ScienCell™ Research Laboratories

REF RX7038, RX7048

100 Specimens

℞ Only

IVD

ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit

For Emergency Use Authorization (EUA) Only

Instructions for Use

Intended Use

ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit is a real-time RT-PCR test intended for the qualitative detection of nucleic acids from the SARS-CoV-2 in nasal, nasopharyngeal, oropharyngeal swab specimens, and bronchoalveolar lavage from individuals suspected of COVID-19 by their healthcare provider. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §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 nasal, nasopharyngeal, oropharyngeal swab specimens, and bronchoalveolar lavage 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. 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.

The ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit is intended for use by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and *in vitro* diagnostic procedures. The ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit is only for use under the Food and Drug Administration's Emergency Use Authorization.

Summary and Explanation

The ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit is a molecular *in vitro* diagnostic test that aids in the detection of SARS-CoV-2 RNA and is based on widely used nucleic acid amplification technology and the standard hydrolysis probe system known as TaqMan® Technology, with primer/probe sets listed below. Each probe contains double quenchers (ZEN and 3IABkFQ).

RX7038-N1, RX7038-N2, and RX7038-RP primer/probe sets in ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit (catalog #RX7038)

RX7038-N1 primer/probe set	***Forward***: GAC CCC AAA ATC AGC GAA AT ***Reverse***: TCT GGT TAC TGC CAG TTG AAT CTG ***Probe***: FAM-ACC CCG CAT-ZEN-TAC GTT TGG TGG ACC-3IABkFQ
RX7038-N2 primer/probe set	***Forward***: TTA CAA ACA TTG GCC GCA AA ***Reverse***: GCG CGA CAT TCC GAA GAA ***Probe***: FAM-ACA ATT TGC-ZEN-CCC CAG CGC TTC AG-3IABkFQ
RX7038-RP primer/probe set	***Forward***: AGA TTT GGA CCT GCG AGC G ***Reverse***: GAG CGG CTG TCT CCA CAA GT ***Probe***: FAM-TTC TGA CCT-ZEN-GAA GGC TCT GCG CG-3IABkFQ

Multiplex primer/probe sets in ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit (catalog #RX7048)

N1-FAM primer/probe set	***Forward***: GAC CCC AAA ATC AGC GAA AT ***Reverse***: TCT GGT TAC TGC CAG TTG AAT CTG ***Probe***: FAM-ACC CCG CAT-ZEN-TAC GTT TGG TGG ACC-3IABkFQ
N2-FAM primer/probe set	***Forward***: TTA CAA ACA TTG GCC GCA AA

	Reverse: GCG CGA CAT TCC GAA GAA ***Probe***: FAM-ACA ATT TGC-ZEN-CCC CAG CGC TTC AG-3IABkFQ
RP-HEX primer/probe set	***Forward***: AGA TTT GGA CCT GCG AGC G ***Reverse***: GAG CGG CTG TCT CCA CAA GT ***Probe***: HEX-TTC TGA CCT-ZEN-GAA GGC TCT GCG CG-3IABkFQ

Principles of the Procedure

The primer/probe sets (catalog #RX7038-N1 and #RX7038-N2, or N1-FAM and N2-FAM) target coronavirus SARS-CoV-2 nucleocapsid (N) gene, and the other one (catalog #RX7038-RP, or #RP-HEX) targets human RPP30 gene and serves as an internal control to assess specimen quality. In addition, a non-infectious positive control and nuclease-free water are included in the kit. The non-infectious positive control also serves as an RNA extraction procedural control.

RNA isolated from respiratory specimens is purified with Viral RNA Isolation Kit (ScienCell, catalog #MB891) or QIAamp® DSP Viral RNA Mini kit (Qiagen, catalog #61904) following manufacturer's procedures. Purified RNA is subsequently reverse transcribed to cDNA and amplified in Roche LightCycler® 96 Real-Time PCR System with LightCycler® Software 1.01.01.0050 using One-Step TaqProbe RT-qPCR Master Mix (catalog #MB802a). In the qPCR process, the primers and the probe anneal to target cDNA sequences with the probe located between the forward and reverse primers. During the extension step of each PCR cycle, while elongating the primers, the 5' nuclease activity of Taq polymerase degrades the probe, causing the FAM or HEX reporter dye to separate from the quenchers (ZEN and 3IABkFQ), generating a measurable fluorescent signal. Fluorescence intensity is quantified at each PCR cycle by Roche LightCycler® 96 Real-Time PCR System with LightCycler® Software 1.01.01.0050.

Materials Required (Provided)

ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit (catalog #RX7038) - Singleplex kit

Catalog #	Component	Quantity
MB802a	One-Step TaqProbe RT-qPCR Mater Mix, 4x	1.5 mL
RX7038-N1	N gene primer/probe set 1, lyophilized	1 nmole of each primer, 0.25 nmoles of probe per vial (100 reactions). Dissolving in 200 µL of H_2O yields 5µM of each primer and 1.25 µM of probe. Final concentration in each RT-qPCR reaction is 500 nM of each primer and 125 nM of probe.
RX7038-N2	N gene primer/probe set 2, lyophilized	1 nmole of each primer, 0.25 nmoles of probe per vial (100 reactions). Dissolving in 200 µL of H_2O yields 5µM of each primer and 1.25 µM of probe. Final concentration in each RT-qPCR reaction is 500 nM of each primer and 125 nM of probe.
RX7038-RP	Human RPP30 gene primer/probe set, lyophilized	1 nmole of each primer, 0.25 nmoles of probe per vial (100 reactions). Dissolving in 200 µL of H_2O yields 5µM of each primer and 1.25 µM of probe. Final concentration in each RT-qPCR reaction is 500 nM of each primer and 125 nM of probe.
RX7038-H2O	Nuclease-free H_2O	8 mL
RX7038-Pos	Positive control (non-infectious RNA spiked into human small airway epithelial cells)	200 µL, RNA: 500 – 1,000 copies/µL Cells: 200-300 counts /µL

ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit (catalog #RX7048) – Multiplex kit

Catalog #	Component	Quantity
MB802a	One-Step TaqProbe RT-qPCR Mater Mix, 4x	1.5 mL
RX7048-MPP	Multiplex primer/probe sets consisting of N gene primer/probe set 1, N gene primer/probe set 2, Human RPP30 gene primer/probe set, Lyophilized	1 nmole of each primer, 0.25 nmoles of probe per vial (100 reactions). Dissolving in 600 µL of H_2O yields 5µM of each primer and 1.25 µM of probe. Final concentration in each RT-qPCR reaction is 500 nM of each primer and 125 nM of probe.
RX7048-H2O	Nuclease-free H_2O	4 mL
RX7048-Pos	Positive control (non-infectious RNA spiked into human small airway epithelial cells)	200 µL, RNA: 500 – 1,000 copies/µL Cells: 200-300 counts /µL

Materials Required (Not Supplied)

RNA Extraction Options

Manufacturer	Extraction Kit	Catalog #
ScienCell	Viral RNA Isolation Kit	MB891
Qiagen	QIAamp® DSP Viral RNA Mini kit	61904

Equipment and Consumables

- LightCycler® 96 Real-Time PCR System with LightCycler® Software 1.01.01.0050 (Roche, catalog #05815916001)
- Vortex mixer
- Microcentrifuge
- Micropipettes (2 or 10 µL, 200 µL and 1000 µL)
- Multichannel micropipettes (5-50 µl)
- Racks for 1.5 mL microcentrifuge tubes
- 2 x 96-well -20°C cold blocks
- 96-well PCR reaction plates (Roche, catalog #04729692001)
- LightCycler® 8-Tube Strips (white) (Roche, catalog #06612601001)
- Aerosol barrier pipette tips
- 1.5 mL microcentrifuge tubes (DNase/RNase free)
- Disposable powder-free gloves and surgical gowns
- 10% bleach (1:10 dilution of commercial 5.25-6.0% hypochlorite bleach)
- DNAZap™ (Ambion, catalog #AM9890) or equivalent
- RNAse Away™ (Fisher Scientific, catalog #21-236-21) or equivalent

Warnings and Precautions

- For use under an Emergency Use Authorization (EUA) only.
- For *in vitro* diagnostic use (IVD).
- For prescription use only.

- The ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit has not been FDA cleared or approved; the test has been authorized by FDA under an Emergency Use Authorization (EUA) for use by laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C. §263a, and meet the requirements to perform high complexity tests.
- The ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- The ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit 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 authorization is terminated or revoked sooner.
- Handle all specimens as if infectious using safe laboratory procedures. Refer to CDC Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with SARS-CoV-2 https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html.
- Proper personal protective equipment including lab coats, gowns, gloves, eye protection, and a biological safety cabinet are recommended for manipulation of clinical specimens. Refer to CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition https://www.cdc.gov/labs/BMBL.html.
- Perform all manipulations of live virus samples within a Class II (or higher) biological safety cabinet (BSC).
- Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.
- PCR-based detection technologies are sensitive to accidental contamination of previous PCR products. False positive results could occur if either the clinical specimen or the real-time reagents become contaminated.
    - Perform for assay setup and handling of nucleic acids in separate areas. Workflow in the laboratory should proceed in a unidirectional manner. Use separate and dedicated equipment and supplies in each area.
    - Do not substitute or mix reagent from different kit lots or from other manufacturers.
    - Only use aerosol barrier pipette tips and change tips between liquid transfers.
    - Good laboratory techniques should be followed to minimize the risk of cross-contamination between samples, and the inadvertent introduction of nucleases into samples. Proper aseptic technique should always be used when working with nucleic acids.
    - Wear a clean lab coat and powder-free disposable gloves when setting up assays, and change gloves between samples and whenever contamination is suspected.
    - Keep reagent and reaction tubes capped or covered as much as possible.
    - Work surfaces, pipettes, and centrifuges should be cleaned and decontaminated with cleaning products such as 10% bleach, “DNAZap™” or “RNase AWAY®” to minimize risk of nucleic acid contamination. Residual bleach should be removed using 70% ethanol.
- Dispose of unused kit reagents and human specimens according to local, state, and federal regulations.

Reagent Storage, Handling, and Stability

- Handle all specimens as if infectious using safe laboratory procedures. Refer to CDC Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with SARS-CoV-2 https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html.
- Upon receipt, store the one-step TaqProbe RT-qPCR master mix (catalog #MB802a) and primer/probe sets (catalog #RX7038-N1, RX7038-N2, and RX7038-RP, or catalog #RX7048-MPP) at -20°C in a manual defrost freezer, the positive control (catalog #RX7038-Pos or catalog #RX7048-Pos) at -80°C, and nuclease-free H_2O (catalog #RX7038-H2O or catalog #RX7048-H2O) at 4°C until ready to use.
- Do not use the kit after the indicated expiry date.

- Aliquot primer/probe sets as needed once rehydrated. Do not freeze-and-thaw primer/probe set for more than once.
- Protect primer/probe sets, lyophilized or rehydrated, from light.
- Keep Primers, probes (including aliquots), control samples, RNA, and enzyme master mix cold at all times during preparation and use.

Specimen Collection, Handling, and Storage

- Human nasal, nasopharyngeal, oropharyngeal swab specimens, and bronchoalveolar lavage may be used with the ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit.
- Inadequate or inappropriate specimen collection, storage, and transport are likely to yield false test results. Training in specimen collection is highly recommended due to the importance of specimen quality. CLSI MM13-A may be referenced as an appropriate resource.
- Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Patients Under Investigation (PUIs) for 2019 Novel Coronavirus (2019-nCoV) **https://www.cdc.gov/coronavirus/2019-nCoV/guidelines-clinical-specimens.html**
- 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.
- Specimens can be stored at 2-8 °C for up to 72 hours after collection. If a delay in extraction is expected, store specimens at -80 °C.
- Extracted nucleic acid should be stored at -80 °C.

Reagent and Controls Preparation

ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit (catalog #RX7038)

No Template Control (NTC) Preparation:

1. NTC is nuclease-free H_2O (catalog #RX7038-H2O).
2. Aliquot in small volumes (approximately 900 µl each).

Primer/probe Set Preparation:

1. Upon receipt, store lyophilized primer/probe sets at -20 °C.
2. Prior to use, allow the primer/probe sets (catalog #RX7038-N1, RX7038-N2, and RX7038-RP) to warm to room temperature in the dark.
3. Centrifuge the vials at 1,500x g for 1 minute.
4. Add 200 µl nuclease-free H_2O (catalog #RX7038-H2O) to N gene primer/probe set 1 (lyophilized, catalog #RX7038-N1) and allow to rehydrate for 15 min at room temperature to make N1 primer/probe stock solution. Aliquot as needed. Store at -20°C in a manual defrost freezer. Avoid repeated freeze-and-thaw cycles. Maintain cold and in the dark when thawed.
5. Add 200 µl nuclease-free H_2O (catalog #RX7038-H2O) to N gene primer/probe set 2 (lyophilized, catalog #RX7038-N2) and allow to rehydrate for 15 min at room temperature to make N2 primer/probe stock solution. Aliquot as needed. Store at -20°C in a manual defrost freezer. Avoid repeated freeze-and-thaw cycles. Maintain cold and in the dark when thawed.
6. Add 200 µl nuclease-free H_2O (catalog #RX7038-H2O) to Human RPP30 gene primer/probe set (lyophilized, catalog #RX7038-RP) and allow to rehydrate for 15 min at room temperature to make RP primer/probe stock solution. Aliquot as needed. Store at -20°C in a manual defrost freezer. Avoid repeated freeze-and-thaw cycles. Maintain cold and in the dark when thawed.

Positive Control Preparation:

1. Positive control (catalog #RX7038-POS) is non-infectious RNA spiked into human small airway epithelial cells.
2. Aliquot in small volumes (approximately 18 µL each), and store at -80°C. Do not freeze-and-thaw for more than once.

ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit (catalog #RX7048)

No Template Control (NTC) Preparation:

1. NTC is nuclease-free H_2O (catalog #RX7048-H2O).
2. Aliquot in small volumes (approximately 600 µl each).

Primer/probe Set Preparation:

1. Upon receipt, store lyophilized primer/probe sets at -20 °C.
2. Prior to use, allow the multiplex primer/probe sets (catalog #RX7048-MPP) to warm to room temperature in the dark.
3. Centrifuge the vials at 1,500x g for 1 minute.
4. Add 600 µl nuclease-free H_2O (catalog #RX7048-H2O) to the multiplex primer/probe sets (catalog #RX7048-MPP) and allow to rehydrate for 15 min at room temperature to make multiplex primer/probe stock solution. Aliquot as needed. Store at -20°C in a manual defrost freezer. Avoid repeated freeze-and-thaw cycles. Maintain cold and in the dark when thawed.

Positive Control Preparation:

1. Positive control (catalog #RX7048-POS) is non-infectious RNA spiked into human small airway epithelial cells.
2. Aliquot in small volumes (approximately 10 µL each), and store at -80°C. Do not freeze-and-thaw for more than once.

Nucleic Acid Extraction

For RNA extraction from human specimens, we recommend using Viral RNA Isolation Kit (ScienCell, catalog #MB891) or QIAamp® DSP Viral RNA Mini kit (Qiagen, catalog #61904) and following manufacturer's protocol.

Assay Set Up

ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit (catalog #RX7038)

1. Clean and decontaminate all work surfaces, pipettes, centrifuges, and other equipment prior to use to minimize the risk of nucleic acid cross-contamination.
2. In the reagent set-up clean area, thaw primer/probe sets, one-step RT-qPCR master mix and place them on ice or cold-block. Mix well by inversion 5 times. ***Do not vortex***.
3. Briefly spin them for 5 seconds, followed by placing them and H_2O on ice or cold-block. Keep cold during preparation and use.
4. Label one 1.5 mL microcentrifuge tube for each primer/probe set.
5. Determine the number of reactions (N) to set up per test run. It is necessary to make excess reaction mix for the two control samples, the non-infectious positive control (catalog #RX7038-Pos) and H_2O (catalog #RX7038-H2O) as the No Template Control (NTC). Use the following guide to determine N:
   a. If number of samples (n) including controls equals 3 through 12, then N = n + 1
   b. If number of samples (n) including controls equals 13 through 24, then N = n + 2
   c. If number of samples (n) including controls is 25 through 32, then N = n + 3. One 96-well plate can hold up to 32 samples.

6. For each primer/probe set, calculate the amount of each reagent to be added for each reaction mixture (N = # of reactions) as shown in the table below. Add reagents into each respectively labeled 1.5 mL microcentrifuge tube. Mix reaction mixtures by pipetting up and down. ***Do not vortex.*** Centrifuge for 5 seconds to collect contents at the bottom of the tube, and then place the tubes in a cold rack.

Reagent	**Volume of Reagent Added**
Primer/probe stock solution (N1, N2, or RP)	N x 2 µl
One-step RT-qPCR Master mix, 4x (catalog #MB802a)	N x 5 µl
Nuclease-free H_2O (catalog #RX7038-H2O)	N x 8 µl
Total volume	***N x 15 µl***

7. For each control sample and test specimen, three RT-qPCR reactions need to be prepared, one with N1 primer/probe stock solution, one with N2 primer/probe stock solution, and one with RP primer/probe stock solution. Dispense 15 µL of each reaction mixture into the appropriate wells going across the column as the example shown below.

Example of Reaction Mixture Plate Set-Up for 28 samples

	1	2	3	4	5	6	7	8	9	10	11	12
A	N1	N2	RP	N1	N2	RP	N1	N2	RP	N1	N2	RP
B	N1	N2	RP	N1	N2	RP	N1	N2	RP	N1	N2	RP
C	N1	N2	RP	N1	N2	RP	N1	N2	RP	N1	N2	RP
D	N1	N2	RP	N1	N2	RP	N1	N2	RP	N1	N2	RP
E	N1	N2	RP	N1	N2	RP	N1	N2	RP			
F	N1	N2	RP	N1	N2	RP	N1	N2	RP			
G	N1	N2	RP	N1	N2	RP	N1	N2	RP			
H	N1	N2	RP	N1	N2	RP	N1	N2	RP			

8. Prior to moving to the nucleic acid handling area, prepare the No Template Control (NTC) reactions for row #A in the reagent set-up clean area by pipetting 5 µL of nuclease-free water into the NTC sample wells as the example shown below. Securely cap NTC wells before proceeding.

	1	2	3	4	5	6	7	8	9	10	11	12
A	NTC	NTC	NTC									
B												
C												
D												
E												
F												

G												
H												

9. Cover the entire reaction plate and move the reaction plate to the specimen nucleic acid handling area.
10. Gently vortex nucleic acid sample tubes for approximately 5 seconds.
11. Centrifuge for 5 seconds to collect contents at the bottom of the tube.
12. After centrifugation, place extracted nucleic acid sample tubes in the cold rack.
13. Samples should be added to wells to the specific assay that is being tested as illustrated in the table below. Carefully pipette 5 µL of the first sample into all the wells labeled for that sample (i.e. Sample "S1" down row #B). Keep other sample wells covered during addition. Change tips after each addition.

	1	2	3	4	5	6	7	8	9	10	11	12
A	NTC	NTC	NTC	S8	S8	S8	S16	S16	S16	S24	S24	S24
B	S1	S1	S1	S9	S9	S9	S17	S17	S17	S25	S25	S25
C	S2	S2	S2	S10	S10	S10	S18	S18	S18	S26	S26	S26
D	S3	S3	S3	S11	S11	S11	S19	S19	S19			
E	S4	S4	S4	S12	S12	S12	S20	S20	S20			
F	S5	S5	S5	S13	S13	S13	S21	S21	S21			
G	S6	S6	S6	S14	S14	S14	S22	S22	S22			
H	S7	S7	S7	S15	S15	S15	S23	S23	S23			

14. Securely cap the wells to which the sample has been added to prevent cross contamination and to ensure sample tracking.
15. Change gloves often and when necessary to avoid contamination.
16. Repeat steps #13 and #14 for the remaining samples.
17. Cover the entire reaction plate and move the reaction plate to the positive template control handling area.
18. Pipette 5 µL of the non-infectious positive control (catalog #RX7038-Pos) to the sample wells of shown in the table below. Securely cap wells after addition of the positive control.
    NOTE: If using 8-tube strips, label the TAB of each strip to indicate sample position. **DO NOT LABEL THE TOPS OF THE REACTION TUBES!**

	1	2	3	4	5	6	7	8	9	10	11	12
A	NTC	NTC	NTC	S8	S8	S8	S16	S16	S16	S24	S24	S24
B	S1	S1	S1	S9	S9	S9	S17	S17	S17	S25	S25	S25
C	S2	S2	S2	S10	S10	S10	S18	S18	S18	S26	S26	S26
D	S3	S3	S3	S11	S11	S11	S19	S19	S19	Pos	Pos	Pos
E	S4	S4	S4	S12	S12	S12	S20	S20	S20			
F	S5	S5	S5	S13	S13	S13	S21	S21	S21			
G	S6	S6	S6	S14	S14	S14	S22	S22	S22			
H	S7	S7	S7	S15	S15	S15	S23	S23	S23			

19. Briefly centrifuge reaction plate or strips for 30 seconds at 500 x g, 4°C. After centrifugation return to cold

rack.

20. Setup RT-qPCR reactions as shown in the table below.
    Instrument settings for RT-qPCR reactions. Fluorescence data (FAM) should be collected during the data acquisition step.

Step	Temperature	Time	Number of cycles
UNG incubation	25°C	2 min	1
Reverse transcription	50°C	15 min	1
Enzyme activation	95°C	2 min	1
Denaturation	95°C	3 sec	45
Annealing and extension	55°C	30 sec	
Data acquisition	Plate read, detector (FAM)		

ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit (catalog #RX7048)

1. Clean and decontaminate all work surfaces, pipettes, centrifuges, and other equipment prior to use to minimize the risk of nucleic acid cross-contamination.
2. In the reagent set-up clean area, thaw primer/probe sets, one-step RT-qPCR master mix and place them on ice or cold-block. Mix well by inversion 5 times. ***Do not vortex***.
3. Briefly spin them for 5 seconds, followed by placing them and H_2O on ice or cold-block. Keep cold during preparation and use.
4. Label one 1.5 mL microcentrifuge tube for reaction mixture (RM).
5. Determine the number of reactions (N) to set up per test run. It is necessary to make excess reaction mix for the two control samples, the non-infectious positive control (catalog #RX7048-Pos) and H_2O (catalog #RX7048-H2O) as the No Template Control (NTC). Use the following guide to determine N:
   a. If number of samples (n) including controls equals 3 through 12, then N = n + 1
   b. If number of samples (n) including controls equals 13 through 24, then N = n + 2
   c. If number of samples (n) including controls equals 25 through 36, then N = n + 3
   d. If number of samples (n) including controls equals 37 through 48, then N = n + 4
   e. If number of samples (n) including controls equals 49 through 60, then N = n + 5
   f. If number of samples (n) including controls equals 61 through 72, then N = n + 6
   g. If number of samples (n) including controls equals 73 through 84, then N = n + 7
   h. If number of samples (n) including controls equals 85 through 96, then N = n + 8. One 96-well plate can hold up to 96 samples.
6. Calculate the amount of each reagent to be added for each reaction mixture (N = # of reactions) as shown in the table below. Add reagents into the labeled 1.5 mL microcentrifuge tube. Mix reaction mixtures by pipetting up and down. ***Do not vortex.*** Centrifuge for 5 seconds to collect contents at the bottom of the tube, and then place the tube in a cold rack.

Reagent	Volume of Reagent Added
Multiplex primer/probe stock solution (MPP)	N x 6 µl
One-step RT-qPCR Master mix, 4x (catalog #MB802a)	N x 5 µl
Nuclease-free H_2O (catalog #RX7048-H2O)	N x 4 µl
Total volume	***N x 15 µl***

7. For each control sample and test specimen, one RT-qPCR reaction needs to be prepared. Dispense 15 µL of the reaction mixture (RM) into the appropriate wells going across the column as the example shown below.

Example of Reaction Mixture (RM) Plate Set-Up for 26 samples

	1	2	3	4	5	6	7	8	9	10	11	12
A	RM	RM	RM	RM								
B	RM	RM	RM	RM								
C	RM	RM	RM	RM								
D	RM	RM	RM	RM								
E	RM	RM	RM									
F	RM	RM	RM									
G	RM	RM	RM									
H	RM	RM	RM									

8. Prior to moving to the nucleic acid handling area, prepare the No Template Control (NTC) reaction for well #A1 in the reagent set-up clean area by pipetting 5 µL of nuclease-free water into the NTC sample well as the example shown below. Securely cap NTC well before proceeding.

	1	2	3	4	5	6	7	8	9	10	11	12
A	NTC											
B												
C												
D												
E												
F												
G												
H												

9. Cover the entire reaction plate and move the reaction plate to the specimen nucleic acid handling area.
10. Gently vortex nucleic acid sample tubes for approximately 5 seconds.
11. Centrifuge for 5 seconds to collect contents at the bottom of the tube.
12. After centrifugation, place extracted nucleic acid sample tubes in the cold rack.
13. Samples should be added to wells to the specific assay that is being tested as illustrated in the table below. Carefully pipette 5 µL of the sample into the well labeled for that sample (i.e. Sample “S1” down row #B). Keep other sample wells covered during addition. Change tips after each addition.

	1	2	3	4	5	6	7	8	9	10	11	12
A	NTC	S8	S16	S24								

B	**S1**	**S9**	**S17**	**S25**								
C	**S2**	**S10**	**S18**	**S26**								
D	**S3**	**S11**	**S19**									
E	**S4**	**S12**	**S20**									
F	**S5**	**S13**	**S21**									
G	**S6**	**S14**	**S22**									
H	**S7**	**S15**	**S23**									

14. Securely cap the wells to which the sample has been added to prevent cross contamination and to ensure sample tracking.
15. Change gloves often and when necessary to avoid contamination.
16. Repeat steps #13 and #14 for the remaining samples.
17. Cover the entire reaction plate and move the reaction plate to the positive template control handling area.
18. Pipette 5 µL of the non-infectious positive control (catalog #RX7048-Pos) to the sample well of shown in the table below. Securely cap wells after addition of the positive control.
    NOTE: If using 8-tube strips, label the TAB of each strip to indicate sample position. **DO NOT LABEL THE TOPS OF THE REACTION TUBES!**

	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
A	**NTC**	**S8**	**S16**	**S24**								
B	**S1**	**S9**	**S17**	**S25**								
C	**S2**	**S10**	**S18**	**S26**								
D	**S3**	**S11**	**S19**	**Pos**								
E	**S4**	**S12**	**S20**									
F	**S5**	**S13**	**S21**									
G	**S6**	**S14**	**S22**									
H	**S7**	**S15**	**S23**									

19. Briefly centrifuge reaction plate or strips for 30 seconds at 500 x g, 4°C. After centrifugation return to cold rack.
20. Setup RT-qPCR reactions as shown in the table below.
    Instrument settings for RT-qPCR reactions. Fluorescence data (both FAM and HEX) should be collected during the data acquisition step.

Step	Temperature	Time	Number of cycles
UNG incubation	25°C	2 min	1
Reverse transcription	50°C	15 min	1
Enzyme activation	95°C	2 min	1
Denaturation	95°C	3 sec	45
Annealing and extension	55°C	30 sec	
Data acquisition	Plate read, detector (FAM and HEX)		

Interpretation of Results and Reporting

ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit (catalog #RX7038)

- Results interpretation of the two controls (catalog #RX7038-Pos and #RX7038-H2O) included in the ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit

Sample	RX7038-N1	RX7038-N2	RX7038-RP	Results Interpretation
RX7038-Pos	+	+	+	Expected
	-	-	-	Reverse transcription and/or PCR failed
RX7038-H_2O	-	-	-	Expected
	If anyone of three targets is positive			Reagent(s) contaminated

Note: a Ct value < 40.00 is considered positive

Note: Any controls not showing the expected results is an indication that reagent(s) and/or equipment(s) are not functioning properly. The run is invalid and should be repeated.

- Results interpretation for patient specimens

RX7038-N1	RX7038-N2	RX7038-RP	Results Interpretation	Action
+	+	±	SARS-CoV-2 detected	Report results.
If only one of two targets is positive		±	SARS-CoV-2 detected	Report results.
-	-	+	SARS-CoV-2 not detected	Report results.
-	-	-	Invalid result	Repeat extraction and RT-qPCR. If the repeated result remains invalid, consider collecting a new specimen from the patient.

Note: a Ct value < 40.00 is considered positive

ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit (catalog #RX7048)

- Results interpretation of the two controls (catalog #RX7048-Pos and #RX7048-H2O) included in the ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit

Channel	FAM (N1, N2)	Hex (RP)	Results Interpretation
RX7048-Pos	+	+	Expected
	-	-	Reverse transcription and/or PCR failed
RX7048-H_2O	-	-	Expected
	If anyone of two targets is positive		Reagent(s) contaminated

Note: a Ct value < 40.00 is considered positive

Note: Any controls not showing the expected results is an indication that reagent(s) and/or equipment(s) are not functioning properly. The run is invalid and should be repeated.

- Results interpretation for patient specimens

FAM (N1, N2)	HEX (RP)	Results Interpretation	Action
+	±	SARS-CoV-2 detected	Report results.
-	+	SARS-CoV-2 not detected	Report results.
-	-	Invalid result	Repeat extraction and RT-qPCR. If the repeated result remains invalid, consider collecting a new specimen from the patient.

Note: a Ct value < 40.00 is considered positive

Quality Control

- Quality control requirements must be performed in conformance with local, state, and federal regulations or accreditation requirements and the user's laboratory's standard quality control procedures (please refer to 42 CFR 493.1256).
- One positive control and one negative control (provided) must be processed with each run. Quality control procedures are intended to monitor reagent and assay performance. For control results interpretation, refer to section "Interpretation of Results and Reporting".
- Test positive control prior to running diagnostic samples with each new kit lot to ensure all reagents and kit components are working properly.
- Good laboratory practice (cGLP) recommends including a positive extraction control in each nucleic acid isolation batch; RX7038-Pos or RX7048-Pos, a positive control (non-infectious RNA spiked into human small airway epithelial cells) included in the assay kit acts as a positive extraction control.

Limitations

- The use of ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit as an *in vitro* diagnostic under the FDA Emergency Use Authorization (EUA) is limited to laboratories that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, and meet the requirements to perform high complexity tests.
- The ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit can be used only with the specimens listed in the Intended Use statement. Other specimen types have not been evaluated and should not be tested with this assay.
- Samples must be collected, transported, and stored using appropriate procedures and conditions. Improper collection, transport, or storage of specimens may hinder the ability of the assay to detect the target sequences.
- Extraction and amplification of nucleic acid from clinical samples must be performed according the specified methods listed in this procedure. Other extraction approaches and processing systems have not been evaluated.
- A false negative result may occur if a specimen is improperly collected, transported or handled. False negative results may also occur if amplification inhibitors are present in the specimen or if inadequate numbers of organisms are present in the specimen.
- A false positive result may arise from cross contamination during specimen handling or preparation, or between patient samples.

- The impacts of vaccines, antiviral therapeutics, antibiotics, chemotherapeutic or immunosuppressant drugs have not been evaluated. The ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit cannot rule out diseases caused by other bacterial or viral pathogens.
- Negative results do not preclude infection with SARS-CoV-2 virus, and should not be the sole basis of a patient management decision.
- Results from the ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit should be used as an adjunct to clinical observations and other information available to the physician.

Conditions of Authorization for the Laboratory

The ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

To assist clinical laboratories using the ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit, the relevant Conditions of Authorization are listed below.

- Authorized laboratories[1] using the ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit will include with result reports of the ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Authorized laboratories will perform the ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit as outlined in the ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit Instructions for Use. Deviations from the authorized procedures, including the authorized RT-PCR instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to perform the ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit are not permitted.
- Authorized laboratories that receive the ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit must notify the relevant public health authorities of their intent to run the test prior to initiating testing.
- Authorized laboratories using the ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories using the ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit will collect information on the performance of the test and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and ScienCell™ (techsupport@ScienCellonline.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the test of which they become aware.
- All laboratory personnel using the test must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit and use the test in accordance with the authorized labeling.

- ScienCell™ Research Laboratories and authorized laboratories using the ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

[1]The letter of authorization refers to "United States (U. S.) laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests" as "authorized laboratories."

Performance Characteristics

Limit of Detection (LoD):

LoD studies determine the lowest detectable concentration of SARS-CoV-2 that could be reliably detected at least 95% of the time.

SARS-CoV-2 extracted RNA obtained from University of Texas Medical Branch (UTMB) with known titer was spiked into pooled nasopharyngeal matrix. Samples were extracted using the Viral RNA Isolation Kit (ScienCell, catalog #MB891) and the QIAamp DSP Viral RNA Mini Kit (Qiagen, catalog #61904). RT-qPCR assays were performed using the One-Step TaqProbe RT-qPCR Mater Mix, 4x (catalog #MB802a) on the Roche LightCycler® 96 Real-Time PCR System with LightCycler® Software 1.01.01.0050 according to the ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit instructions for use.

A preliminary LoD was determined testing four replicates of 3-fold serial dilutions of quantified SARS-CoV-2 extracted RNA. A confirmation of the LoD was determined using 3-fold serial dilution RNA samples with 20 extracted replicates. The LoD was determined as the lowest concentration where ≥ 95% (19/20) of the replicates were positive by the ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit as per the results interpretation algorithm.

Limit of Detection confirmation of the ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit with SCIENCELL Viral RNA Isolation Kit

Targets	RX7038-N1				RX7038-N2			
RNA Concentration (copies/µL)	10^{1}	$10^{0.5}$	10^{0}	$10^{-0.5}$	$10^{1.5}$	10^{1}	$10^{0.5}$	10^{0}
Positive/Total	20/20	20/20	20/20	3/20	20/20	20/20	20/20	3/20
Mean Ct[a]	28.36	30.13	31.95	NA	27.90	29.82	31.91	NA
Standard Deviation (Ct)	0.10	0.19	0.88	NA	0.10	0.12	0.53	NA

[a]Mean Ct reported for dilutions that are ≥95% positive
NA: not applicable

Limit of Detection confirmation of the ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit with QIAGEN QIAamp DSP Viral RNA Mini Kit

Targets	RX7038-N1				RX7038-N2			
RNA Concentration (copies/µL)	10^{1}	$10^{0.5}$	10^{0}	$10^{-0.5}$	$10^{1.5}$	10^{1}	$10^{0.5}$	10^{0}
Positive/Total	20/20	20/20	20/20	4/20	20/20	20/20	20/20	4/20

Mean Ct[a]	27.31	28.98	30.52	NA	28.16	29.05	31.10	NA
Standard Deviation (Ct)	0.05	0.13	0.20	NA	0.12	0.12	0.49	NA

[a]Mean Ct reported for dilutions that are ≥95% positive
NA: not applicable

Limit of Detection of the ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit as per results interpretation algorithm with both extraction kits is **10^0 copies/µL**.

A complete LoD study (preliminary and confirmatory) was repeated with the multiplex kit (ScienCell, catalog #RX7048) in parallel with the previously authorized singleplex kit (ScienCell, catalog #RX7038) using the UTMB virus material and the procedure described earlier.

Limit of Detection confirmation of the ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit using the singleplex kit (ScienCell, catalog #RX7038)

Targets	**RX7038-N1**				**RX7038-N2**			
RNA Concentration (copies/µL)	10^1	$10^{0.5}$	10^0	$10^{-0.5}$	$10^{1.5}$	10^1	$10^{0.5}$	10^0
Positive/Total	20/20	20/20	20/20	2/20	20/20	20/20	20/20	2/20
Mean Ct[a]	28.24	30.02	31.73	NA	28.48	30.18	30.99	NA
Standard Deviation (Ct)	0.07	0.19	0.19	NA	0.08	0.11	0.19	NA

[a]Mean Ct reported for dilutions that are ≥95% positive
NA: not applicable

Limit of Detection confirmation of the ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit using the multiplex kit (ScienCell, catalog #RX7048)

Channel (Targets)	**FAM (N1, N2)**			
RNA Concentration (copies/µL)	10^1	$10^{0.5}$	10^0	$10^{-0.5}$
Positive/Total	20/20	20/20	20/20	2/20
Mean Ct[a]	27.29	28.07	28.78	NA
Standard Deviation (Ct)	0.13	0.15	0.16	NA
Control Tested	**FAM (N1, N2)**		**HEX (RP)**	
Positive control	21.14		21.73	
Negative control	NA		NA	

[a]Mean Ct reported for dilutions that are ≥95% positive
NA: not applicable

Limit of Detection of the ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit as per results interpretation algorithm (ScienCell, catalog #RX7048) with both multiplex and singleplex kits is **10^0 copy/µL**.

Cross-reactivity:

The ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit utilizes oligos that have identical sequences to those used in the CDC 2019-Novel Coronavirus (2019-CoV) Real-Time RT-PCR Diagnostic Panel the CDC assay. The cross-reactivity of CDC assay under an EUA has been evaluated and therefore, additional evaluation is not required.

Endogenous Interference Substances Studies:

The ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit uses conventional well-established nucleic acid extraction method that is also authorized with the CDC 2019-Novel Coronavirus (2019-CoV) Real-Time RT-PCR Diagnostic Panel the CDC assay. We do not anticipate interference from common endogenous substances using this method.

Clinical Performance:

Clinical evaluation of the ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit (ScienCell, catalog #RX7038) was conducted using contrived nasopharyngeal swabs (30 positives and 30 negatives). The 30 positive samples were spiked by SARS-CoV-2 extracted RNA obtained from University of Texas Medical Branch. 20 of the contrived positive samples (Samples #1-20) were prepared by spiking the SARS-CoV-2 RNA at 1–2x LoD and the rest (Samples #21-30) 10 contrived positive samples spanned the testing range of the assay (< 5x LoD). The positive and negative agreements between the ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit and the expected results are shown below:

Results summary:

	ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit (ScienCell, catalog #RX7038) - Singleplex	
SARS-CoV-2 concentration	**Results (Detected/Tested)**	**Agreements (95% CI)**
1-2x LoD	20/20	100% (83.9%, 100%)
3-5x LoD	10/10	100% (72.3%, 100%)
Negative	30/30*	100% (88.7%, 100%)

***Negative results detected/tested**

Clinical evaluation of the ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit (ScienCell, catalog #RX7048) was conducted in a blinded fashion using 60 clinical nasopharyngeal swab specimens. Testing was performed according to the ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit Instructions for Use. Each patient sample was tested by the ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit using both the singleplex (ScienCell, catalog #RX7038) and multiplex (ScienCell, catalog #RX7048) formats and the results of the two were compared as shown below.

Results summary:

		FDA-authorized ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit (ScienCell, catalog #RX7038)	
		Positive	**Negative**
ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit (ScienCell, catalog #RX7048)	**Positive**	30	0
	Negative	0	30
Positive percent agreement (95% CIs)	100% (88.7%, 100%)		
Negative Percent agreement (95% CIs)	100% (88.7%, 100%)		

FDA SARS-CoV-2 Reference Panel Testing

The evaluation of sensitivity and MERS-CoV cross-reactivity was performed using reference material (T1),

blinded samples and a standard protocol provided by the FDA. The study included a range finding study and a confirmatory study for LoD. Blinded sample testing was used to establish specificity and to confirm the LoD. Samples were extracted using the Viral RNA Isolation Kit (ScienCell, catalog #MB891). RT-qPCR assays were performed in singleplex format (Sciencell, catalog #RX7038) using the One-Step TaqProbe RT-qPCR Mater Mix, 4x (catalog #MB802a) on the Roche LightCycler® 96 Real-Time PCR System with LightCycler® Software 1.01.01.0050 according to the ScienCell™ SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit instructions for use. The results are summarized in the Table below.

Summary of LoD Confirmation Result using the FDA SARS-CoV-2 Reference Panel

Reference Materials Provided by FDA	**Specimen Type**	**Product LoD**	**Cross-Reactivity**
SARS-CoV-2	Spiked nasopharyngeal clinical matrix	$5.4x10^2$ NDU/mL	N/A
MERS-CoV		N/A	ND

NDU/mL = RNA NAAT detectable units/mL
N/A: Not applicable
ND: Not detected

Disposal

Dispose of hazardous or biologically contaminated materials according to the practices of your institution.

References

1. Ballew, H. C., *et al*. "Basic Laboratory Methods in Virology," DHHS, Public Health Service 1975 (Revised 1981), Centers for Disease Control and Prevention, Atlanta, Georgia 30333.
2. Clinical Laboratory Standards Institute (CLSI), "Collection, Transport, Preparation and Storage of Specimens for Molecular Methods: Proposed Guideline," MM13-A.
3. CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel. 2020, US Centers for Disease Control and Prevention. https://www.fda.gov/media/134922/download
4. Research Use Only 2019-Novel Coronavirus (2019-nCoV) Real-time RT-PCR Primer and Probe Information. 2020, US Centers for Disease Control and Prevention. https://www.cdc.gov/coronavirus/2019-ncov/downloads/rt-pcr-panel-primer-probes.pdf

Revision History

Revision #	**Effective Date**	**Summary of Revisions**
1	April 3, 2020	Original Instructions for Use
2	May 26, 2020	• Addition of an alternative nucleic acid extraction platform
3	August 25, 2020	• Addition of a multiplex-format detection kit (catalog #RX7048)

Contact Information, Ordering, and Product Support

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Trademarks

Trademarks: ScienCell™

All other trademarks that appear in this IFU are the property of their respective owners.

Symbols

The following table describes the symbols that may appear on the labeling or in this IFU.

REF	Catalog number
Rx Only	For prescription use only
IVD	*in vitro* diagnostic medical device
TM	Trademark
®	Registered
©	Copyright