PATHNOSTICS®

MOVING CARE FORWARD

Introducing

PATHNOSTICS COVID-19 RT-PCR TEST

SIMPLE COLLECTION

WORLD-CLASS ACCURACY

QUICK RESULTS

TEST PERFORMANCE CHARACTERISTIC

The analytic sensitivity of the Pathnostics RT-PCR COVID-19 test was determined to be 100%* in detecting known amounts of SARS-Cov-2 RNA with no cross reactivity to other known respiratory pathogens.

A Not Detected (negative) test result for this test means that SARS- CoV-2 RNA was not present in the specimen above the manufacturer recommended cutoff value. An interpretation indicating “Not Detected” does not rule out the possibility of COVID-19 and should not be used as the sole basis for treatment or patient management decisions.

If COVID-19 is still suspected, based on exposure history together with other clinical findings, re-testing should be considered in consultation with public health authorities. Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions.

In general, it is believed that nasal swabs (nasopharyngeal, mid-turbinate, anterior nares) method of collection in conjunction with PCR testing reliably detects 70-80% of true COVID-19 positive cases.

*Published studies involving ThermoFisher TaqPath showed an average of 94.6% sensitive and 100% specific (5 studies) Studies performed on symptomatic patients in the hospital. Data unknown on asymptomatic screening

ABOUT THE TEST

Intended Use	• Qualitative detection of 3 genes of the SARS-CoV-2 taken from nasal swabs of individuals suspected of COVID-19 by their healthcare provider
Method	• Molecular test (RT-PCR) that detects 3 genes from SARS-CoV-2
Technology	• LDT based on Thermo Fisher TaqPathTM RT-PCR COVID-19 test, which received FDA EUA
Reliability	• Clinical studies show an average of 94.6% sensitive and 100% specific (5 studies)*
Limit of Detection	• 125 copies/ml of SARS-CoV-2
Time to result	• 48 hrs from Specimen receipt
Sampling	• Non-invasive nasal/nostril swab • Fast and painless • Authorized provider ordered • Trained individual on site to oversee testing

*https://finddx.shinyapps.io/COVID19DxData/

HAS THE PATHNOSTICS TEST BEEN FDA APPROVED?

The Pathnostics COVID-19 PCR test is a Laboratory Developed Test (LDT) employing real-time PCR (RT-PCR) for the molecular detection of SARS-CoV-2 RNA and has been modified from the Thermo Fisher Scientific, Inc. Taqpath COVID-19 Combo Kit that was authorized for Emergency Use on 3/13/2020. As referenced in the FDA “Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency”, a laboratory certified under Clinical Laboratory Improvement Amendments (CLIA) that meets the CLIA regulatory requirements to perform high complexity testing may use their LDT test without a new or amended EUA where the test is validated using a bridging study to a EUA-authorized test. Pathnostics is a CLIA laboratory authorized to perform high complexity testing and the Pathnostics COVID-19 PCR test has been validated with a bridging study to the EUA TaqPath COVID-19 Combo Kit.

To order the test or receive more information, call Customer Care at (800) 493 4490.

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