



LumiraDx™ SARS-CoV-2 Ag Test & SARS-CoV-2 Ag Pool 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 SARSCoV-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 asymptomatic individuals. The Test aids in the diagnosis of current SARS-CoV-2 infection by detection of SARSCoV-2 antigen.

The LumiraDx SARS-CoV-2 Ag Pool 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 1 to 5 individual samples from professionally supervised & self-collected nasal swab samples or professionally collected nasal or nasopharyngeal swab samples which are then pooled for testing. Samples should be collected from 1 to 5 individuals suspected of COVID-19 infection within the first twelve days of symptom onset or from asymptomatic individuals. The Test aids 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 Pool Test, split into both nasal and nasopharyngeal swab configurations.

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)
- SterilPack™ 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)
- Nerbe Plus dry swab (Supplier Product Code: 09-511-5017)
- Nerbe Plus PS Stick (Supplier Product Code: 09-812-8053)
- Plast Labor 06913 Swab Haste Plastica Ponta Rayon Estéril Embalagem Indv (Supplier Product Code: 50X100)
- Citotest Citoswab (Supplier Product Code: 2122-0008)
- Gongdong Disposable Sterile Swab (Supplier Product Code: G1029FT77)

Nasopharyngeal:

- Copan FLOQSwab mini-tip (NP Adult) (Supplier Product Code: 501CS01)
- Copan FLOQSwab Ultra mini-tip (NP Pediatric) (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)
- Cral. Swab em tubo sem meio de culture estéril haste de plastico PT/100 – Absorve (Supplier Product Code: 23125)
- Kolplast Swab para Nasofaringe (Supplier Product Code: 10237610223)
- NerbePlus PS Stick (Supplier Product Code:: 09-812-8052)



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

SARS-CoV-2 Ag Pool Test – Approved Swabs

Nasal:

- Copan Nasal FLOQSwab™ Regular (Supplier Product Code: 502CS01)
- Gongdong Disposable Sterile Swab (Supplier Product Code: G1029FT77)

Nasopharyngeal:

- Copan FLOQSwab mini-tip (NP Adult) (Supplier Product Code: 501CS01)

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 & SARS-CoV-2 Ag Pool 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 or the SARS-CoV-2 Ag Pool Test. 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 or the SARS-CoV-2 Ag Pool Test. 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.

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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.

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