Explanation of GENETWORx COVID-19 Test

Since 2013, GENTEWORx has been performing clinical testing to assist physicians by providing molecular diagnostic testing as a high-complexity laboratory certified by the College of American Pathologist (CAP).

We are performing COVID-19 testing using the same primer and probe sequences developed by the Centers for Disease Control (CDC) in their Emergency Use Authorization (EUA) to perform nucleic acid amplification (NAA) and detection of COVID-19.

The GENETWORx COVID-19 assay demonstrates 99% specificity and sensitivity to the CDC EUA version of the test and a limit of detection at 10 copies of viral RNA per microliter while providing faster analysis and reduced turnaround time.

We have accomplished this by adapting the test to a fast, reliable high throughput format which provides results for thousands of samples and increasing capacity on a daily basis and within 1 business day of receipt. We have received approval to perform COVID-19 testing for all 50 states including New York.

On March 26, 2020 the FDA acknowledged that GENETWORx meets the conditions outline in the FDA Guidelines for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency for the allowable modifications to the CDC EUA.

Thank you,

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