Development of Molecular Testing for SARS-CoV-2: Challenges with Implementation during a Pandemic

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LEARNING OBJECTIVES

1. Discuss the diagnostic challenges and opportunities with SARS-CoV-2.
2. Explain the types of molecular platforms available and strategies for timely detection of SARS-CoV-2.
3. Describe the current and future state of molecular diagnostics for SARS-CoV-2 detection.

ABSTRACT

The coronavirus disease-19 (COVID-19) pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has necessitated the rapid deployment of molecular diagnostic assays to identify infected individuals. The recommended test for diagnosis of SARS-CoV-2 infection is one that detects one or more specific viral RNA gene sequences in a respiratory tract specimen. However, lack of sustained adequate amounts of supplies of SARS-CoV-2 RNA detection tests, test components and collection materials from commercial manufacturers has necessitated that laboratories undertake verification and implementation of multiple types of analytic test systems as well as reagents and materials used in the pre-analytic process in order to meet the demand for testing capacity. The U.S. Food and Drug Administration (FDA) has provided Emergency Use Authorization (EUA) status to over 200 different RNA detection test systems, most of which are designed to detect only SARS-CoV-2 and some that include detection of other respiratory pathogens that may manifest with symptoms similar to COVID-19. Laboratories unable to perform high complexity molecular testing are limited in the number of EUA assay options available and a number of EUA test systems require acquisition of manufacturer-specific instrumentation; a purchasing process which can delay platform placement for scaling up testing capacity. Lack of coordinated efforts for SARS-CoV-2 testing at the national level has left most labs to fend for themselves and many continue to struggle with meeting testing demands and timely reporting in their communities.