



1340 Hal Greer Blvd. Huntington, WV 25701

Date: 04/21/2020

Purpose: Addition of Ustar Biotechnologies' 2019-nCoV RNA Assay.

Testing: Multiple technologists ran our validation during the day. The same COVID order will be used in the LIS as is currently being used for other covid testing.

Technologists ran 20 positive and 20 negative controls for the 2019-nCoV assay for nine consecutive days. The technologists also repeated 10 previous positive specimens that were provided by WV State Laboratory and 10 previous negative patients that were tested on the other in-house test or by one of the reference laboratory test sites. These results were compared to results on the Ustar instrument and all results proved accurate to the originals. This was repeated for nine days.

A second Ustar instrument was validated as well. The same technologists ran validations for this instrument. A total of 10 positive and 10 negative controls were run on this analyzer as well as 5 previous positive specimens that were provided by WV State Laboratory and 5 previous negative patients that were tested on the other in-house test or by one of the reference laboratory test sites.

Results: All testing went as expected. The Ustar instruments accurately detected all 2019-nCoV RNA in QC samples as well as expected results from patient samples. There are no expected issues in going live with this new test and instrument.

Conclusion: The Ustar Biotechnologies' instrument has been fully validated for RUO purposes with plans to immediately submit for EUA approval by the FDA. We feel confident that this system is working correctly and are ready to go live with this instrument 4/21/2020.

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04/21/2020

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Reviewed by: \_\_\_\_\_ Date: 4/21/2020  
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