lumiraDx™
Fast Lab Solutions

IVD Rx Only

SARS-CoV-2 RNA STAR Complete

FOR EMERGENCY USE AUTHORIZATION (EUA) ONLY

REF L018180130096 and L018180130384

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 RNA STAR Complete before running any samples.

Users should refer to the LumiraDx SARS-CoV-2 RNA STAR Complete IFU and QRI posted on the LumiraDx website www.lumiradx.com. A free paper copy of the full IFU and QRI can be obtained by contacting us at 1-888-586-4721 or CustomerServices@lumiradx.com

Intended Use

LumiraDx SARS-CoV-2 RNA STAR Complete is a rapid, non-isothermal nucleic acid amplification qSTAR (Selective Temperature Amplification Reaction) method intended for the qualitative detection of nucleic acid from SARS-CoV-2 anterior nasal, mid-turbinate nasal, nasopharyngeal and oropharyngeal swabs collected dry or in transport media from individuals suspected of COVID-19 by their healthcare provider (HCP).

This test is also authorized for use with anterior nasal swab specimens collected dry or in transport media from any individual, including individuals without symptoms or other reasons to suspect COVID-19 when collected by a HCP or self-collected under the supervision of a HCP.

This test is also authorized for use with anterior nasal swab specimens that are collected using a collection kit that conforms to HealthPulse@home when used consistent with its authorization.

The LumiraDx SARS-CoV-2 RNA STAR Complete is also intended for the qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples containing up to five individual anterior nasal swab specimens, using specified workflows, that are Healthcare Provider collected in individual vials either dry or containing transport medium from any individual, including individuals without symptoms or other reasons to suspect COVID-19. Negative results from pooled samples should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, pooled samples should be tested individually. Specimens included in pools with a positive or presumptive positive result must be tested individually prior to reporting a result. Specimens with low SARS-CoV-2 RNA concentrations may not be detected in sample pools due to the decreased sensitivity of pooled testing.

Testing is limited to laboratories—certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 USC. §263a that meet requirements to perform high complexity tests.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 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 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. LumiraDx SARS-CoV-2 RNA STAR Complete is only for use under the Food and Drug Administration's Emergency Use Authorization.

Procedure/Interpretation/Limitations

Users should refer to the LumiraDx SARS-CoV-2 RNA STAR Complete Instructions for Use posted on the FDA website for all IVD products used under Emergency Use Authorization, http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm.

Quick Reference Instructions

Read the full Instructions for Use available at https://www.lumiradx.com/us-en/what-we-do/diagnostics/fast-lab-solutions/rna-star-complete thoroughly for LumiraDx SARS-CoV-2 RNA STAR Complete before using the quick setup described below in this product insert. This Product Insert is not a complete set of instructions. A free paper copy of the full Instructions for Use can be obtained by using the contact info under Reagent complaints/questions below, if needed.

Package Contents

SARS-CoV-2 RNA STAR Complete – 96-Well (Catalog #L018180130096)

COMPONENT	DESCRIPTION	VOLUME	STORAGE
LumiraDx SARS-CoV-2 RNA STAR Complete Positive Control Media (Pos. Ctrl. Med.)	SARS-CoV-2 Positive Control (ZeptoMetrix 50,000cp/mL)	500µL	≤ 8°C
LumiraDx SARS-CoV-2 RNA STAR Complete Negative Control Media (Neg. Ctrl. Med.)	Negative Control (Phosphate Buffered Saline)	1.5mL	-25°C to -15°C
LumiraDx SARS-CoV-2 RNA STAR Complete Salt Mix	Salt Mix	1mL	-25°C to -15°C
LumiraDx SARS-CoV-2 RNA STAR Complete Extraction Buffer	Nucleic Acid Extraction Buffer	500µL	-25°C to -15°C
LumiraDx SARS-CoV-2 RNA STAR Complete Internal Control & Primer Mix (IC/P Mix)	Internal Control & Primer Mix	120µL	-25°C to -15°C
LumiraDx SARS-CoV-2 RNA STAR Complete Master Mix	Master Mix	2 x 1mL	-25°C to -15°C

SARS-CoV-2 RNA STAR Complete – 384-Well (Catalog #L018180130384)

COMPONENT	DESCRIPTION	VOLUME	STORAGE
LumiraDx SARS-CoV-2 RNA STAR Complete Positive Control Media (Pos. Ctrl. Med.)	SARS-CoV-2 Positive Control (ZeptoMetrix 50,000cp/mL)	500 µL	≤ 8°C
LumiraDx SARS-CoV-2 RNA STAR Complete Negative Control Media (Neg. Ctrl. Med.)	Negative Control (Phosphate Buffered Saline)	1.5 mL	-25°C to -15°C
LumiraDx SARS-CoV-2 RNA STAR Complete Salt Mix	Salt Mix	2 mL	-25°C to -15°C
LumiraDx SARS-CoV-2 RNA STAR Complete Extraction Buffer	Nucleic Acid Extraction Buffer	1 mL	-25°C to -15°C
LumiraDx SARS-CoV-2 RNA STAR Complete Internal Control & Primer Mix (IC/P Mix)	Internal Control & Primer Mix	240 µL	-25°C to -15°C
LumiraDx SARS-CoV-2 RNA STAR Complete Master Mix	Master Mix	2 x 2 mL	-25°C to -15°C

Storage Instructions

Upon receipt, store the LumiraDx SARS-CoV-2 RNA STAR Complete kit between - 15°C and– 25°C. Refer to the LumiraDx SARS-CoV-2 RNA STAR Complete Instruc-tions for Use before opening and preparing reagents.

Precautions

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.

This product has not been FDA cleared or approved but has been authorized by FDA for emergency use under an EUA for use by authorized laboratories.

This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of 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 declaration is terminated, or authorization is revoked sooner.

Specimen Preparation

External Controls

1. Thaw Pos. Ctrl. Med. and Neg. Ctrl. Med. on a cold block, vortex for 5 seconds then centrifuge for 5 seconds to collect reagents at the bottom of the tube.
2. For a 96-well configuration, assemble the 1x PCM (Positive Control Media) by diluting 20 µL Pos. Ctrl. Med. with 60 µL Neg. Ctrl. Med. in a pre-chilled microcentrifuge tube. Assemble the 1x NCM (Negative Control Media) by transferring 80 µL Neg. Ctrl. Med into a pre-chilled microcentrifuge tube.
3. For a 384-well configuration, assemble the PCM (Positive Control Media), freshly dilute 20.0 µL Pos. Ctrl. Med. with 20.0 µL Neg. Ctrl. Med. in a pre-chilled microcentrifuge tube and in an area separate from the sample handling areas. To assemble the 1x NCM (Negative Control Media), always freshly pipette 40.0 µL Neg. Ctrl. Med into a pre-chilled microcentrifuge tube.

Sample Processing

1. For a 96-well configuration
   a. Dry Swab (Single or Deepwell Format) - If swab is provided dry, transfer one (1) mL of a compatible transport media into a suitable tube (e.g. polypropylene microcentrifuge tube). Place and soak the swab for at least 30 seconds then swirl thoroughly by rotating the swab against the side of the tube up to 5 times. Express the swab on the side of tube, outside of the liquid, prior to removing (beware of cross-contamination from splashing). Discard the swab in biohazard waste.
   b. Healthpulse@home COVID-19 Collection Kit (dry swab)- transfer one (1) mL of PBS to the dry swab 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. Proceed to Sample Processing.
   c. Wet Swab - If swab specimen is provided wet, up to 3 mL of compatible transport media (VTM, 0.85% and 0.90% Saline, or PBS) is acceptable, but this higher volume may impact sensitivity.
2. For a 96-well configuration – Pooling
   a. Dry Swabs - If swabs are provided dry, transfer 700 µl of a compatible transport media into a suitable tube (e.g. polypropylene microcentrifuge tube). Place and soak the swab for at least 30 seconds then swirl thoroughly by rotating the swab against the side of the tube up to 5 times. Express the swab on the side of tube, outside of the liquid, prior to removing (beware of cross-contamination from splashing). Discard the swab in biohazard waste.
   b. Healthpulse@home COVID-19 Collection Kit (dry swab)- transfer 700 µl of PBS to the dry swab 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. Proceed to Sample Processing.
   c. Wet Swab - If swab sample is provided wet, 700 µL to 1mL of compatible transport media (VTM, 0.85% and 0.90% Saline, or PBS) is recommended, higher volumes of media may impact sensitivity.
3. For a 384-well configuration
   a. Dry Swab - If swab is provided dry, transfer one (1) mL of a compatible transport media into a suitable tube (e.g. polypropylene microcentrifuge tube). Place and soak the swab for at least 30 seconds then swirl thoroughly by rotating the swab against the side of the tube up to 5 times. Express the swab on the side of tube, outside of the liquid, prior to removing (beware of cross-contamination from splashing). Discard the swab in biohazard waste.
   b. Healthpulse@home COVID-19 Collection Kit (dry swab)- transfer one (1) mL of PBS to the dry swab 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. Proceed to Sample Processing.
   c. Wet Swab - If swab specimen is provided wet, up to 3 mL of compatible transport media (VTM, 0.85% and 0.90% Saline, or PBS) is acceptable, but this higher volume may impact sensitivity.

Plate Set-up

1. qSTAR reagent preparation for Individual and Pooled Samples in a 96-well format

1. Thaw Salt Mix, Extraction Buffer, IC/P Mix and Master Mix on a cold block.
2. Transfer 24 µL of specimen and 24 µL of external controls into an appropriate, pre-chilled 96-well plate. Add 4.8 µL of Extraction Buffer, per well, and mix by slowly pipetting up and down 10 times while minimizing bubbles. If needed, seal and centrifuge the 96-well plate to collect the specimen at the bottom of the well.
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	1.2 µL	120 µL	N x 1.2 µL
Master Mix	20.0 µL	2000 µL	N x 20.0 µL
Total Volume	**31.2 µL**	**3120 µL**	**N x 31.2 µL**

4. 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).
5. Vigorously vortex the Salt Mix for 20 seconds and centrifuge for 5 seconds to collect reagent at the bottom of tube.
6. Assuming one reaction is needed, perform the following to make the Reaction Mix:
   a. Combine 10.0 µL Salt Mix and 1.2 µL IC/P Mix in a pre-chilled microcentrifuge tube, mix by slowly pipetting up and down 4 times without introducing 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.
   b. Add 20.0 µL Master Mix to finalize the Reaction Mix, mix by pipetting up and down 10 times without introducing bubbles, centrifuge briefly, then place tube back on the cold block.
7. Transfer 31.2 µL of Reaction Mix, per well, into an appropriate, pre-chilled, 96-well plate. Mix by slowly pipetting up and down 10 times without introducing bubbles. Seal the 96-well plate using an appropriate optically clear adhesive and centrifuge the plate at 2000 rpm for 20 seconds to collect contents at bottom of the plate.
8. Place the 96-well plate in a validated thermocycler and follow instrument specific protocols and analysis procedures detailed in the IFU.

2. qSTAR reagent preparation for Individual Samples in a 384-well format for ABI QS5 and QS7

1. Thaw Salt Mix, Extraction Buffer, IC/P Mix and Master Mix on a cold block.
2. Transfer 10 µL of specimen and 10 µL of external controls into an appropriate, pre-chilled 384-well plate. Add 2.0 µL of Extraction Buffer, per well, and mix by slowly pipetting up and down 10 times while minimizing bubbles. If needed, seal and centrifuge the 384-well plate to collect the specimen at the bottom of the well.
3. Determine the number of reactions (N) to be prepared per assay:

REACTION MIX SETUP	1 REACTION	400 REACTIONS	N REACTIONS
Salt Mix	4.2 µL	1680 µL	N x 4.2 µL
IC/P Mix	0.5 µL	200 µL	N x 0.5 µL
Master Mix	8.3 µL	3320 µL	N x 8.3 µL
Total Volume	**13.0 µL**	**5200 µL**	**N x 13.0 µL**

4. 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).
5. Vigorously vortex the Salt Mix for 20 seconds and centrifuge for 5 seconds to collect reagent at the bottom of tube.
6. Assuming one reaction is needed, perform the following to make the Reaction Mix:
   a. Combine 4.2 µL Salt Mix and 0.5 µL IC/P Mix in a pre-chilled microcentrifuge tube, mix by slowly pipetting up and down 4 times without introducing 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.
   b. Add 8.3 µL Master Mix to finalize the Reaction Mix, mix by pipetting up and down 10 times without introducing bubbles, centrifuge briefly, then place tube back on the cold block.
7. Transfer 13.0 µL of Reaction Mix, per well, into an appropriate, pre-chilled, 384-well plate. Mix by slowly pipetting up and down 10 times without introducing bubbles. Seal the 384-well plate using an appropriate optically clear adhesive and centrifuge the plate at 2000 rpm for 2 minutes to collect contents at bottom of the plate.
8. Place the 384-well plate in a validated thermocycler and follow instrument specific protocols and analysis procedures detailed in the IFU.

3. qSTAR reagent preparation for Individual Samples in a 384-well format for Roche LightCycler 480II

1. Thaw Salt Mix, Extraction Buffer, IC/P Mix and Master Mix on a cold block.
2. Transfer 12 µL of specimen and 12 µL of external controls into an appropriate, pre-chilled 384-well plate. Add 2.4 µL of Extraction Buffer, per well, and mix by slowly pipetting up and down 10 times while minimizing bubbles. If needed, seal and centrifuge the 384-well plate to collect the specimen at the bottom of the well.
3. Determine the number of reactions (N) to be prepared per assay:

REACTION MIX SETUP	1 REACTION	400 REACTIONS	N REACTIONS
Salt Mix	5.0 µL	2000 µL	N x 5.0µL
IC/P Mix	0.6 µL	240 µL	N x 0.6 µL
Master Mix	10.0 µL	4000 µL	N x 10.0 µL
Total Volume	**15.6 µL**	**6240 µL**	**N x 15.6 µL**

4. 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).
5. Vigorously vortex the Salt Mix for 20 seconds and centrifuge for 5 seconds to collect reagent at the bottom of tube.
6. Assuming one reaction is needed, perform the following to make the Reaction Mix:
   c. Combine 5.0 µL Salt Mix and 0.6 µL IC/P Mix in a pre-chilled microcentrifuge tube, mix by slowly pipetting up and down 4 times without introducing 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.
   d. Add 10.0 µL Master Mix to finalize the Reaction Mix, mix by pipetting up and down 10 times without introducing bubbles, centrifuge briefly, then place tube back on the cold block.
7. Transfer 15.6 µL of Reaction Mix, per well, into an appropriate, pre-chilled, 384-well plate. Mix by slowly pipetting up and down 10 times without introducing bubbles. Seal the 384-well plate using an appropriate optically clear adhesive and centrifuge the plate at 2000 rpm for 2 minutes to collect contents at bottom of the plate.
8. Place the 384-well plate in a validated thermocycler and follow instrument specific protocols and analysis procedures detailed in the IFU.

For Return Policy

If there is a problem with the LumiraDx SARS-CoV-2 RNA STAR Complete Test you may be asked to return the item. Before returning Tests please obtain a return authorization number from LumiraDx Customer Services (customerservices.US@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 RNA STAR Complete – As per shelf life. Unused Tests 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 Test. 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 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 claim by customer pursuant to the Limited Warranty shall be made in writing within the applicable Limited Warranty period.

Intellectual Property

The LumiraDx Test 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 telephone at 1-888-586-4721 or by email at customerservices.US lumiradx.com. Please include "LumiraDx SARS-CoV-2 RNA STAR Complete" in the subject line of the email.

Glossary of Symbols

Temperature limitation	Use-by Date – The date after which the unopened reagent cannot be used.
IVD In vitro diagnostic medical device	Contains sufficient reagent for 'n' reactions.
REF Catalog Reference Number	Refer to www.lumiradx.com for the electronic form of the Instructions for Use.
LOT Lot Number/Batch Code	CONTROL + Positive Control Media
Manufacturer	CONTROL − Negative Control Media
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.	**Caution:** Federal Law restricts this device to sale by or on the order of a licensed practitioner.

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