Summary and Recommendation for Performing Rapid Antigen Tests for Detection of SARS-CoV-2

Executive Summary
Over the past several months new test methods for detection of SARS-CoV-2 have emerged including rapid antigen testing. This document provides a summary and recommendation for performing rapid antigen tests.

Rapid Antigen Tests
Rapid antigen tests have recently emerged and offer significant improvement for near patient turn-around-time. Rapid antigen testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) that meet the requirements to perform moderate, high or waived complexity tests. Testing is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. Providers and health systems performing antigen tests must coordinate with the NM Department of Health (NMDOH) to report ALL test results performed utilizing rapid antigen test platforms to the NMDOH.

Although there is limited data on the various platforms, rapid antigen tests have acceptable performance when used under the following conditions:

- Analysis is performed in a CLIA certified laboratory
- Testing is performed on symptomatic patients ONLY
- Test is performed within 7 days after symptom onset
- Direct/dry nasal or nasopharyngeal swab is placed into test provided vial containing extraction buffer and/or tested directly
  - Specimen is NOT placed in transport media

At this time, there is no evidence to support the use of rapid antigen tests in the following populations:

- Asymptomatic individuals
- Asymptomatic contacts of symptomatic patients
- surveillance testing

The performance of rapid antigen tests in an individual patient is highly dependent on the pretest probability or the clinical likelihood that the patient has infection AND that the test was performed in the appropriate testing window (early symptomatic phase). A summary of the five major symptoms associated with COVID-19 can be found at the end of this document.

If the appropriate patient is tested for SARS-CoV-2 by a rapid antigen test and the rapid antigen test is positive, the patient should be considered SARS-CoV-2 positive. The result should be reported to the New Mexico Department of Health, and the patient should begin quarantine if hospital admission is not necessary. For patients with an indeterminate rapid antigen test result, providers should consider retesting for SARS-CoV-2 by PCR and/or test for influenza A, influenza B, or other respiratory illness. The flowchart below can be used to determine when a rapid antigen test should be used and how to interpret the result.
Summary of symptoms associated with SARS-CoV-2 infection

- Cough, shortness of breath or difficulty breathing
- Fever or chills
- Muscle or body aches
- Vomiting or diarrhea
- New loss of taste or smell