LumiraDx™ SARS-CoV-2 RNA STAR Complete

Quick Reference Instructions for Single Sample Format

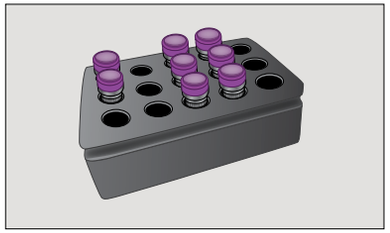
For Research Use Only (RUO) · Not for use in diagnostic procedures.

SD-QMS-SPEC-30181 R1 · SD-COM-ART-00068 R3 · Rev Date 2021/02

LumiraDx SARS-CoV-2 RNA STAR Complete is a rapid, non -isothermal nucleic acid amplification technique utilizing qSTAR technology, which detects SARS -CoV-2 viral nucleic acid in under twenty minutes, without needing to perform any purification or extraction.

Study the Product Insert and Instructions for Use (IFU) thoroughly before using this Procedure Card. This Procedure Card is not a complete set of instructions. Refer to the Materials Required (But Not Provided) document for specific vendors and catalog numbers for materials used below that are not provided in the LumiraDx SARS-CoV-2 RNA STAR Complete kit.

LumiraDx SARS-CoV-2 RNA STAR Complete components

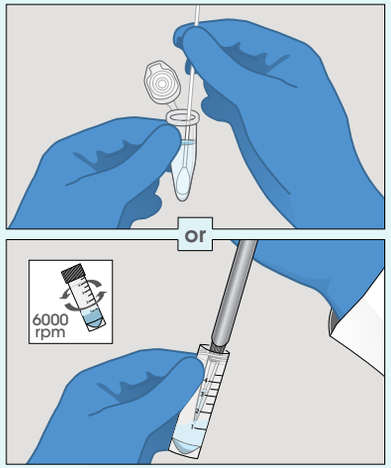


1. Thaw reagents

Thaw the LumiraDx SARS-CoV-2 RNA STAR Complete kit components in a cold block equilibrated between 2 to 8 °C; i.e. Positive Control Media (Pos. Ctrl. Med.), Negative Control Media (Neg. Ctrl. Med.), Saliva Reagent, Salt Mix, Extraction Buffer, Internal Control & Primer (IC/P) Mix, and Master Mix. Once thawed, invert to mix then centrifuge for 5 seconds to collect reagents at bottom of the tube (do not vortex).

Preparing the sample – single sample format

Collect samples (can be dry swab sample, wet swab sample, or a saliva sample) before following steps 2 to 4.

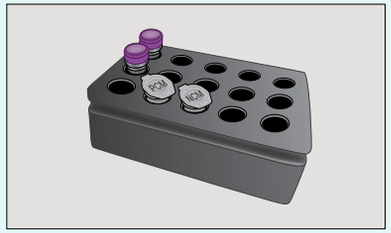


2a. For swab sample

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. If swab sample is provided wet, up to 3 mL of compatible transport media (VTM, 0.85% Saline, or PBS) is acceptable, but this higher volume may impact sensitivity.

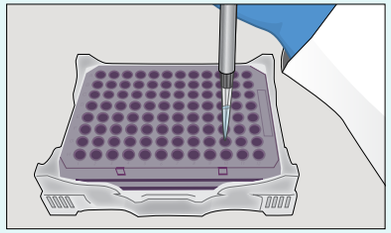
2b. For saliva sample

At minimum one (1) mL saliva can be collected in any vial (e.g. 5 mL tube) that does not contain preservatives. Immediately before use, centrifuge the saliva sample at 6000 rpm for 1 to 5 minutes. If storage is needed, the supernatant (~ 500 µL) can be transferred to a microcentrifuge tube and will not need future spinning.



3. Prepare external controls

Assemble fresh 1x PCM (Positive Control Media) by diluting 20.0 µL Pos. Ctrl. Med. with 60.0 µL Neg. Ctrl. Med. in a pre-chilled microcentrifuge tube. Assemble the 1x NCM (Negative Control Media) by transferring 80.0 µL Neg. Ctrl. Med. into a pre-chilled microcentrifuge tube.

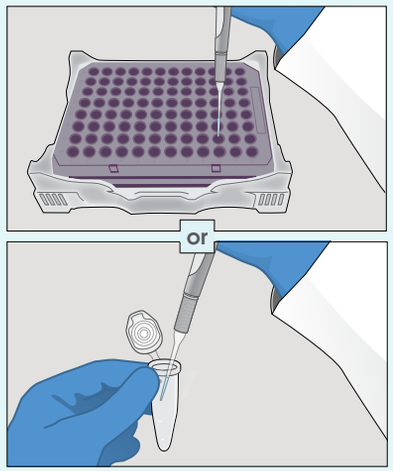


4. Prepare sample plate

Transfer 24.0 µL of swab samples prepared in Step 2a or 22.8 µL of saliva supernatant prepared in Step 2b and transfer 24.0 µL of external controls prepared in Step 3 using a single-channel pipette into an appropriate, pre-chilled, 96-well plate.

qSTAR reagent preparation

All components should be kept cold to maintain the integrity of the reagents.

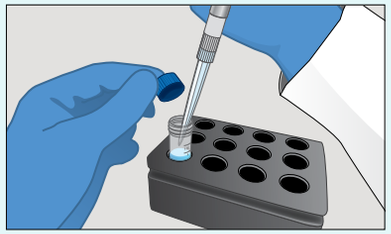


5a. For swab sample

Add 4.8 µL of Extraction Buffer to the 96-well plate and mix by slowly pipetting up and down 10 times without introducing bubbles. The addition and mixing of Extraction Buffer can be simplified by using a multi-channel pipette and chilled reagent reservoir. If needed, seal and centrifuge the 96-well plate to collect the sample at the bottom of the well.

5b. For saliva sample

Premix in a suitable pre-chilled tube (i.e. microcentrifuge tube or 5 mL tube) the Saliva Extraction Mix by combining N x 1.2 µL Saliva Reagent and N x 4.8 µL Extraction Buffer, then slowly pipette up and down 4 to 6 times without introducing bubbles and centrifuge. Transfer 6.0 µL Saliva Extraction Mix to the 96-well plate and mix by slowly pipetting up and down 10 times without introducing bubbles.



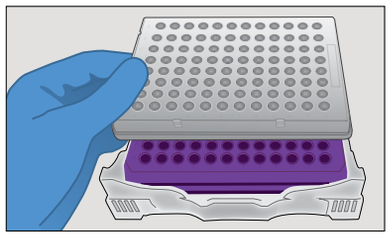
6. Prepare reaction mix

Determine the number of reactions (N) to be prepared per assay and prepare Reaction Mix in a suitable pre-chilled tube by following the order in the table below. Between each reagent, slowly mix by pipetting up and down 4 to 6 times without introducing bubbles and pulse centrifuge.

Reaction Mix	1 Rxn	N Rxns
Salt Mix	10.0 µL	N x 10.0 µL
IC/P Mix	1.2 µL	N x 1.2 µL
Master Mix	20.0 µL	N x 20.0 µL
Total Volume	31.2 µL	N x 31.2 µL

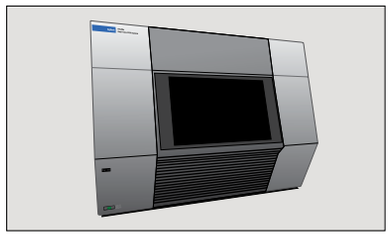
Final setup

Thermocycler setup (i.e. Roche LC 480 II, ABI 7500 Fast Dx, ABI QS 5, ABI QS 7 Flex, ABI QS 7 Pro, Bio-Rad CFX96, Agilent AriaMx, or the Mx3005P) is described in the IFU.



7. Add reaction mix to plate

Transfer 31.2 µL of Reaction Mix to each well with sample and external controls. 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 10 seconds to collect contents at bottom of plate.



8. Run reaction

Place the 96-well plate in a thermocycler and follow instrument specific protocols and analysis procedures detailed in the LumiraDx SARS-CoV-2 RNA STAR Complete IFU.

LumiraDx™ SARS-CoV-2 RNA STAR Complete

Quick Reference Instructions for Deepwell/Dry Swab Format

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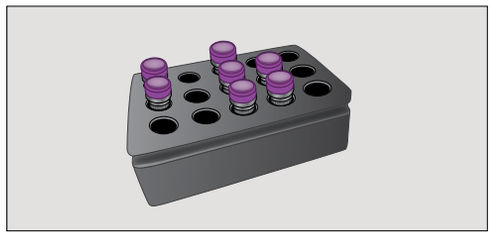
LumiraDx SARS-CoV-2 RNA STAR Complete kit components

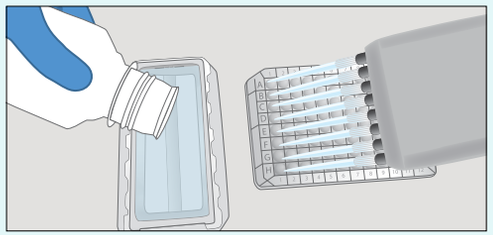


1. Thaw reagents

Thaw the LumiraDx SARS-CoV-2 RNA STAR Complete kit components in a cold block equilibrated between 2 to 8 °C; i.e. Positive Control Media (Pos. Ctrl. Med.), Negative Control Media (Neg. Ctrl. Med.), Salt Mix, Extraction Buffer, Internal Control & Primer (IC/P) Mix, and Master Mix. Once thawed, invert to mix then centrifuge for 5 seconds.

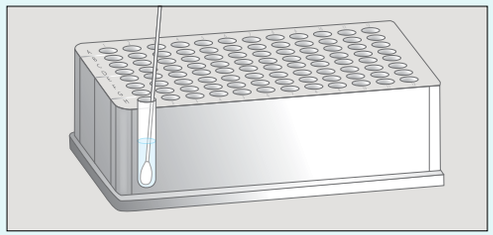
Preparing the sample – deepwell/dry swab format

Collect a dry swab sample before following the steps below.



2. Prepare deepwell

Pour 100 mL of a compatible transport media (VTM, 0.85 % Saline, or PBS) into a suitable reagent reservoir. Transfer 1 mL to each deepwell using a multichannel pipette. Leave two designated wells, A1 and A12, empty for the external controls assembled in Step 4.



3. Soak swab

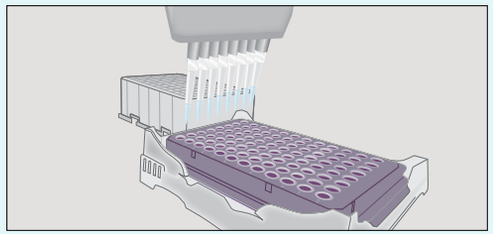
Add a single dry swab to each deepwell in use. Soak the swab for a minimum of 30 seconds then swirl thoroughly by rotating the swab against the side of the deepwell 5 times. Express the swab on the side of the tube, outside of the liquid, prior to removing (beware of cross-contamination from splashing). Discard the swab in biohazard waste.

4. Prepare external controls

Assemble the 1x PCM (Positive Control Media) by diluting 200 µL Pos. Ctrl. Med. with 600 µL Neg. Ctrl. Med. in a pre-chilled microcentrifuge tube. Assemble the 1x NCM (Negative Control Media) by transferring 800 µL Neg. Ctrl. Med. into a pre-chilled microcentrifuge tube. Alternatively, the PCM and NCM can be prepared in the deepwell.

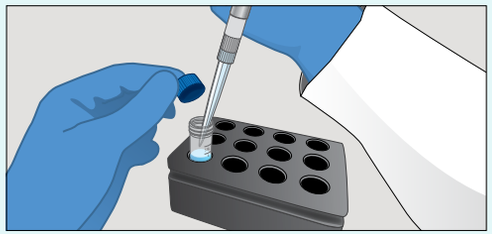
qSTAR reagent preparation

All components should be kept cold to maintain the integrity of the reagents.



5. Prepare sample plate

Mix the sample prepared in Step 3 and the external controls prepared in Step 4 by slowly pipetting up and down 4 to 6 times without introducing air bubbles then transfer 24.0 µL using a multi-channel pipette into an appropriate, pre-chilled, 96-well plate. Add 4.8 µL of Extraction Buffer, per well of sample, 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 sample at the bottom of the well.



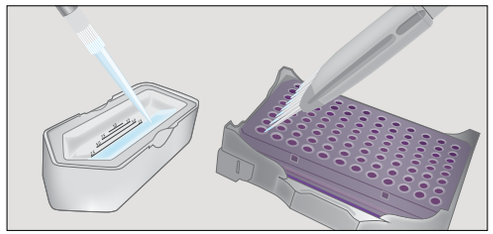
6. Prepare reaction mix

Assuming 96 reactions are needed, prepare Reaction Mix in a pre-chilled 5mL tube by following the order in the table below. Between each reagent, slowly mix by pipetting up and down 4 to 6 times without introducing bubbles.

Reaction Mix	100 Rxns
Salt Mix	1000 µL
IC/P Mix	120 µL
Master Mix	2x 1000 µL
Total Volume	3120 µL

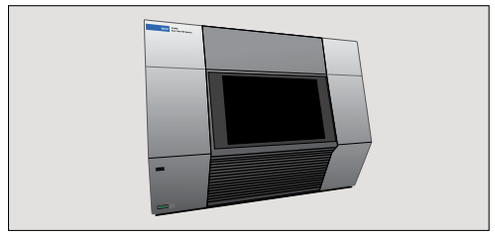
Final setup

Thermocycler setup (i.e. Roche LC 480 II, ABI 7500 Fast Dx, ABI QS 5, ABI QS 7 Flex, ABI QS 7 Pro, Bio-Rad CFX96, Agilent AriaMx, or the Agilent Stratagene Mx3005P) is described in the IFU.



7. Add reaction mix to plate

Transfer Reaction Mix to a pre-chilled reagent reservoir (for minimal dead volume) using a single channel pipette. Then, using a multi-channel pipette, transfer 31.2 µL of Reaction Mix to each well with sample and external controls. Mix by slowly pipetting up and down 3 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 plate.



8. Run reaction

Place the 96-well plate in a thermocycler and follow instrument specific protocols and analysis procedures detailed in the LumiraDx SARS -CoV-2 RNA STAR Complete IFU.

Precautions: The Controls should be handled in an approved BSL -2 handling area to avoid contamination of laboratory equipment and reagents that could affect results. This Test is non -infectious. However, this Test should be handled in accordance with Good Laboratory Practices. **Customer Service:** If the LumiraDx SARS-CoV-2 RNA STAR Complete kit does not perform as expected, contact LumiraDx Customer Services 1-888-586-4721 or customerservices@lumiradx.com. **Manufacturer Information:** LumiraDx UK Ltd, 3 More London Riverside, London, SE1 2AQ, UK. Company Number 09206123.