MAKO 2019 Novel Coronavirus, TaqPath COVID-19 Assay (720100)

FAQ

COVID-19 is a respiratory disease caused by infection with a new form of coronavirus (SARS-CoV-2) that has now been detected in multiple locations around the world, including the United States.

Below are answers to questions about MAKO's test for COVID-19, including test methodology, appropriate specimen types, specimen packaging and shipping, and test result reporting.

1) Does MAKO offer a test to detect the presence of the 2019 novel coronavirus?

Answer: Yes. The MAKO COVID-19 {TaqPath RT-PCR} {720100} is available for ordering by physicians and other authorized medical providers. The test detects the presence of the underlying virus (SARS-CoV-2) that causes COVID-19 and is for use with patients who meet current guidance for evaluation of infection with COVID-19.

2) What instrumentation does MAKO utilize for COVID-19 testing?

Answer: MAKO utilizes Life Technologies QuantStudio 12K Flex Systems to perform TaqPath COVID-19 assays. This instrumentation is Real Time – Polymerase Chain Reaction.

3) What assay does MAKO utilize for COVID-19 testing?

Answer: MAKO utilizes the ThermoFisher TaqPath assay for COVID-19. The TaqPath assay has a targeted specificity is 100% of currently available complete genomes for SARS-CoV-2.

4) What types of specimens are required for testing?

Answer: COVID-19 testing requires specimens collected from the nose or throat. The preferred sample types are nasopharyngeal (NP) or oropharyngeal (OP) swabs.

5) What types of collection kits does MAKO accept?

Answer: MAKO validated multiple collection media, including universal transport media, saline, and liquid amies. MAKO utilizes collection kits from Hardy Diagnostics, Puritan, Copan, Purflock, BD Viral Transport, and Starplex.

(FAQ's Continued »)

6) How should samples be shipped?

Answer: Samples/specimens should be shipped refrigerated if received for testing within 72 hours of collection, room temperature if received within 24 hours of collection, or frozen if samples are older than 72 hours and have been frozen prior.

7) How should specimens be collected?

Answer: Detailed illustrations and instructions for NP and OP specimen collection can be found on page four and five of this document.

8) What are criteria for sample rejection?

Answer: Unacceptable specimens include those that are:

- Room temperature swabs greater than 24 hours old;
- Refrigerated swabs greater than 72 hours old;
- Calcium alginate tip swabs or swabs with wooden shafts
- Glass tubes
- Improperly labeled, contaminated, broken, or leaking transport device

9) How long will it take MAKO to report results back?

Answer: MAKO will report results within 48 hours of receipt within the laboratory.

10) How will test results be reported?

Answer: Test results will be reported as “positive” or “not detected.”

11) How will ordering physicians be notified of positive results?

Answer: Positive results are treated as a critical result and called to the ordering physician or health care provider. Negative results will not be called into the order provider.

12) What are the clinical features of COVID-19?

Answer: The clinical spectrum of COVID-19 ranges from mild disease with non-specific signs and symptoms of acute respiratory illness, to severe pneumonia with respiratory failure and septic shock. There have also been reports of asymptomatic infection with COVID-19.

(FAQ’s Continued »)

13) Will MAKO send detected results for confirmation, and if so, where will results be sent?

Answer: Mako does not plan to perform additional onsite confirmatory testing on positive or negative results unless the FDA or the CDC changes current recommendations. Mako will comply with applicable public health requirements or requests for specimens from state public health departments (see below).

14) Is this test approved by the FDA?

Answer: The test has been validated by FDA's independent review through the Emergency Use Authorization (EUA) process