

TaqPath™ COVID-19 Fast PCR Combo Kit 2.0

INSTRUCTIONS FOR USE

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

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Revision B.0

IVD

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

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S C I E N T I F I C



The customer is responsible for compliance with regulatory requirements that pertain to their procedures and uses of the instrument.

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Revision	Date	Description
B.0	29 July 2021	<ul style="list-style-type: none"> • Updated the following: <ul style="list-style-type: none"> – Regulatory label – “Intended Use” on page 5 – “Required materials not supplied” on page 7 – “Warnings and precautions” on page 9 – “Assay limitations” on page 10 – “Samples and controls” on page 12 – “Sample collection, transport, and storage” on page 12 – “Guidelines for saliva collection” on page 14 – Chapter 7, “Conditions of authorization for labs” – “Limit of detection (LoD)” on page 34 – “Reactivity (Inclusivity)” on page 36 – “Cross-reactivity” on page 37 – “Interfering substances” on page 38 – “Clinical evaluation” on page 41 • Added statement regarding personal data in “Set up and run the QuantStudio™ 5 Real-Time PCR Instrument (96-well plates)” on page 21 and “Set up and run the QuantStudio™ 7 Flex Real-Time PCR Instrument (384-well plates)” on page 25. • Added instructions for obtaining the EUO label for RUO instruments in Appendix B, “EUO label for RUO instruments”.
A.0	21 May 2021	New document.

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Intended Use

The TaqPath™ COVID-19 Fast PCR Combo Kit 2.0 is a real-time reverse transcription polymerase chain reaction (RT-PCR) test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in saliva collected without preservatives in a sterile container under the supervision of a healthcare provider in a healthcare setting from individuals suspected of COVID-19 by their healthcare provider. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in saliva 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. Negative results for SARS-CoV-2 RNA from saliva should be confirmed by testing of an alternative specimen type, if clinically indicated.

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

Product description

The TaqPath™ COVID-19 Fast PCR Combo Kit 2.0 includes the following components:

- TaqPath™ COVID-19 Fast PCR Assay 2.0—Multiplexed assays that contain primer and probe sets specific to the following targets:
 - SARS-CoV-2 ORF1a
 - SARS-CoV-2 N gene
 - SARS-CoV-2 ORF1b
 - RNase P (human sample collection control)
- TaqPath™ COVID-19 Plus Control—RNA control that contains targets specific to the SARS-CoV-2 genomic regions targeted by the assays and RNase P
- TaqPath™ COVID-19 Control Dilution Buffer—Dilution buffer for the control
- SalivaReady™ Solution—Lysis buffer

Table 1 Dyes, targets, and quenchers

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

^[1] The TaqPath™ COVID-19 Fast PCR Combo Kit 2.0 probes contain QSY™ quenchers, which do not fluoresce. Select 'None' for Quencher in the instrument set up procedure (see “Set up and run the QuantStudio™ 5 Real-Time PCR Instrument (96-well plates)” on page 21 or “Set up and run the QuantStudio™ 7 Flex Real-Time PCR Instrument (384-well plates)” on page 25).

Results are analyzed using the following software:

- Applied Biosystems™ Pathogen Interpretive Software v1.1.0
- One of the following assay panels:
 - C19-FastPCR-EUA_QS5-9602_1.0.0
 - C19-FastPCR-EUA_QS7-384_1.0.0
- SAE Administrator Console Dx v1.0.0 (for security and audit functions)

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

Contents and storage

Table 2 TaqPath™ COVID-19 Fast PCR Combo Kit 2.0, 1,000 reactions (Cat. No. [A51606](#))

Component	Amount	Storage
TaqPath™ COVID-19 Fast PCR Assay 2.0	1 × 1 mL	-30°C to -10°C
TaqPath™ COVID-19 Plus Control	10 × 10 µL	≤ -20°C
TaqPath™ COVID-19 Control Dilution Buffer	10 × 250 µL	-30°C to -10°C
SalivaReady™ Solution	1 × 20 mL	-30°C to -10°C

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	
Applied Biosystems™ QuantStudio™ 5 Real-Time PCR Instrument, 96-well, 0.2-mL block (used with QuantStudio™ Design and Analysis Desktop Software v1.5.1)	A28569 (with laptop computer) A28574 (with desktop computer) A28139 (instrument only)
Applied Biosystems™ QuantStudio™ 7 Flex Real-Time PCR Instrument, 384-well block (used with QuantStudio™ Real-Time PCR Software v1.3)	4485695 (with laptop computer) 4485701 (with desktop computer)
Equipment	
Laboratory freezers <ul style="list-style-type: none"> -30°C to -10°C 	MLS
BSL-2 biological safety cabinet	MLS
Centrifuge, with a rotor that accommodates standard microplates	MLS
Microcentrifuge	MLS
Laboratory mixer, vortex or equivalent	MLS
Single and multichannel adjustable pipettors (2.00 µL to 1,000.0 µL)	MLS
Cold block (96-well or 384-well) or ice	MLS
Veriti™ 96-Well Thermal Cycler, 0.2-mL block	4375786 , or equivalent

(continued)

Item	Source
Reagents	
TaqPath™ 1-Step Multiplex Master Mix (No ROX™)	A28522 , A28523
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	
Sterile tube with leak-proof, screw-top lid for sample collection IMPORTANT! Do not use tubes that contain preservative.	339652 , or equivalent
Reservoir for multichannel pipettes	MLS
Sterile aerosol barrier (filtered) pipette tips	thermofisher.com/pipettetips
MicroAmp™ Optical 96-Well Reaction Plate, 0.2 mL	<ul style="list-style-type: none"> • 4306737 (with barcode) • 4326659 (with barcode) • N8010560 (without barcode) • 4316813 (without barcode)
MicroAmp™ Optical 384-Well Reaction Plate	<ul style="list-style-type: none"> • 4309849 (with barcode) • 4326270 (with barcode) • 4343814 (with barcode) • 4343370 (without barcode)
MicroAmp™ Clear Adhesive Film	4306311
MicroAmp™ Optical Adhesive Film	4311971 , 4360954
MicroAmp™ Adhesive Film Applicator	4333183
MicroAmp™ Optical Film Compression Pad (for use with 96-well plates)	4312639
Nonstick, RNase-free microcentrifuge tubes (1.5 mL and 2.0 mL)	thermofisher.com/plastics
DNase and RNase-free tubes for mixing reagents (capable of mixing 5 mL) ^[1]	thermofisher.com

^[1] Only needed if using 384-well plates.

Warnings and precautions

The TaqPath™ COVID-19 Fast PCR 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.

- For *in vitro* diagnostic use under the FDA Emergency Use Authorization.
- For use under an Emergency Use Authorization.
- For Prescription Use 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 Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- Quality control requirements must be performed in conformance with local, state, and/or federal regulations or accreditation requirements and your laboratory's standard quality control procedures.
- 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.
- Modifications to assay reagents, assay protocol, or instrumentation are not permitted, and are in violation of the product Emergency Use Authorization.
- Reagents must be stored and handled as specified in "Contents and storage" on page 7.
- Do not use the kit after the indicated expiry date.
- Dispose of waste in compliance with local, state, and federal regulations.
- Safety Data Sheets are available upon request.
- Laboratories within the United States and its territories are required to report all SARS-CoV-2 results to the appropriate public health authorities.
- Positive results are indicative of the presence of SARS-CoV-2 RNA.

Assay limitations

- Testing of saliva specimens is limited to patients with symptoms of COVID-19.
- Negative results for SARS-CoV-2 RNA from saliva should be confirmed by testing of an alternative specimen type if clinically indicated.
- The TaqPath™ COVID-19 Fast PCR Combo Kit 2.0 performance was established using raw saliva samples collected without preservatives in a sterile container only. Specimen types other than raw saliva samples collected without preservatives in a sterile container should not be tested with this assay.
- Saliva 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.
- Preparation and amplification of nucleic acid from clinical samples must be performed according to the specified methods listed in this procedure. Other approaches and processing systems have not been evaluated.
- 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 reagents
 - The presence of RT-PCR inhibitors
 - Mutation in the SARS-CoV-2 virus
 - Failure to follow instructions for use
- 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
 - Improper vortexing and centrifuging when preparing RT-PCR reactions
- Inconclusive calls may arise from:
 - Sample at concentrations near the limit of detection of the test
 - Assay cross-reactivity with SARS-CoV
 - Other factors
- Based on the *in silico* analysis, SARS-CoV and other SARS-like coronaviruses in the same subgenus (Sarbecovirus) as SARS-CoV may cross react with the N gene and ORF1b primer/probe sets of the assay. SARS-CoV is not known to be currently circulating in the human population, therefore it is highly unlikely to be present in patient specimens.
- Human blood may interfere with the detection of low positive samples by the TaqPath™ COVID-19 Fast PCR Combo Kit 2.0 at concentrations greater than 1%.
- The impacts of vaccines, antiviral therapeutics, antibiotics, chemotherapeutic or immunosuppressant drugs have not been evaluated. The TaqPath™ COVID-19 Fast PCR Combo Kit 2.0 cannot rule out diseases caused by other bacterial or viral pathogens.

- Negative results do not preclude infection with SARS-CoV-2 virus, and should not be the sole basis of a patient management decision.
- Laboratories are required to report all test results to the appropriate public health authorities.
- 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.
- The clinical performance has not been established in 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.

General laboratory recommendations

- Follow the sample inactivation guidelines and requirements established by your laboratory and local regulatory bodies. Some inactivation methods (such as chemical inactivation) may affect primary samples quality and lead to deviations in the expected result.
- 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)
- Saliva samples should always be treated as if infectious and/or biohazardous in accordance with safe laboratory procedures.
- To prevent degradation, keep 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.
- To ensure reliable performance of the real-time PCR instrument, perform preventive maintenance according to the instructions provided by the manufacturer in the instrument documentation (see “Related documentation” on page 46).

Samples and controls

Patient samples must be collected according to appropriate laboratory guidelines. Positive and negative test controls must be included to accurately interpret patient test results.

Include the following controls:

Control	Used to monitor	Assays
Positive Control (TaqPath™ COVID-19 Plus Control)	RT-PCR reaction setup, reagent integrity, and sample adequacy	All three SARS-CoV-2 assays
		RNase P assay
Negative Control (Nuclease-free water)	Contamination during RT-PCR reaction setup	All three SARS-CoV-2 assays
		RNase P assay

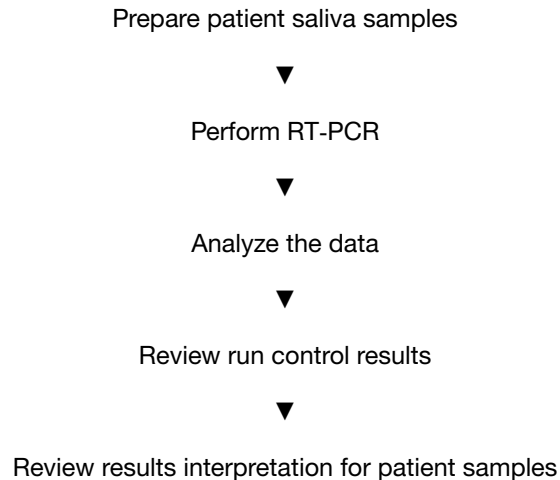
Sample collection, transport, and storage

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

- 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 guidelines. For more information about collection containers, see Chapter 2, “Prepare saliva samples”.
- 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)).

Saliva specimen stability has been demonstrated at ambient temperature for up to 72 hours after collection. For longer term storage, the saliva specimen should be stored at 2–8°C for up to 96 hours.

Workflow



The workflow begins with preparing raw saliva from patients using SalivaReady™ Solution.

The prepared patient sample (saliva plus SalivaReady™ Solution) is reverse transcribed into cDNA and amplified using the TaqPath™ COVID-19 Fast PCR Combo Kit 2.0 and one of the following real-time PCR instruments:

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

In the process, the probes anneal to the following target sequences located between unique forward and reverse primers:

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

During the extension phase of the PCR cycle, the 5' nuclease 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 Applied Biosystems™ Pathogen Interpretive Software v1.1.0.

2

Prepare saliva samples



WARNING! Saliva samples have the potential to transmit infectious diseases. Use safe laboratory procedures, including wearing personal protective equipment (PPE) and handling samples in a BSL-2 biological safety cabinet.

IMPORTANT! The saliva preparation protocol in this chapter is only compatible with raw saliva specimens collected without preservatives in a sterile container.

Saliva samples are prepared using a 1:1 ratio of saliva to SalivaReady™ Solution.

Guidelines for saliva collection

Collect saliva samples in a sterile collection container. We recommend that you follow best practices to minimize the presence of inhibitors in the saliva:

- Ensure that there was no eating, drinking, smoking, chewing tobacco, chewing gum, brushing teeth, or use of mouthwash for at least 30 minutes before giving a saliva sample.
- If debris is present in the mouth, the patient can rinse the mouth with water 30 minutes before saliva collection. Swish water for 10 seconds, then swallow to rid the mouth of debris.
- During collection, allow saliva to passively pool in the mouth, then drool into the collection container. Do not cough while performing collection, and ensure that the sample is free of phlegm or other debris.

Before you begin

- If the saliva samples are frozen, thaw completely at room temperature before processing.
- Thaw the SalivaReady™ Solution at room temperature, then mix gently by inversion at least 10 times.

Prepare the samples

1. For the required number of samples, add 20 μL of SalivaReady™ Solution to each well of a new 96-well plate at room temperature.
2. Vortex each saliva sample at maximum speed for a minimum of 10 seconds, or until the sample appears homogenous.

Note: Samples that are particularly viscous or contain high amounts of particulate may require longer vortex times. Some samples may contain particulate that does not fully homogenize.

3. Add 20 μL of saliva sample to each well containing the SalivaReady™ Solution.

Note:

- Aspirate the sample slowly and closely monitor the volume in the pipette tip. Ensure that 20 μL of sample is pipetted into each well.
 - If you are unable to accurately pipette 20 μL due to viscosity, the sample may not be suitable for testing.
-

4. Seal the plate with a clear adhesive film, then vortex by tilting the plate at approximately a 45° angle. Vortex each side for at least 5 seconds, up to 30 seconds total.
5. Centrifuge the plate until the speed reaches 1,000 x *g* to collect the samples at the bottom of the wells.
6. Heat the plate in a thermal cycler using the following thermal conditions.

Step	Temperature	Time	Number of cycles
1	62°C	5 minutes	1
2	92°C	5 minutes	1
3	4°C	Hold ^[1]	1

^[1] The thermal cycler can be stopped once at 4°C.

7. Centrifuge the plate until the speed reaches 1,000 x *g* to collect the samples at the bottom of the wells.

Place the plate on ice for immediate use in real-time RT-PCR.

3

Prepare RT-PCR reactions

In this chapter, select the appropriate RT-PCR preparation procedure based on the size of the RT-PCR reaction plate (96-well or 384-well).

Guidelines for RT-PCR

IMPORTANT!

- Prepare the RT-PCR plate on ice or a cold block. Keep the RT-PCR plate on ice or a cold block until it is loaded into the real-time PCR instrument.
 - Run the RT-PCR plate within an hour after preparation. Failure to do so could result in degraded samples.
 - To prevent contamination, prepare reagents in a PCR workstation or equivalent amplicon-free area. Do not use the same pipette for controls and samples, and always use aerosol barrier pipette tips.
 - Maintain an RNase-free environment.
 - Protect assays from light.
 - Keep samples and components on ice during use.
 - For each RT-PCR plate, include the following controls:
 - One Positive Control
 - One Negative Control
-

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

1. If frozen, thaw the reagents on ice or on a cold block.
2. Gently vortex the reagents, then briefly centrifuge the tube or swirl the bottle to collect the liquid at the bottom of the container.
3. Dilute TaqPath™ COVID-19 Plus Control to a working stock:
 - a. Pipet 120.0 µL of TaqPath™ COVID-19 Control Dilution Buffer into a microcentrifuge tube, then add 2.0 µL of TaqPath™ COVID-19 Plus Control. Mix well, then centrifuge briefly.
 - b. Pipet 120.0 µL of TaqPath™ COVID-19 Control Dilution Buffer into a second microcentrifuge tube, then add 2.0 µL of the dilution created in substep 3a. Mix well, then centrifuge briefly.

Keep on ice until use.

4. Prepare the Reaction Mix:

- a. For each 96-well plate, combine the following components sufficient for the number of samples plus one Positive Control and one Negative Control.

Component	Volume per sample or control	Volume for n samples plus 2 controls ^[1]	Volume for 94 samples plus 2 controls ^[1]
TaqPath™ 1-Step Multiplex Master Mix (No ROX™) (4X)	5.0 µL	$5.5 \times (n + 2)$ µL	528.0 µL
TaqPath™ COVID-19 Fast PCR Assay 2.0 (20X)	1.0 µL	$1.1 \times (n + 2)$ µL	105.6 µL
Total Reaction Mix volume	6.0 µL	—	633.6 µL

^[1] All volumes include 10% overage.

5. Set up the reaction plate, according to the following table:

Component	Volume per reaction		
	Sample reaction	Positive Control reaction	Negative Control reaction
Reaction Mix (from step 4)	6.0 µL	6.0 µL	6.0 µL
Prepared sample (saliva plus SalivaReady™ Solution)	14.0 µL	—	—
Positive Control (diluted TaqPath™ COVID-19 Plus Control from step 3)	—	14.0 µL	—
Nuclease-free water	—	—	14.0 µL
Total volume	20.0 µL	20.0 µL	20.0 µL

- a. Add 6.0 µL of the Reaction Mix prepared in step 4 to each well of a MicroAmp™ Optical 96-Well Reaction Plate, 0.2 mL.
- b. Pipet up and down at least five times to mix the prepared sample (saliva plus SalivaReady™ Solution), then add 14.0 µL of prepared sample to each sample well of the reaction plate.

IMPORTANT! Ensure sample is completely aspirated and bubbles are not created during mixing.

- c. Add 14.0 µL of the diluted TaqPath™ COVID-19 Plus Control to the Positive Control well of the reaction plate.
- d. Add 14.0 µL of Nuclease-free water to the Negative Control well of the reaction plate.
- e. Seal the plate thoroughly with MicroAmp™ Optical Adhesive Film.

IMPORTANT! 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.

6. Vortex the reaction plate by tilting the plate at approximately a 45° angle. Vortex each side for at least 5 seconds, up to 30 seconds total.

IMPORTANT! Failure to vortex the plate for the recommended time can result in inaccurate sample results.

7. Centrifuge the reaction plate for 1 minute at 1,400 × g to remove bubbles and to collect the liquid at the bottom of the reaction plate.

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

1. If frozen, thaw the reagents on ice or on a cold block.
2. Gently vortex the reagents, then briefly centrifuge the tube or swirl the bottle to collect the liquid at the bottom of the container.
3. Dilute TaqPath™ COVID-19 Plus Control to a working stock:
 - a. Pipet 120.0 µL of TaqPath™ COVID-19 Control Dilution Buffer into a microcentrifuge tube, then add 2.0 µL of TaqPath™ COVID-19 Plus Control. Mix well, then centrifuge briefly.
 - b. Pipet 120.0 µL of TaqPath™ COVID-19 Control Dilution Buffer into a second microcentrifuge tube, then add 2.0 µL of the dilution created in substep 3a. Mix well, then centrifuge briefly.

Keep on ice until use.

4. Prepare the Reaction Mix:
 - a. For each 384-well plate, combine the following components sufficient for the number of samples plus one Positive Control and one Negative Control.

Component	Volume per sample or control	Volume for n samples plus 2 controls ^[1]	Volume for 382 samples plus 2 controls ^[1]
TaqPath™ 1-Step Multiplex Master Mix (No ROX™) (4X)	5.0 µL	$5.5 \times (n + 2)$ µL	2,112.0 µL
TaqPath™ COVID-19 Fast PCR Assay 2.0 (20X)	1.0 µL	$1.1 \times (n + 2)$ µL	422.4 µL
Total Reaction Mix volume	6.0 µL	—	2,534.4 µL

^[1] All volumes include 10% overage.

5. Set up the reaction plate, according to the following table:

Component	Volume per reaction		
	Sample reaction	Positive Control reaction	Negative Control reaction
Reaction Mix (from step 4)	6.0 µL	6.0 µL	6.0 µL
Prepared sample (saliva plus SalivaReady™ Solution)	14.0 µL	—	—
Positive Control (diluted TaqPath™ COVID-19 Plus Control from step 3)	—	14.0 µL	—
Nuclease-free water	—	—	14.0 µL
Total volume	20.0 µL	20.0 µL	20.0 µL

- a. Add 6.0 µL of the Reaction Mix prepared in step 4 to each well of a MicroAmp™ Optical 384-Well Reaction Plate.
- b. Pipet up and down at least five times to mix the prepared sample (saliva plus SalivaReady™ Solution), then add 14.0 µL of prepared sample to each sample well of the reaction plate.

IMPORTANT! Ensure sample is completely aspirated and bubbles are not created during mixing.

- c. Add 14.0 µL of the diluted TaqPath™ COVID-19 Plus Control to the Positive Control well of the reaction plate.
- d. Add 14.0 µL of Nuclease-free water to the Negative Control well of the reaction plate.
- e. Seal the plate thoroughly with MicroAmp™ Optical Adhesive Film.

IMPORTANT! 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.

6. Vortex the reaction plate by tilting the plate at approximately a 45° angle. Vortex each side for at least 5 seconds, up to 30 seconds total.

IMPORTANT! Failure to vortex the plate for the recommended time can result in inaccurate sample results.

7. Centrifuge the reaction plate for 1 minute at 1,400 × g to remove bubbles and to collect the liquid at the bottom of the reaction plate.



Perform RT-PCR using the Applied Biosystems™ QuantStudio™ 5 Real-Time PCR Instrument (96-well block)

- Dye calibration for the QuantStudio™ 5 Real-Time PCR Instrument 20
- Transfer the template (EDT) file for the QuantStudio™ 5 Real-Time PCR Instrument (96-well block) 20
- Set up and run the QuantStudio™ 5 Real-Time PCR Instrument (96-well plates) 21

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

A maintained instrument will be calibrated for all dyes that are used with this kit. Ensure that the calibrations for FAM™ dye, VIC™ dye, ABY™ dye, and JUN™ dye are current. If calibration is required, refer to the standard calibration process in the instrument user guide.

Transfer the template (EDT) file for the QuantStudio™ 5 Real-Time PCR Instrument (96-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 v1.1.0. The folder is `FastPCR_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 v1.5.1 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 Fast PCR Template QS5 0_2ml da1_5_1 v1_0.edt`
2. Transfer the EDT file to the computer with QuantStudio™ Design and Analysis Desktop Software v1.5.1, 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 46.

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 v1.5.1, 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 (96-well block)” on page 20.

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 20 µL, then confirm the thermal protocol.

Step	Temperature	Ramp rate	Time	Number of cycles
Reverse transcription	53°C	3.2°C per second	5 minutes	1
Preincubation	85°C	3.2°C per second	5 minutes	1
Activation	95°C	3.2°C per second	2 minutes	1
Denaturation	95°C	3.2°C per second	1 second	40
Anneal / extension	62°C	2.5°C per second	30 seconds	

5. In the **Plate** tab, 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 reporter dye and the target pairs are correct.

Reporter dye	Detector	Quencher
FAM	ORF1a	None
VIC	N gene	None
ABY	ORF1b	None
JUN	RNase P	None

IMPORTANT! The detectors 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)**.
12. For all targets in the negative control well, confirm that **Task** is set to **N (Negative Control)**.
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)**.

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 thermal cycler.

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 Applied Biosystems™ QuantStudio™ 7 Flex Real-Time PCR Instrument (384-well block)

- Dye calibration for the QuantStudio™ 7 Flex Real-Time PCR Instrument 24
- Transfer the template (EDT) file for the QuantStudio™ 7 Flex Real-Time PCR Instrument (384-well block) 24
- Set up and run the QuantStudio™ 7 Flex Real-Time PCR Instrument (384-well plates) 25

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

A maintained instrument will be calibrated for many dyes. In addition to those dyes, the instrument operator must calibrate the instrument for ABY™ dye and JUN™ dye that are used with this kit. For all other assays, refer to the standard calibration process.

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 v1.1.0. The folder is `FastPCR_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 v1.3 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 Fast PCR Template QS7 384 1_3 v1_0.edt`
2. Transfer the EDT file to the computer with QuantStudio™ Real-Time PCR Software v1.3, using a USB drive or other method.

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

For more information about the instrument, see the documents listed in “Related documentation” on page 46.

1. In the QuantStudio™ Real-Time PCR Software v1.3 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 24.

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 **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™
 - **Properties:** Standard
4. In the **Define** tab, in the **Targets** pane, confirm that the targets, reporter dyes, and quenchers are listed correctly.

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

IMPORTANT! The targets are case-sensitive and must be named as described.

5. In the **Define** tab, in the **Samples** pane, define 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** tab, confirm that the **Passive Reference** is set to **None**.
7. In the **Assign** tab, confirm that four targets are assigned to each well in the plate layout. To assign a target to a well, select the well, then check the **Assign** checkbox.

8. In the **Assign** tab, in the **Samples** 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.

9. In the **Assign** tab, confirm the **Task** assignments.
- For wells with a Positive Control (PC), confirm that the **Task** is set to **S** for Standard for all of the targets.
 - For wells with a Negative Control (NC), confirm that the **Task** is set to **N** for Negative for all of the targets.
 - For the wells with a patient sample, confirm that the **Task** is set to **U** for Unknown for all of the targets.
10. In the **Assign** tab, assign a sample name to each well to match the physical plate.
To assign a sample to a well, select the well, then check the **Assign** checkbox.
11. In the **Run Method** tab, confirm that the **Reaction Volume Per Well** is 20 µL, then confirm the thermal protocol.

Step	Temperature	Ramp rate	Time	Number of cycles
Reverse transcription	53°C	1.9°C per second	5 minutes	1
Preincubation	85°C	1.9°C per second	5 minutes	1
Activation	95°C	1.9°C per second	2 minutes	1
Denaturation	95°C	1.9°C per second	1 second	40
Anneal / extension	62°C	1.64°C per second	30 seconds	

12. In the **Run Method** tab, select **Optical Filters**, then select the 8 PCR filters shown in Table 3.
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 3 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 thermal cycler.
14. In the **Run** tab, 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.

6

Analysis and results

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Software and instrument compatibility

Software	Description
Applied Biosystems™ Pathogen Interpretive Software v1.1.0	Data analysis and results interpretation software
SAE Administrator Console Dx v1.0.0	Security and audit tool
C19-FastPCR-EUA_QS5-9602_1.0.0	Assay panel for QuantStudio™ 5 Real-Time PCR Instrument (96-well, 0.2-mL block)
C19-FastPCR-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 29.

The following table lists the assay panel that is compatible with the Applied Biosystems™ Pathogen Interpretive Software v1.1.0, your instrument, and its associated analysis software.

Instrument	Analysis software used with the instrument	Pathogen Interpretive Software version	Assay panel code and version ^[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	v1.1.0	C19-FastPCR-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	v1.1.0	C19-FastPCR-EUA_QS7-384_1.0.0

^[1] For information on how to install the assay panel, see “Install the assay panel” on page 29.

To obtain the analysis software or firmware for your real-time PCR instrument, go to [thermofisher.com/qpcrsoftware](https://www.thermofisher.com/qpcrsoftware), then select your instrument in the **Real-Time PCR** section.

Obtain the software package

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

- Applied Biosystems™ Pathogen Interpretive Software v1.1.0
- SAE Administrator Console Dx v1.0.0
- Assay panel for your instrument

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

- Operating system—Windows™ 10 (64-bit), 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 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 your local instrument service team. Go to <https://www.thermofisher.com/contactus>.

For more information about the software, see “Related documentation” on page 46.

Install the assay panel

An assay panel contains the analysis settings that are used for data analysis in the Pathogen Interpretive Software v1.1.0.

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

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

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

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

Instrument	Folder name
QuantStudio™ 5 Real-Time PCR Instrument	FastPCR_2.0_EUA_QS5_96_0.2mL_AssayPanel_Template
QuantStudio™ 7 Flex Real-Time PCR Instrument	FastPCR_2.0_EUA_QS7_384_AssayPanel_Template

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

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

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

- 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 software (“Related documentation” on page 46).

Analyze the data

For detailed instructions about using the software, click the **Help** menu in the Pathogen Interpretive Software v1.1.0.

- 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 v1.1.0.
- 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 Applied Biosystems™ Pathogen Interpretive Software v1.1.0. For information about the C_t values that are used by the software to interpret results, see Appendix A, “Ct 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 4).

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

Table 4 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 5 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-CoV2 Inconclusive
NEG	POS	NEG	POS or NEG	Inconclusive	RETEST ^[2] /REPORT - SARS-CoV2 Inconclusive
POS	NEG	NEG	POS or NEG	Inconclusive	RETEST ^[2] /REPORT - SARS-CoV2 Inconclusive

^[1] Controls must pass for viral targets to be interpreted (Table 4).

^[2] Retesting must be performed by re-preparing the original sample and repeating the RT-PCR. If the repeat result remains invalid, consider collecting a new specimen.

7

Conditions of authorization for labs

The TaqPath™ COVID-19 Fast PCR 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).

To assist clinical laboratories using the TaqPath™ COVID-19 Fast PCR Combo Kit 2.0, the relevant Conditions of Authorization are listed below.

- Authorized laboratories^[1] using the TaqPath™ COVID-19 Fast PCR Combo Kit 2.0 must include with test result reports of the TaqPath™ COVID-19 Fast PCR 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 Fast PCR Combo Kit 2.0 must use the TaqPath™ COVID-19 Fast PCR Combo Kit 2.0 as outlined in the *TaqPath™ COVID-19 Fast PCR Combo Kit 2.0 Instructions for Use*. Deviations from the authorized procedures, including the authorized instruments, authorized specimen preparation, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents, and authorized materials required to perform the TaqPath™ COVID-19 Fast PCR Combo Kit 2.0 are not permitted.
- Authorized laboratories that receive the TaqPath™ COVID-19 Fast PCR 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 Fast PCR Combo Kit 2.0 must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories must 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.
- All laboratory personnel using this 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.
- Thermo Fisher Scientific, its authorized distributor(s), and authorized laboratories using the TaqPath™ COVID-19 Fast PCR Combo Kit 2.0 must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records must be made available to FDA for inspection upon request.

^[1] The letter of authorization refers 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.”



Performance characteristics

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- Clinical evaluation 41

Analytical performance of the TaqPath™ COVID-19 Fast PCR Combo Kit 2.0 was evaluated by determining limit of detection (LoD), characterizing the impact of endogenous and exogenous interfering substances, and assessing reactivity and cross-reactivity. In addition, a Clinical Evaluation study was performed for the TaqPath™ COVID-19 Fast PCR Combo Kit 2.0. All studies are described in the following sections.

Limit of detection (LoD)

The LoD study established the lowest SARS-CoV-2 viral concentrations (Genomic Copy Equivalents or GCE/mL) that can be detected by the TaqPath™ COVID-19 Fast PCR Combo Kit 2.0 at least 95% of the time.

The LoD for SARS-CoV-2 was determined using pooled, contrived raw saliva samples that were spiked with inactivated SARS-CoV-2 virus at several concentrations and processed through the TaqPath™ COVID-19 Fast PCR Combo Kit 2.0 workflow.

A two-phase approach was used to determine the LoD. In phase I, the preliminary LoD was established and confirmed in phase II by testing 20 replicates.

Table 6 LoD determination in saliva samples (QuantStudio™ 5 Real-Time PCR Instrument with a 96-well, 0.2-mL block)

Concentration	Replicate	C _t				Interpretation	% Positive
		ORF1a	N gene	ORF1b	RNase P		
1,000 GCE/mL	1	40.00	37.48	37.28	27.56	Negative	95%
	2	33.23	33.26	32.98	27.16	Positive	
	3	34.00	34.74	34.42	27.34	Positive	
	4	34.04	33.95	34.25	27.06	Positive	
	5	34.29	33.50	34.47	27.46	Positive	
	6	34.45	34.19	34.10	27.40	Positive	

Table 6 LoD determination in saliva samples (QuantStudio 5 Real-Time PCR Instrument with a 96-well, 0.2-mL block) (continued)

Concentration	Replicate	C _t				Interpretation	% Positive
		ORF1a	N gene	ORF1b	RNase P		
1,000 GCE/mL	7	33.88	33.78	33.41	27.55	Positive	95%
	8	33.67	33.76	34.72	27.43	Positive	
	9	32.91	33.19	33.36	27.00	Positive	
	10	33.26	34.09	33.45	27.65	Positive	
	11	34.38	34.22	34.41	27.32	Positive	
	12	36.34	33.90	34.14	27.39	Positive	
	13	33.69	32.97	33.26	27.45	Positive	
	14	33.26	33.41	33.88	27.21	Positive	
	15	33.88	34.26	34.17	27.30	Positive	
	16	33.54	33.55	34.37	27.40	Positive	
	17	33.62	34.11	34.11	27.26	Positive	
	18	34.23	34.37	34.81	27.12	Positive	
	19	33.78	33.70	34.15	27.23	Positive	
	20	33.45	33.81	34.34	27.32	Positive	
	Mean	34.19	34.01	34.20	27.33	—	

Table 7 LoD determination in saliva samples (QuantStudio™ 7 Flex Real-Time PCR Instrument with a 384-well block)

Concentration	Replicate	C _t				Interpretation	% Positive
		ORF1a	N gene	ORF1b	RNase P		
750 GCE/mL	1	33.36	33.33	34.30	26.07	Positive	100%
	2	31.23	33.88	34.64	25.76	Positive	
	3	32.90	35.06	34.04	25.99	Positive	
	4	32.79	32.72	33.75	25.72	Positive	
	5	33.53	33.64	34.25	25.66	Positive	
	6	32.62	34.58	34.68	25.97	Positive	
	7	33.37	33.67	34.15	25.94	Positive	
	8	33.40	33.39	35.03	25.95	Positive	

Table 7 LoD determination in saliva samples (QuantStudio 7 Flex Real-Time PCR Instrument with a 384-well block) (continued)

Concentration	Replicate	C _t				Interpretation	% Positive
		ORF1a	N gene	ORF1b	RNase P		
750 GCE/mL	9	31.70	33.10	33.74	25.62	Positive	100%
	10	31.36	33.24	33.36	25.62	Positive	
	11	33.38	36.37	35.63	26.33	Positive	
	12	32.00	33.39	34.36	25.93	Positive	
	13	33.55	33.41	34.14	25.50	Positive	
	14	28.72	33.10	31.27	24.85	Positive	
	15	32.52	33.11	33.61	25.85	Positive	
	16	32.48	33.89	34.99	25.77	Positive	
	17	33.18	34.31	34.79	25.88	Positive	
	18	34.76	34.89	35.93	25.84	Positive	
	19	36.31	33.38	34.19	25.59	Positive	
	20	36.11	33.68	33.81	25.69	Positive	
	Mean	32.96	33.81	34.23	25.78	—	

Reactivity (Inclusivity)

In silico analysis was executed using 1,802,689 complete SARS-CoV-2 genomes from the GISAID database, as of June 09, 2021. A positive is called when a sample shows a melting temperature higher than the annealing temperature for at least one assay per target region for at least two targets (ORF1a, N gene, and ORF1b). Based upon BLAST analysis, the TaqPath™ COVID-19 Fast PCR Assay 2.0 maps with 100% homology to 100% of SARS-CoV-2 genome sequences found in the GISAID database.

Cross-reactivity

In silico analysis of the following fifty-five (55) organisms was performed.

Table 8 Organisms used for *in silico* cross-reactivity analysis

Bacteria	Viruses	Fungi
<i>Bacillus anthracis</i>	Adenovirus (for example, C1 Ad 71)	<i>Candida albicans</i>
<i>Bacteroides oralis</i>	Cytomegalovirus (CMV)	<i>Pneumocystis jirovecii</i>
<i>Bordetella pertussis</i>	Enterovirus	—
<i>Chlamydia psittaci</i>	Epstein Barr virus (EBV/HHV-4)	—
<i>Chlamydophila pneumoniae</i>	Hepatitis B Virus (HBV)	—
<i>Corynebacterium diphtheriae</i>	Hepatitis C Virus (HCV)	—
<i>Coxiella burnetii</i> (Q-fever)	Herpes Simplex Virus-1 (HSV-1)	—
<i>Eikenella</i> spp.	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</i> spp.	Human Immunodeficiency Virus (HIV)	—
<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</i> spp.	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>	Parechovirus	—
<i>Streptococcus mutans</i>	Respiratory Syncytial Virus A	—
<i>Streptococcus pneumoniae</i>	Respiratory Syncytial Virus B	—

Table 8 Organisms used for *in silico* cross-reactivity analysis (continued)

Bacteria	Viruses	Fungi
<i>Streptococcus pyogenes</i>	Rhinovirus	—
<i>Streptococcus salivarius</i>	SARS Coronavirus	—
—	Varicella-zoster virus (VZV)	—

BLAST analysis demonstrated that for each bacterial, viral, or fungal microbe sequence, with the exception of SARS-CoV isolates, no TaqPath™ COVID-19 Fast PCR Combo Kit 2.0 assay aligned with more than one assay component for 36 bacterial species, one fungal species, and human coronaviruses HKU1, NL63, and OC43 (no hits to 229E or MERS were detected). These microbes shared $\geq 80\%$ homology to either the reverse primer, forward primer, or probe sequence of at least one of the four assays (SARS-CoV-2 ORF1a, N gene, ORF1b, or RNase P endogenous control assay). Amplification of these microbes is not anticipated because hybridization of both primers is required to produce an amplicon, and the three assay components are necessary to generate a signal.

SARS-CoV isolates shared a $\geq 80\%$ level of identity with the N gene and ORF1b assays. Isolates sharing the highest level of homology and most prevalent pattern of individual component homology were examined by alignment of assay amplicons to SARS-CoV sequences and examination of mismatched positions between the assay reverse primer, probe, and forward primer and viral sequences to evaluate each assay's ability to amplify and detect SARS-CoV sequences. The assays components appear to be sufficiently mismatched with SARS-CoV sequences to prevent efficient amplification and generation of a cross-reactive signal in isolation; however, combinatorial effects cannot be ruled out. Given the apparent *in silico* specificity of the assays and the requirement for at least two of the three ORF1a, N gene, and ORF1b multiplexed assays to generate signal to call a sample SARS-CoV-2 positive, it would be unlikely to interfere with SARS-CoV-2 detection. To note, SARS-CoV is not a common respiratory pathogen given that it has not been in circulation since the 2003 outbreak.

Interfering substances

During preliminary interfering substances studies performed with pooled negative saliva specimens spiked with inactivated SARS-CoV-2 virus at approximately 1X the limit of detection, interference was detected, for example with human blood^[2]. However, since one of the six replicates of the no-interferent control was inconclusive, the interfering substances studies were repeated. Human blood may interfere with the detection of low positive samples by the TaqPath™ COVID-19 Fast PCR Combo Kit 2.0 at concentrations greater than 1%.

Pooled negative saliva specimens were spiked with inactivated SARS-CoV-2 virus at 3X the limit of detection and ran in six replicates for each of the potential interfering substances and one no-interferent control at the concentrations listed in Table 9 and Table 10.

^[2] In the preliminary study, of the six replicates with the addition of blood, there were five inconclusive results run on the QuantStudio™ 5 Real-Time PCR Instrument and four inconclusive results and one false negative result run on the QuantStudio™ 7 Flex Real-Time PCR Instrument.

Interference was not observed at the concentrations tested for any of the tested substances for both the QuantStudio™ 5 Real-Time PCR Instrument and QuantStudio™ 7 Flex Real-Time PCR Instrument.

Table 9 Interfering substances (QuantStudio™ 5 Real-Time PCR Instrument, 96-well, 0.2-mL block—3,000 GCE/mL)

Interfering substance	Final concentration in sample	Agreement with expected results			
		Positive agreement	Number of positive / Number tested	Negative agreement	Number of negative / Number tested
None	N/A	100%	6/6	100%	6/6
Mucin: bovine submaxillary gland, type I-S	2.5 mg/mL	100%	6/6	100%	6/6
Human whole blood	1% v/v	100%	6/6	100%	6/6
Nasal sprays or drops—Afrin™ Original	15% v/v	100%	6/6	100%	6/6
Nasal gel—NeilMed™ Nasogel™	1.25%	100%	6/6	100%	6/6
Throat lozenges—Cepacol™	3 mg/mL	100%	6/6	100%	6/6
Throat spray—Chloraseptic™	5% v/v	100%	6/6	100%	6/6
Toothpaste—Colgate™	0.5% v/v	100%	6/6	100%	6/6
Mouthwash—Crest™	5% v/v	100%	6/6	100%	6/6
Nicotine	0.03 mg/mL	100%	6/6	100%	6/6
Human genomic DNA	10 ng/μL	100%	6/6	100%	6/6

Table 10 Interfering substances (QuantStudio™ 7 Flex Real-Time PCR Instrument, 384-well block—2,250 GCE/mL)

Interfering substance	Final concentration in sample	Agreement with expected results			
		Positive agreement	Number of positive / Number tested	Negative agreement	Number of negative / Number tested
None	N/A	100%	6/6	100%	6/6
Mucin: bovine submaxillary gland, type I-S	2.5 mg/mL	100%	6/6	100%	6/6
Human whole blood	1% v/v	100% ^[1]	6/6	100%	6/6
Nasal sprays or drops—Afrin™ Original	15% v/v	100%	6/6	100%	6/6
Nasal gel—NeilMed™ Nasogel™	1.25%	100%	6/6	100%	6/6
Throat lozenges—Cepacol™	3 mg/mL	100%	6/6	100%	6/6
Throat spray—Chloraseptic™	5% v/v	100%	6/6	100%	6/6
Toothpaste—Colgate™	0.5% v/v	100%	6/6	100%	6/6
Mouthwash—Crest™	5% v/v	100% ^[2]	6/6	100%	6/6
Nicotine	0.03 mg/mL	100%	6/6	100%	6/6
Human genomic DNA	10 ng/μL	100%	6/6	100%	6/6

^[1] One of six replicates produced a $C_t > 37$ for Orf1a, but all replicates were called Positive based on the interpretation algorithm.

^[2] One of six replicates produced a $C_t > 37$ for Orf1b, but all replicates were called Positive based on the interpretation algorithm.

Clinical evaluation

A clinical evaluation study was performed to evaluate the performance of the TaqPath™ COVID-19 Fast PCR Combo Kit 2.0 using archived paired raw saliva and nasopharyngeal (NP) swab specimens from individuals with COVID-19 symptoms.

The raw saliva specimens were tested using the TaqPath™ COVID-19 Fast PCR Combo Kit 2.0.

The NP specimens were tested using an FDA EUA-Authorized molecular comparator assay.

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

Table 11 TaqPath™ COVID-19 Fast PCR Combo Kit 2.0 clinical evaluation study agreements (QuantStudio™ 5 Real-Time PCR Instrument, 96-well, 0.2-mL block)

TaqPath™ COVID-19 Fast PCR Combo Kit 2.0	Comparator: EUA Authorized Molecular SARS-CoV-2 Assay		
	SARS-CoV-2 Positive	SARS-CoV-2 Negative	Total
SARS-CoV-2 Positive	33	1	34
SARS-CoV-2 Negative	1	41	42
Total	34	42	76 ^[1]

^[1] One invalid sample was excluded from analysis per the protocol.

PPA: 97.1% (95% CI: 84.6% LCL to 99.9% UCL)

NPA: 97.6% (95% CI: 87.4% LCL to 99.9% UCL)

Table 12 TaqPath™ COVID-19 Fast PCR Combo Kit 2.0 clinical evaluation study agreements (QuantStudio™ 7 Flex Real-Time PCR Instrument, 384-well block)

TaqPath™ COVID-19 Fast PCR Combo Kit 2.0	Comparator: EUA Authorized Molecular SARS-CoV-2 Assay		
	SARS-CoV-2 Positive	SARS-CoV-2 Negative	Total
SARS-CoV-2 Positive	33	0	33
SARS-CoV-2 Negative	1	42	43
Total	34	42	76 ^[1]

^[1] One inconclusive sample was excluded from analysis per the protocol.

PPA: 97.1% (95% CI: 84.6% LCL to 99.9% UCL)

NPA: 100.0% (95% CI: 91.5% LCL to 100.0% UCL)



C_t cutoff values for assay targets

The Applied Biosystems™ Pathogen Interpretive Software v1.1.0 uses the following C_t cutoff values for assay targets during interpretation of the results.

Table 13 Assay 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.

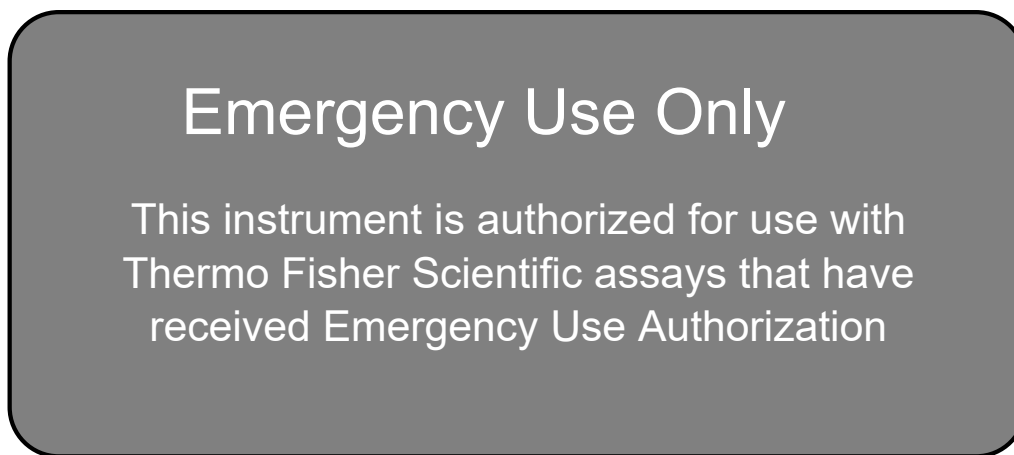


EUO label for RUO instruments

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 following instruments.

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

1. 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



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, see the “Documentation and Support” section in this document.

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:
<https://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

Document	Publication Number
<i>Veriti™ Thermal Cycler User Guide</i>	MAN0018441
<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 Maintenance and Administration Guide</i>	4489821
<i>QuantStudio™ Real-Time PCR Software Getting Started Guide</i>	4489822
<i>Pathogen Interpretive Software Installation Quick Reference</i>	MAN0019535
<i>SAE Administrator Console Dx User Guide</i>	MAN0019574

Customer and technical support

For additional documentation and information about this kit, visit:

<http://www.thermofisher.com/TaqPathFastEUA>

For download instructions for the software, see “Obtain the software package” on page 29.

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 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.

