

TaqPath™ COVID-19 RNase P Combo Kit 2.0

INSTRUCTIONS FOR USE

Multiplex real-time RT-PCR test intended for the qualitative detection of nucleic acids from SARS-CoV-2 and RNase P internal control in a single reaction well.

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For In Vitro Diagnostic Use. For Emergency
Use Authorization Only | Rx Only

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Revision	Date	Description
F.0	6 April 2023	Table 23 data was updated in "Clinical evaluation".
E.0	14 September 2022	<ul style="list-style-type: none">• Compatible firmware and software versions were updated.• The following topics were updated:<ul style="list-style-type: none">– "Required materials not supplied" on page 8– "Software and instrument compatibility" on page 34– "Install the assay panel" on page 36– "Cross-reactivity" on page 48– "Reactivity (Inclusivity)" on page 45– "Related documentation" on page 59
D.0	3 May 2022	<ul style="list-style-type: none">• Chapter table of contents were added.• The HIPAA acronym was corrected.• The following topics were updated:<ul style="list-style-type: none">– "Intended Use" on page 6– "Product description" on page 7– "Contents and storage" on page 8– "Required materials not supplied" on page 8– "Assay limitations" on page 10– "In-use reagent stability" on page 14– "Before you begin" on page 17– "Prepare the RT-PCR reactions (96-well reaction plate)" on page 21– "Prepare the RT-PCR reactions (384-well reaction plate)" on page 23– "Set up and run the QuantStudio™ 7 Flex Real-Time PCR Instrument (384-well block)" on page 31– "Software and instrument compatibility" on page 34– "Reactivity (Inclusivity)" on page 45– "Clinical evaluation" on page 50
C.0	11 March 2022	<ul style="list-style-type: none">• Pathogen Interpretive Software v1.1.0 was changed to Pathogen Interpretive Software v1.1.• SAE Administrator Console Dx v1.0.0 was changed to SAE Administrator Console Dx v1.0.• The following topics were updated:<ul style="list-style-type: none">– "Product description" on page 7– "Contents and storage" on page 8– "Required materials not supplied" on page 8– "Assay limitations" on page 10– "Workflow" on page 15– "Before you begin" on page 17– "Prepare the RT-PCR reactions (96-well reaction plate)" on page 21– "Prepare the RT-PCR reactions (384-well reaction plate)" on page 23– "Dye calibration for the QuantStudio™ 5 Real-Time PCR Instrument" on page 26

Revision	Date	Description
C.0 (continued)	11 March 2022	<ul style="list-style-type: none"> - “Software and instrument compatibility” on page 34 - “Obtain the software package” on page 35 - Chapter 7, “Conditions of authorization for labs” - “Limit of detection (LoD)” on page 41 - “Reactivity (Inclusivity)” on page 45 - “Related documentation” on page 59
B.0	2 September 2021	<ul style="list-style-type: none"> • Guidance was added for samples collected using the Color COVID-19 Self-Swab Collection Kit with Saline (Color Health, Inc). • Update to the “Required materials not supplied” on page 8. • Update to “Set up and run the QuantStudio™ 5 Real-Time PCR Instrument (96-well plates)” on page 27
A.0	9 July 2021	New document for the launch of TaqPath™ COVID-19 RNase P Combo Kit 2.0 (A51333).

The information in this guide is subject to change without notice.

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Contents

■	CHAPTER 1	Product information	6
		Intended Use	6
		Product description	7
		Contents and storage	8
		Required materials not supplied	8
		General laboratory recommendations	10
		Assay limitations	10
		Warnings and precautions	12
		Samples and controls	13
		In-use reagent stability	14
		Workflow	15
■	CHAPTER 2	Extract RNA	17
		Before you begin	17
		Set up the instrument	18
		Prepare the processing plates	18
		Prepare Binding Bead Mix	19
		Prepare sample plate	19
		Process the samples	20
■	CHAPTER 3	Prepare RT-PCR reactions	21
		Guidelines for RT-PCR	21
		Prepare the RT-PCR reactions (96-well reaction plate)	21
		Prepare the RT-PCR reactions (384-well reaction plate)	23
■	CHAPTER 4	Perform RT-PCR using the QuantStudio™ 5 Real-Time PCR Instrument (96-well, 0.2-mL block)	26
		Dye calibration for the QuantStudio™ 5 Real-Time PCR Instrument	26
		Transfer the template (EDT) file for the QuantStudio™ 5 Real-Time PCR Instrument	26
		Set up and run the QuantStudio™ 5 Real-Time PCR Instrument (96-well plates)	27

■	CHAPTER 5	Perform RT-PCR using the QuantStudio™ 7 Flex Real-Time PCR Instrument (384-well block)	30
		Dye calibration for the QuantStudio™ 7 Flex Real-Time PCR Instrument	30
		Transfer the template (EDT) file for the QuantStudio™ 7 Flex Real-Time PCR Instrument (384-well block)	30
		Set up and run the QuantStudio™ 7 Flex Real-Time PCR Instrument (384-well block)	31
■	CHAPTER 6	Analysis and results	34
		Software and instrument compatibility	34
		Obtain the software package	35
		Install the assay panel	36
		Analyze the data	37
		Interpretation of the results	37
■	CHAPTER 7	Conditions of authorization for labs	39
■	CHAPTER 8	Performance characteristics	41
		Limit of detection (LoD)	41
		Reactivity (Inclusivity)	45
		Interfering substances	46
		Cross-reactivity	48
		Clinical evaluation	50
■	APPENDIX A	C_t cutoff values for assay targets	54
■	APPENDIX B	EUO label for RUO instruments	55
■	APPENDIX C	Safety	56
		Chemical safety	57
		Biological hazard safety	58
■	APPENDIX D	Documentation and support	59
		Related documentation	59
		Customer and technical support	59
		Limited product warranty	60



Product information

- Intended Use 6
- Product description 7
- Contents and storage 8
- Required materials not supplied 8
- General laboratory recommendations 10
- Assay limitations 10
- Warnings and precautions 12
- Samples and controls 13
- In-use reagent stability 14
- Workflow 15

Intended Use

The Applied Biosystems™ TaqPath™ COVID-19 RNase P Combo Kit 2.0 contains the assays and controls for a real-time reverse transcription polymerase chain reaction (RT-PCR) test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in nasopharyngeal swabs and anterior or mid-turbinate nasal swabs from any individual, including individuals without symptoms or other epidemiological reasons to suspect COVID-19.

This test is also authorized for use with anterior nasal swab specimens that are collected using the Color COVID-19 Self-Swab Collection Kit with Saline when used consistent with its authorization.

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 upper respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status.

Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all test 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 TaqPath™ COVID-19 RNase P Combo Kit 2.0 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.

The TaqPath™ COVID-19 RNase P Combo Kit 2.0 is only for use under the Food and Drug Administration’s Emergency Use Authorization.

Product description

The TaqPath™ COVID-19 RNase P Combo Kit 2.0 is a multiplexed real-time PCR testing solution that can detect the RNA from the SARS-CoV-2 virus and RNase P in a single reaction well.

Each kit includes the following components:

- TaqPath™ COVID-19 RNase P Kit 2.0 (assay mix tube)—Multiplexed assays that contain primer/probe sets specific to different SARS-CoV-2 genomic regions and primers/probes for human RNase P.
- TaqPath™ COVID-19 Plus Control—*In vitro* transcribed RNA control that contains templates specific to the SARS-CoV-2 and RNase P regions targeted by the assays.
- TaqPath™ COVID-19 Control Dilution Buffer—Dilution buffer for the control.

TaqPath™ 1-Step Multiplex Master Mix (No ROX™) must be ordered separately (see “Required materials not supplied” on page 8).

The assay contains primers and probe sets specific to the following targets:

- SARS-CoV-2 N Gene
- SARS-CoV-2 ORF1a
- SARS-CoV-2 ORF1b
- RNase P (human sample collection control)

Table 1 Dyes, quenchers, and targets

Target	Dye	Quencher
SARS-CoV-2 ORF1a	FAM™ dye	None ^[1]
SARS-CoV-2 N Gene	VIC™ dye	
SARS-CoV-2 ORF1b	ABY™ dye	
RNase P	JUN™ dye	

^[1] The TaqPath™ COVID-19 RNase P Combo Kit 2.0 probes contain QSY™ quenchers, which do not fluoresce. Select None for Quencher in the instrument set up procedure (see page 27 or page 31).

Results are analyzed using the following software:

- Applied Biosystems™ Pathogen Interpretive Software v1.1
- SAE Administrator Console Dx v1.0 (for security and audit functions)
- Pathogen Interpretive Software 1.0.0 DAT (SAE Profile)
- The appropriate assay panel for your instrument:
 - C19-RNaseP-EUA_QS5-9602_1.0.0
 - C19-RNaseP-EUA_QS7-384_1.0.0

For more information, see Chapter 6, “Analysis and results”.

Contents and storage

Table 2 TaqPath™ COVID-19 RNase P Combo Kit 2.0, 1,000 reactions (Cat. No. [A51333](#))

Component	Quantity	Amount per tube or bottle	Storage
TaqPath™ COVID-19 RNase P Kit 2.0 (assay mix tube)	1 tube	1,500 µL	-30°C to -10°C ^[1]
TaqPath™ COVID-19 Plus Control (1 x 10 ⁴ copies/µL)	10 tubes	10 µL	≤ -20°C
TaqPath™ COVID-19 Control Dilution Buffer	10 tubes	250 µL	-30°C to -10°C

^[1] Do not freeze-thaw assays more than 12 times.

Required materials not supplied

Unless otherwise indicated, all materials are available through [thermofisher.com](https://www.thermofisher.com). "MLS" indicates that the material is available from [fisherscientific.com](https://www.fisherscientific.com) or another major laboratory supplier.

Catalog numbers that appear as links open the web pages for those products.

Item	Source
Real-time PCR instrument (for firmware and software compatibility for each instrument, see “Software and instrument compatibility” on page 34)	
Applied Biosystems™ QuantStudio™ 5 Real-Time PCR System, 96-well, 0.2-mL block	A28569 (with laptop computer) A28574 (with desktop computer) A28139 (instrument only)
Applied Biosystems™ QuantStudio™ 7 Flex Real-Time PCR System, 384-well	4485695 (with laptop computer) 4485701 (with desktop computer)
Equipment	
Laboratory freezers <ul style="list-style-type: none"> -30°C to -10°C 	MLS
Centrifuge, with a rotor that accommodates standard and deepwell microplates	MLS
Microcentrifuge	MLS
Laboratory mixer, vortex or equivalent	MLS
Single and multichannel adjustable pipettors (1.0 µL to 1.0 mL)	MLS
Cold block (96-well or 384-well) or ice	MLS
Nucleic acid extraction system and materials	
KingFisher™ Flex Magnetic Particle Processor with 96 Deep-Well Head	5400630

(continued)

Item	Source
KingFisher™ Flex 96 Deep-Well Heating Block	24075430
KingFisher™ 96 Deep-Well Plate	95040450 , A48305 , 95040455
KingFisher™ 96 tip comb for deep-well magnets	A48438 , 97002534
96-well plate for the tip comb, one of the following:	
KingFisher™ 96 KF microplate	97002540
Nunc™ MicroWell™ 96-Well Microplate, Flat Bottom	167008
Nunc™ MicroWell™ 96-Well Microplate, barcoded	269787
Abgene™ 96-Well Polypropylene Storage Microplate	AB0796
Abgene™ 96-Well 1.2-mL Polypropylene Deepwell Storage Plate	AB1127
KingFisher™ 96 Deep-Well Plate	95040450 , A48305 , 95040455
Kits and reagents	
MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit	A48383
TaqPath™ 1-Step Multiplex Master Mix (No ROX™)	A28522 , A28523
Fisher BioReagents™ Ethanol, Absolute, Molecular Biology Grade ^[1] , or equivalent	BP2818100 , BP2818500 , BP28184
Nuclease-Free Water (not DEPC-Treated)	MLS
Calibration plates (QuantStudio™ 7 Flex Real-Time PCR Instrument)	
ABY™ Dye Spectral Calibration Plate for Multiplex qPCR, 384-well	A24736
JUN™ Dye Spectral Calibration Plate for Multiplex qPCR, 384-well	A24733
Tubes, plates, and other consumables	
MicroAmp™ Optical 96-Well Reaction Plate with Barcode, 0.2 mL	4306737 , 4326659
MicroAmp™ Optical 96-Well Reaction Plate, 0.2 mL	N8010560 , 4316813
MicroAmp™ Optical 384-Well Reaction Plate with Barcode	4309849 , 4326270 , 4343814
MicroAmp™ Optical 384-Well Reaction Plate	4343370
MicroAmp™ Clear Adhesive Film	4306311
MicroAmp™ Optical Adhesive Film	4311971 , 4360954
MicroAmp™ Adhesive Film Applicator	4333183
MicroAmp™ Optical Film Compression Pad ^[2]	4312639
Nonstick, RNase-free microcentrifuge tubes (1.5 mL and 2.0 mL)	thermofisher.com/plastics

(continued)

Item	Source
Sterile aerosol barrier (filtered) pipette tips	thermofisher.com/pipettetips
DNase and RNase-free tubes for mixing reagents (capable of mixing 5 mL) ^[3]	thermofisher.com

^[1] Available at [fisherscientific.com](https://www.fisherscientific.com).^[2] Required for use with QuantStudio™ 5 Real-Time PCR Instrument, 96-well, 0.2-mL block.^[3] Only needed if using 384-well plates.

General laboratory recommendations

- Follow standard operating procedures in your laboratory to prevent contamination, such as the following:
 - Frequent glove changes
 - Frequent decontamination of surfaces, equipment, and pipettes with fresh 10% bleach or decontamination solution, followed by 70% ethanol
 - Use of ultraviolet light during biosafety cabinet decontamination (when available)
- To prevent degradation, keep eluted sample RNA, master mixes, assays, and controls on ice or in cold blocks while in use.
- Limit freeze-thaw cycles.
- Aliquot reagents to prevent stock contamination and reduce the number of freeze-thaw cycles.
- After each run, review the amplification curves for signs of inadequate vortexing or centrifugation.

Assay limitations

- The use of this assay 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, that meet requirements to perform high complexity tests.
- The kit performance was established using nasopharyngeal swab, anterior nasal swab, and mid-turbinate nasal swab samples only. Specimen types other than nasopharyngeal swabs, anterior nasal swabs, and mid-turbinate nasal swabs should not be tested with this assay.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- 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.
- Chemical inactivation and other known clinically relevant interfering substances and techniques can lead to inappropriate primary samples and interfere with test results.

- The workflow must be performed according to the specified methods described in the instructions for use.
- The quality of the biological samples is essential for the quality of the results generated with this kit.
- This kit uses purified RNA as a sample for the analysis. The quality of the RNA recovered from biological samples is essential for the quality of the results generated with this kit.
- Performance was established using the MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit (Cat. No. [A48383](#)). Other purification methods may lead to deviations in the expected result.
- Assay performance was established with a maximum of 12 freeze-thaw cycles. Additional freeze-thaw cycles may result in deviations in the expected results.
- False-negative results may arise from:
 - Improper sample collection
 - Degradation of the SARS-CoV-2 RNA during shipping/storage
 - Specimen collection after SARS-CoV-2 RNA can no longer be found in the specimen matrix
 - Using unauthorized extraction or assay reagents
 - The presence of RT-PCR inhibitors
 - Mutation in the SARS-CoV-2 virus
 - Failure to follow instructions for use
 - Absence of specimen
- False-positive results may arise from:
 - Cross contamination during specimen handling or preparation
 - Cross contamination between patient samples
 - Specimen mix-up
 - RNA contamination during product handling
- Inconclusive calls may arise from:
 - Sample at concentrations near the limit of detection of the test
 - Assay cross-reactivity with SARS-CoV-1
 - Other factors
- Negative results do not preclude infection with SARS-CoV-2 virus, and should not be the sole basis of a patient management decision.
- The impacts of vaccines, antiviral therapeutics, antibiotics, chemotherapeutic or immunosuppressant drugs have not been evaluated. The TaqPath™ COVID-19 RNase P Combo Kit 2.0 cannot rule out diseases caused by other bacterial or viral pathogens.
- Detection of RNase P indicates that human nucleic acid is present and implies that human biological material was collected and successfully extracted and amplified. It does not necessarily indicate that the specimen is of appropriate quality to enable detection of SARS-CoV-2.

Warnings and precautions

The TaqPath™ COVID-19 RNase P Combo Kit 2.0 workflow should be performed by qualified and trained staff to avoid the risk of erroneous results. Use separate areas for the preparation of patient samples and controls to prevent false positive results. Samples and reagents must be handled in a biological safety cabinet.

- Samples and controls should always be treated as if infectious and/or biohazardous in accordance with safe laboratory procedures.
- Follow necessary precautions when handling specimens. Use personal protective equipment (PPE) consistent with current guidelines for the handling of potentially infectious samples.
- Always use pipette tips with aerosol barriers. Tips that are used must be sterile and free from DNases and RNases.
- Do not eat, drink, smoke, or apply cosmetic products in the work areas.
- Do not use the kits after the indicated expiry date.
- Dispose of waste in compliance with local, state, and federal regulations.
- Safety Data Sheets are available upon request.
- Positive results are indicative of the presence of SARS-CoV-2 RNA.
- Reagents must be stored and handled as specified in “Contents and storage” on page 8.
- Encrypt, pseudonymize, or anonymize personal data where possible following the requirements of HIPAA (Health Insurance Portability and Accountability Act)
- Modifications to assay reagents, assay protocol, or instrumentation are not permitted, and are in violation of the product Emergency Use Authorization.
- For Use under Emergency Use Authorization Only.
- For prescription use only.
- For *in vitro* diagnostic use.
- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- Laboratories are required to report all test results to the appropriate public health authorities.

Samples and controls

Note: Handle all samples and controls as if they are capable of transmitting infectious agents.

- Patient nasopharyngeal swabs or anterior or mid-turbinate nasal swabs must be collected, transported, and stored in non-inactivating viral transport medium (VTM/UTM) according to CDC guidelines. See the CDC website: <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>.
- Laboratories designated by Color Health, Inc. and Thermo Fisher Scientific may also test anterior nasal swabs collected using the Color COVID-19 Self-Swab Collection Kit with Saline.
- Specimens must be packaged, shipped, and transported according to the current edition of the *International Air Transport Association (IATA) Dangerous Goods Regulations* ([iata.org/en/programs/cargo/dgr](https://www.iata.org/en/programs/cargo/dgr)).
- Refer to the *Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19)*, published by the Centers for Disease Control and Prevention, for specimen collection and storage guidelines.

Positive and negative test controls must be included and evaluated prior to interpreting patient test results.

Include the following controls:

Control	Used to monitor	Assays
Positive Control (TaqPath™ COVID-19 Plus Control)	RT-PCR reaction setup and reagent integrity	SARS-CoV-2 N Gene, SARS-CoV-2 ORF1a, SARS-CoV-2 ORF1b, and RNase P
Negative Control	Cross-contamination during RNA extraction and reaction setup	SARS-CoV-2 N Gene, SARS-CoV-2 ORF1a, SARS-CoV-2 ORF1b, and RNase P

For information on isolation and purification of viral nucleic acid from human respiratory specimens, see the *MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit Instructions For Use* in “Related documentation” on page 59.

In-use reagent stability

Reagent	Stability information
TaqPath™ COVID-19 RNase P Kit 2.0 (assay mix tube)	Once thawed, the TaqPath™ COVID-19 RNase P Kit 2.0 is stable for up to 24 hours at 2°C–8°C. Do not exceed 12 freeze/thaw cycles.
TaqPath™ COVID-19 Plus Control (1 x 10 ⁴ copies/μL)	Single-use only.
TaqPath™ COVID-19 Plus Control working stock (1/2,856 dilution)	The working stock of the TaqPath™ COVID-19 Plus Control is stable for up to 24 hours at 2°C–8°C.
TaqPath™ COVID-19 Control Dilution Buffer	Single-use only.

Workflow

TaqPath™ COVID-19 RNase P Combo Kit 2.0 workflow

Extract RNA from patient samples (see Chapter 2, Extract RNA)

Perform automated RNA extraction using the KingFisher™ Flex Magnetic Particle Processor with 96 Deep-Well Head and the MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit with a 200-µL sample input volume.

Perform RT-PCR

1. Prepare RT-PCR reactions (see page 21).
2. Perform RT-PCR using one of the following real-time PCR instruments:
 - QuantStudio™ 5 Real-Time PCR Instrument, 96-well, 0.2-mL block (see page 27)
 - QuantStudio™ 7 Flex Real-Time PCR Instrument, 384-well block (see page 31)

Analyze data and interpret the results using the Pathogen Interpretive Software (see Chapter 6, Analysis and results)

1. Install the appropriate assay panel for your instrument (see page 36).
2. Analyze the data (see page 37).
3. Review run control results and interpret patient samples (see page 37).

The workflow begins with nucleic acid extraction from nasopharyngeal swab (NP), anterior nasal swab, or mid-turbinate nasal swab (NS) specimens that were collected in transport media according to appropriate laboratory procedures.

Nucleic acids are isolated and purified from the specimens using the MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit. Nucleic acid isolation is performed via an automated process using the KingFisher™ Flex Purification System (KingFisher). For more information about using the kit, see “Related documentation” on page 59.

The nucleic acid is reverse transcribed into cDNA and amplified using the TaqPath™ COVID-19 RNase P Combo Kit 2.0 and one of the following real-time PCR instruments:

- QuantStudio™ 5 Real-Time PCR Instrument, 96-well, 0.2-mL block
- QuantStudio™ 7 Flex Real-Time PCR Instrument, 384-well block

In the process, the probes anneal to specific SARS-CoV-2 target sequences located between unique forward and reverse primers for the following targets:

- SARS-CoV-2 N Gene
- SARS-CoV-2 ORF1a
- SARS-CoV-2 ORF1b
- RNase P (human sample collection control)



During the extension phase of the PCR cycle, the 5' exonuclease activity of Taq polymerase degrades the probe, causing the reporter dye to separate from the quencher dye, generating a fluorescent signal. With each cycle, additional reporter dye molecules are cleaved from their respective probes, increasing the fluorescence intensity. Fluorescence intensity is monitored at each PCR cycle by the real-time PCR instrument.

The data are analyzed, then interpreted by the Pathogen Interpretive Software and the appropriate assay panel for your instrument.



Extract RNA

- Before you begin 17
- Set up the instrument 18
- Prepare the processing plates 18
- Prepare Binding Bead Mix 19
- Prepare sample plate 19
- Process the samples 20

IMPORTANT! The RNA extraction protocols in this chapter are compatible with upper respiratory specimens (nasopharyngeal swabs, anterior nasal swabs, or mid-turbinate nasal swabs).

Automated RNA extraction is performed using the KingFisher™ Flex Magnetic Particle Processor with 96 Deep-Well Head, KingFisher™ Flex 96 Deep-Well Heating Block, and the MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit with a sample input volume of 200 µL.

Before you begin

Note: During the wash steps, the Wash Solution from the MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit, may develop inert white or brown particulates that float in solution. This is not a cause for concern and does not negatively affect performance.

- Determine the number of required reactions based on the number of patient samples to be processed, plus one Negative Control per plate.
- Prepare fresh 80% ethanol in accordance with standard laboratory procedures using Ethanol, Absolute, Molecular Biology Grade and Nuclease-Free Water (not DEPC-Treated) for the required number of reactions, sufficient for 1 mL per reaction, plus 10% overage. See “Required materials not supplied” on page 8.
- Mark the Negative Control well on the plate.
- Label the short side of each KingFisher™ 96 Deep-Well Plate (4):

Label	Number of plates
Sample Plate	1
Wash 1 Plate	1
Wash 2 Plate	1
Elution Plate	1

- Label the short side of the KingFisher™ 96 KF microplate (1):

Label	Number of plates
Tip Comb Plate	1

Note: The following items can be used to hold the tip comb instead of the KingFisher™ 96 KF microplate:

- Nunc™ MicroWell™ 96-Well Microplate, Flat Bottom
- Nunc™ MicroWell™ 96-Well Microplate, barcoded
- Abgene™ 96-Well Polypropylene Storage Microplate
- Abgene™ 96-Well 1.2-mL Polypropylene Deepwell Storage Plate
- KingFisher™ 96 Deep-Well Plate

Set up the instrument

- Ensure that the KingFisher™ Flex Magnetic Particle Processor with 96 Deep-Well Head is set up with the KingFisher™ Flex 96 Deep-Well Heating Block.

IMPORTANT! Failure to use the proper magnetic head and heat block results in lower yields and potential harm to the instrument.

- Ensure that the **MVP_2Wash_200_Flex** program has been downloaded from the MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit product page at www.thermofisher.com and loaded onto the instrument.

Prepare the processing plates

Prepare the processing plates according to the following table. Cover the plates with a temporary seal (such as MicroAmp™ Clear Adhesive Film), then store at room temperature for up to 1 hour while you set up the sample plate.

Plate ID	Plate position	Plate type	Reagent	Volume per well
Wash 1 Plate	2	KingFisher™ 96 Deep-Well Plate	Wash Solution	500 µL
Wash 2 Plate	3		80% Ethanol	1,000 µL
Elution Plate	4		Elution Solution	50 µL
Tip Comb Plate	5	Place a KingFisher™ 96 tip comb for deep-well magnets in a KingFisher™ 96 KF microplate		

Prepare Binding Bead Mix



WARNING! Do not use bleach or bleached pipette tips with the Binding Bead Mix. The Binding Solution contains guanidium thiocyanate, which produces cyanide gas when combined with bleach.

Prepare the required amount of Binding Bead Mix on each day of use.

1. Vortex the Total Nucleic Acid Magnetic Beads to ensure that the bead mixture is homogeneous.
2. For the number of required reactions, prepare the Binding Bead Mix according to the following table:

Component	Volume per well ^[1]
Binding Solution	265 μ L
MagMAX™ Viral/Pathogen Binding Magnetic Beads	10 μ L
Total volume per well	275 μL

^[1] Include 10% overage when making the Binding Bead Mix for use with multiple reactions.

3. Mix well by inversion, then store at room temperature.

Prepare sample plate



WARNING! Do not use bleach or bleached pipette tips with the Binding Bead Mix. The Binding Solution contains guanidium thiocyanate, which produces cyanide gas when combined with bleach.

1. Invert the Binding Bead Mix 5 times gently to mix, then add 275 μ L to each sample well and the Negative Control well in the Sample Plate.

Note: Remix the Binding Bead Mix by inversion frequently during pipetting to ensure even distribution of beads to all samples or wells. The Binding Bead Mix is viscous, so pipet slowly to ensure that the correct amount is added. DO NOT reuse pipette tips to add Binding Bead Mix to the samples, as the high viscosity will cause variations in the volumes added.

2. Add 200 μ L of sample to each sample well.

Note: Change tips between samples to eliminate cross-contamination.

3. Add 200 μ L of Nuclease-Free Water (not DEPC-Treated) to the Negative Control well.
4. Add 5 μ L of Proteinase K to each sample-containing well in the KingFisher™ 96 Deep-Well Plate labeled "Sample Plate", including the Negative Control well.

Process the samples

1. Select the **MVP_2Wash_200_Flex** on the KingFisher™ Flex Magnetic Particle Processor with 96 Deep-Well Head.
2. Start the run, then load the prepared plates into position when prompted by the instrument.
3. After the run is complete (~24 minutes after start), immediately remove the Elution Plate from the instrument, then cover the plate with MicroAmp™ Clear Adhesive Film.

IMPORTANT! To prevent evaporation, seal the plate containing the eluate immediately.

The samples are eluted in 50 µL of Elution Solution (see “Process the samples” on page 20).

4. Place the Elution Plate on ice for immediate use in RT-PCR.

Note:

- Significant bead carry over may adversely impact RT-PCR performance. If bead carry over is observed, re-extract a new aliquot of the sample.
 - To ensure reliable performance of the KingFisher™ Flex Magnetic Particle Processor, perform preventive maintenance as instructed by the manufacturer.
-

3

Prepare RT-PCR reactions

■ Guidelines for RT-PCR	21
■ Prepare the RT-PCR reactions (96-well reaction plate)	21
■ Prepare the RT-PCR reactions (384-well reaction plate)	23

Guidelines for RT-PCR

IMPORTANT!

- Prepare and keep the run plate on ice (or cold block) until it is loaded into the real-time PCR instrument.
 - Run the plate immediately after preparation. Failure to do so could result in degraded RNA samples.
 - To prevent contamination, prepare reagents in a PCR workstation or equivalent amplicon-free area. Do not use the same pipette for controls and RNA samples, and always use aerosol barrier pipette tips.
 - Maintain a RNase-free environment. Periodically decontaminate surfaces.
 - Protect assays from light.
 - Keep RNA samples and components on ice during use.
 - Add samples (templates) to reactions in an area designated for handling templates.
 - For each RT-PCR plate, include the following controls:
 - One Positive Control
 - One Negative Control from each extraction run.
For example, if RNA samples from 4 extraction runs are combined on one 384-well real-time RT-PCR plate, then 4 Negative Control wells must be run on that 384-well real-time RT-PCR plate.
-

Prepare the RT-PCR reactions (96-well reaction plate)

If frozen, thaw the reagents on ice.

1. Gently vortex the reagents, then centrifuge briefly to collect liquid at the bottom of the tube.
2. Serially dilute the TaqPath™ COVID-19 Plus Control (1×10^4 copies/ μL):
 - a. Pipet 100 μL of TaqPath™ COVID-19 Control Dilution Buffer into a microcentrifuge tube, then add 2 μL of TaqPath™ COVID-19 Plus Control. Mix well, then centrifuge briefly.
 - b. Pipet 110 μL of TaqPath™ COVID-19 Control Dilution Buffer into a second microcentrifuge tube, then add 2 μL of the dilution created in substep 2a. Mix well, then centrifuge briefly.

3. Prepare the Reaction Mix on ice:

- a. For each run, combine the following components sufficient for the number of RNA samples to be tested plus one Positive Control and one Negative Control.

All volumes include 10% overage.

IMPORTANT! The volumes in this table assume that you extracted sample RNA using an original sample input volume of 200 μL .

Component	Volume per RNA Sample or Control	Volume for n RNA Samples plus 2 Controls	Volume for 94 RNA Samples plus 2 Controls
TaqPath™ 1-Step Multiplex Master Mix (No ROX™) (4X)	6.25 μL	$6.875 \times (n + 2)$ μL	660.0 μL
TaqPath™ COVID-19 RNase P Kit 2.0 (assay mix tube)	1.25 μL	$1.375 \times (n + 2)$ μL	132.0 μL
Total Reaction Mix volume	7.5 μL	—	792.0 μL

4. Set up the reaction plate on ice:

- a. Pipet 7.5 μL of the Reaction Mix prepared in step 3 into each well of a MicroAmp™ Optical 96-Well Reaction Plate with Barcode, 0.2 mL.
For other reaction plates that can be used, see “Required materials not supplied” on page 8.
- b. Gently vortex the sealed plate containing the purified sample RNA and Negative Control from the RNA extraction procedure, then centrifuge briefly to collect liquid at the bottom of the plate.
- c. Unseal the plate containing the purified sample RNA and Negative Control from the RNA extraction procedure. Add either sample RNA, Negative Control, or Positive Control to each well of the reaction plate, according to Table 3.
- d. Seal the plate thoroughly with MicroAmp™ Optical Adhesive Film.

IMPORTANT!

- Use ONLY MicroAmp™ Optical Adhesive Film (Cat. No. [4311971](#), [4360954](#)).
- DO NOT use optical caps, MicroAmp™ Clear Adhesive Film (Cat. No. [4306311](#)), or any other film or sealing method.
- DO NOT heat seal the plate.
- When applying the MicroAmp™ Optical Adhesive Film, ensure that pressure is applied across the entire plate and that there is a tight seal across every individual well. Failure to do so runs the risk of an improperly sealed well, leading to potential well-to-well contamination during vortexing and evaporation during PCR.

- e. Vortex the plate at the highest setting speed for 10–30 seconds with medium pressure. Move the plate around to ensure equal contact on the vortex mixer platform.

IMPORTANT! Vortex for 10–30 seconds to ensure proper mixing. Failure to do so might result in incorrect (or inaccurate) clinical calls.

- f. Centrifuge the reaction plate for 1–2 minutes at $\geq 650 \times g$ (≥ 650 RCF) to remove bubbles and to collect the liquid at the bottom of the reaction plate.

IMPORTANT! Centrifuge the plate for 1–2 minutes to ensure bubbles are removed. Failure to do so might result in incorrect (or inaccurate) clinical calls.

Table 3 Reaction plate volumes

Component	Volume per reaction		
	RNA Sample	Positive Control	Negative Control
Reaction Mix (from step 3)	7.5 μL	7.5 μL	7.5 μL
Purified sample RNA (from RNA extraction)	17.5 μL	—	—
Positive Control (diluted TaqPath™ COVID-19 Plus Control from step 2)	—	17.5 μL	—
Negative Control (from RNA extraction)	—	—	17.5 μL
Total volume	25.0 μL	25.0 μL	25.0 μL

IMPORTANT!

- Keep the RT-PCR reaction plate on ice or a cold block until it is loaded into the real-time PCR instrument.
- Run the RT-PCR reaction plate immediately after preparation. Failure to do so could result in degraded samples.

Prepare the RT-PCR reactions (384-well reaction plate)

If frozen, thaw the reagents on ice.

1. Gently vortex the reagents, then centrifuge briefly to collect liquid at the bottom of the tube.
2. Dilute TaqPath™ COVID-19 Plus Control (1×10^4 copies/ μL):
 - a. Pipet 100 μL of TaqPath™ COVID-19 Control Dilution Buffer into a microcentrifuge tube, then add 2 μL of TaqPath™ COVID-19 Plus Control. Mix well, then centrifuge briefly.
 - b. Pipet 110 μL of TaqPath™ COVID-19 Control Dilution Buffer into a second microcentrifuge tube, then add 2 μL of the dilution created in substep 2a. Mix well, then centrifuge briefly.
3. Prepare the Reaction Mix on ice.
 - a. For each run, combine the following components sufficient for the number of RNA samples, plus one Positive Control per 384-well RT-PCR reaction plate, and one Negative Control from each extraction run.
For example, if RNA samples from 4 extraction runs are combined on one 384-well RT-PCR plate, then 4 Negative Control wells (one from each extraction plate) need to be run on that 384-well real-time RT-PCR plate.

All volumes include 10% overage.

IMPORTANT! The volumes in this table assume that you extracted sample RNA using an original sample input volume of 200 μL .

Component	Volume per RNA Sample or Control	Volume for n RNA Samples plus 5 Controls	Volume for 379 RNA Samples plus 5 Controls
TaqPath™ 1-Step Multiplex Master Mix (No ROX™) (4X)	5.0 μL	$5.5 \times (n + 5) \mu\text{L}$	2,112.0 μL
TaqPath™ COVID-19 RNase P Kit 2.0 (assay mix tube)	1.0 μL	$1.1 \times (n + 5) \mu\text{L}$	422.4 μL
Total Reaction Mix volume	6.0 μL	—	2,534.4 μL

4. Set up the reaction plate on ice.
 - a. Pipet 6.0 μL of the Reaction Mix prepared in step 3 into each well of a MicroAmp™ Optical 384-Well Reaction Plate with Barcode.
For other reaction plates that can be used, see “Required materials not supplied” on page 8.
 - b. Gently vortex the sealed plate containing the purified sample RNA and Negative Control from the RNA extraction procedure, then centrifuge briefly to collect liquid at the bottom of the plate.
 - c. Unseal the plate containing the purified sample RNA and Negative Control from the RNA extraction procedure. Add either sample RNA, Negative Control, or Positive Control to each well of the reaction plate according to Table 4.

IMPORTANT! To prevent sample contamination, unseal one extraction plate at a time, then reseal it after adding the samples to the RT-PCR reaction plate.

- d. Seal the plate thoroughly with MicroAmp™ Optical Adhesive Film.

IMPORTANT!

- Use ONLY MicroAmp™ Optical Adhesive Film (Cat. No. [4311971](#), [4360954](#)).
 - DO NOT use optical caps, MicroAmp™ Clear Adhesive Film (Cat. No. [4306311](#)), or any other film or sealing method.
 - DO NOT heat seal the plate.
 - When applying the MicroAmp™ Optical Adhesive Film, ensure that pressure is applied across the entire plate and that there is a tight seal across every individual well. Failure to do so runs the risk of an improperly sealed well, leading to potential well-to-well contamination during vortexing and evaporation during PCR.
- e. Vortex the plate at the highest setting speed for 10–30 seconds with medium pressure. Move the plate around to ensure equal contact on the vortex mixer platform.

IMPORTANT! Vortex for 10–30 seconds to ensure proper mixing. Failure to do so might result in incorrect (or inaccurate) clinical calls.

- f. Centrifuge the reaction plate for 1–2 minutes at $\geq 650 \times g$ (≥ 650 RCF) to remove bubbles and to collect the liquid at the bottom of the reaction plate.

IMPORTANT! Centrifuge the plate for 1–2 minutes to ensure bubbles are removed. Failure to do so might result in incorrect (or inaccurate) clinical calls.

Table 4 Reaction plate volumes

Component	Volume per reaction		
	RNA Sample	Positive Control	Negative Control
Reaction Mix (from step 3)	6.0 μL	6.0 μL	6.0 μL
Purified sample RNA (from RNA extraction)	14.0 μL	—	—
Positive Control (diluted TaqPath™ COVID-19 Plus Control from step 2)	—	14.0 μL	—
Negative Control (from RNA extraction)	—	—	14.0 μL
Total volume	20.0 μL	20.0 μL	20.0 μL

Place the plate(s) on ice for immediate use. Proceed immediately to performing the RT-PCR.



Perform RT-PCR using the QuantStudio™ 5 Real-Time PCR Instrument (96-well, 0.2-mL block)

- Dye calibration for the QuantStudio™ 5 Real-Time PCR Instrument 26
- Transfer the template (EDT) file for the QuantStudio™ 5 Real-Time PCR Instrument 26
- Set up and run the QuantStudio™ 5 Real-Time PCR Instrument (96-well plates) 27

Dye calibration for the QuantStudio™ 5 Real-Time PCR Instrument

Ensure the system calibrations are current. Refer to the standard calibration process in the instrument user guide.

Transfer the template (EDT) file for the QuantStudio™ 5 Real-Time PCR Instrument

The template (EDT) file contains the settings for the instrument run.

It is in the same compressed folder as the Pathogen Interpretive Software. The folder is
`RNaseP_2.0_EUA_QS5_96_0.2mL_AssayPanel_Template`

The template must be transferred via a USB drive or other method to the computer on which QuantStudio™ Design and Analysis Desktop Software is installed.

IMPORTANT! Be careful to select the appropriate template file for your instrument and block type. Failure to do so can cause errors in the analysis.

1. After extracting the files from the compressed folder, select the following EDT file:

`TaqPath COVID-19 RNase P Template QS5 0_2ml da1_5_1 v1_0.edt`

Note: The same template file is used for QuantStudio™ Design and Analysis Desktop Software v1.5.1 and v1.5.2.

2. Transfer the EDT file to the computer with QuantStudio™ Design and Analysis Desktop Software, using a USB drive or other method.

Set up and run the QuantStudio™ 5 Real-Time PCR Instrument (96-well plates)

For more information about the instrument, see the documents listed in “Related documentation” on page 59.

Note: For the QuantStudio™ 5 Real-Time PCR Instrument, 96-well, 0.2-mL block, use the system defaults for the PCR filters.

1. In the QuantStudio™ Design and Analysis Desktop Software home screen, in the **New Experiment** box, select **Create New Experiment ▶ Template**.
2. Browse to, then open the EDT file that you transferred in “Transfer the template (EDT) file for the QuantStudio™ 5 Real-Time PCR Instrument” on page 26.

IMPORTANT! Be careful to select the appropriate template file for your instrument and block type. Failure to do so can cause errors in the analysis.

3. In the **Properties** tab, enter or confirm the following.
 - **Name:** Enter a unique name
 - **Instrument type:** **QuantStudio™ 5 System**
 - **Block type:** **96-Well 0.2-mL Block**
 - **Experiment type:** **Standard Curve**
 - **Chemistry:** **TaqMan™ Reagents**
 - **Run Mode:** **Standard**
4. In the **Method** tab, confirm that the **Volume** is **25 µL**, then confirm the thermal cycling protocol.

Step	Temperature ^[1]	Time	Number of cycles
UNG incubation	25°C	2 minutes	1
Reverse transcription	53°C	10 minutes	1
Preincubation	85°C	10 minutes	1
Activation	95°C	2 minutes	1
Denaturation	95°C	3 seconds	40
Anneal / extend	60°C	30 seconds	

^[1] Confirm that the ramp rate for each step is 1.6°C per second.

5. In the **Plate** screen, click **Quick Setup**.
6. In the **Plate Attributes** pane, confirm that the **Passive Reference** is set to **None**.
7. In the **Plate** tab, click **Advanced Setup**.

8. In the **Targets** table, confirm that the targets, reporter dyes, and quencher are listed correctly.

Target name	Reporter dye	Quencher
ORF1a	FAM	None
N Gene	VIC	
ORF1b	ABY	
RNase P	JUN	

IMPORTANT! Target names are case-sensitive and must be named as described.

9. Confirm that the targets above are assigned to each well in the plate layout.
10. In the plate layout pane, confirm the labeling of the control wells.
- The template has one positive control (PC) and one negative control (NC) assigned to wells for reference.
 - The positive control must be named **PC**. If additional characters are included, it must be named **PC<>**, where <> is defined by the user, for example **PC1**.
 - The negative control must be named **NC**. If additional characters are included, it must be named **NC<>**, where <> is defined by the user, for example **NC1**.
 - Move the control well assignments by copying the existing control wells and pasting them according to their location on the physical plate.

IMPORTANT! The positive and negative controls must be named as described.

11. For all targets in the positive control well, confirm that **Task** is set to **S (Standard)** for all of the targets.
12. For all targets in the negative control well, confirm that **Task** is set to **N (Negative Control)** for all of the targets.
13. In the **Samples** table, click **Add** to define the sample names. Create a unique sample name for each well in the physical plate.

IMPORTANT! Encrypt, pseudonymize, or anonymize personal data where possible following the requirements of HIPAA (Health Insurance Portability and Accountability Act)

14. To assign a sample to a well, select the well in the plate layout, then select the sample from the **Samples** table.

For all targets in the patient sample wells, confirm that **Task** is set to **U (Unknown)** for all of the targets.

Note: Wells that do not have a sample name will not be analyzed by the software.

15. Load the prepared and sealed RT-PCR reaction plate into the real-time PCR instrument.

16. Place a MicroAmp™ Optical Film Compression Pad gray side down on the surface of the RT-PCR reaction plate, to ensure a proper seal between the thermal cycler and the adhesive film.

IMPORTANT!

- Be careful to place the compression pad with the brown side up and the gray side down, centered on top of the plate.
 - Ensure the compression pad is free from wrinkles and signs of deterioration prior to use.
-

17. In the **Run** tab, click **Start Run**, then select your instrument from the drop-down list.

18. Enter a file name in the dialog box that prompts you to save the run file, then save the file.

19. At the end of the run, remove the MicroAmp™ Optical Film Compression Pad from the plate and store the compression pad inside the pack.

IMPORTANT!

- If the compression pad becomes stuck inside the thermal cycler, call service to clean the heated cover.
 - Between each use, place the pad back in the pouch so that it does not dry out.
 - Each compression pad may be used up to 20 times before discarding. Do not use more than 20 times.
 - Do NOT use the pad with other instruments, unless expressly instructed to do so in the user documentation.
-



Perform RT-PCR using the QuantStudio™ 7 Flex Real-Time PCR Instrument (384-well block)

- Dye calibration for the QuantStudio™ 7 Flex Real-Time PCR Instrument 30
- Transfer the template (EDT) file for the QuantStudio™ 7 Flex Real-Time PCR Instrument (384-well block) 30
- Set up and run the QuantStudio™ 7 Flex Real-Time PCR Instrument (384-well block) 31

Dye calibration for the QuantStudio™ 7 Flex Real-Time PCR Instrument

Ensure the system calibrations are current. In addition, ABY™ dye and JUN™ dye must be calibrated for use with this kit. Refer to the standard calibration process in the instrument user guide.

Transfer the template (EDT) file for the QuantStudio™ 7 Flex Real-Time PCR Instrument (384-well block)

The template (EDT) file contains the settings for the instrument run.

It is in the same compressed folder as the Pathogen Interpretive Software. The folder is RNaseP_2.0_EUA_QS7_384_AssayPanel_Template

The template must be transferred via a USB drive or other method to the computer on which the QuantStudio™ Real-Time PCR Software is installed.

IMPORTANT! Be careful to select the appropriate template file for your instrument and block type. Failure to do so can cause errors in the analysis.

1. After extracting the files from the compressed folder, select the following EDT file:
TaqPath COVID-19 RNase P Template QS7 384 1_3 v1_0.edt
2. Transfer the EDT file to the computer with QuantStudio™ Real-Time PCR Software, using a USB drive or other method.

Set up and run the QuantStudio™ 7 Flex Real-Time PCR Instrument (384-well block)

For more information about the instrument, see the documents listed in “Related documentation” on page 59.

1. In the QuantStudio™ Real-Time PCR Software home screen, click **Template**.
2. Browse to, then open the EDT file that you transferred in “Transfer the template (EDT) file for the QuantStudio™ 7 Flex Real-Time PCR Instrument (384-well block)” on page 30.

IMPORTANT! Be careful to select the appropriate template file for your instrument, block type, and assay type. Failure to do so can cause errors in the analysis.

3. In the **Experiment Properties** tab, enter or confirm the following.
 - **Experiment Name:** Enter a unique name
 - **Instrument type:** QuantStudio™ 7 Flex System
 - **Block:** 384-well
 - **Type of Experiment:** Standard Curve
 - **Reagents:** TaqMan™ Reagents
 - **Properties:** Standard
4. In the **Define** tab, in the **Targets** pane, confirm that the targets, reporter dyes, and quenchers are listed correctly.

Target name	Reporter dye	Quencher
ORF1a	FAM	None
N Gene	VIC	
ORF1b	ABY	
RNase P	JUN	

IMPORTANT! Target names are case-sensitive and must be named as described.

5. In the **Define** tab, in the **Samples** pane, define a sample name for each sample. Create a unique sample name for each well in the physical plate.

Note: Wells that do not have a sample name will not be analyzed by the software.

IMPORTANT! Encrypt, pseudonymize, or anonymize personal data where possible following the requirements of HIPAA (Health Insurance Portability and Accountability Act)

6. In the **Define** screen, confirm that the **Passive Reference** is set to **None**.

7. In the **Assign** screen, confirm that targets are assigned to each well in the **Plate Layout** tab.
To assign a target to a well, select the well in the plate layout, then select the targets from the **Targets** table.
8. In the **Assign** screen, in the **Plate Layout** tab, confirm the labeling of the control wells.
 - The template has one positive control (PC) and one negative control (NC) assigned to wells for reference.
 - The positive control must be named **PC**. If additional characters are included, it must be named **PC<>**, where <> is defined by the user, for example **PC1**.
 - The negative control must be named **NC**. If additional characters are included, it must be named **NC<>**, where <> is defined by the user, for example **NC1**.
 - Move the control well assignments by copying the existing control wells and pasting them according to their location on the physical plate.

IMPORTANT! The positive and negative controls must be named as described.

9. In the **Assign** screen, confirm the **Task** assignments.
 - For wells with a Positive Control (**PC**), confirm that the **Task** is set to **S (Standard)** for all of the targets.
 - For wells with a Negative Control (**NC**), confirm that the **Task** is set to **N (Negative Control)** for all of the targets.
 - For the wells with a patient sample, confirm that the **Task** is set to **U (Unknown)** for all of the targets.
10. In the **Assign** screen, assign a sample name to each well to match the physical plate.
To assign a sample to a well, select the well in the plate layout, then select the sample from the **Samples** table.

Note: Wells that do not have a sample name will not be analyzed by the software.

11. In the **Run Method** tab, confirm that the **Reaction Volume Per Well** is 20 µL, then confirm the thermal protocol.

Step	Temperature ^[1]	Time	Number of cycles
UNG incubation	25°C	2 minutes	1
Reverse transcription	53°C	10 minutes	1
Preincubation	85°C	10 minutes	1
Activation	95°C	2 minutes	1
Denaturation	95°C	3 seconds	40
Anneal / extend	60°C	30 seconds	

^[1] Confirm that the ramp rate for each step is 1.6°C per second.

12. In the **Run Method** screen, select **Optical Filters**, then select the 8 PCR filters shown in Table 5.
To enable **Optical Filters**, navigate to **Tools ▶ Preferences**, then in the **Defaults** tab, select **Show optical filters for run method**.

Note: Five filters are pre-selected by default.

Table 5 PCR Filters

		Emission Filter					
		m1(520±15)	m2(558±11)	m3(586±10)	m4(623±14)	m5(682±14)	m6(711±12)
Excitation Filter	x1(470±15)	✓	✓				
	x2(520±10)		✓	✓			
	x3(550±11)			✓	✓		
	x4(580±10)				✓		
	x5(640±10)					✓	
	x6(662±10)						

13. Load the prepared and sealed RT-PCR reaction plate into the real-time PCR instrument.
14. In the **Run** screen, click **Start Run**, then select your instrument from the drop-down list.
15. Enter a file name in the dialog box that prompts you to save the run file, then save the file.



Analysis and results

- Software and instrument compatibility 34
- Obtain the software package 35
- Install the assay panel 36
- Analyze the data 37
- Interpretation of the results 37

Software and instrument compatibility

Software	Description
Pathogen Interpretive Software v1.1	Data analysis and results interpretation software
SAE Administrator Console Dx v1.0	Security and audit tool
Pathogen Interpretive Software 1.0.0 DAT (SAE Profile)	Provides settings to connect the SAE Administrator Console Dx with the Pathogen Interpretive Software
C19-RNaseP-EUA_QS5-9602_1.0.0	Assay panel for QuantStudio™ 5 Real-Time PCR Instrument (96-well, 0.2-mL block)
C19-RNaseP-EUA_QS7-384_1.0.0	Assay panel for QuantStudio™ 7 Flex Real-Time PCR Instrument (384-well block)

For information on how to obtain the software, see “Obtain the software package” on page 35.

The following table lists the assay panel that is compatible with the Pathogen Interpretive Software v1.1, your instrument, and its associated analysis software.

To obtain the correct analysis software or firmware version for your real-time PCR instrument, go to [thermofisher.com/validatedfirmware](https://www.thermofisher.com/validatedfirmware), then select your instrument in the **Real-Time PCR** section. If you have questions or problems finding the correct version, contact technical support (see Appendix D, “Documentation and support”).

Instrument	Data collection software used with the instrument	Pathogen Interpretive Software	Assay panel file name ^[1]
QuantStudio™ 5 Real-Time PCR Instrument with instrument firmware v1.3.3 <ul style="list-style-type: none"> • 96-well, 0.2-mL block 	QuantStudio™ Design and Analysis Desktop Software v1.5.1 or v1.5.2	v1.1	C19-RNaseP-EUA_QS5-9602_1.0.0

(continued)

Instrument	Data collection software used with the instrument	Pathogen Interpretive Software	Assay panel file name ^[1]
QuantStudio™ 5 Real-Time PCR Instrument with instrument firmware v1.5.1 <ul style="list-style-type: none"> 96-well, 0.2-mL block 	QuantStudio™ Design and Analysis Desktop Software v1.5.2	v1.1	C19-RNaseP-EUA_QS5-9602_1.0.0
QuantStudio™ 7 Flex Real-Time PCR Instrument with instrument firmware v1.0.4 <ul style="list-style-type: none"> 384-well block 	QuantStudio™ Real-Time PCR Software v1.3	v1.1	C19-RNaseP-EUA_QS7-384_1.0.0

^[1] For information on how to install the assay panel, see “Install the assay panel” on page 36.

Obtain the software package

To perform data analysis and results interpretation, you must use the following software:

- Pathogen Interpretive Software v1.1
- SAE Administrator Console Dx v1.0
- Pathogen Interpretive Software 1.0.0 DAT (SAE Profile)
- The appropriate assay panel for your instrument:
 - C19-RNaseP-EUA_QS5-9602_1.0.0
 - C19-RNaseP-EUA_QS7-384_1.0.0

For installation and configuration instructions, see Appendix D, “Documentation and support”.

The software and assay panel can be installed on a customer-provided computer with the following minimum computer system specifications:

- Operating system—Windows™ 10 (64-bit), with language set to English
- Processor—Pentium® 4 or higher
- Memory—8 GB RAM minimum
- Hard drive—10 GB minimum free space
- Monitor—1280 × 1024 resolution or higher

Note: Do not install the Pathogen Interpretive Software and SAE Administrator Console Dx if it is already installed on your computer. The software can be used with several assay panels.

To obtain the software, contact the instrument service team. Go to [thermofisher.com/contactus](https://www.thermofisher.com/contactus).

Install the assay panel

An assay panel contains the analysis settings that are used for data analysis in the Pathogen Interpretive Software.

The assay panel is located in the same compressed folder as the software and is instrument-specific. Select the folder for your instrument.

Note: The software must be installed before installing the assay panel.

Only one matching assay panel is required to analyze a data file.

1. Extract the files from the compressed folder for your instrument.

Instrument	Folder name
QuantStudio™ 5 Real-Time PCR Instrument	RNaseP_2.0_EUA_QS5_96_0.2mL_AssayPanel_Template
QuantStudio™ 7 Flex Real-Time PCR Instrument	RNaseP_2.0_EUA_QS7_384_AssayPanel_Template

2. In the software, click  **System** ▶ **Assay Panels** ▶ **Actions** ▶ **Install**.

3. Navigate to, then open the assay panel for your instrument.

Instrument	Assay panel file name
QuantStudio™ 5 Real-Time PCR Instrument	C19-RNaseP-EUA_QS5-9602_1.0.0
QuantStudio™ 7 Flex Real-Time PCR Instrument	C19-RNaseP-EUA_QS7-384_1.0.0

4. Click **Install**.

Note: If the assay panel is already installed, you will be prompted to confirm the assay panel upgrade.

The assay panel is added to the **Assay Panels** library.

For more information about assay panels, including uninstalling assay panels, see the documentation for the Pathogen Interpretive Software (Appendix D, “Documentation and support”).

Analyze the data

For detailed instructions about using the software, click the **Help** menu in the Pathogen Interpretive Software.

- Using a USB drive or other method, transfer the EDS files from the computer with the data collection software to the computer with the Pathogen Interpretive Software.
- In the software screen, select one of the following options:

Option	Description
In the Data Gallery , click Actions ▶ Open File .	The data file will open in the current window.
In the Data Gallery , click Actions ▶ Open File in New Window .	The data file will open in a new window.

- Navigate to, then open the data file.
 - The data file opens and the results are displayed in the **Presence Absence** tab.
 - The data file is added to the **Data Gallery**.

Note: If the data file has already been added to the **Data Gallery**, click the file to open the file in the current window or hover over the file, then click **⋮ (Actions) ▶ Open in new window** to open the file in a new window.

Interpretation of the results

Interpretation of the results is performed by the Pathogen Interpretive Software using one of the following panels:

Instrument	Assay panel file name
QuantStudio™ 5 Real-Time PCR Instrument	C19-RNaseP-EUA_QS5-9602_1.0.0
QuantStudio™ 7 Flex Real-Time PCR Instrument	C19-RNaseP-EUA_QS7-384_1.0.0

For information about the C_t values that are used by the software to interpret results, see Appendix A, “ C_t cutoff values for assay targets”.

Quality control and validity of results

A minimum of one Negative Control and one Positive Control must be present for each run. All control wells must pass for the real-time RT-PCR plate to be considered valid (Table 6).

Negative Control wells must be run for each extraction that is represented on a real-time RT-PCR plate. All control wells must pass for the real-time RT-PCR plate to be considered valid.

Validation of results is performed automatically by the software based on performance of the Positive and Negative Controls.

Table 6 Control wells

Negative Control (NC)				Positive Control (PC)				Overall Control Call
ORF1a	N Gene	ORF1b	RNase P	ORF1a	N Gene	ORF1b	RNase P	
NEG	NEG	NEG	NEG	POS	POS	POS	POS	Pass
All other scenarios								Fail

Table 7 Results interpretation for viral targets in patient samples

Sample ^[1]				Call	Assessment
ORF1a	N Gene	ORF1b	RNase P		
POS	POS	POS	POS or NEG	Presence	REPORT - SARS-CoV-2 Detected
POS	POS	NEG	POS or NEG	Presence	REPORT - SARS-CoV-2 Detected
POS	NEG	POS	POS or NEG	Presence	REPORT - SARS-CoV-2 Detected
NEG	POS	POS	POS or NEG	Presence	REPORT - SARS-CoV-2 Detected
NEG	NEG	NEG	POS	Absence	REPORT - SARS-CoV-2 Not Detected
NEG	NEG	NEG	NEG	Invalid	RETEST ^[2]
NEG	NEG	POS	POS or NEG	Inconclusive	RETEST ^[2] /REPORT - SARS-CoV-2 Inconclusive
NEG	POS	NEG	POS or NEG	Inconclusive	RETEST ^[2] /REPORT - SARS-CoV-2 Inconclusive
POS	NEG	NEG	POS or NEG	Inconclusive	RETEST ^[2] /REPORT - SARS-CoV-2 Inconclusive

^[1] Controls must pass for viral targets to be interpreted (Table 6).

^[2] Retesting must be performed by re-extracting the RNA from the original sample and repeating the RT-PCR. If the repeat result remains invalid, consider collecting a new specimen. If the repeat result remains inconclusive, the healthcare provider should conduct additional confirmation testing with a new specimen, if clinically indicated.

7

Conditions of authorization for labs

The TaqPath™ COVID-19 RNase P Combo Kit 2.0 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: [fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas](https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas).

However, to assist clinical laboratories using the TaqPath™ COVID-19 RNase P Combo Kit 2.0, the relevant Conditions of Authorization are listed below.

- Authorized laboratories^[1] using the TaqPath™ COVID-19 RNase P Combo Kit 2.0 will include with result reports of the TaqPath™ COVID-19 RNase P Combo Kit 2.0 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 using the TaqPath™ COVID-19 RNase P Combo Kit 2.0 will perform the TaqPath™ COVID-19 RNase P Combo Kit 2.0 as outlined in the *TaqPath™ COVID-19 RNase P Combo Kit 2.0 Instructions For Use*. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents, and authorized materials required to perform the TaqPath™ COVID-19 RNase P Combo Kit 2.0 are not permitted.
- Authorized laboratories that receive the TaqPath™ COVID-19 RNase P Combo Kit 2.0 must notify the relevant public health authorities of their intent to run the test prior to initiating testing.
- Authorized laboratories using the TaqPath™ COVID-19 RNase P Combo Kit 2.0 will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories 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 Thermo Fisher Scientific (techservices@thermofisher.com; 1 800 955 6288) 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.
- Authorized laboratories testing anterior nasal swab specimens that are collected using the Color COVID-19 Self-Swab Collection Kit with Saline must follow the standard operating procedure *Specimen Receipt and Handling for the Color COVID-19 Self-Swab Collection Kit with Saline* for specimen receipt and handling when accepting specimens for testing.
- 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.

^[1] For ease of reference, this letter will refer 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” as “authorized laboratories.”

- Thermo Fisher Scientific, its authorized distributor(s), and authorized laboratories using the TaqPath™ COVID-19 RNase P Combo Kit 2.0 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.



Performance characteristics

- Limit of detection (LoD) 41
- Reactivity (Inclusivity) 45
- Interfering substances 46
- Cross-reactivity 48
- Clinical evaluation 50

Analytical performance of the TaqPath™ COVID-19 RNase P Combo Kit 2.0 was evaluated by determining limit of detection (LoD), and by characterizing the impact of interfering substances and cross-reactivity, as described in the following sections.

Limit of detection (LoD)

The LoD study with 17.5 µL and 14.0 µL of purified sample RNA established the lowest SARS-CoV-2 viral concentration (Genomic Copy Equivalents or GCE) that can be detected by the TaqPath™ COVID-19 RNase P Combo Kit 2.0 at least 95% of the time. Banked nasopharyngeal swab (NP) and anterior nasal swab (NS) samples, negative for SARS-CoV-2, were obtained from patients in the years 15-2019. The samples were pooled, spiked with gamma-irradiated SARS-CoV-2 isolate USA-WA1/2020 at several concentrations), then processed through the TaqPath™ COVID-19 RNase P Combo Kit 2.0 workflow. A two-phase approach was used to determine the LoD for each specimen type. A preliminary LoD was established in phase I, and LoD was confirmed in phase II by testing 20 replicates.

Table 8 LoD determination in nasopharyngeal (NP) specimens spiked with gamma-irradiated SARS-CoV-2 isolate USA-WA1/2020 (QuantStudio™ 5 Real-Time PCR Instrument (96-well), 17.5 µL of purified sample RNA)

Concentration	Replicate	C _t				Interpretation	% Positive
		ORF1a	N Gene	ORF1b	RNase P		
75 GCE/mL of sample	1	30.44	31.32	31.35	22.88	Positive	100%
	2	30.81	32.07	31.57	23.23	Positive	
	3	31.28	31.78	31.59	23.22	Positive	
	4	30.33	31.11	31.03	23.05	Positive	
	5	30.83	31.83	31.14	23.15	Positive	
	6	30.16	30.89	30.81	22.93	Positive	
	7	31.06	30.95	31.18	23.16	Positive	

Table 8 LoD determination in nasopharyngeal (NP) specimens spiked with gamma-irradiated SARS-CoV-2 isolate USA-WA1/2020 (QuantStudio 5 Real-Time PCR Instrument (96-well), 17.5 µL of purified sample RNA) (continued)

Concentration	Replicate	C _t				Interpretation	% Positive
		ORF1a	N Gene	ORF1b	RNase P		
75 GCE/mL of sample	8	29.73	30.63	30.29	23.05	Positive	100%
	9	30.44	31.44	31.44	23.08	Positive	
	10	30.70	31.11	31.30	23.05	Positive	
	11	30.57	30.98	31.01	23.01	Positive	
	12	31.16	32.14	32.26	23.33	Positive	
	13	30.73	31.10	31.21	23.20	Positive	
	14	30.62	31.43	31.37	23.19	Positive	
	15	30.67	31.75	31.43	23.14	Positive	
	16	30.48	31.09	30.96	23.20	Positive	
	17	30.30	31.13	30.90	23.07	Positive	
	18	30.46	31.04	30.90	23.14	Positive	
	19	30.76	31.27	31.23	23.04	Positive	
	20	30.70	31.40	31.34	23.18	Positive	

Table 9 LoD determination in nasopharyngeal (NP) specimens spiked with gamma-irradiated SARS-CoV-2 isolate USA-WA1/2020 (QuantStudio™ 7 Flex Real-Time PCR Instrument (384-well), 14.0 µL of purified sample RNA)

Concentration	Replicate	C _t				Interpretation	% Positive
		ORF1a	N Gene	ORF1b	RNase P		
75 GCE/mL of sample	1	30.93	33.15	36.44	22.76	Positive	100%
	2	28.85	32.34	31.63	22.73	Positive	
	3	32.94	33.51	35.75	22.73	Positive	
	4	29.39	32.41	31.66	22.65	Positive	
	5	30.87	32.96	32.25	22.63	Positive	
	6	31.74	32.26	33.06	22.68	Positive	
	7	31.14	32.31	32.26	22.57	Positive	
	8	31.94	32.78	32.31	22.59	Positive	
	9	32.56	33.98	36.35	22.87	Positive	

Table 9 LoD determination in nasopharyngeal (NP) specimens spiked with gamma-irradiated SARS-CoV-2 isolate USA-WA1/2020 (QuantStudio 7 Flex Real-Time PCR Instrument (384-well), 14.0 µL of purified sample RNA) (continued)

Concentration	Replicate	C _t				Interpretation	% Positive
		ORF1a	N Gene	ORF1b	RNase P		
75 GCE/mL of sample	10	36.69	33.31	36.24	22.90	Positive	100%
	11	29.91	32.70	32.54	22.62	Positive	
	12	30.70	31.99	31.54	23.20	Positive	
	13	31.64	32.48	32.00	22.98	Positive	
	14	31.13	32.52	32.22	22.61	Positive	
	15	31.99	32.74	32.32	22.70	Positive	
	16	32.32	32.52	32.20	22.97	Positive	
	17	31.08	31.96	32.32	22.65	Positive	
	18	29.90	31.65	31.30	22.58	Positive	
	19	31.29	32.70	32.93	22.63	Positive	
	20	31.63	34.09	32.62	23.25	Positive	

Table 10 LoD determination in anterior nasal swab (NS) specimens spiked with gamma-irradiated SARS-CoV-2 isolate USA-WA1/2020 (QuantStudio™ 5 Real-Time PCR Instrument (96-well), 17.5 µL of purified sample RNA)

Concentration	Replicate	C _t				Interpretation	% Positive
		ORF1a	N Gene	ORF1b	RNase P		
75 GCE/mL of sample	1	31.52	32.34	32.19	24.60	Positive	100%
	2	30.93	31.49	31.28	24.89	Positive	
	3	31.47	31.46	31.43	24.73	Positive	
	4	30.99	31.18	31.30	24.66	Positive	
	5	30.95	31.68	31.32	24.40	Positive	
	6	30.47	31.31	30.81	24.31	Positive	
	7	30.82	31.61	31.47	24.45	Positive	
	8	31.13	31.90	31.63	24.45	Positive	
	9	30.92	31.46	31.50	24.52	Positive	
	10	30.66	31.41	31.14	24.54	Positive	
	11	31.41	31.94	31.62	24.23	Positive	

Table 10 LoD determination in anterior nasal swab (NS) specimens spiked with gamma-irradiated SARS-CoV-2 isolate USA-WA1/2020 (QuantStudio 5 Real-Time PCR Instrument (96-well), 17.5 µL of purified sample RNA) (continued)

Concentration	Replicate	C _t				Interpretation	% Positive
		ORF1a	N Gene	ORF1b	RNase P		
75 GCE/mL of sample	12	31.39	31.94	31.47	24.42	Positive	100%
	13	30.96	31.35	31.38	24.50	Positive	
	14	30.50	31.09	30.57	24.53	Positive	
	15	31.10	31.42	31.63	24.34	Positive	
	16	30.24	30.77	30.58	24.37	Positive	
	17	30.90	31.82	31.13	24.38	Positive	
	18	30.76	31.57	31.20	24.39	Positive	
	19	30.92	31.46	30.99	24.32	Positive	
	20	31.45	31.55	31.67	24.39	Positive	

Table 11 LoD determination in anterior nasal swab (NS) specimens spiked with gamma-irradiated SARS-CoV-2 isolate USA-WA1/2020 (QuantStudio™ 7 Flex Real-Time PCR Instrument (384-well), 14.0 µL of purified sample RNA)

Concentration	Replicate	C _t				Interpretation	% Positive
		ORF1a	N Gene	ORF1b	RNase P		
75 GCE/mL of sample	1	31.85	32.71	33.43	24.53	Positive	100%
	2	31.84	32.54	32.22	24.89	Positive	
	3	30.98	33.12	32.39	24.80	Positive	
	4	31.83	32.55	32.42	24.52	Positive	
	5	32.25	32.72	32.37	24.39	Positive	
	6	31.24	32.73	32.15	24.53	Positive	
	7	31.71	32.92	32.92	24.52	Positive	
	8	32.44	33.47	32.89	24.53	Positive	
	9	31.96	32.50	32.31	24.52	Positive	
	10	32.21	33.63	32.64	25.01	Positive	
	11	28.71	32.73	33.20	24.21	Positive	
	12	31.77	33.62	32.98	24.56	Positive	
	13	31.66	32.23	32.12	24.50	Positive	

Table 11 LoD determination in anterior nasal swab (NS) specimens spiked with gamma-irradiated SARS-CoV-2 isolate USA-WA1/2020 (QuantStudio 7 Flex Real-Time PCR Instrument (384-well), 14.0 µL of purified sample RNA) (continued)

Concentration	Replicate	C _t				Interpretation	% Positive
		ORF1a	N Gene	ORF1b	RNase P		
75 GCE/mL of sample	14	31.97	33.00	32.67	24.48	Positive	100%
	15	31.35	32.56	31.79	24.32	Positive	
	16	31.42	33.52	32.23	24.36	Positive	
	17	31.54	32.28	32.11	24.44	Positive	
	18	31.48	32.49	32.29	24.41	Positive	
	19	32.09	32.73	32.37	24.60	Positive	
	20	32.25	32.67	32.74	24.54	Positive	

Table 12 LoD results

Specimen type	Limit of Detection (GCE/mL of sample)
Nasopharyngeal swab	75 GCE/mL of sample
Anterior nasal swab	75 GCE/mL of sample

Reactivity (Inclusivity)

In silico analysis was executed using 108,046 complete SARS-CoV-2 genomes that were deposited in the GISAID database, from May 10, 2022 to June 10, 2022, and which includes the following variants:

- 10 genomes of the Delta variant
- 107,646 genomes of the Omicron variant
- 131 genomes of the XE variant
- 259 genomes of variants without a WHO label

For the purposes of this analysis, a sequence was considered detected if the calculated melting temperatures for the probe and each of the primers for at least one assay from each of two target regions (ORF1a, ORF1b, or N gene) were above the annealing temperature set-point. Based upon this analysis, the primers and probes for the TaqPath™ COVID-19 RNase P Combo Kit 2.0 are predicted to detect all currently circulating variants of SARS-CoV-2.

Interfering substances

Pooled SARS-CoV-2-negative nasopharyngeal swab specimens were spiked with inactivated SARS-CoV-2 at 3 times the limit of detection (225 GCE/mL) and potential interfering substances at the concentrations listed in Table 13. In addition, pooled negative swab specimens without spiked SARS-CoV-2 were spiked with potential interfering substances at the same concentrations. Each substance was tested with triplicate extractions. The results are presented in Table 13.

No false positive or false negative results were observed for any of the substances at the concentrations tested.

Table 13 Interfering substances

Interfering substance	Final concentration in sample	Agreement with expected results			
		Positive NP samples		Negative NP samples	
		QuantStudio™ 5 Real-Time PCR Instrument	QuantStudio™ 7 Flex Real-Time PCR Instrument	QuantStudio™ 5 Real-Time PCR Instrument	QuantStudio™ 7 Flex Real-Time PCR Instrument
None	N/A	100%	100%	100%	100%
Mucin: bovine submaxillary gland, type I-S	0.1 mg/mL	100%	100%	100%	100%
Blood (human)	1% v/v	100%	100%	100%	100%
Nasal spray (Afrin™)	10% v/v	100%	100%	100%	100%
Nasal corticosteroids—Fluticasone Propionate	5 µg/mL	100%	100%	100%	100%
Nasal gel—NeilMed™ Nasogel™	1% w/v	100%	100%	100%	100%
Homeopathic allergy relief medicine—bioAllers®	10% v/v	100%	100%	100%	100%
Throat lozenges, oral anesthetic and analgesic—Dorithricin®	1% w/v	100%	100%	100%	100%
Oseltamivir phosphate	33 µg/mL	100%	100%	100%	100%
Antibiotic, nasal ointment—Pseudomonic Acid	5 µg/mL	100%	100%	100%	100%
Antibacterial, systemic—Tobramycin	0.6 mg/mL	100%	100%	100%	100%

Cross-reactivity

Functional testing was performed using the following 37 organisms plus pooled human nasal wash. No calls of **Presence** were generated using the TaqPath™ COVID-19 RNase P Combo Kit 2.0 and one call of **Inconclusive** was obtained with the SARS coronavirus due to positive amplification of one of the three SARS-CoV-2 targets.

Table 14 Organisms used for *in vitro* cross-reactivity analysis

Human coronavirus 229E	Hepatitis B virus
Human coronavirus OC43	Hepatitis C virus
Human coronavirus HKU1	Varicella-zoster virus
Human coronavirus NL63	Cytomegalovirus
SARS-coronavirus ^[1]	<i>Chlamydomphila pneumoniae</i>
MERS-coronavirus	<i>Haemophilus influenzae</i>
Adenovirus	<i>Legionella pneumophila</i>
Human Metapneumovirus (hMPV)	<i>Mycobacterium tuberculosis</i>
Parainfluenza 1	<i>Streptococcus pneumoniae</i>
Parainfluenza 2	<i>Streptococcus pyogenes</i>
Parainfluenza 3	<i>Bordetella pertussis</i>
Parainfluenza 4	<i>Mycoplasma pneumoniae</i>
Influenza A	<i>Pseudomonas aeruginosa</i>
Influenza B	<i>Staphylococcus epidermidis</i>
Enterovirus	<i>Streptococcus salivarius</i>
Respiratory Syncytial Virus	<i>Candida albicans</i>
Rhinovirus	<i>Pneumocystis carinii</i>
Epstein-Barr virus (human herpesvirus 4)	<i>Pneumocystis jirovecii</i>
Human immunodeficiency virus (HIV)	Pooled human nasal wash

^[1] SARS coronavirus generated a call of Inconclusive (amplification was observed for the N Gene, while no amplification was observed for the ORF1a and ORF1b targets).

In addition to functional testing, an *in silico* study was performed to assess cross-reactivity between the TaqPath™ COVID-19 RNase P Combo Kit 2.0 primer/probe sequences and the organisms in Table 15, using BLAST analysis. With the exception of SARS-CoV, no bacterial, viral, or fungal microbe sequence aligned with $\geq 80\%$ identity to more than one TaqPath™ COVID-19 RNase P Combo Kit 2.0 assay component. The majority of the 285 SARS coronavirus isolates tested in this study shared $\geq 80\%$ identity with more than one assay component for N gene and ORF1b assays.

Table 15 Organisms used for *in silico* cross-reactivity analysis

<i>Bacillus anthracis</i>	Adenovirus
<i>Bacteroides oralis</i>	Cytomegalovirus (human herpesvirus 5)
<i>Bordetella pertussis</i>	Enterovirus
<i>Chlamydophila psittaci</i>	Epstein-Barr virus (human herpesvirus 4)
<i>Chlamydophila pneumoniae</i>	Hepatitis B Virus
<i>Corynebacterium diphtheriae</i>	Hepatitis C Virus
<i>Coxiella burnetii</i>	Herpes Simplex Virus type 1
<i>Eikenella spp.</i>	Human coronavirus 229E
<i>Haemophilus influenzae</i>	Human coronavirus HKU1
<i>Legionella non-pneumophila</i>	Human coronavirus NL63
<i>Legionella pneumophila</i>	Human coronavirus OC43
<i>Leptospira spp.</i>	Human Immunodeficiency Virus
<i>Moraxella catarrhalis</i>	Human Metapneumovirus (hMPV)
<i>Mycobacterium tuberculosis</i>	Influenza A virus
<i>Mycoplasma pneumoniae</i>	Influenza B virus
<i>Neisseria elongata</i>	Influenza C virus
<i>Neisseria meningitidis</i>	MERS Coronavirus
<i>Nocardia spp.</i>	Parainfluenza 1 virus
<i>Porphyromonas gingivalis</i>	Parainfluenza 2 virus
<i>Pseudomonas aeruginosa</i>	Parainfluenza 3 virus
<i>Staphylococcus aureus</i>	Parainfluenza 4 virus
<i>Staphylococcus epidermidis</i>	Parvovirus
<i>Streptococcus mutans</i>	Respiratory Syncytial Virus A
<i>Streptococcus pneumoniae</i>	Respiratory Syncytial Virus B
<i>Streptococcus pyogenes</i>	Rhinovirus
<i>Streptococcus salivarius</i>	SARS-coronavirus
<i>Candida albicans</i>	Varicella-zoster virus (human herpesvirus 3)
<i>Pneumocystis jirovecii</i>	

Clinical evaluation

A clinical evaluation study was carried out to evaluate the performance of the TaqPath™ COVID-19 RNase P Combo Kit 2.0 using archived nasopharyngeal swab (NP) and anterior nasal swab (NS) specimens.

The following specimens were tested:

- 60 specimens positive for SARS-CoV-2 (54 nasopharyngeal swabs and 6 anterior nasal swabs)
- 60 specimens negative for SARS-CoV-2 (45 nasopharyngeal swabs and 15 anterior nasal swabs)

Samples were tested using the TaqPath™ COVID-19 RNase P Combo Kit 2.0 and an FDA EUA- Authorized comparator assay.

Samples were extracted using the MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit for testing with TaqPath™ COVID-19 RNase P Combo Kit 2.0 and RT-PCR was performed on the QuantStudio™ 5 Real-Time PCR Instrument (96-well, 0.2-mL block) and the QuantStudio™ 7 Flex Real-Time PCR Instrument (384-well). The comparator method was conducted according to the Instructions for Use for the comparator assays.

Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) were calculated relative to the comparator test. Results are shown below.

Table 16 Clinical evaluation study—nasopharyngeal swabs and anterior nasal swabs (QuantStudio™ 5 Real-Time PCR Instrument, 96-well, 0.2-mL block)

TaqPath™ COVID-19 RNase P Combo Kit 2.0	Comparator assay		
	SARS-CoV-2 Positive	SARS-CoV-2 Negative	Total
SARS-CoV-2 Positive	58	3	61
SARS-CoV-2 Negative	2	57	59
Total	60	60	120
PPA: 96.7% (95% CI: 88.5% LCL - 99.6% UCL) ^[1]			
NPA: 95% (95% CI: 86.1% LCL - 99.0% UCL) ^[1]			

^[1] An exact two-sided 95% Confidence Interval (CI) was calculated using the Clopper-Pearson method.

Table 17 Clinical evaluation study—nasopharyngeal swabs and anterior nasal swabs (QuantStudio™ 7 Flex Real-Time PCR Instrument, 384-well)

TaqPath™ COVID-19 RNase P Combo Kit 2.0	Comparator assay		
	SARS-CoV-2 Positive	SARS-CoV-2 Negative	Total
SARS-CoV-2 Positive	57	2	59
SARS-CoV-2 Negative	3	58	61
Total	60	60	120
PPA: 95.0% (95% CI: 86.1% LCL - 99.0% UCL) ^[1]			
NPA: 96.7% (95% CI: 88.5% LCL - 99.6% UCL) ^[1]			

^[1] An exact two-sided 95% Confidence Interval (CI) was calculated using the Clopper-Pearson method.

Table 18 Clinical evaluation study—nasopharyngeal swabs only (QuantStudio™ 5 Real-Time PCR Instrument, 96-well, 0.2-mL block)

TaqPath™ COVID-19 RNase P Combo Kit 2.0	Comparator assay		
	SARS-CoV-2 Positive	SARS-CoV-2 Negative	Total
SARS-CoV-2 Positive	52	3	55
SARS-CoV-2 Negative	2	42	44
Total	54	45	99

Table 19 Clinical evaluation study—nasopharyngeal swabs only (QuantStudio™ 7 Flex Real-Time PCR Instrument, 384-well)

TaqPath™ COVID-19 RNase P Combo Kit 2.0	Comparator assay		
	SARS-CoV-2 Positive	SARS-CoV-2 Negative	Total
SARS-CoV-2 Positive	51	1	52
SARS-CoV-2 Negative	3	44	47
Total	54	45	99

Table 20 Clinical evaluation study—anterior nasal swabs only (QuantStudio™ 5 Real-Time PCR Instrument, 96-well, 0.2-mL block)

TaqPath™ COVID-19 RNase P Combo Kit 2.0	Comparator assay		
	SARS-CoV-2 Positive	SARS-CoV-2 Negative	Total
SARS-CoV-2 Positive	6	0	6
SARS-CoV-2 Negative	0	15	15
Total	6	15	21

Table 21 Clinical evaluation study— anterior nasal swabs only (QuantStudio™ 7 Flex Real-Time PCR Instrument, 384-well)

TaqPath™ COVID-19 RNase P Combo Kit 2.0	Comparator assay		
	SARS-CoV-2 Positive	SARS-CoV-2 Negative	Total
SARS-CoV-2 Positive	6	1	7
SARS-CoV-2 Negative	0	14	14
Total	6	15	21

A clinical evaluation study was also carried out to evaluate the performance of the TaqPath™ COVID-19 RNase P Combo Kit 2.0 in an asymptomatic population. Nasopharyngeal swabs and mid-turbinate nasal swabs were collected from donors who showed no symptoms of COVID-19 or any other reason to suspect COVID-19. Retrospective and prospective samples were consecutively collected between September 2021 and February 2022.

A total of 206 samples were enrolled for this clinical evaluation study.

Samples were tested using the TaqPath™ COVID-19 RNase P Combo Kit 2.0 and an FDA EUA- Authorized comparator assay.

Samples were extracted using the MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit for testing with TaqPath™ COVID-19 RNase P Combo Kit 2.0 and RT-PCR was performed on the QuantStudio™ 5 Real-Time PCR Instrument (96-well, 0.2-mL block) and the QuantStudio™ 7 Flex Real-Time PCR Instrument (384-well). The comparator method was conducted according to the Instructions for Use for the comparator assays.

Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) were calculated relative to the comparator test. Results are shown below.

Table 22 Clinical evaluation study (QuantStudio™ 5 Real-Time PCR Instrument, 96-well, 0.2-mL block)

TaqPath™ COVID-19 RNase P Combo Kit 2.0	Comparator assay		
	SARS-CoV-2 Positive	SARS-CoV-2 Negative	Total
SARS-CoV-2 Positive	27	0	27
SARS-CoV-2 Negative	1	172	173
Total	28	172	200^[1]
PPA: 96.43% (95% CI: 81.65% LCL - 99.91% UCL) ^[2]			
NPA: 100% (95% CI: 97.88% LCL - 100% UCL) ^[2]			

^[1] Six invalid/inconclusive samples were excluded from analysis per the protocol.

^[2] An exact two-sided 95% Confidence Interval (CI) was calculated using the Clopper-Pearson method.

Table 23 Clinical evaluation study (QuantStudio™ 7 Flex Real-Time PCR Instrument, 384-well)

TaqPath™ COVID-19 RNase P Combo Kit 2.0	Comparator assay		
	SARS-CoV-2 Positive	SARS-CoV-2 Negative	Total
SARS-CoV-2 Positive	26	0	26
SARS-CoV-2 Negative	1	172	173
Total	27	172	199^[1]
PPA: 96.30% (95% CI: 81.03% LCL - 99.91% UCL) ^[2]			
NPA: 100% (95% CI: 97.88% LCL - 100% UCL) ^[2]			

^[1] Seven invalid/inconclusive samples were excluded from analysis per the protocol.

^[2] An exact two-sided 95% Confidence Interval (CI) was calculated using the Clopper-Pearson method.



C_t cutoff values for assay targets

The Pathogen Interpretive Software uses the following C_t cutoff values for assay targets during interpretation of the results.

Table 24 C_t cutoff values

Sample or Control	Target	C _t cutoff
Positive Control	RNase P	Valid C _t values are ≤35
	Viral targets	Valid C _t values are ≤37
Negative Control	RNase P	Valid C _t values are >35
	Viral targets	Valid C _t values are >37
Clinical samples	RNase P	Valid C _t values are ≤32 ^[1]
	Viral targets	Positive C _t values are ≤37

^[1] If any of the viral targets is positive, the C_t for RNase P can be >32.

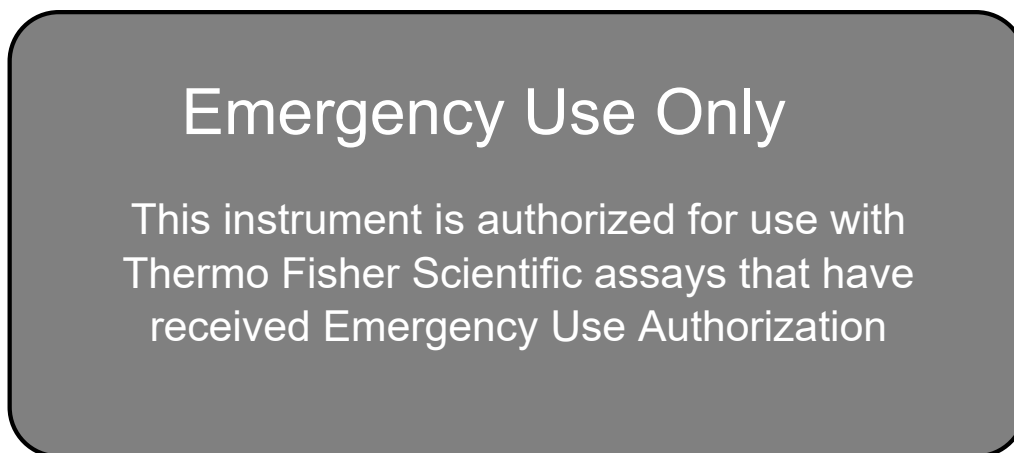


EUO label for RUO instruments

Affix the Emergency Use Only (EUO) label on each of the following instruments. Retain this labeling throughout the Emergency Use Authorization (EUA) use of the instruments.

- QuantStudio™ 5 Real-Time PCR Instrument
- QuantStudio™ 7 Flex Real-Time PCR Instrument

1. Download or print the following EUO label:



2. Visibly affix the EUO instrument verification label on your instrument. If the instrument includes labeling indicating “For Research Use Only”, cover with the EUO instrument verification label.



Safety

■ Chemical safety	57
■ Biological hazard safety	58



WARNING! GENERAL SAFETY. Using this product in a manner not specified in the user documentation may result in personal injury or damage to the instrument or device. Ensure that anyone using this product has received instructions in general safety practices for laboratories and the safety information provided in this document.

- Before using an instrument or device, read and understand the safety information provided in the user documentation provided by the manufacturer of the instrument or device.
- Before handling chemicals, read and understand all applicable Safety Data Sheets (SDSs) and use appropriate personal protective equipment (gloves, gowns, eye protection, and so on). To obtain SDSs, visit [thermofisher.com/support](https://www.thermofisher.com/support).



Chemical safety



WARNING! GENERAL CHEMICAL HANDLING. To minimize hazards, ensure laboratory personnel read and practice the general safety guidelines for chemical usage, storage, and waste provided below. Consult the relevant SDS for specific precautions and instructions:

- Read and understand the Safety Data Sheets (SDSs) provided by the chemical manufacturer before you store, handle, or work with any chemicals or hazardous materials. To obtain SDSs, see the "Documentation and Support" section in this document.
- Minimize contact with chemicals. Wear appropriate personal protective equipment when handling chemicals (for example, safety glasses, gloves, or protective clothing).
- Minimize the inhalation of chemicals. Do not leave chemical containers open. Use only with sufficient ventilation (for example, fume hood).
- Check regularly for chemical leaks or spills. If a leak or spill occurs, follow the manufacturer cleanup procedures as recommended in the SDS.
- Handle chemical wastes in a fume hood.
- Ensure use of primary and secondary waste containers. (A primary waste container holds the immediate waste. A secondary container contains spills or leaks from the primary container. Both containers must be compatible with the waste material and meet federal, state, and local requirements for container storage.)
- After emptying a waste container, seal it with the cap provided.
- Characterize (by analysis if needed) the waste generated by the particular applications, reagents, and substrates used in your laboratory.
- Ensure that the waste is stored, transferred, transported, and disposed of according to all local, state/provincial, and/or national regulations.
- **IMPORTANT!** Radioactive or biohazardous materials may require special handling, and disposal limitations may apply.



Biological hazard safety



WARNING! Potential Biohazard. Depending on the samples used on this instrument, the surface may be considered a biohazard. Use appropriate decontamination methods when working with biohazards.



WARNING! BIOHAZARD. Biological samples such as tissues, body fluids, infectious agents, and blood of humans and other animals have the potential to transmit infectious diseases. Conduct all work in properly equipped facilities with the appropriate safety equipment (for example, physical containment devices). Safety equipment can also include items for personal protection, such as gloves, coats, gowns, shoe covers, boots, respirators, face shields, safety glasses, or goggles. Individuals should be trained according to applicable regulatory and company/ institution requirements before working with potentially biohazardous materials. Follow all applicable local, state/provincial, and/or national regulations. The following references provide general guidelines when handling biological samples in laboratory environment.

- U.S. Department of Health and Human Services, *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, 6th Edition, HHS Publication No. (CDC) 300859, Revised June 2020; found at:
www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2020-P.pdf
- Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs); found at:
www.who.int/publications/i/item/9789240011311



Documentation and support

- Related documentation 59
- Customer and technical support 59
- Limited product warranty 60

Related documentation

Document	Publication Number
<i>QuantStudio™ 3 and 5 Real-Time PCR Systems Installation, Use, and Maintenance Guide</i>	MAN0010407
<i>QuantStudio™ 6 and 7 Flex Real-Time PCR Systems (v1.3) Maintenance and Administration Guide</i>	4489821
<i>QuantStudio™ Real-Time PCR Software Getting Started Guide</i>	4489822
<i>MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit Instructions For Use</i>	MAN0019746
<i>Thermo Scientific™ KingFisher™ Flex User Manual</i>	MAN0019870
<i>Pathogen Interpretive Software Installation Quick Reference</i>	MAN0019535
<i>SAE Administrator Console Dx User Guide^[1]</i>	MAN0019574

^[1] For use with the Pathogen Interpretive Software.

Customer and technical support

For additional documentation and information about this kit, visit:

<http://thermofisher.com/TaqPathC19RNaseP-EUA>

For download instructions for the software package, see “Obtain the software package” on page 35.

Visit: <https://www.thermofisher.com/contactus> for service and support information for this kit, including the following:

- Worldwide contact telephone numbers
- Product support information
- Order and web support



- Product documentation such as:
 - Certificates of Analysis
 - Safety Data Sheets (SDSs; also known as MSDSs)

Note: For SDSs for reagents and chemicals from other manufacturers, contact the manufacturer.

Limited product warranty

Life Technologies Corporation and/or its affiliate(s) warrant their products as set forth in the Life Technologies' General Terms and Conditions of Sale at www.thermofisher.com/us/en/home/global/terms-and-conditions.html. If you have any questions, please contact Life Technologies at www.thermofisher.com/support.

TaqPath™ COVID-19 RNase P Combo Kit 2.0

Multiplex real-time RT-PCR test for the detection of SARS-CoV-2 RNA

Catalog Number A51333

Pub. No. 100102546 Rev. D

For Emergency Use Authorization Only

Intended Use

The Applied Biosystems™ TaqPath™ COVID-19 RNase P Combo Kit 2.0 contains the assays and controls for a real-time reverse transcription polymerase chain reaction (RT-PCR) test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in nasopharyngeal swabs and anterior or mid-turbinate nasal swabs from any individual, including individuals without symptoms or other epidemiological reasons to suspect COVID-19.

This test is also authorized for use with anterior nasal swab specimens that are collected using the Color COVID-19 Self-Swab Collection Kit with Saline when used consistent with its authorization.

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 upper respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status.

Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all test 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 TaqPath™ COVID-19 RNase P Combo Kit 2.0 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.

The TaqPath™ COVID-19 RNase P Combo Kit 2.0 is only for use under the Food and Drug Administration's Emergency Use Authorization.

Instructions for Use/Interpretation/Limitations

The complete *TaqPath™ COVID-19 RNase P Combo Kit 2.0 Instructions For Use* (Pub. No. MAN0024969) can be downloaded from the following link:

thermofisher.com/findyourifu

If you require a printed copy (no charge) or cannot access the document at this location, visit thermofisher.com/askaquestion or call 1 800 955 6288 (U.S. only).

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

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

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

IVD

Obtain the software package

To perform data analysis and results interpretation, you must use the following software:

- Applied Biosystems™ Pathogen Interpretive Software v1.1
- SAE Administrator Console Dx v1.0 (for security and audit functions)
- Pathogen Interpretive Software 1.0.0 DAT (SAE Profile)
- Assay panel for your instrument

To obtain the software, contact your local technical support team. Go to <https://www.thermofisher.com/contactus>.

Contents and storage

Table 1 TaqPath™ COVID-19 RNase P Combo Kit 2.0, 1,000 reactions (Cat. No. [A51333](#))

Component	Quantity	Amount per tube or bottle	Storage
TaqPath™ COVID-19 RNase P Kit 2.0	1 tube	1,500 µL	-30°C to -10°C ^[1]
TaqPath™ COVID-19 Plus Control (1 x 10 ⁴ copies/µL)	10 tubes	10 µL	≤ -20°C
TaqPath™ COVID-19 Control Dilution Buffer	10 tubes	250 µL	-30°C to -10°C

^[1] Do not freeze-thaw assays more than 12 times.

Customer and technical support

For additional documentation and information about this kit, visit:

<http://www.thermofisher.com/TaqPathC19RNaseP-EUA>

For download instructions for the software package, see “Obtain the software package”. Refer to the Software Release Notes provided with the software before contacting support for the software.

Visit: <https://www.thermofisher.com/contactus> for service and support information for this kit, including worldwide contact telephone numbers, product support information, order and web support, Certificates of Analysis, and Safety Data Sheets (SDSs; also known as MSDSs).

Note: For SDSs for reagents and chemicals from other manufacturers, contact the manufacturer.

Limited product warranty

Life Technologies Corporation and/or its affiliate(s) warrant their products as set forth in the Life Technologies' General Terms and Conditions of Sale at www.thermofisher.com/us/en/home/global/terms-and-conditions.html. If you have any questions, please contact Life Technologies at www.thermofisher.com/support.



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For descriptions of symbols on product labels or product documents, go to thermofisher.com/symbols-definition.

The information in this guide is subject to change without notice.

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Revision history: Pub. No. 100102546

Revision	Date	Description
D	03 May 2022	The “Intended Use” was updated.
C	7 March 2022	<ul style="list-style-type: none">• “Obtain the software package” was updated to include Pathogen Interpretive Software 1.0.0 DAT (SAE Profile) and change software version format to two digits for Pathogen Interpretive Software v1.1 and SAE Administrator Console Dx v1.0.• The storage temperature of TaqPath™ COVID-19 Plus Control was updated in “Contents and storage”.
B	30 August 2021	Update to the and “Customer and technical support”.
A	9 July 2021	New document for the TaqPath™ COVID-19 RNase P Combo Kit 2.0 (Cat. No. A51333).

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