

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Renée D. Coleman-Mitchell, MPH
Commissioner



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Governor
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Lt. Governor

HEALTHCARE QUALITY AND SAFETY BRANCH

BLAST FAX 2020-06

TO: Hospital Administration
Laboratory Directors

FROM: Commissioner Renée D. Coleman-Mitchell, MPH *RCM*

DATE: March 6, 2020

SUBJECT: Laboratory Testing for 2019 Corona Virus (COVID-19)

In an effort to address the coronavirus outbreak, on February 29, 2020 the Food and Drug Administration (FDA) issued a new policy that permits certain laboratories seeking to develop diagnostic tests for 2019 coronavirus (COVID-19) the opportunity to test. A laboratory that has Clinical Laboratory Improvement Amendments (CLIA) certification to perform high complexity testing may participate with approval from FDA.

The FDA's Emergency Use Authority (EUA) will allow for more rapid and aggressive testing which will provide greater access and reduce burden and/or potential burden to existing approved laboratories. The Department is currently reaching out to laboratory providers who are CLIA certified to perform high complexity testing and determine their willingness to conduct testing for COVID-19 and is encouraging other interested laboratory providers who have the capability (CLIA certified to perform high complexity testing) to pursue testing.

Please refer to the following link for guidance related to implementation:

<https://www.fda.gov/media/135659/download>

Further, should you have any questions, please contact the Healthcare Quality and Safety Branch at COVID19.DPH@ct.gov or the State Public Health Laboratory at 860-920-6500.

Thank you for any consideration that you give to this opportunity.



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