LumiraDx™
Fast Lab Solutions

Dual-Target SARS-CoV-2 **STAR Complete**

Quick Reference Instructions **Standard Format**

REF L018180801096

IVD

IMPORTANT: This Quick Reference Instructions (QRI) is not a complete set of instructions. Read the full Instructions for Use (IFU) and Package Insert (PI) thoroughly for LumiraDx Dual-Target SARS-CoV-2 STAR Complete before running any samples. Users should refer to the LumiraDx Dual-Target SARS-CoV-2 STAR Complete IFU and PI 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 +44 (0)1172 842535 or CustomerServices@lumiradx.com.

qSTAR REAGENT PREPARATION

All components should be kept cold to maintain the integrity of the reagents. To ensure the performance of the assay, setup the validated thermocyclers described in the IFU before preparation of samples and reagents.

PRECAUTIONS

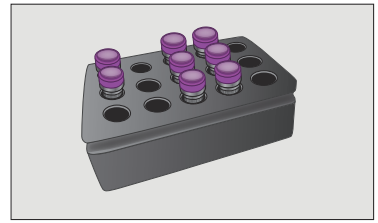
LumiraDx Dual-Target SARS-CoV-2 STAR Complete is intended for use by qualified clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and *in vitro* diagnostic procedures.

Customer Service: If the LumiraDx Dual-Target SARS-CoV-2 STAR Complete does not perform as expected, contact Customer Services +44 (0)1172 842535 or CustomerServices@lumiradx.com.

Kit Components (100 reactions)

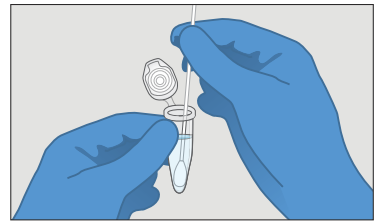
Store at -15 °C and -25 °C until use

COMPONENT	AMOUNT
Positive Control Media (PCM)	250 µL
Negative Control Media (NCM)	1.5 mL
Salt Mix	1.0 mL
Extraction Buffer	500 µL
Internal Control/Primer Mix (IC/P)	200 µL
Master Mix	2.0 mL



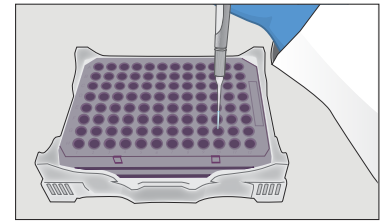
1. Thaw reagents

- Thaw components in a pre-chilled cold block equilibrated between 2 and 8 °C.



2. Sample preparation

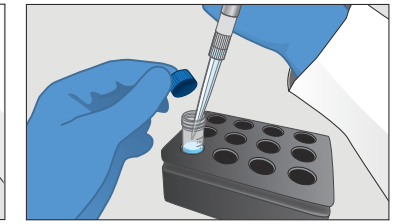
- Dry Swab - If swab is provided dry, transfer one (1) mL of a compatible transport medium into the tube and recap tube. Vortex the tube containing the swab for 30 seconds with intermittent pulsing. Incubate the swab at room temperature for at least 10 minutes. Remove and discard the swab in biohazard waste.
- Wet Swab - If swab specimen is provided wet, up to 3 mL of compatible transport medium is acceptable, higher volume may impact sensitivity. One (1) mL of transport medium is recommended.



3. Sample and Control Extraction

- In a pre-chilled RT-PCR plate, transfer 23.0 µL of PCM, 23.0 µL of NCM, and 23.0 µL of sample to the appropriate wells.
- Add 5.0 µL of Extraction Buffer to each well containing controls and sample(s).
- Mix thoroughly for at least 10 seconds (avoid creating bubbles).
- Seal the RT-PCR plate with sealing film and spin down for 5 seconds.
- Place the plate 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.

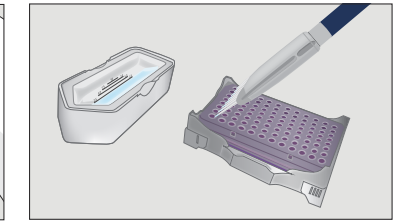


4. Prepare Reaction Mix

- In a pre-chilled tube prepare Reaction Mix in the order of the table.
- Determine the number of reactions (N) to be prepared per assay:

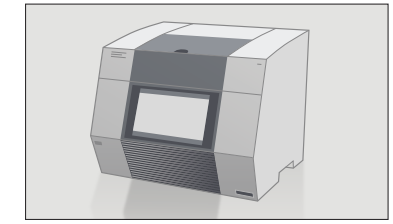
REACTION MIX	1 RXN	100 RXNS	N RXNS
Salt Mix	10.0 µL	1000 µL	N x 10.0 µL
IC/P Mix	2.0 µL	200 µL	N x 2.0 µL
Master Mix	20.0 µL	2000 µL	N x 20.0 µL
Total Volume	32.0 µL	3200 µL	N x 32.0 µL

- Vigorously vortex the Salt Mix for 20 seconds, centrifuge for 5 seconds then **IMMEDIATELY** add the appropriate volume to the pre-chilled tube.
- Invert the IC/P vial to mix, centrifuge for 5 seconds then **IMMEDIATELY** add the appropriate volume to the Salt Mix.
- Mix thoroughly for at least 10 seconds (avoid creating bubbles). Centrifuge briefly then place tube back on the cold block.
- Invert the Master Mix vial to mix, centrifuge for 5 seconds then **IMMEDIATELY** add the appropriate volume to finalize the Reaction Mix.
- Mix thoroughly for at least 10 seconds (avoid creating bubbles).
- Centrifuge briefly, then place tube back on the cold block.



5. Prepare amplification plate

- In pre-chilled reagent reservoir transfer Reaction Mix.
- Carefully remove the sealing film from Step 3.
- Add 32.0 µL of Reaction Mix to each well with controls and sample(s).
- Mix thoroughly for at least 10 seconds (avoid creating bubbles).
- Apply the optical adhesive plate film.
- Centrifuge the plate for at least 20 seconds at 2000 rpm. Confirm that no bubbles persist. If bubbles are observed repeat step.



6. Run amplification

Note: Final setup for validated RT-PCR instruments is described in the IFU.

- Place the 96-well plate in the RT-PCR instrument and follow instrument specific protocols and analysis procedures detailed in the Instructions for Use.

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LumiraDx™
Fast Lab Solutions

Dual-Target SARS-CoV-2 **STAR Complete**

Quick Reference Instructions
Deep Well Format

REF **L018180801096**

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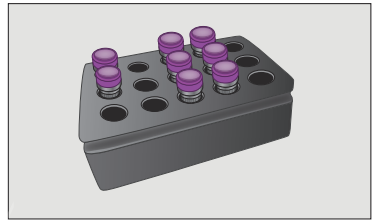

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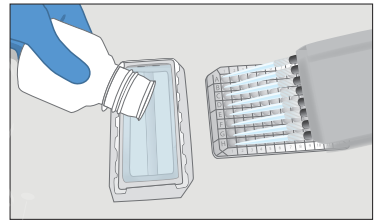
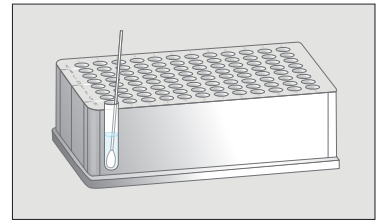


2. Prepare deepwell plate

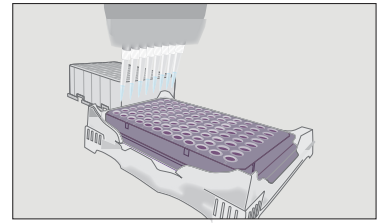
- Pour 100 mL of a compatible media into a reagent reservoir.
- Transfer 1 mL to each deep well using a multichannel pipette.

Note Leave two designated wells empty for the external controls.



3. Sample preparation

- Dry Swab - Place and soak the swab for at least 10 minutes into the appropriate well.
- Express the liquid from the swab by rotating the swab against the side of the well up to 5 times while removing the swab from the well.
- Discard the swab in biohazard waste.



4. Sample and Control Extraction

- From the deep well plate transfer 23.0 µL of the sample(s) to the appropriate wells.
- Add 23.0 µL of PCM and 23.0 µL of NCM to the appropriate wells.
- Add 5.0 µL of Extraction Buffer to each well containing controls or sample(s).
- Mix thoroughly for at least 10 seconds (avoid creating bubbles).
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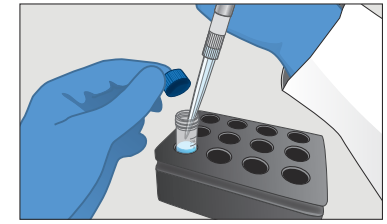

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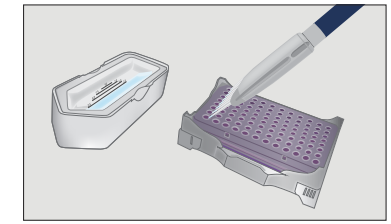

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- Carefully remove the sealing film from Step 4.
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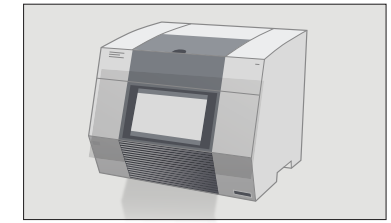

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