SARS-CoV-2 Ag

LumiraDx™ SARS-CoV-2 Ag Test 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 in nasal swab and nasopharyngeal swab samples. Samples are collected from individuals suspected of COVID-19 infection within the first twelve days of symptom onset or from individuals without symptoms or other epidemiological reasons to suspect COVID-19. The Test is an aid in the diagnosis of current SARS-CoV-2 infection by detection of SARS-CoV-2 antigen.

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 – Approved Swabs

Nasal:

- **Copan Nasal FLOQSwab™ Regular** (Supplier Product Code: 502CS01)
- **Copan eSwab** (Supplier Product Code: 490CE.A)
- **Copan Regular PL/Swab NY/VEL Drytube** (Supplier Product Code: 552C)
- **Copan REGULAR APPL.NYLON PF100** (Supplier Product Code: 519CS01)
- **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: 60564REVA)
- **mwe medical wire DrySwab™ Rayon Swab** (Supplier Product Code: MW112)
- **Kang Jian™ Virus Collection Swab** (Supplier Product Code: KJ502-19)
- **Gongdong Disposable Sterile Swab** (Supplier Product Code: G1029FT77)
- **OPT Industries InstaSwab™** Nasal (Anterior) (Supplier Product Code: INS-T4BAA)

Nasopharyngeal:

- **Copan FLOQSwab mini-tip** (Supplier Product Code: 501CS01)
- **Copan FLOQSwab Ultra mini-tip** (Supplier Product Code: 516CS01)
- **Copan FLOQSwab mini-tip with 100mm Breakpoint** (Supplier Product Code: 518CS01)
- **Copan FLOQSwab - Flexible Minitip with 100mm Breakpoint** (Supplier Product Code: 503CS01)
- **Copan FLOQSwab – Flexible Minitip** (Supplier Product Code: 534CS01)
- **Copan FLOQswab Minitip (Drytube)**(Supplier Product Code: 551C)
- **Copan FLOQswab Minitip (Drytube)**(Supplier Product Code: 553C)
- **Copan FLOQswab Minitip (Drytube)**(Supplier Product Code: 518C)

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

This Technical Bulletin includes a complete list of swabs specific to a supplier and a product code whose performance was confirmed acceptable for use with the LumiraDx SARS-CoV-2 Ag Test at the time of validation testing. LumiraDx cannot guarantee that swab suppliers will not change raw materials or other swab specifications, which could affect performance.

Swabs from alternative suppliers have not been validated for use with the LumiraDx SARS-CoV-2 Ag Test and should not be used. The Test may not perform as expected if using swabs from alternative suppliers.

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 should not be used. The Test may not perform as expected if using swabs other than the exact product codes listed above.

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

US
Email: **customerservices.US@lumiradx.com**
Telephone: **1-888-586-4721**
www.lumiradx.com

International
Email: **customerservices@lumiradx.com**
Telephone: **+44 (0)1172841222**
www.lumiradx.com

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 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.

Manufactured by:
LumiraDx UK Ltd
Dumyat Business Park
Alloa
FK10 2PB, UK

Registration Number:
09206123

US Office:
LumiraDx
221 Crescent Street
Suite 502
Waltham
Massachusetts 02453
USA

S-COM-ART-00673 R6 Date of Rev 2022/03