



February 5, 2020

Dear Colleagues,

FDA has announced that the Emergency Use Authorization ([EUA](#)) of CDC's 2019-Novel Coronavirus (2019-nCoV) Real-time RT-PCR Diagnostic Panel is now in place. Kits are available for ordering immediately through the International Reagent Resource (IRR). CDC has projected that public health laboratories will have kits in their hands this week.

Just like any other test, the Centers for Medicare & Medicaid Services requires that the performance of a test made available under an EUA is verified in every individual laboratory that will use that test. This means that upon receiving the 2019-nCoV kits from CDC public health laboratories will need to complete a limited verification process to ensure that the assay produces accurate results in their laboratory to meet their regulatory obligations. The amount of time required for this process varies by laboratory based on their verification policies and procedures. We estimate that verification may take up to one to two weeks.

Public health laboratories and epidemiologists should coordinate with each other to ensure rapid reporting of positive and negative results from public health laboratories to epidemiologists through existing mechanisms in your jurisdiction.

Public health laboratories are committed to ensuring that quality testing is available as soon as possible. Please be patient as they complete this important quality assurance step.

Best regards,

A handwritten signature in black ink that reads 'Jeffery Engel'.

Jeffery Engel, MD
Executive Director
CSTE

A handwritten signature in black ink that reads 'Scott J. Becker'.

Scott J. Becker, MS
Executive Director
APHL