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

The LumiraDx SARS-CoV-2 Ag Surveillance Test is a rapid microfluidic immunofluorescence assay for the direct and qualitative detection of nucleocapsid protein antigen in nasal and nasopharyngeal specimens allowing a pooled testing approach of up to 5 specimens.

This Technical Bulletin provides a comprehensive list of LumiraDx validated swabs for use with the SARS-CoV-2 Ag Surveillance Test.

SARS-CoV-2 Ag Surveillance 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 have been confirmed acceptable for use with the LumiraDx SARS-CoV-2 Ag Surveillance 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 Surveillance 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 also not been validated for use with the LumiraDx SARS-CoV-2 Ag Surveillance 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.

The LumiraDx SARS-CoV-2 Ag Surveillance Test has not been cleared, approved, or authorized by FDA. This test should be used for surveillance purposes (i.e., to inform population or community-level decision-making on de-identified specimens) only. FDA does not regulate surveillance tests.

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