Date: March 27, 2020

To whom it may concern:

Several laboratories in Iowa are considering bringing testing for COVID-19 in house. Laboratories are required to meet all CLIA and/or their accrediting agency's requirements for performing non-waived EUA COVID-19 testing.

To meet the verification requirements, laboratories can run external quality controls for their verification plan and send the first 5 positive and 5 negatives for confirmation to the State Hygienic Laboratory.

On those first 10 samples, laboratories will need to report "Presumptive" results until those 10 results are confirmed.

The State Hygienic Laboratory at the University of Iowa has confirmed this will meet CLIA validation requirements for laboratories in Iowa that hold a Certificate of Compliance.

If a laboratory holds a Certificate of Accreditation, they will need to follow their accrediting organization requirements.

For further CLIA questions please contact Kristine Rotzoll at kristine-rotzoll@uiowa.edu.

Sincerely,

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