

SARS-CoV-2 Ag Ultra and SARS-CoV-2 Ag Ultra Pool

Technical Bulletin - Swabs

The LumiraDx SARS-CoV-2 Ag Ultra test is an automated rapid microfluidic immunofluorescence assay for use with the LumiraDx Platform, for near-patient testing, intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 directly from anterior nasal swab samples collected from individuals suspected of COVID-19 by their healthcare provider within the first twelve days of symptom onset or from individuals without symptoms or other epidemiological reasons to suspect COVID-19.

The LumiraDx SARS-CoV-2 Ag Ultra Pool test is an automated 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 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.

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

Approved swabs for nasal swab sample collection

Swab name	Supplier Product Code	Approved for SARS-CoV-2 Ag Ultra test	Approved for SARS-CoV-2 Ag Ultra Pool test
Copan Nasal FLOQSwab® Regular with 30mm breakpoint	520CS01	✓	✓
Copan Nasal FLOQSwab® Regular with 80mm breakpoint	502CS01	✓	✓
Copan Nasal FLOQSwab® Regular with 100mm breakpoint	519CS01	✓	✓
Copan Nasal FLOQSwab® Regular with no breakpoint	5U060S01	✓	✓
Copan FLOQSwab® Regular Tip with 30mm breakpoint (in dry tube)	520C	✓	✓
Copan FLOQSwab® Regular Tip with 80mm breakpoint (in dry tube)	552C	✓	✓
Copan FLOQSwab® Regular Tip with 100mm breakpoint (in dry tube)	519C	✓	✓
Copan FLOQSwab® Minitip with 80mm breakpoint	501CS01	✓	
Copan FLOQSwab® Minitip with 100mm breakpoint	518CS01	✓	
Copan FLOQSwab® Minitip with 80mm breakpoint (in dry tube)	551C	✓	
Copan FLOQSwab® Minitip with 100mm breakpoint (in dry tube)	518C	✓	
Copan FLOQSwab® Mini-Flexible with 100mm breakpoint	516CS01	✓	

SARS-CoV-2 Ag Ultra and SARS-CoV-2 Ag Ultra Pool

Technical Bulletin - Swabs

Approved swabs for nasal swab sample collection

Swab name	Supplier Product Code	Approved for SARS-CoV-2 Ag Ultra test	Approved for SARS-CoV-2 Ag Ultra Pool test
Copan FLOQSwab® Mini-Flexible with no breakpoint	535CS01	✓	
Copan FLOQSwab® Mini-Flexible with 100mm breakpoint (in dry tube)	516C	✓	
Copan FLOQSwab® Mini-Flexible with no breakpoint (in dry tube)	535C	✓	
Puritan® HydraFlock Sterile Standard Flock Swab	25-3506-H	✓	
mwe medical wire DRYSWAB™ Rayon Swab	MW112	✓	
Medico Technology Co., Ltd Specimen Collection Swab	MFS-94000KQ	✓	
Gongdong Disposable Sterile Swab with 77mm breakpoint	G1029FT77	✓	✓

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 Ultra or SARS-CoV-2 Ag Ultra 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. Please review the swab supplier's limitations and intended use before sample collection. LumiraDx cannot guarantee the availability of the swabs listed.

Swabs from alternative suppliers have not been validated for use with the LumiraDx SARS-CoV-2 Ag Ultra and SARS-CoV-2 Ag Ultra 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 Ultra and SARS-CoV-2 Ag Ultra 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.

Email: customerservices@lumiradx.com

Phone: +44 (0)1172841222

www.lumiradx.com

Copyright © 2024 LumiraDx UK LTD. All rights reserved worldwide. LumiraDx and Flame logo are trademarks of LumiraDx International LTD. Full details of these and other registrations of LumiraDx can be found at lumiradx.com/IP. All other trademarks are the property of their respective owners. Content should be used for the use of the LumiraDx products only and in line with instructions provided. You may not, except with our express written permission, distribute or commercially exploit the content. Nor may you transmit it or store it in any other form of electronic retrieval system other than for the purpose of use of the LumiraDx Instrument or LumiraDx Test Strips. Information provided is subject to change without notice.

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

Manufactured by:

LumiraDx UK Ltd
 Dumyat Business Park
 Alloa
 FK10 2PB
 UK
 Registration Number: 09206123

Authorized representative

in the European Union:
 LumiraDx AB,
 Västra Vägen 5A,
 16961 Solna, Sweden