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Overview

Corona Virus Disease-2019 (COVID-19), caused by the severe acute respiratory syndrome corona virus-2 (SARS-CoV-2), has now been with us in the United States for over two years, and has caused about 80 million cases and almost 1 million deaths (due primarily to respiratory failure, overwhelming inflammation, and multi-organ failure). Our laboratories offer excellent nasal swab testing and antibody testing. New SARS-CoV-2 variants and questions on the duration of vaccine immunity are important issues for the next phase of the pandemic. Widescale testing continues to be critical for diagnosis and documentation of potential immunity, public health measures (e.g. face masks, shields, social distancing, and hand washing), and surveillance of the virus.

COVID-19 disease symptoms include fever, fatigue, cough, loss of smell and taste, GI symptoms, and shortness of breath. The virus spreads between people mainly via respiratory droplets, talking, singing, coughing, sneezing). The time between exposure and symptom onset is about five days (range 2-14 days). Severe complications include severe acute respiratory distress due to pneumonia (which may require a ventilator), and potentially death from overwhelming infection and inflammation.[1,2] The virus is highly contagious, with about 50% of infected people being asymptomatic.[3]

Clinical Enterprise (CE) SARS-CoV-2 RT-PCR test

The diagnosis of SARS-CoV-2 infection is made by the finding of SARS-CoV-2 RNA in upper respiratory samples.[4] This testing is available from our laboratory. To date, Eurofins laboratories have performed over 1 million SARS-CoV-2 RT-PCR tests. The CE SARS-CoV-2 RT-PCR test is a fully validated, EUA authorized test under EUA210023 (DTC) and EUA210239 (Rx). The CE SARS-CoV-2 RT-PCR Assay is intended for use with the direct-to-consumer EmpowerDX COVID-19 Home Collection Kit DTC by any individuals, including those without symptoms or other reasons to suspect COVID-19. The CE Assay is also authorized for use on healthcare provider collected or observed nasal, NP, and OP swabs.

During validation, the CE Assay was evaluated against three different EUA authorized SARS-CoV-2 tests and overall showed 100% (107/107) Positive agreement and 98.8% Negative agreement (173/175) from both symptomatic and asymptomatic individuals. The limit of detection (LOD) was demonstrated to be 250 viral copies/mL, which is considered equivalent in performance to the Viracor SARS-CoV-2 Assay. Notably, the Viracor SARS-CoV-2 Assay was the best performing test of those who participated in the FDA's SARS-CoV-2 Analytical Sensitivity Reference Panel Study.[5] The CE SARS-CoV-2 RT-PCR Assay was also validated and authorized for testing of asymptomatic individuals, and for use with the EmpowerDx COVID-19 Home Collection Kit DTC.

On June 24, 2021, the CE SARS-CoV-2 RT-PCR Assay Rx was authorized under the FDA Pooling and Serial Testing Amendment for pooling of up to 10 individual human anterior nasal swabs placed in a single vial.

Laboratory Contact and Test Information

We recommend shipping all samples FedEx overnight to Clinical Enterprise, 175 Crossing Boulevard, Framingham, MA 01702. We are a CLIA and CAP certified high complexity laboratory, and we follow all FDA guidelines for our RNA testing. To order these tests, please contact Customer Care at 833-644-0860 or customercare@clinicalenterprise.com. For questions, please contact EJ Schaefer, MD at eschaefer@bostonheartdx.com or 781 258-1454.

CE SARS-CoV-2 RT-PCR Assay Rx

RNA testing requires a nasopharyngeal (NP) swab, a nasal swab, or an oropharyngeal (OP) swab in a sterile screw top tube using appropriate transport media (0.9% sterile saline, Viral Transport Medium (VTM), Universal Transport Medium (UTM), or liquid amies). NP and OP Swabs must be collected by a healthcare provider. Nasal swabs can be self-collected under medical observation.

CE SARS-CoV-2 RT-PCR Assay DTC

The CE SARS-CoV-2 RT-PCR Assay DTC can be ordered through the EmpowerDx website (https://empowerdxlab.com). Collection and shipping instructions are included with the kit.

More Information

CDC webpages:

General: https://www.cdc.gov/coronavirus/2019-ncov/index.html
Healthcare Professionals: https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-hcf.html
Information for Laboratories: https://www.cdc.gov/coronavirus/2019-nCoV/lab/index.html
Laboratory Biosafety: https://www.cdc.gov/coronavirus/2019-ncov/lab/biosafety.html
Infection Control: https://www.cdc.gov/coronavirus/2019-ncov/php/infection-control.html

FDA webpages:

General: www.fda.gov/novelcoronavirus
EUAs:(includes links to patient fact sheet and manufacturer's instructions) https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

References

1. Zhu N et al. A novel coronavirus from patients with pneumonia in China. *New Engl J. Med* 2020; 382:727-33.
2. Zhou P et al. A pneumonia outbreak associated with a new coronavirus of probable bat origin. *Nature* 2020; 579:270-73.
3. Mizumoto K et al. Estimating the asymptomatic proportion of coronavirus disease 2019 (COVID-19) cases on board the Diamond Princess cruise ship, Yokohama, Japan, 2020. *Euro Surveill.* 2020;25(10).
4. Kleiboeker S et al. SARS-CoV-2 viral load assessment in respiratory samples. Journal of Clinical Virology 2020;129 (epub)
5. https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-reference-panel-comparative-data