QIAstat-Dx Respiratory SARS-CoV-2 Panel

IVD RX ONLY

Emergency Use Authorization (EUA) only

Please be advised:

- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories;
- This product has been authorized only for the detection and differentiation of nucleic acid of SARS-CoV-2 from multiple respiratory viral and bacterial organisms; and;
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1)of the Act, 21 U.S.C. § 360bbb-3 (b)(1), unless the declaration is terminated or authorization is revoked sooner.

This is not the complete instructions for use. Please find the instructions for use at the following web address:

https://www.qiagen.com/us/products/diagnostics-and-clinical-research/infectious-disease/qiastat-dx-syndromic-testing/qiastat-dx-eua-us/

Please contact QIAGEN Technical Services (1-800-426-8157) if you require a printed copy free of charge.

Ordering www.qiagen.com/contact | Technical Support support.qiagen.com | Website www.qiagen.com