LumiraDx™ SARS-CoV-2 Ag Technical Bulletin – Swabs

The LumiraDx SARS-CoV-2 Ag Test is a rapid microfluidic immunofluorescence assay for use with the LumiraDx Platform intended for the qualitative detection of the nucleocapsid protein antigen to SARS-CoV-2 directly from nasal swab specimens collected from individuals suspected of COVID-19 by their healthcare provider within the first twelve days of symptom onset.

When collecting nasal swab samples, the following swabs have been validated for use with the LumiraDx SARS-CoV-2 Ag Test:

- Copan Nasal FLOQswab™ Regular
- Puritan HydraFlock™ Sterile Standard Flock Swab
- Aspen Surgical™ Polyester Swab
- SteriPack™ Sterile Polyester Spun Swab
- mwe medical wire Dryswab™ Rayon Swab
- Kang Jian™ Virus Collection Swab

Swabs from other suppliers have not been validated and the performance with other swabs may not perform as expected. This bulletin includes a complete list of swabs currently validated for use with the LumiraDx SARS-CoV-2 Ag Test. Commercial availability of swabs may vary by country. Please be aware that the CDC does not recommend use of calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and inhibit PCR testing.[1]

For product inquires and technical support please contact LumiraDx Technical Support.

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Product is not available in all countries and regions. Please check with your local LumiraDx sales representative or distributor for availability in specific markets. 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.

[1]see https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html

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