



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 antigens from SARS-CoV-2 in direct anterior nasal swab and nasopharyngeal swab specimens collected by a healthcare provider from individuals who are suspected of COVID-19 within the first twelve (12) days of symptom onset when tested at least twice over three days with at least 48 hours between tests and from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested at least three times over five days with at least 48 hours between tests.

This Technical Bulletin will aim to provide a comprehensive list of LumiraDx validated swabs for use with the SARS-CoV-2 Ag test.

SARS-CoV-2 Ag Test

Nasal:

- Copan FLOQSwabs® 502CS01 Regular Flocked Swab with 80mm Breakpoint
- Copan eSwab (Supplier Product Code: 490CE.A)
- Copan FLOQSwabs® 552C Regular Flocked Swab with 80mm Breakpoint
- Copan FLOQSwabs® 519CS01 Regular Flocked Swab with 100mm Breakpoint
- Puritan HydraFlock™ Sterile Standard Flock Swab (Supplier Product Code: 25-3306-H)
- Puritan HydraFlock™ Sterile Standard Flock Swab (Supplier Product Code: 25-3506-H)
- Aspen Surgical™ Polyester Swab (Supplier Product Code: 20200062)
- SteriPack™ Sterile Polyester Spun Swab (Supplier Product Code: 60564)
- mwe medical wire DrySwab™ Rayon Swab (Supplier Product Code: MW112)

Nasopharyngeal:

- Copan FLOQSwabs® 501CS01 Minitip Flocked Swab with 80mm Breakpoint
- Copan FLOQSwabs® 516CS01 Ultra Minitip Flocked Swab with 100mm Breakpoint
- Copan FLOQSwabs® 518CS01 Minitip Flocked Swab with 100mm Breakpoint
- Copan FLOQSwabs® 503CS01 Flexible Minitip Flocked Swab with 100mm Breakpoint
- Copan FLOQSwabs® 534CS01 Flexible Minitip Flocked Swab with No Breakpoint
- Copan FLOQSwabs® 551C Minitip Flocked Swab with 80mm Breakpoint
- Copan FLOQSwabs® 553C Flexible Minitip Flocked Swab with 100mm Breakpoint
- Copan FLOQSwabs® 518C Minitip Flocked Swab with 100mm Breakpoint

This Technical Bulletin includes a complete list of swabs specific to a supplier and a product code whose performance have been confirmed acceptable for use with the LumiraDx SARS-CoV-2 Ag Test at the time of validation testing.

Only use the list of validated swabs with the LumiraDx SARS-CoV-2 Ag Test. Swabs from alternative suppliers are not validated for use with the LumiraDx SARS-CoV-2 Ag Test and must not be used.

Furthermore, the above suppliers may offer similar swabs under a different product code. These swabs have not been validated for use with the LumiraDx SARS-CoV-2 Ag Test and must not be used.

For product enquiries and technical support please contact LumiraDx Customer Services.

E-mail: customerservices.US@lumiradx.com Telephone: 1-888-586-4721 www.lumiradx.com

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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.

In the USA, this product has not been FDA cleared or approved; this product 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 product 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 product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. In the USA, - 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 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.

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