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Fast Lab Solutions

IVD

FOR EXPORT ONLY

SARS-CoV-2 & Flu A/B RNA STAR Complete

ENGLISH

REF L022180201096

This Product Insert is not a complete set of instructions. Read the full Instructions for Use (IFU) and Quick Reference Instructions (QRI) thoroughly for LumiraDx SARS-CoV-2 & Flu A/B RNA STAR Complete before use.
A free paper copy of the full IFU and QRI can be obtained by contacting us at +44(0)1172 842535 or CustomerServices@LumiraDx.com.

Intended Use
The LumiraDx SARS-CoV-2 & Flu A/B RNA STAR Complete assay is a rapid, non-isothermal nucleic acid amplification qSTAR (Selective Temperature Amplification Reaction) method intended for the qualitative detection and differentiation of nucleic acid from the SARS-CoV-2, Influenza A, and/or Influenza B viruses in upper respiratory specimens (such as anterior nasal and nasopharyngeal swabs) collected dry or in a transport medium from individuals suspected of COVID-19 and/or influenza by their healthcare provider.
The LumiraDx SARS-CoV-2 & Flu A/B RNA STAR Complete assay is intended for use in simultaneous detection and differentiation of SARS-CoV-2, Influenza A, and/or Influenza B nucleic acid in clinical specimens and is not intended to detect influenza C virus. The SARS-CoV-2, Influenza A, and Influenza B RNA is generally detectable in upper respiratory samples during the acute phase of infection. Positive results are indicative of active infection but do not rule out bacterial infection or co-infection with other pathogens not detected by the test. The agent detected may not be the definite cause of disease.
Negative LumiraDx SARS-CoV-2 & Flu A/B RNA STAR Complete assay results do not preclude SARS-CoV-2, Influenza A, and/or Influenza B infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.
LumiraDx SARS-CoV-2 & Flu A/B RNA STAR Complete is intended for use by qualified clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures.

Procedure/Interpretation/Limitations
For a list of warnings and precautions see the Instructions for Use for the LumiraDx SARS-CoV-2 & Flu A/B RNA STAR Complete kit.

Quick Reference Instructions
Read the full Instructions for Use thoroughly before using the Quick Reference Instructions or the quick setup described in this package insert. The Quick Reference Instructions is not a complete set of instructions. A free paper copy of the full Instructions for Use can be obtained by by contacting us at +44(0)1172 842535 or CustomerServices@LumiraDx.com.

Package Contents/Amounts

COMPONENT	96-WELL (L022180209096)
SARS-CoV-2 & Flu A/B RNA STAR Complete Positive Control Media (PCM)	250 µL
SARS-CoV-2 & Flu A/B RNA STAR Complete Negative Control Media (NCM)	1.5 mL
SARS-CoV-2 & Flu A/B RNA STAR Complete Salt Mix	1.0 mL
SARS-CoV-2 & Flu A/B RNA STAR Complete Extraction Buffer	500 µL
SARS-CoV-2 & Flu A/B RNA STAR Complete Internal Control & Primer Mix (IC/P Mix)	400 µL
SARS-CoV-2 & Flu A/B RNA STAR Complete Master Mix	2.0 mL

Storage Instructions
Upon receipt, store LumiraDx SARS-CoV-2 & Flu A/B RNA STAR Complete kit components between -15 °C and -25 °C. Refer to the Reagent Storage, Handling, and Stability section in the IFU before opening and preparing reagents.

Warnings and Limitations
For a complete list of warnings and limitation see the Instructions for Use for the LumiraDx SARS-CoV-2 & Flu A/B RNA STAR Complete kit.
The Controls should be handled in an approved BSL-2 handling area to avoid contamination of laboratory equipment and reagents that could cause false positive results. This test is non-infectious. However, this test should be handled in accordance with Good Laboratory Practices.

Sample Transport
- Specimens must be packaged, shipped, and transported according to the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulation. Follow shipping regulations for UN-3373 Biological Substance, Category B when sending potential SARS-CoV-2 specimens.
- Samples must be shipped in accordance with applicable local, regional, national, and international transportation regulations.
- Maintain sample storage conditions as described below when transporting specimens.

Sample Collection, Handling, Storage, and Transport
Proper collection and handling of specimens is critical to laboratory diagnosis of infectious diseases. A specimen that is not collected correctly may lead to incorrect test results. Testing for respiratory viruses should be conducted in consultation with a healthcare provider. Specimens should be collected as soon as possible once a decision has been made to pursue testing, regardless of the time of symptom onset. Training in specimen collection is highly recommended due to the importance of specimen quality.

Sample Collection and Handling
- Follow the sample collection device's instructions for proper collection and handling procedures.
- Swab specimens should be collected using only swabs with a synthetic tip, such as nylon or Dacron®, and an aluminum or plastic shaft. Calcium alginate swabs are unacceptable and cotton swabs with wooden shafts are not recommended.
- Wet swab: specimens should be collected and placed into appropriate transport medium, such as Corning Transport Medium (Catalog# 25-500-CM) or medium of similar formulation, 0.85% or 0.90% saline solution, or 1x PBS (pH 7.4). Swabs provided in up to 3 mL of compatible transport media are acceptable, however, for optimal performance, 1 mL of buffer is suggested.
- Dry swab: specimens should be collected and placed in a sterile, dry transport tube, such as a standard 15 mL Falcon tube. For elution of a dry swab specimen, add 1 mL of compatible transport medium and recap tube. Vortex the tube containing the swab for 30 seconds with intermittent pulsing. Incubate the swab at room temperature for at least 10 minutes. Remove and discard the swab in the biohazard waste.

Sample Storage
- Dry swab specimens are stable either at room temperature for up to 48 hours or refrigerated (2–8 °C) for up to 72 hours before processing.
- Wet swab specimens should be stored refrigerated (2–8 °C) for up to 72 hours before processing. If a delay in testing is expected, store specimens at -20 °C or below for up to 6 days.
- If specimens cannot be tested within 72 hours of collection, both dry-swab and wet-swab specimens should be frozen at < -20 °C for up to 6 days until tested.

Sample Processing
Dry Swab (Standard Format)
1. If swab is provided dry, transfer one (1) mL of a compatible transport medium into the tube and recap tube.
2. Vortex the tube containing the swab for 30 seconds with intermittent pulsing.
3. Incubate the swab at room temperature for at least 10 minutes.
4. Remove and discard the swab in biohazard waste.

Dry Swab (Deep-well Format)
1. If swab is provided dry, transfer one (1) mL of a compatible transport medium into appropriate wells.
2. Place and soak the swab for at least 30 seconds then swirl thoroughly by rotating the swab against the side of each well up to 5 times.
3. Express the swab on the side of each well, outside of the liquid, prior to removing (beware of cross-contamination from splashing).
4. Remove and discard the swab in biohazard waste.

Wet Swab
1. If swab specimen is provided wet, up to 3 mL of compatible transport medium is acceptable, though this higher volume may impact sensitivity.

Plate Set-up, and Reagent Preparation
96-Well Format Control, Samples, and Extraction Buffer
1. Thaw PCM, NCM, and Extraction Buffer on a cold block and vortex for 5 seconds then centrifuge for 5 seconds to collect reagents at the bottom of the tube.
2. Directly transfer 21.0 µL of PCM, 21.0 µL of NCM, and 21.0 µL of sample to the appropriate wells of the pre-chilled RT-PCR Plate.
3. Add 5.0 µL of Extraction Buffer to each well containing a control or sample.
4. Pipette up and down 10 times to mix without generating bubbles.
5. Seal the plate with sealing film and place at 65°C for 5 minutes, then immediately place the RT-PCR Plate back on the cold block.

Note: If condensation is present, the plate may be spun down to collect the liquid at the bottom of the wells.

96-Well Format Reaction Mix
1. Thaw Salt Mix, IC/P Mix and Master Mix on a cold block.
2. Obtain a sterile (RNase/DNase free) tube and place on cold block.
3. Determine the number of reactions (N) to be prepared per assay:

REACTION MIX SETUP	1 REACTION	100 REACTIONS	N REACTIONS
Salt Mix	10.0 µL	1000 µL	N x 10.0 µL
IC/P Mix	4.0 µL	400 µL	N x 4.0 µL
Master Mix	20.0 µL	2000 µL	N x 20.0 µL
Total Volume	**34.0 µL**	**3400 µL**	**N x 34.0 µL**

4. Vigorously vortex the Salt Mix for 20 seconds, centrifuge for 5 seconds to collect reagent at the bottom of tube, and **IMMEDIATELY** add the appropriate volume to the pre-chilled microcentrifuge tube.
5. Invert the IC/P Mix and Master Mix to mix then centrifuge for 5 seconds to collect reagents at the bottom of the tube (do not vortex samples), and **IMMEDIATELY** add the appropriate volume to the Salt Mix.
6. Mix thoroughly for at least 10 seconds (avoid creating bubbles). Centrifuge briefly (do not vortex and do not spin down for an excessive amount of time), then place tube back on the cold block.
7. Invert the Master Mix to mix then centrifuge for 5 seconds to collect reagents at the bottom of the tube (do not vortex samples), and **IMMEDIATELY** add the appropriate volume to finalize the Reaction Mix.
8. Mix thoroughly for at least 10 seconds (avoid creating bubbles). Centrifuge briefly, then place tube back on the cold block.
9. Carefully remove the sealing film and add 32.0 µL of Reaction Mix to each well with control or sample, pipetting up and down 10 times to mix without generating bubbles.
10. Apply the optical adhesive plate film. Centrifuge the plate for at least 20 seconds at 2000 rpm to collect the reaction mix at the bottom of each well, confirming that no bubbles persist. If bubbles are observed repeat this step.
11. Place the 96-well plate in the RT-PCR instrument and run the appropriate thermal profile.

Interpretation/Performance/Limitations
Users should refer to the LumiraDx SARS-CoV-2 & Flu A/B RNA STAR Complete IFU for interpretation of results, performance and limitations.

For Return Policy
If there is a problem with the LumiraDx SARS-CoV-2 & Flu A/B RNA STAR Complete Kit you may be asked to return the item. Before returning, please obtain a return authorization number from LumiraDx Customer Services (CustomerServices@LumiraDx.com). This return authorization number must be on the shipping carton for return. For ordinary returns following purchase, please contact LumiraDx Customer Services for terms and conditions.

Limited Warranty
LumiraDx SARS-CoV-2 & Flu A/B RNA STAR Complete – As per shelf life. Unused product must be stored according to the required storage conditions as printed in this product insert and, they can be used only up to the expiry date printed on packaging. For the applicable warranty period, LumiraDx warrants that each product shall be (i) of good quality and free of material defects, (ii) function in accordance with the material specifications referenced in the product insert, and (iii) approved by the proper governmental agencies required for the sale of products for their intended use (the "limited warranty"). If the product fails to meet the requirements of the limited warranty, then as customer's sole remedy, LumiraDx shall either repair or replace, at LumiraDx's discretion, the product. Except for the limited warranty stated in this section, LumiraDx disclaims any and all warranties, express or implied, including but not limited to, any warranty of merchantability, fitness for a particular purpose and non-infringement regarding the product. LumiraDx's maximum liability with any customer claim shall not exceed the net product price paid by the customer. Neither party shall be liable to the other party for special, incidental or consequential damages, including, without limitation, loss of business, profits, data or revenue, even if a party receives notice in advance that these kinds of damages might result. The Limited Warranty above shall not apply if the customer has subjected LumiraDx SARS-CoV-2 & Flu A/B RNA STAR Complete to physical abuse, misuse, abnormal use, use inconsistent with product insert provided, fraud, tampering, unusual physical stress, negligence or, accidents. Any warranty claims by customer pursuant to the Limited Warranty shall be made in writing within the applicable Limited Warranty period.

Intellectual Property
The LumiraDx Kit and all provided LumiraDx documentation ('Products') are protected by law. The Intellectual Property of the LumiraDx Products remains at LumiraDx. Details of relevant Intellectual Property regarding our products can be found at LumiraDx.com/IP.

Legal Notices

Reagent Complaints/Questions
If you have a question/comment about this product, please contact LumiraDx by email at CustomerServices@LumiraDx.com. Please include "LumiraDx SARS-CoV-2 & Flu A/B RNA STAR Complete" in the subject line.

Glossary of Symbols

	Temperature limitation		Use-by Date – The date after which the unopened reagent cannot be used
IVD	In vitro diagnostic medical device	Σ 'n'	Contains sufficient reagent for 'n' reactions
REF	Catalog Reference Number		Refer to www.lumiradx.com for the electronic form of the Instructions for Use
			Positive Control Media
LOT	Lot Number/Batch Code	CONTROL +	Negative Control Media
	Manufacturer	CONTROL −	
CE	CE Mark of Conformity	EC REP	Authorized representative in the European Community
	European Importer		

Uncontaminated recycled content packaging, kit box, Instructions for Use is recyclable if it can be collected, separated, or otherwise recovered from the waste stream through an established recycling program.

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