LumiraDx SARS-CoV-2 Antigen Test

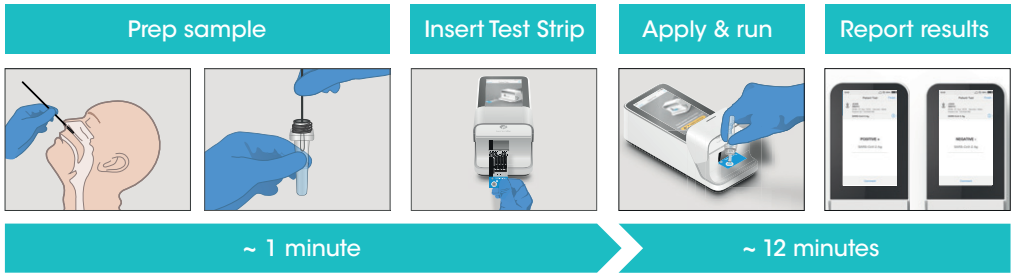
The LumiraDx SARS-CoV-2 Antigen Test delivers rapid results in 12 minutes. The Test uses nasal samples to detect nucleocapsid protein antigen with 97.6 % positive agreement to an EUA approved RT-PCR method within the first 12 days of symptom onset.

lumiraDx™

Fast. Accurate. Connected.

SARS-CoV-2 Antigen (Ag) Test

- Nasal swab
- Immunofluorescence assay
- Time to result: 12 minutes
- Storage at room temperature
- Performance – Referenced to RT-PCR
  - Positive percent agreement: 97.6 % (CI* 91.6 % - 99.3 %)
  - Negative percent agreement: 96.6 % (CI 92.7 % - 98.4 %)
  - Overall percent agreement: 96.9 % (CI 94.0 % - 98.4 %)
- Limit of detection - 32 $TCID_{50}$/mL
- Catalogue Number:
  12 tests L016000109012, 24 tests L016000109024, 48 tests L016000109048



*CI: Confidence Interval

LumiraDx Platform

A next generation point of care diagnostic system, that combines a small, portable Instrument; microfluidic Test Strip; simple, standardized workflow; and seamless, secure digital connectivity to the cloud and hospital IT systems.

For use by healthcare professionals only. Products not available in all countries or regions. Available in the USA under FDA Emergency Use Authorization.

In the USA, this test has not been FDA cleared or approved; this test has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. In the USA, this test 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 the virus that causes COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Contact Us. We are looking forward to your call!

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