Medical Diagnostic Laboratories

SARS-CoV-2 Test Results Summary: Inconclusive and Invalid Results

The MDL SARS-CoV-2 test uses polymerase chain reaction (PCR) to detect nucleic acids, or genetic material, from the virus. Nucleic acids from an appropriate specimen are extracted and specific regions of the viral genome are amplified and detected. Two regions of the viral genome are amplified by the SARS-CoV-2 test and, as such, the test results are:

- Positive, if both regions are detected
- Inconclusive, if only one region is found, or both regions are detected below the measured limits of the test
- Not Detected, if neither region is detected

The SARS-CoV-2 test also amplifies and detects a human gene. This helps determine if an adequate specimen was taken and processed correctly. The inclusion of the human gene helps determine the following result:

- Invalid, if both viral regions AND the human gene are not detected

If the initial testing yields an Inconclusive or Invalid result, the test is repeated. If the second test yields the same result, the test result is Inconclusive or Invalid, respectively.
As of April 28, 2020, the rate of Inconclusive and Invalid results from the MDL SARS-CoV-2 test are:

- Inconclusive, 1.10%
- Invalid, 0.06%

If you receive an Inconclusive or Invalid result, it is suggested to obtain a new specimen from the patient and have it tested. Optimum timing for peak viral levels during infections caused by SARS-CoV-2 have not been determined. As of April 16, 2020, the CDC states that the optimal specimen type is nasopharyngeal, collected with a synthetic, flocked swab and placed in Viral Transport Media (VTM). When not available, collection of oropharyngeal, nasal mid-turbinate, or nares specimens are acceptable alternatives. Therefore, collection of multiple specimens (types and time points) from the same patient may increase the probability of detecting the virus during active infection.

SARS-CoV-2 testing should not be used as the sole basis for treatment or other patient management decisions.