoV-2 to their testing menu along with the full validation studies to CLIS for review and approval prior to performing any patient testing. Please be sure to follow the FDA Guidance Document found at: https://www.fda.gov/media/135659/download for validation study recommendations and reporting requirements. Upon CLIS approval of the test expansion request, and while your laboratory is awaiting the FDA determination of your EUA request, you must obtain confirmation of the first five positive and the first five negative patient specimens by sending the ten specimens to the New Jersey Public Health and Environmental Laboratories. If any of the results cannot be confirmed, your laboratory needs to notify FDA and take appropriate actions such as terminating patient specimen testing and issuing a corrected test report that indicates the prior result may not be valid.

2. **Laboratories implementing FDA EUA approved tests**

For laboratories that will be implementing a test covered by an existing EUA (such as the CDC Real-Time RT-PCR Panel for Detection of 2019- Novel Coronavirus and others as they become available), please refer to https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov for more information. You must submit a written request to add SARS-CoV-2 to your testing menu along with a completed verification study as specified by the EUA guidance and/or device manufacturer. **However, you may begin clinical testing as soon as the successful verification is complete.**

3. Laboratories that have developed LDTs and are seeking New Jersey State approval only

Each clinical laboratory director must submit a written request to add SARS-CoV-2 to their testing menu along with the full validation studies to CLIS for review and approval prior to performing any patient testing. Please be sure to follow the FDA Guidance Document at: https://www.fda.gov/media/135659/download for validation study recommendations. Please submit the results of the first five positive and first five negative clinical specimens along with correlation results from another laboratory using a test assay (comparable method) licensed by CLIS for SARS-CoV-2.

As per N.J.A.C. 8:57 Subchapter 1, reporting of cases (and their laboratory test results) for immediately reportable diseases is required within 24 hours of obtaining the result. Currently the Communicable Disease Reporting and Surveillance System (CDRSS), is the data repository of all communicable diseases (with the exception of HIV, TB and STDs) and is designed to accept electronic laboratory reporting (ELR) in the CDC-recommended, PHIN compliant format of Health Level 7 (HL7), utilizing LOINCs and SNOMED codes as applicable.

Laboratories conducting testing for COVID-19 must either: report test results via Electronic Laboratory Reporting (ELR) using HL7 standard messaging protocol; or enter results directly into the Communicable Disease Reporting and Surveillance System (CDRSS). Facilities should use their existing reporting mechanism to submit COVID-19 test results to CDRSS, whether that is via ELR or web data entry directly into CDRSS. If a facility does not currently report lab results to CDRSS, they should submit an email to cdrs.train@doh.nj.gov to request user access.

CLIS will notify the clinical laboratory in writing as to approval or disapproval of the test expansion request. If you have questions, please contact NJ PHEL at Joan.Mikita@doh.nj.gov or 609-406-6830.

Sincerely,

Thomas Kirn, MD, PHD
Medical Director
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