lumiraDx™
Fast Lab Solutions

SARS-CoV-2
RNA STAR Complete

Quick Reference Instructions for Single Swab Format

REF L018180501096

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 SARS-CoV-2 RNA STAR Complete before running any samples. Users should refer to the LumiraDx SARS-CoV-2 RNA 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.

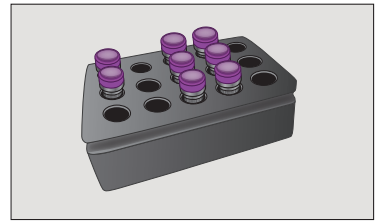
CUSTOMER SERVICE

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

Kit Components (100 reactions)

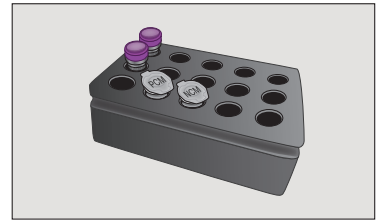
Store at -25°C to -15°C until use

COMPONENT	AMOUNT
Positive Control Media (Pos. Ctl. Med.)	500 µL
Negative Control Media (Neg. Ctl. Med.)	1.5 mL
Salt Mix	1 mL
Extraction Buffer	500 µL
Internal Control/Primer (IC/P) Mix	120 µL
Master Mix	2 x 1 mL



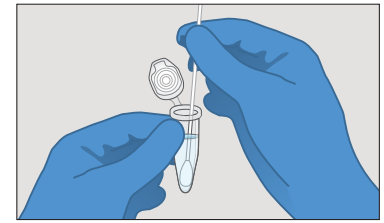
1. Thaw reagents

- Thaw components in a pre-chilled cold block equilibrated between 2 and 8°C. Once thawed, invert the IC/P Mix, Pos. Ctl. Med., Neg. Ctl. Med. and Master Mix to mix then centrifuge for 5 seconds. Once thawed, vigorously vortex the Salt Mix for 20 seconds and centrifuge for 5 seconds to collect reagent at the bottom of tube.



2. Prepare external controls

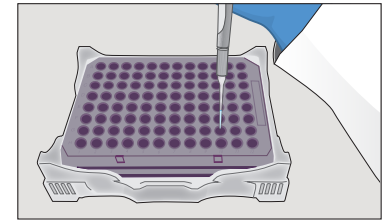
- Prepare fresh 1x Pos. Ctrl. Med. by diluting 20.0 µL Pos. Ctrl. Med. with 60.0 µL Neg. Ctrl. Med. in a pre-chilled microfuge tube.
- Prepare fresh 1x Neg. Ctrl. Med. by transferring 80.0 µL Neg. Ctrl. Med. into a pre-chilled microfuge tube.



3. Sample preparation

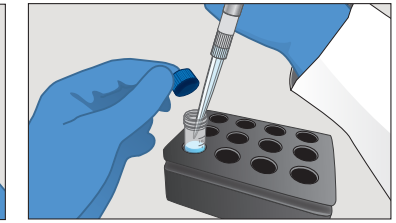
1. Dry Swab - If swab is provided dry, transfer one (1) mL of a compatible transport media into a suitable tube (e.g. polypropylene microcentrifuge tube). Place and soak the swab for at least 30 seconds then swirl thoroughly by rotating the swab against the side of the tube up to 5 times. Express the 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.

2. Wet Swab - If swab specimen 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.



4. Prepare sample plate

- Place a 96-well plate onto a pre-chilled 96-well plate cooler.
- Add 24.0 µL of specimen per well.
- Add 24.0 µL of external controls prepared in Step 2 to designated wells.
- Add 4.8 µL of Extraction Buffer to each well, then mix by slowly pipetting up and down 10 times without introducing bubbles. **NOTE:** The addition and mixing of Extraction Buffer can be simplified by using a multi-channel pipette and chilled reagent reservoir.
- Seal and centrifuge the 96-well plate to collect the sample at the bottom of the well.

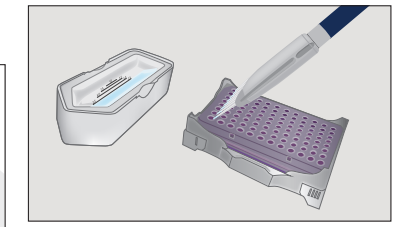


5. Prepare reaction mix

- Determine the number of reactions (N) to be prepared per assay:

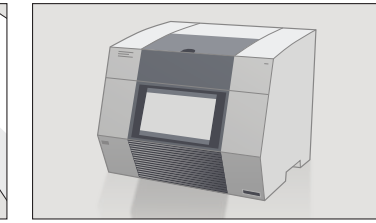
REACTION MIX	1 RXN	100 RXNS	N RXNS
Salt Mix	10.0 µL	1000 µL	N x 10.0 µL
IC/P Mix	1.2 µL	120 µL	N x 1.2 µL
Master Mix	20.0 µL	2000 µL	N x 20.0 µL
Total Volume	31.2 µL	3120 µL	N x 31.2 µL

- In a pre-chilled tube, prepare Reaction Mix by combining the Salt Mix and IC/P Mix to the tube and gently pipette up and down 4 times. Centrifuge briefly.
- Add Master Mix and then gently pipette up and down 10 times. Centrifuge briefly.
- Place back in cold block until use.



6. Prepare amplification plate

- In pre-chilled reagent reservoir transfer reaction mix.
- Add 31.2 µL of reaction mix to each well with specimen 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.



7. Run amplification

NOTE: Final setup for validated thermocyclers (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, Analytik Jena qTOWER^3, or the Agilent Stratagene Mx3005P) is described in the IFU.

- Place the 96-well plate in a validated thermocycler and follow instrument specific protocols and analysis procedures detailed in the Instructions for Use.

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SARS-CoV-2
RNA STAR Complete

Quick Reference Instructions for Deep Well Format

REF L018180501096

IVD

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CUSTOMER SERVICE

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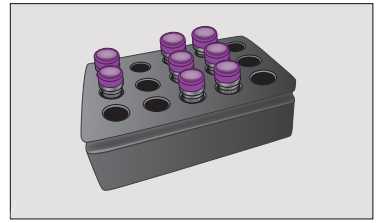
Kit Components (100 reactions)

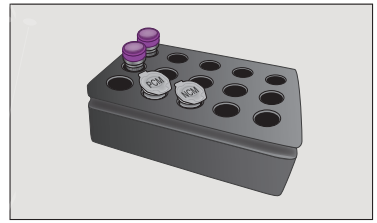
Store at -25°C to -15°C until use

COMPONENT	AMOUNT
Positive Control Media (Pos. Ctl. Med.)	500 µL
Negative Control Media (Neg. Ctl. Med.)	1.5 mL
Salt Mix	1 mL
Extraction Buffer	500 µL
Internal Control/Primer (IC/P) Mix	120 µL
Master Mix	2 x 1 mL



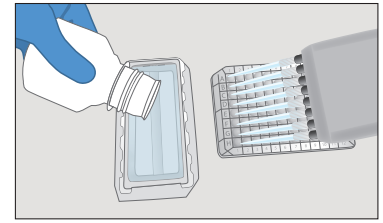
1. Thaw reagents

- Thaw components in a pre-chilled cold block equilibrated between 2 and 8°C. Once thawed, invert the IC/P Mix, Pos. Ctl. Med., Neg. Ctl. Med. and Master Mix to mix then centrifuge for 5 seconds. Once thawed, vigorously vortex the Salt Mix for 20 seconds and centrifuge for 5 seconds to collect reagent at the bottom of tube.



2. Prepare external controls

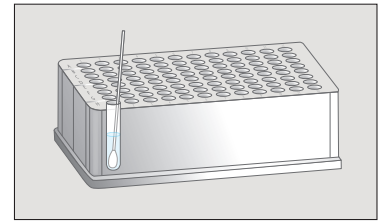
- Prepare fresh 1x Pos. Ctrl. Med. by diluting 20.0 µL Pos. Ctrl. Med. with 60.0 µL Neg. Ctrl. Med. in a pre-chilled microfuge tube.
- Prepare fresh 1x Neg. Ctrl. Med. by transferring 80.0 µL Neg. Ctrl. Med. into a pre-chilled microfuge tube.



3. Prepare deepwell plate

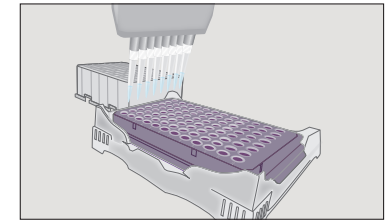
- Pour 100 mL of a compatible media into a reagent reservoir.
- Transfer 1 mL to each deepwell using a multichannel pipette.

NOTE: Leave two designated wells empty for the external controls.



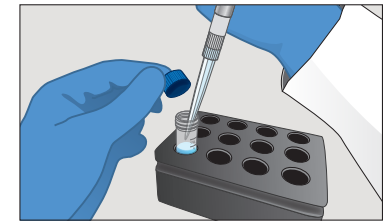
4. Sample preparation

- 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.



5. Prepare sample plate

- Place a 96-well plate onto a pre-chilled 96-well plate cooler.
- Add 24.0 µL of specimen per well.
- Add 24.0 µL of external controls prepared in Step 2 to designated wells.
- In pre-chilled reagent reservoir transfer Extraction Buffer.
- Add 4.8 µL of Extraction Buffer to each well, then mix slowly pipetting up and down 10 times without introducing bubbles.
- Seal and centrifuge the 96-well plate to collect the sample at the bottom of the well.

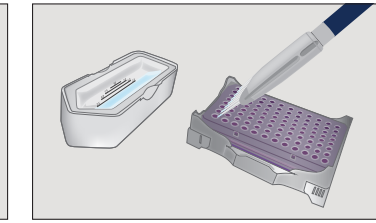


6. Prepare reaction mix

- Determine the number of reactions (N) to be prepared per assay:

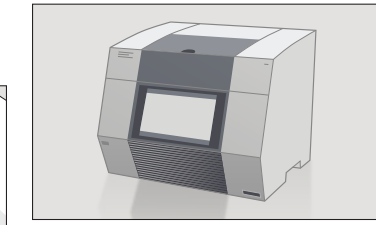
REACTION MIX	1 RXN	100 RXNS	N RXNS
Salt Mix	10.0 µL	1000 µL	N x 10.0 µL
IC/P Mix	1.2 µL	120 µL	N x 1.2 µL
Master Mix	20.0 µL	2000 µL	N x 20.0 µL
Total Volume	31.2 µL	3120 µL	N x 31.2 µL

- In a pre-chilled tube prepare Reaction Mix in the order of the table.
- Combine the Salt Mix and IC/P Mix to the tube and gently pipette up and down 4 times. Centrifuge briefly.
- Add Master Mix and then gently pipette up and down 10 times. Centrifuge briefly.
- Place back in cold block until use.



7. Prepare amplification plate

- In pre-chilled reagent reservoir transfer reaction mix.
- Add 31.2 µL of reaction mix to each well with specimen 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.



8. Run amplification

NOTE: Final setup for validated thermocyclers (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, Analytik Jena qTOWER^3, or the Agilent Stratagene Mx3005P) is described in the IFU.

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SD-COM-ART-00104 R3 REV DATE 2022/07

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SARS-CoV-2
RNA STAR Complete

Quick Reference Instructions for 5 Pooled Swabs/96-Well Format

WARNING: NOT FOR USE WITH 384-WELL RT-PCR SYSTEM CONFIGURATION

REF **L018180501096**

IVD

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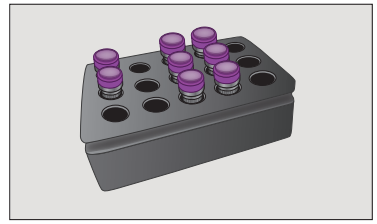
Kit Components (100 reactions)

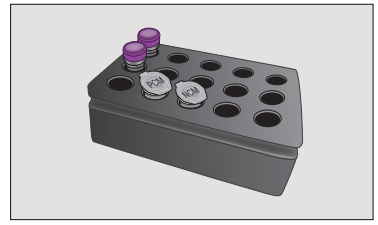
Store at -25°C to -15°C until use

COMPONENT	AMOUNT
Positive Control Media (Pos. Ctl. Med.)	500 µL
Negative Control Media (Neg. Ctl. Med.)	1.5 mL
Salt Mix	1 mL
Extraction Buffer	500 µL
Internal Control/Primer (IC/P) Mix	120 µL
Master Mix	2 x 1 mL



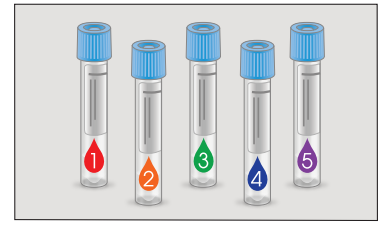
1. Thaw reagents

- Thaw components in a pre-chilled cold block equilibrated between 2 and 8°C. Once thawed, invert the IC/P Mix, Pos. Ctl. Med., Neg. Ctl. Med. and Master Mix to mix then centrifuge for 5 seconds. Once thawed, vigorously vortex the Salt Mix for 20 seconds and centrifuge for 5 seconds to collect reagent at the bottom of tube.



2. Prepare external controls

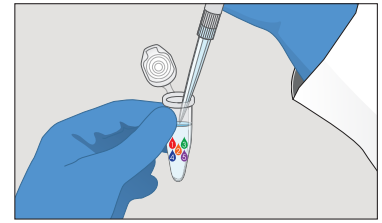
- Prepare fresh 1x Pos. Ctrl. Med. by diluting 20.0 µL Pos. Ctrl. Med. with 60.0 µL Neg. Ctrl. Med. in a pre-chilled microfuge tube.
- Prepare fresh 1x Neg. Ctrl. Med. by transferring 80.0 µL Neg. Ctrl. Med. into a pre-chilled microfuge tube.



3. Sample preparation

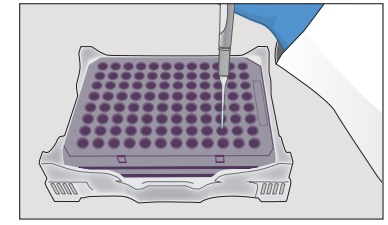
1. Dry Swabs - If swabs are provided dry, transfer 700 µl to 1mL of a compatible transport media into a microcentrifuge tube. Place and soak the swab for at least 30 seconds then swirl thoroughly by rotating the swab against the side of the tube up to 5 times. Express the swab on the side of tube, outside of the liquid, prior to removing (beware of cross-contamination from splashing). Discard the swab in biohazard waste. **WARNING:** No more than 1mL must be used for rehydration when samples are pooled.

2. Wet Swab - If swab sample is provided wet, 700 µL to 1mL of compatible transport media (VTM, 0.85% Saline, or PBS) is recommended, higher volumes of media may impact sensitivity.



4. Prepare a pool of 5 samples

- Combining 50 µL each, from 5 collected samples described above, into a clean microcentrifuge tube to produce a 5-sample pool totaling 250 µL.
- Vortex each sample pool micro-centrifuge tube to mix.
- Centrifuge for 5 seconds to collect reagents at the bottom of the tube.



5. Prepare sample plate

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- Add 24.0 µL of specimen per well.
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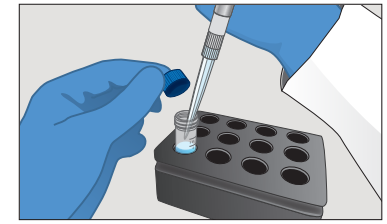
- Add 4.8 µL of Extraction Buffer to each well, then mix by slowly pipetting up and down 10 times without introducing bubbles. **NOTE:** The addition and mixing of Extraction Buffer can be simplified by using a multi-channel pipette and chilled reagent reservoir.
- Seal and centrifuge the 96-well plate to collect the sample at the bottom of the well.



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Salt Mix	10.0 µL	1000 µL	N x 10.0 µL
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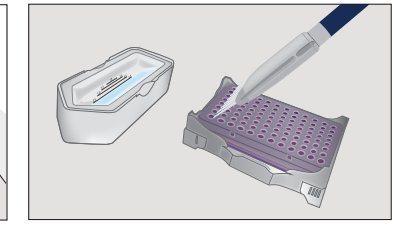
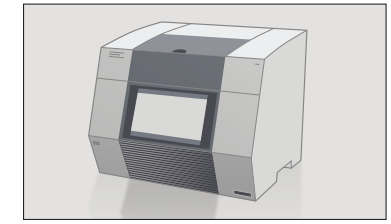
Master Mix	20.0 µL	2000 µL	N x 20.0 µL
Total Volume	31.2 µL	3120 µL	N x 31.2 µL

- In a pre-chilled tube, prepare Reaction Mix by combining the Salt Mix and IC/P Mix to the tube and gently pipette up and down 4 times. Centrifuge briefly.
- Add Master Mix and then gently pipette up and down 10 times. Centrifuge briefly.
- Place back in cold block until use.



7. Prepare amplification plate

- In pre-chilled reagent reservoir transfer reaction mix.
- Add 31.2 µL of reaction mix to each well with specimen 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.



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SARS-CoV-2 RNA STAR Complete

Quick Reference Instructions for Single Swab Format Lightcycler 480 II - 384

REF L0181805013 84

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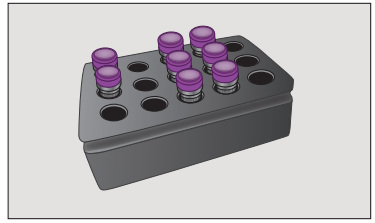
Positive Control Media (Pos. Ctl. Med.)	500 µL
Negative Control Media (Neg. Ctl. Med.)	1.5 mL
Salt Mix	2 mL
Extraction Buffer	1 mL
Internal Control/Primer (IC/P) Mix	240 µL
Master Mix	2 x 2 mL



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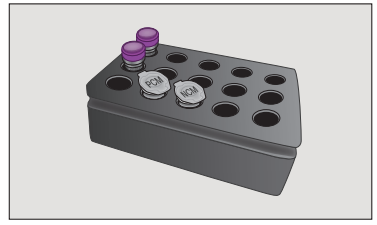
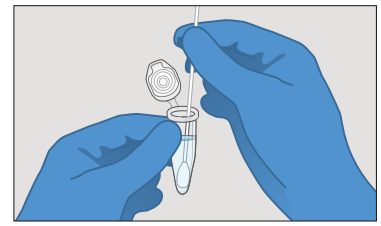


2. Prepare external controls

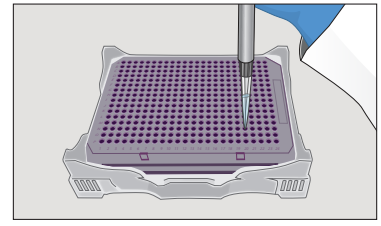
- Prepare fresh 1x Pos. Ctrl. Med. by diluting 20.0 µL Pos. Ctrl. Med. with 20.0 µL Neg. Ctrl. Med. in a pre-chilled microfuge tube.
- Prepare fresh 1x Neg. Ctrl. Med. by transferring 80.0 µL Neg. Ctrl. Med. into a pre-chilled microfuge tube.



3. Sample preparation

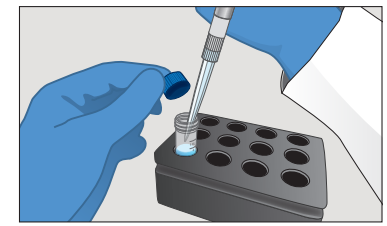
1. Dry Swab - If swab is provided dry, transfer one (1) mL of a compatible transport media into a suitable tube (e.g. polypropylene microcentrifuge tube). Place and soak the swab for at least 30 seconds then swirl thoroughly by rotating the swab against the side of the tube up to 5 times. Express the 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.

2. Wet Swab - If swab specimen 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.



4. Prepare sample plate

- Place a 384-well plate onto a pre-chilled 384-well plate cooler.
- Add 12.0 µL of specimen per well.
- Add 12.0 µL of external controls prepared in Step 2 to designated wells.
- Add 2.4 µL of Extraction Buffer to each well, then mix by slowly pipetting up and down 10 times without introducing bubbles. **NOTE:** The addition and mixing of Extraction Buffer can be simplified by using a multi-channel pipette and chilled reagent reservoir.
- Seal and centrifuge the 384-well plate to collect the sample at the bottom of the well.

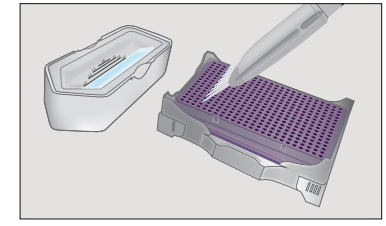


5. Prepare reaction mix

- Determine the number of reactions (N) to be prepared per assay:

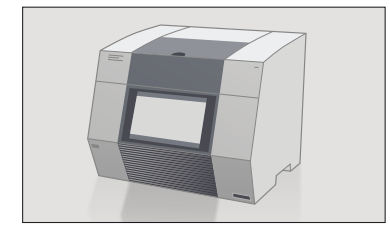
REACTION MIX	1 RXN	400 RXNS	N RXNS
Salt Mix	5.0 µL	2000 µL	N x 5.0 µL
IC/P Mix	0.6 µL	240 µL	N x 0.6 µL
Master Mix	10.0 µL	4000 µL	N x 10.0 µL
Total Volume	15.6 µL	6240 µL	N x 15.6 µL

- In a pre-chilled tube, prepare Reaction Mix by combining the Salt Mix and IC/P Mix to the tube and gently pipette up and down 4 times. Centrifuge briefly.
- Add Master Mix and then gently pipette up and down 10 times. Centrifuge briefly.
- Place back in cold block until use.



6. Prepare amplification plate

- In pre-chilled reagent reservoir transfer reaction mix.
- Add 15.6 µL of reaction mix to each well with specimen and external controls. 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.



7. Run amplification

NOTE: Final setup for validated thermocyclers (i.e. Lightcycler 480 II-384, is described in the IFU).

- Place the 384-well plate in a validated thermocycler and follow instrument specific protocols and analysis procedures detailed in the Instructions for Use.

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lumiraDx™
Fast Lab Solutions

SARS-CoV-2
RNA STAR Complete

Quick Reference Instructions for Single Swab Format QS5 and QS7 Flex - 384

REF L018180501384

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 SARS-CoV-2 RNA STAR Complete before running any samples. Users should refer to the LumiraDx SARS-CoV-2 RNA 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.

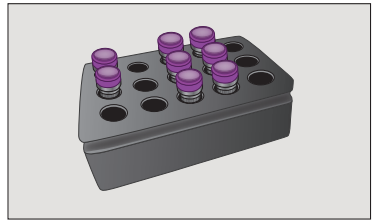
CUSTOMER SERVICE

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

Kit Components (400 reactions)

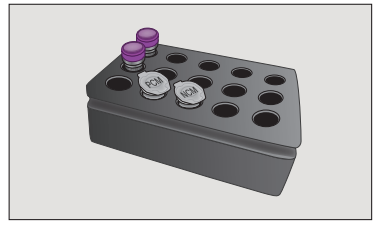
Store at -25°C to -15°C until use

COMPONENT	AMOUNT
Positive Control Media (Pos. Ctl. Med.)	500 µL
Negative Control Media (Neg. Ctl. Med.)	1.5 mL
Salt Mix	2 mL
Extraction Buffer	1 mL
Internal Control/Primer (IC/P) Mix	240 µL
Master Mix	2 x 2 mL



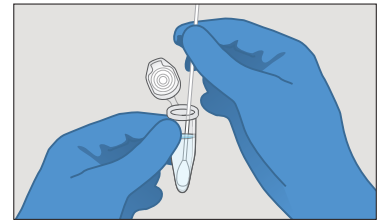
1. Thaw reagents

- Thaw components in a pre-chilled cold block equilibrated between 2 and 8°C. Once thawed, invert the IC/P Mix, Pos. Ctl. Med., Neg. Ctl. Med. and Master Mix to mix then centrifuge for 5 seconds. Once thawed, vigorously vortex the Salt Mix for 20 seconds and centrifuge for 5 seconds to collect reagent at the bottom of tube.



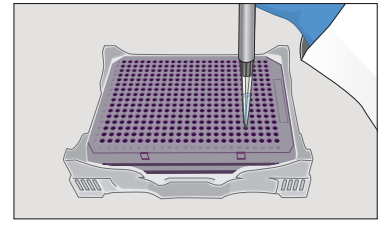
2. Prepare external controls

- Prepare fresh 1x Pos. Ctrl. Med. by diluting 20.0 µL Pos. Ctrl. Med. with 20.0 µL Neg. Ctrl. Med. in a pre-chilled microfuge tube.
- Prepare fresh 1x Neg. Ctrl. Med. by transferring 80.0 µL Neg. Ctrl. Med. into a pre-chilled microfuge tube.



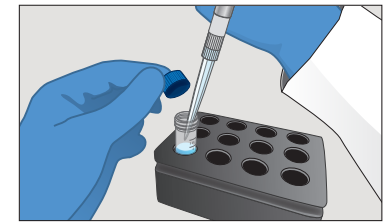
3. Sample preparation

1. 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.
2. Wet Swab - If swab specimen 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.



4. Prepare sample plate

- Place a 384-well plate onto a pre-chilled 384-well plate cooler.
- Add 10.0 µL of specimen per well.
- Add 10.0 µL of external controls prepared in Step 2 to designated wells.
- Add 2.0 µL of Extraction Buffer to each well, then mix by slowly pipetting up and down 10 times without introducing bubbles. **NOTE:** The addition and mixing of Extraction Buffer can be simplified by using a multi-channel pipette and chilled reagent reservoir.
- Seal and centrifuge the 384-well plate to collect the sample at the bottom of the well.

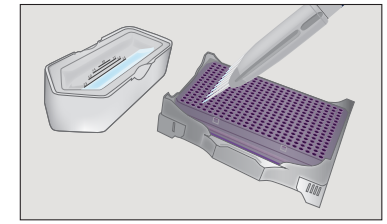


5. Prepare reaction mix

- Determine the number of reactions (N) to be prepared per assay:

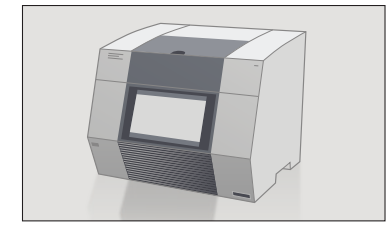
REACTION MIX	1 RXN	400 RXNS	N RXNS
Salt Mix	4.2 µL	1680 µL	N x 4.2 µL
IC/P Mix	0.5 µL	200 µL	N x 0.5 µL
Master Mix	8.3 µL	3320 µL	N x 8.3 µL
Total Volume	13.0 µL	5200 µL	N x 13.0 µL

- In a pre-chilled tube, prepare Reaction Mix by combining the Salt Mix and IC/P Mix to the tube and gently pipette up and down 4 times. Centrifuge briefly.
- Add Master Mix and then gently pipette up and down 10 times. Centrifuge briefly.
- Place back in cold block until use.



6. Prepare amplification plate

- In pre-chilled reagent reservoir transfer reaction mix.
- Add 13.0 µL of reaction mix to each well with specimen and external controls. 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.



7. Run amplification

NOTE: Final setup for validated thermocyclers (i.e. ABI QS5 384, ABI QS7 Flex 384 is described in the IFU).

- Place the 384-well plate in a validated thermocycler and follow instrument specific protocols and analysis procedures detailed in the Instructions for Use.

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