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TaqPath™ COVID-19, FluA, FluB Combo Kit

INSTRUCTIONS FOR USE

Multiplex real-time RT-PCR test for the detection and differentiation of SARS-CoV-2, influenza A, and influenza B RNA

Catalog Number A49868

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Revision A.0

IVD

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

Thermo Fisher SCIENTIFIC

Life Technologies Corporation | 6055 Sunol Blvd | Pleasanton, California 94566 USA
For descriptions of symbols on product labels or product documents, go to **thermofisher.com/symbols-definition**.

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

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

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Revision	Date	Description
A.0	9 February 2021	New document for the TaqPath™ COVID-19, FluA, FluB Combo Kit.

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Contents

■ CHAPTER 1 TaqPath™ COVID-19, FluA, FluB Combo Kit product information 5

Intended Use 5
Product description 6
Contents and storage 6
Required materials not supplied 7
Warnings and precautions 9
Assay limitations 10
General laboratory recommendations 11
Samples and controls 11
Sample collection, transport, and storage 12
Workflow 12

■ CHAPTER 2 Extract RNA 14

Before you begin 14
Extract RNA 15
- Set up the instrument 15
- Prepare the processing plates 15
- Prepare Binding Bead Mix 16
- Prepare a Proteinase K and MS2 Phage Control Mix 16
- Prepare sample plate 16
- Process the samples 17

■ CHAPTER 3 Prepare RT-PCR reactions 18

Guidelines for RT-PCR 18
Prepare the RT-PCR reactions 18

■ CHAPTER 4 Perform RT-PCR using the Applied Biosystems™ 7500 Fast Dx Real-Time PCR Instrument 21

Dye calibration for the 7500 Real-Time PCR Instrument series 21
Transfer the template (SDT) file for the 7500 Fast Dx Real-Time PCR Instrument 21
Set up and run the 7500 Fast Dx Real-Time PCR Instrument 22

CHAPTER 5 Perform RT-PCR using the Applied Biosystems™ QuantStudio™ 5 Real-Time PCR Instrument 24

Dye calibration for the QuantStudio™ 5 Real-Time PCR Instrument 24
Transfer the template (EDT) file for the QuantStudio™ 5 Real-Time PCR Instrument 24
Set up and run the QuantStudio™ 5 Real-Time PCR Instrument 25

CHAPTER 6 Analysis and results 27

Obtain the software 27
Analyze the data 27
Interpretation of the results 28

CHAPTER 7 Conditions of authorization for labs 30

CHAPTER 8 Performance characteristics 31

Limit of detection (LoD) 31
Reactivity (Inclusivity) 41
Competitive interference 43
Cross-reactivity 47
Interfering substances 50
Clinical evaluation 52

APPENDIX A C_t cutoff values for assay targets 55

APPENDIX B Safety 56

Chemical safety 56
Biological hazard safety 57

APPENDIX C Documentation and support 58

Related documentation 58
Customer and technical support 58
Limited product warranty 59

TaqPath™ COVID-19, FluA, FluB Combo Kit product information

- Intended Use 5
- Product description 6
- Contents and storage 6
- Required materials not supplied 7
- Warnings and precautions 9
- Assay limitations 10
- General laboratory recommendations 11
- Samples and controls 11
- Sample collection, transport, and storage 12
- Workflow 12

Intended Use

The TaqPath™ COVID-19, FluA, FluB Combo Kit is a multiplex real-time RT-PCR test intended for the simultaneous qualitative detection and differentiation of RNA from the SARS-CoV-2, influenza A, and/or influenza B viruses in nasopharyngeal swab and anterior nasal swab specimens collected from individuals suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high-complexity tests.

The TaqPath™ COVID-19, FluA, FluB Combo Kit is intended for use in simultaneous detection and differentiation of SARS-CoV-2, influenza A, and/or influenza B nucleic acid in clinical specimens and is not intended to detect influenza C virus. The SARS-CoV-2, influenza A, and influenza B RNA is generally detectable in upper respiratory samples during the acute phase of infection.

Positive results are indicative of active infection but do not rule out bacterial infection or co-infection with other pathogens not detected by the test. Clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. The agent detected may not be the definite cause of disease.

Laboratories within the United States and its territories are required to report all SARS-CoV-2 results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2, influenza A, and/or influenza B infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and/or epidemiological information.

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

Product description

The TaqPath™ COVID-19, FluA, FluB Combo Kit includes the assays and controls for a multiplex real-time RT-PCR test for the qualitative detection and differentiation of RNA from SARS-CoV-2, influenza A, and/or influenza B viruses in nasopharyngeal swabs and anterior nasal swabs from individuals suspected of COVID-19 by their healthcare provider.

The kit includes the following components:

- TaqPath™ RT-PCR COVID-19, FluA, FluB Kit
  - TaqPath™ COVID-19, FluA, FluB RT-PCR Assay Multiplex—Multiplexed assays that contain primer and probe sets specific to the following targets:
    - Two SARS-CoV-2 targets
    - One influenza A target
    - One influenza B target
    - Bacteriophage MS2
  - MS2 Phage Control—Internal process control for nucleic acid extraction
- TaqPath™ COVID-19, FluA, FluB Control—RNA control that contains targets specific to the SARS-CoV-2, influenza A, and influenza B genomic regions targeted by the assays

Contents and storage

Table 1 TaqPath™ COVID-19, FluA, FluB Combo Kit, 1,000 reactions (Cat. No. A49868)

Component	Contents	Amount	Storage
TaqPath™ RT-PCR COVID-19, FluA, FluB Kit, 1,000 reactions	TaqPath™ COVID-19, FluA, FluB RT-PCR Assay Multiplex	1,500 µL	–30°C to –10°C
	MS2 Phage Control	10 × 1,000 µL	–30°C to –10°C
TaqPath™ COVID-19, FluA, FluB Control		10 × 10 µL	≤ –70°C
TaqPath™ Control Dilution Buffer		10 × 250 µL	–30°C to –10°C

Required materials not supplied

Unless otherwise indicated, all materials are available through **thermofisher.com**. "MLS" indicates that the material is available from **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™ 7500 Fast Dx Real-Time PCR Instrument (used with SDS Software v1.4.1)	4406984 (with laptop computer) 4406985 (with tower computer)
Applied Biosystems™ QuantStudio™ 5 Real-Time PCR Instrument, 96-well, 0.2-mL block (used with instrument firmware v1.3.3 and QuantStudio™ Design and Analysis Desktop Software v1.5.1)	A28569 (with laptop computer) A28574 (with desktop computer) A28139 (instrument only)
Software	
Pathogen Interpretive Software	See "Obtain the software" on page 27
SAE Administrator Console Dx	
Equipment	
Laboratory freezers • –30°C to –10°C • ≤ –70°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 (1.00 µL to 1,000.0 µL)	MLS
Cold block (96-well or 384-well) or ice	MLS
Automated nucleic acid extraction system and materials	
KingFisher™ Flex Magnetic Particle Processor with 96 Deep-Well Head	5400630
KingFisher™ Flex 96 Deep-Well Heating Block	24075430
KingFisher™ Deep-Well 96 Plate	95040450, A48305, A48424, 95040455

(continued)

Item	Source
96-well plate for the tip comb, one of the following: • KingFisher™ 96 KF microplate • Tip Comb Presenting Plate for KF 96 • 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 • Nunc™ F96 MicroWell™ Black Polystyrene Plate • Nunc™ F96 MicroWell™ White Polystyrene Plate • KingFisher™ Deep-Well 96 Plate	• 97002540 • 267600 • 167008 • 269787 • AB0796 • AB1127 • 137101 • 136101 • 95040450, A48305, A48424, 95040455
KingFisher™ 96 tip comb for DW magnets	97002534, A48438, A48414
Kits and reagents	
MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit (up to 2,000 preparations, when 200 µL of sample is used)	A48383
TaqPath™ 1-Step Multiplex Master Mix (No ROX™)	A28521, A28522, A28523
Fisher BioReagents™ Ethanol, Absolute, Molecular Biology Grade[1], or equivalent	BP2818100, BP2818500, BP28184
Nuclease-free Water (not DEPC-Treated)	MLS
Calibration plates (7500 Real-Time PCR Instrument series)	
ABY™ Dye Spectral Calibration Plate for Multiplex qPCR, Fast 96-well (0.1-mL)	A24734
JUN™ Dye Spectral Calibration Plate for Multiplex qPCR, Fast 96-well (0.1-mL)	A24735
Tubes, plates, and other consumables	
MicroAmp™ Fast Optical 96-Well Reaction Plate with Barcode, 0.1 mL	4346906, 4366932
MicroAmp™ Fast Optical 96-Well Reaction Plate, 0.1 mL	4346907
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™ Clear Adhesive Film	4306311
MicroAmp™ Optical Adhesive Film	4311971, 4360954

(continued)

Item	Source
MicroAmp™ Adhesive Film Applicator	4333183
Nonstick, RNase-free microcentrifuge tubes (1.5 mL and 2.0 mL)	**thermofisher.com/plastics**
Sterile aerosol barrier (filtered) pipette tips	**thermofisher.com/pipettetips**

[1] Available at **fisherscientific.com**.

Warnings and precautions

The TaqPath™ COVID-19, FluA, FluB Combo Kit 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 only.
- This test has not been FDA cleared or approved but has been authorized for emergency use by authorized laboratories.
- This test has been authorized for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
- This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, influenza A, and influenza B, not for any other viruses or pathogens.
- The emergency use of this test 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, influenza A, and/or influenza B 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.
- 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 Table 1 on page 6.
- 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, influenza A, and/or influenza B.

Assay limitations

- The TaqPath™ COVID-19, FluA, FluB Combo Kit performance was established using nasopharyngeal swabs. Anterior nasal swabs are considered an acceptable specimen type for use with the TaqPath™ COVID-19, FluA, FluB Combo Kit, but performance with this specimen type has not been established. Refer to FDA's *FAQs on Diagnostic Testing for SARS-CoV-2* for additional information. Specimen types other than nasopharyngeal and anterior nasal swabs should not be tested with this assay.
- Samples must be collected, transported, and stored using appropriate procedures and conditions. Improper collection, transport, or storage of specimens may hinder the ability of the assay to detect the target sequences.
- Extraction and amplification of nucleic acid from clinical samples must be performed according the specified methods listed in this procedure. Other extraction approaches and processing systems have not been evaluated.
- FluMist™ was not tested as a potential interferent. It is anticipated that a live virus vaccine such as FluMist™ may produce a positive result for influenza A.
- Afrin™ nasal spray causes inhibition at 10% v/v. False negative results may occur if samples contain Afrin™ nasal spray.
- False-negative results may arise from:
  - Improper sample collection
  - Degradation of the SARS-CoV-2 RNA, influenza A RNA, or influenza B RNA during shipping/storage
  - Specimen collection after SARS-CoV-2 RNA, influenza A RNA, or influenza B RNA can no longer be found in the specimen matrix
  - Using unauthorized extraction or assay reagents
  - The presence of RNA extraction inhibitors or RT-PCR inhibitors
  - Mutation in the SARS-CoV-2 virus, the influenza A virus, or the influenza B 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.
- The impacts of vaccines, antiviral therapeutics, antibiotics, chemotherapeutic or immunosuppressant drugs have not been evaluated. The TaqPath™ COVID-19, FluA, FluB Combo Kit cannot rule out diseases caused by other bacterial or viral pathogens.
- Negative results do not preclude infection with SARS-CoV-2 virus, influenza A virus, or influenza B virus, and should not be the sole basis of a patient management decision.

- 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

- Implement standard operating procedures in your laboratory to prevent contamination, such as the following:
  - Frequent glove changes
  - Frequent decontamination of surfaces, equipment, and pipettes with 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 in the interpretive software for signs of inadequate vortexing or centrifugation. Contact your Applications Support team for additional information or training on data QC in your instrument software.

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.

Store patient samples according to CDC guidelines. See the CDC website: **https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html**.

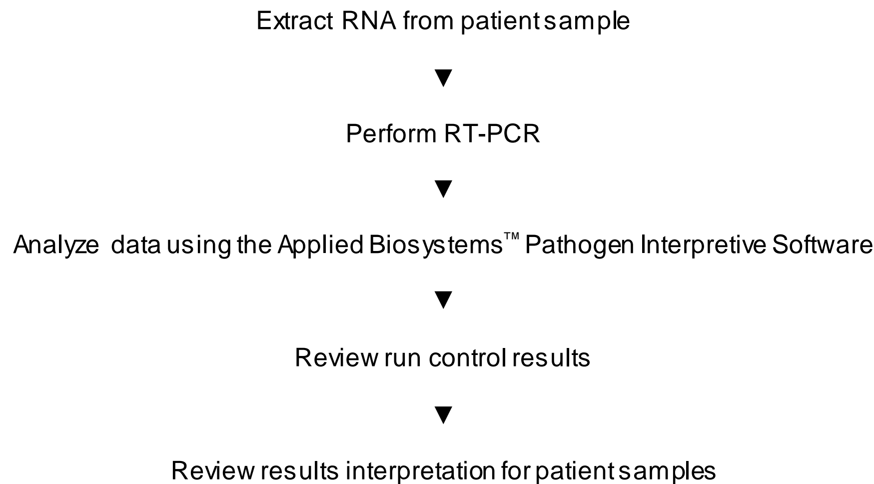
Include the following controls:

Control	Used to monitor	Assays
Positive Control (TaqPath™ COVID-19, FluA, FluB Control)	RT-PCR reaction setup and reagent integrity	Two SARS-CoV-2 assays, one influenza A assay, and one influenza B assay
MS2 Phage Control	RNA extraction	MS2 assay
Negative Control	Cross-contamination during RNA extraction and reaction setup	Two SARS-CoV-2 assays, one influenza A assay, and one influenza B assay
		MS2 assay

Sample collection, transport, and storage

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

Workflow



The workflow begins with nucleic acid extraction from nasopharyngeal or anterior nasal swabs that arrive at the testing site in transport media. 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 58.

The purified nucleic acid is reverse transcribed into cDNA and amplified using the TaqPath™ COVID-19, FluA, FluB Combo Kit and one of the following real-time PCR instruments:

- Applied Biosystems™ 7500 Fast Dx Real-Time PCR instrument
- Applied Biosystems™ QuantStudio™ 5 Real-Time PCR Instrument, 96-well, 0.2–mL block

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

- SARS-CoV-2 (N Gene)
- SARS-Cov-2 (S Gene)
- Influenza A
- Influenza B

Note: The targets for SARS-CoV-2 N Gene and the SARS-CoV-2 S Gene are in a single optical channel. They cannot be differentiated.

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.

2 Extract RNA

RNA extraction is performed using the KingFisher™ Flex Magnetic Particle Processor with 96 Deep-Well Head and the MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit with a sample input volume of 400 µL.

Before you begin

Note: During the wash steps, the Wash Solution 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 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.
- Label the short side of each KingFisher™ Deep-Well 96 Plate (4):

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

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

Label	Number of plates
Tip comb	1

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

- Tip Comb Presenting Plate for KF 96
- 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
- Nunc™ F96 MicroWell™ Black Polystyrene Plate

- Nunc™ F96 MicroWell™ White Polystyrene Plate
- KingFisher™ Deep-Well 96 Plate

- Mark the Negative Control well on the plate.

Extract RNA

Set up the instrument

1. 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.

2. Ensure that the **MVP_2Wash_400_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™ Deep-Well 96 Plate	Wash Solution	1,000 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 DW magnets in a KingFisher™ 96 KF microplate		

Note: The following items can be used to hold the tip comb instead of the KingFisher™ 96 KF microplate:
- Tip Comb Presenting Plate for KF 96
- 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
- Nunc™ F96 MicroWell™ Black Polystyrene Plate
- Nunc™ F96 MicroWell™ White Polystyrene Plate
- KingFisher™ Deep-Well 96 Plate

Prepare Binding Bead Mix

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	530 µL
Total Nucleic Acid Magnetic Beads	20 µL
Total volume per well	550 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 a Proteinase K and MS2 Phage Control Mix

Prepare the required amount of the Proteinase K and MS2 Phage Control Mix on each day of use. Keep on ice.

1. Thaw the vial of MS2 Phage Control.

2. For the number of required reactions, prepare the Proteinase K and MS2 Phage Control Mix according to the following table:

Component	Volume per well[1]	Volume per 96-well plate
Proteinase K	10 µL	1,056 µL
MS2 Phage Control	10 µL	1,056 µL
Total volume per well	20 µL	2,112 µL

[1] Include 10% overage when preparing the Proteinase K and MS2 Phage Control Mix for use with multiple reactions.

3. Mix well by inversion, then store on ice.

Prepare sample plate

1. Invert the Binding Bead Mix 5 times gently to mix, then add 550 µL 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 400 µL of sample to each sample well.

3. Add 400 µL of Nuclease-free Water (not DEPC-Treated) to the Negative Control well.

4. Add 20 µL of the Proteinase K and MS2 Phage Control Mix to each well in the KingFisher™ Deep-Well 96 Plate labeled "Sample Plate", including the Negative Control well.

Process the samples

1. Select the **MVP_2Wash_400_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 "Prepare the processing plates" on page 15).

Note: Significant bead carry over may adversely impact RT-PCR performance.

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

3

Prepare RT-PCR reactions

Guidelines for RT-PCR

IMPORTANT!

- Prepare the run plate on ice and keep it on ice 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 an RNase-free environment.
- Protect assays from light.
- Keep RNA samples and components on ice during use.
- For each RT-PCR plate, include the following controls:
  - One Positive Control
  - One Negative Control from each extraction run.

Prepare the RT-PCR reactions

1. If frozen, thaw the reagents on ice.
2. Gently vortex the reagents, then centrifuge briefly to collect liquid at the bottom of the tube.
3. Dilute TaqPath™ COVID-19, FluA, FluB Control to a working stock:
   a. Pipet 98.0 µL of TaqPath™ Control Dilution Buffer into a microcentrifuge tube, then add 2.0 µL of TaqPath™ COVID-19, FluA, FluB Control. Mix well, then centrifuge briefly.
   b. Pipet 98.0 µL of TaqPath™ 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.

   Note: The TaqPath™ COVID-19, FluA, FluB Control does not contain the MS2 template.
4. Prepare the Reaction Mix:
   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 for pipette error.

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 x (*n* + 2) µL	660 µL
TaqPath™ COVID-19, FluA, FluB RT-PCR Assay Multiplex	1.25 µL	1.375 x (*n* + 2) µL	132 µL
Total Reaction Mix volume	7.5 µL	—	792 µL

5. Set up the reaction plate:
   a. Pipet 7.5 µL of the Reaction Mix prepared in step 4 into each well of a MicroAmp™ Fast Optical 96-Well Reaction Plate with Barcode, 0.1 mL or a MicroAmp™ Optical 96-Well Reaction Plate with Barcode, 0.2 mL.

      Plates without a barcode can be used (see "Required materials not supplied" on page 7).

      Note: Use the 0.1-mL plates for the 7500 Fast Dx Real-Time PCR Instrument. Use the 0.2-mL plates for the QuantStudio™ 5 Real-Time PCR Instrument (0.2-mL block).

   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 2 on page 20.

   d. 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 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 false classification of samples.

f. Centrifuge the reaction plate for 1–2 minutes at ≥650 × *g* (≥650 RCF) to remove bubbles and to collect the liquid at the bottom of the reaction plate.

Table 2 Reaction plate

Component	Volume per reaction		
	RNA Sample reaction	Positive Control reaction	Negative Control reaction
Reaction Mix	7.5 µL	7.5 µL	7.5 µL
Purified sample RNA (from RNA extraction)	17.5 µL	—	—
Positive Control (diluted TaqPath™ COVID-19, FluA, FluB Control from step 3)	—	2.0 µL	—
Purified Negative Control (from RNA extraction)	—	—	17.5 µL
Nuclease-free Water	—	15.5 µL	—
Total volume	25.0 µL	25.0 µL	25.0 µL

4 Perform RT-PCR using the Applied Biosystems™ 7500 Fast Dx Real-Time PCR Instrument

- Dye calibration for the 7500 Real-Time PCR Instrument series 21
- Transfer the template (SDT) file for the 7500 Fast Dx Real-Time PCR Instrument 21
- Set up and run the 7500 Fast Dx Real-Time PCR Instrument 22

Dye calibration for the 7500 Real-Time PCR Instrument series

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 (SDT) file for the 7500 Fast Dx Real-Time PCR Instrument

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

It is installed on the computer with the Applied Biosystems™ Pathogen Interpretive Software.

The template file must be transferred via a USB drive or other method to the computer on which SDS Software v1.4.1 is installed.

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

---

1. In the Pathogen Interpretive Software, click **Help ▸ Run Templates**.
2. Click **Download** to access the template file for your version of the data collection software.
3. In the **Save** dialog box, select the location to save the template file, then save the file.

4. Ensure that the correct template file was downloaded and saved.
   `TaqPath COVID-19 FluA FluB template 7500fast Dx sds1_4_1 v1_0.sdt`

5. Transfer the SDT file to the computer with SDS Software v1.4.1, using a USB drive or other method.

Set up and run the 7500 Fast Dx Real-Time PCR Instrument

For more information about the instrument, see the documents listed in "Related documentation" on page 58.

1. Using SDS Software v1.4.1, open the SDT file that you transferred in "Transfer the template (SDT) file for the 7500 Fast Dx Real-Time PCR Instrument" on page 21.

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

2. Confirm the run settings in the template and adjust as necessary.
   - **Assay**: **Standard Curve (Absolute Quantitation)**
   - **Run mode**: **Standard 7500**
   - **Passive reference**: **None**
   - **Sample volume**: **25 µL**

   IMPORTANT! The passive reference must be set to **None**.

3. Confirm that the reporter dye and the detector pairs are correct in the **Detector Manager** in the **Tools** menu.

Reporter dye	Detector
FAM	FluA
VIC	C19[1]
ABY	FluB
JUN	MS2

[1] SARS-CoV-2 N gene and SARS-CoV-2 S gene

   IMPORTANT! The detectors are case-sensitive.

4. Confirm that the targets above are assigned to each well in the plate layout.

5. 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.

6. For wells with a positive control, confirm that **Task** is set to **Standard**.
7. For wells with a negative control, confirm that **Task** is set to **NTC**.
8. Edit the plate layout to assign a unique sample name to each well in the physical plate.
   For wells with a patient sample, confirm that **Task** is set to **Unknown** for all detectors.

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

9. Confirm the thermal protocol.

Step	Temperature	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	46
Anneal / extension	60°C	30 seconds	

10. Click **Save As**, enter a file name, then click **Save**.
11. Reopen the file to connect the computer to the instrument, load the plate, then start the run on the real-time PCR instrument.
12. After the instrument run is complete, open the SDS file in SDS Software v1.4.1. Analyze, then save the file.

5 Perform RT-PCR using the Applied Biosystems™ QuantStudio™ 5 Real-Time PCR Instrument

- Dye calibration for the QuantStudio™ 5 Real-Time PCR Instrument 24
- Transfer the template (EDT) file for the QuantStudio™ 5 Real-Time PCR Instrument 24
- Set up and run the QuantStudio™ 5 Real-Time PCR Instrument 25

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

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

It is installed on the computer with the Applied Biosystems™ Pathogen Interpretive Software.

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. Failure to do so can cause errors in the analysis.

---

1. In the Pathogen Interpretive Software, click **Help ▸ Run Templates**.
2. Click **Download** to access the template file for your version of the data collection software.
3. In the **Save** dialog box, select the location to save the template file, then save the file.

4. Ensure that the correct template file was downloaded and saved.
   `TaqPath COVID-19 FluA FluB template QS5 0_2ml da1_5_1 v1_0.edt`

5. 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

For more information about the instrument, see the documents listed in "Related documentation" on page 58.

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" on page 24.

   IMPORTANT! Be careful to select the appropriate template file for your instrument. 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 protocol.

Step	Temperature	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	46
Anneal / extension	60°C	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	FluA	None
VIC	C19[1]	None
ABY	FluB	None
JUN	MS2	None

[1] SARS-CoV-2 N gene and SARS-CoV-2 S gene

IMPORTANT! The detectors are case-sensitive.

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.
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. In the **Run** tab, click **Start Run**, then select your instrument from the drop-down list.
16. Enter a file name in the dialog box that prompts you to save the run file, then save the file.

6 Analysis and results

Obtain the software

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

- Applied Biosystems™ Pathogen Interpretive Software
- SAE Administrator Console Dx

For instructions to obtain the software, see *TaqPath™ COVID-19, FluA, FluB Combo Kit Product Information Sheet* (Pub. No. 100097258). The product information sheet is included with the TaqPath™ COVID-19, FluA, FluB Combo Kit.

Analyze the data

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

1. Using a USB drive or other method, transfer the SDS or EDS files from the computer with the data collection software to the computer with the Pathogen Interpretive Software.

2. 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.

3. 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. 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. Additional 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 (Table 3).

Validation of results is performed automatically by the Applied Biosystems™ Pathogen Interpretive Software based on performance of the Positive and Negative Controls.

Table 3 Control wells

Negative Control (NC)				Positive Control (PC)				Overall Control Call
C19	FluA	FluB	MS2	C19	FluA	FluB	MS2	
NEG	NEG	NEG	POS	POS	POS	POS	NEG	Pass
All other scenarios								Fail

Table 4 Results interpretation for viral targets in patient samples

Sample[1]				Call	Assessment
C19	FluA	FluB	MS2		
POS	POS	POS	POS or NEG	Presence	REPORT - SARS-CoV-2, Flu A, Flu B Detected
POS	POS	NEG	POS or NEG	Presence	REPORT - SARS-CoV-2, Flu A Detected
POS	NEG	POS	POS or NEG	Presence	REPORT - SARS-CoV-2, Flu B Detected
POS	NEG	NEG	POS or NEG	Presence	REPORT - SARS-CoV-2 Detected
NEG	NEG	NEG	POS	Absence	REPORT - SARS-CoV-2, Flu A, Flu B Not Detected
NEG	NEG	NEG	NEG	Invalid	RETEST[2]
NEG	POS	POS	POS or NEG	Presence	REPORT - Flu A, Flu B Detected
NEG	POS	NEG	POS or NEG	Presence	REPORT - Flu A Detected
NEG	NEG	POS	POS or NEG	Presence	REPORT - Flu B Detected

[1] Controls must pass for viral targets to be interpreted (Table 3).
[2] Retesting must be performed by re-extracting 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, FluA, FluB Combo Kit Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: **https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas**.

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

- Authorized laboratories[1] using the TaqPath™ COVID-19, FluA, FluB Combo Kit will include with result reports of the TaqPath™ COVID-19, FluA, FluB Combo Kit all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Authorized laboratories using the TaqPath™ COVID-19, FluA, FluB Combo Kit will perform the TaqPath™ COVID-19, FluA, FluB Combo Kit as outlined in the *TaqPath™ COVID-19, FluA, FluB Combo Kit 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, FluA, FluB Combo Kit are not permitted.
- Authorized laboratories that receive the TaqPath™ COVID-19, FluA, FluB Combo Kit 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, FluA, FluB Combo Kit 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.
- 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, FluA, FluB Combo Kit will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

[1] The letter of authorization refers to, “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

- Limit of detection (LoD) 31
- Reactivity (Inclusivity) 41
- Competitive interference 43
- Cross-reactivity 47
- Interfering substances 50
- Clinical evaluation 52

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

Limit of detection (LoD)

The LoD study established the lowest SARS-CoV-2, influenza A, and influenza B viral concentrations (Genomic Copy Equivalents or GCE, or $TCID_{50}$/mL, as indicated) that can be detected by the TaqPath™ COVID-19, FluA, FluB Combo Kit at least 95% of the time.

Negative nasopharyngeal swab (NP) specimens were pooled and spiked with the indicated strains of SARS-CoV-2 virus, influenza A virus, or influenza B virus, at several concentrations and processed through the TaqPath™ COVID-19, FluA, FluB Combo Kit workflow. A three-phase approach was used to determine the LoD for each virus. In phases I and II, the preliminary LoD was established and confirmed in phase III by testing 20 replicates.

Table 5 LoD determination in NP specimens spiked with gamma-irradiated SARS-CoV-2 isolate USA-WA1/2020 (7500 Fast Dx Real-Time PCR Instrument)

Concentration	Replicate	C_t value		Interpretation	% Positive
		C19 (SARS-CoV-2)	MS2		
100 GCE/mL	1	32.43	22.94	Positive	100%
	2	32.54	22.75	Positive	
	3	32.76	22.71	Positive	
	4	32.63	22.64	Positive	
	5	32.86	22.78	Positive	

Table 5 LoD determination in NP specimens spiked with gamma-irradiated SARS-CoV-2 isolate USA-WA1/2020 (7500 Fast Dx Real-Time PCR Instrument) *(continued)*

Concentration	Replicate	C_t value		Interpretation	% Positive
		C19 (SARS-CoV-2)	MS2		
100 GCE/mL	6	32.68	22.71	Positive	100%
	7	32.95	22.58	Positive	
	8	32.89	22.46	Positive	
	9	32.52	22.53	Positive	
	10	32.99	22.56	Positive	
	11	32.90	22.98	Positive	
	12	32.85	22.84	Positive	
	13	33.09	22.71	Positive	
	14	32.66	22.77	Positive	
	15	32.63	22.64	Positive	
	16	32.42	22.62	Positive	
	17	32.50	22.89	Positive	
	18	32.81	22.87	Positive	
	19	32.98	22.74	Positive	
	20	33.04	22.46	Positive	

Table 6 LoD determination in NP specimens spiked with gamma-irradiated SARS-CoV-2 isolate USA-WA1/2020 (QuantStudio™ 5 Real-Time PCR Instrument, 96-well, 0.2-mL block)

Concentration	Replicate	C_t value		Interpretation	% Positive
		C19 (SARS-CoV-2)	MS2		
100 GCE/mL	1	34.22	24.66	Positive	100%
	2	34.17	24.57	Positive	
	3	34.07	24.51	Positive	
	4	33.91	24.48	Positive	
	5	34.81	24.37	Positive	
	6	34.13	24.63	Positive	
	7	34.23	24.42	Positive	

Table 6 LoD determination in NP specimens spiked with gamma-irradiated SARS-CoV-2 isolate USA-WA1/2020 (QuantStudio 5 Real-Time PCR Instrument, 96-well, 0.2-mL block) *(continued)*

Concentration	Replicate	C_t value		Interpretation	% Positive
		C19 (SARS-CoV-2)	MS2		
100 GCE/mL	8	34.95	24.43	Positive	100%
	9	34.11	23.99	Positive	
	10	34.28	24.29	Positive	
	11	34.66	24.93	Positive	
	12	34.62	24.82	Positive	
	13	34.79	24.47	Positive	
	14	34.57	24.47	Positive	
	15	34.34	24.39	Positive	
	16	34.60	24.44	Positive	
	17	34.14	24.50	Positive	
	18	34.13	24.62	Positive	
	19	34.14	24.40	Positive	
	20	34.65	24.48	Positive	

Table 7 LoD determination in NP specimens spiked with live influenza A virus strain A/Perth/16/2009 (H3N2) (7500 Fast Dx Real-Time PCR Instrument)

Concentration	Replicate	C_t value		Interpretation	% Positive
		Flu A	MS2		
200 GCE/mL	1	35.58	22.62	Positive	100%
	2	36.63	22.91	Positive	
	3	36.60	22.87	Positive	
	4	36.54	23.01	Positive	
	5	36.13	22.87	Positive	
	6	35.61	22.84	Positive	
	7	35.86	22.84	Positive	
	8	36.93	22.70	Positive	
	9	41.95	22.81	Positive	

Table 7 LoD determination in NP specimens spiked with live influenza A virus strain A/Perth/16/2009 (H3N2) (7500 Fast Dx Real-Time PCR Instrument) *(continued)*

Concentration	Replicate	C_t value		Interpretation	% Positive
		Flu A	MS2		
200 GCE/mL	10	36.57	22.90	Positive	100%
	11	35.68	23.26	Positive	
	12	39.28	22.70	Positive	
	13	36.57	22.80	Positive	
	14	34.24	22.58	Positive	
	15	38.07	22.67	Positive	
	16	41.25	22.78	Positive	
	17	38.62	22.72	Positive	
	18	36.80	22.72	Positive	
	19	37.19	22.82	Positive	
	20	37.12	22.58	Positive	

Table 8 LoD determination in NP specimens spiked with live influenza A virus strain A/Perth/16/2009 (H3N2) (QuantStudio™ 5 Real-Time PCR Instrument, 96-well, 0.2-mL block)

Concentration	Replicate	C_t value		Interpretation	% Positive
		Flu A	MS2		
200 GCE/mL	1	41.91	25.50	Positive	95%
	2	39.25	25.88	Positive	
	3	37.68	25.07	Positive	
	4	37.27	25.23	Positive	
	5	36.66	25.21	Positive	
	6	40.03	25.37	Positive	
	7	38.58	24.57	Positive	
	8	38.19	24.69	Positive	
	9	43.06	24.71	Positive	
	10	44.91	24.76	Positive	
	11	Undetermined	25.80	Negative	
	12	44.87	25.40	Positive	

Table 8 LoD determination in NP specimens spiked with live influenza A virus strain A/Perth/16/2009 (H3N2) (QuantStudio 5 Real-Time PCR Instrument, 96-well, 0.2-mL block) *(continued)*

Concentration	Replicate	C_t value		Interpretation	% Positive
		Flu A	MS2		
200 GCE/mL	13	37.03	25.19	Positive	95%
	14	35.83	25.10	Positive	
	15	37.44	24.83	Positive	
	16	35.78	24.92	Positive	
	17	37.06	25.33	Positive	
	18	37.81	24.89	Positive	
	19	43.77	24.41	Positive	
	20	38.58	24.17	Positive	

Table 9 LoD determination in NP specimens spiked with live influenza A virus strain A/Brisbane/59/2007 (H1N1) (7500 Fast Dx Real-Time PCR Instrument)

Concentration	Replicate	C_t value		Interpretation	% Positive
		Flu A	MS2		
500 GCE/mL	1	35.72	22.99	Positive	100%
	2	32.98	23.18	Positive	
	3	34.81	22.86	Positive	
	4	36.51	22.61	Positive	
	5	37.40	22.35	Positive	
	6	33.14	22.35	Positive	
	7	36.03	22.56	Positive	
	8	36.06	22.77	Positive	
	9	36.37	22.73	Positive	
	10	39.29	22.67	Positive	
	11	40.24	23.51	Positive	
	12	34.71	22.92	Positive	
	13	36.02	22.81	Positive	
	14	35.90	23.10	Positive	
	15	36.94	22.58	Positive	

Table 9 LoD determination in NP specimens spiked with live influenza A virus strain A/Brisbane/59/2007 (H1N1) (7500 Fast Dx Real-Time PCR Instrument) *(continued)*

Concentration	Replicate	C_t value		Interpretation	% Positive
		Flu A	MS2		
500 GCE/mL	16	35.42	22.76	Positive	100%
	17	35.32	22.55	Positive	
	18	35.18	22.64	Positive	
	19	38.19	23.11	Positive	
	20	37.60	22.49	Positive	

Table 10 LoD determination in NP specimens spiked with live influenza A virus strain A/Brisbane/59/2007 (H1N1) (QuantStudio™ 5 Real-Time PCR Instrument, 96-well, 0.2-mL block)

Concentration	Replicate	C_t value		Interpretation	% Positive
		Flu A	MS2		
500 GCE/mL	1	42.74	25.32	Positive	95%
	2	33.12	25.27	Positive	
	3	37.67	25.62	Positive	
	4	36.02	24.92	Positive	
	5	37.51	25.34	Positive	
	6	34.53	25.02	Positive	
	7	38.67	24.96	Positive	
	8	39.48	24.90	Positive	
	9	39.31	25.41	Positive	
	10	Undetermined	24.99	Negative	
	11	40.79	25.90	Positive	
	12	36.36	24.57	Positive	
	13	38.23	25.23	Positive	
	14	39.40	24.94	Positive	
	15	37.79	25.28	Positive	
	16	39.48	24.72	Positive	
	17	38.41	25.30	Positive	
	18	36.77	24.84	Positive	

Table 10 LoD determination in NP specimens spiked with live influenza A virus strain A/Brisbane/59/2007 (H1N1) (QuantStudio 5 Real-Time PCR Instrument, 96-well, 0.2-mL block) *(continued)*

Concentration	Replicate	C_t value		Interpretation	% Positive
		Flu A	MS2		
500 GCE/mL	19	44.31	24.76	Positive	95%
	20	38.61	25.03	Positive	

Table 11 LoD determination in NP specimens spiked with live influenza B virus strain B/Florida/04/2006 (Yamagata lineage) (7500 Fast Dx Real-Time PCR Instrument)

Concentration	Replicate	C_t value		Interpretation	% Positive
		Flu B	MS2		
500 GCE/mL	1	36.78	22.97	Positive	95%
	2	36.96	23.06	Positive	
	3	37.40	22.89	Positive	
	4	Undetermined	23.14	Negative	
	5	36.56	23.02	Positive	
	6	37.65	23.58	Positive	
	7	36.26	22.66	Positive	
	8	36.40	22.67	Positive	
	9	35.35	22.68	Positive	
	10	37.97	23.33	Positive	
	11	37.64	23.28	Positive	
	12	36.04	23.06	Positive	
	13	36.71	23.19	Positive	
	14	37.18	23.20	Positive	
	15	36.49	22.76	Positive	
	16	36.66	22.68	Positive	
	17	37.64	22.82	Positive	
	18	37.09	22.96	Positive	
	19	35.70	22.54	Positive	
	20	36.66	22.98	Positive	

Table 12 LoD determination in NP specimens spiked with live influenza B virus strain B/Florida/04/2006 (Yamagata lineage) (QuantStudio™ 5 Real-Time PCR Instrument, 96-well, 0.2-mL block)

Concentration	Replicate	C_t value		Interpretation	% Positive
		Flu B	MS2		
500 GCE/mL	1	39.13	24.52	Positive	95%
	2	38.84	24.75	Positive	
	3	37.57	24.34	Positive	
	4	42.76	25.26	Positive	
	5	38.67	24.96	Positive	
	6	Undetermined	25.97	Negative	
	7	41.18	24.32	Positive	
	8	36.76	24.41	Positive	
	9	38.22	24.37	Positive	
	10	39.35	25.52	Positive	
	11	39.30	24.54	Positive	
	12	37.87	24.56	Positive	
	13	40.50	24.79	Positive	
	14	39.98	24.55	Positive	
	15	38.59	24.99	Positive	
	16	38.83	24.50	Positive	
	17	38.48	24.48	Positive	
	18	37.40	24.52	Positive	
	19	39.63	24.49	Positive	
	20	38.88	24.93	Positive	

Table 13 LoD determination in NP specimens spiked with live influenza B virus strain B/Wisconsin/1/2010 (Victoria lineage) (7500 Fast Dx Real-Time PCR Instrument)

Concentration	Replicate	C_t value		Interpretation	% Positive
		Flu B	MS2		
1,000 GCE/mL	1	36.17	23.00	Positive	100%
	2	37.69	22.94	Positive	
	3	35.79	22.81	Positive	
	4	36.03	22.73	Positive	
	5	36.47	22.78	Positive	
	6	37.03	22.63	Positive	
	7	35.99	22.50	Positive	
	8	37.82	22.60	Positive	
	9	35.28	22.76	Positive	
	10	36.97	22.98	Positive	
	11	36.84	23.11	Positive	
	12	36.51	23.00	Positive	
	13	36.77	23.00	Positive	
	14	37.10	23.40	Positive	
	15	35.29	22.83	Positive	
	16	36.73	22.82	Positive	
	17	36.97	22.77	Positive	
	18	37.75	22.93	Positive	
	19	37.42	22.92	Positive	
	20	38.01	22.99	Positive	

Table 14 LoD determination in NP specimens spiked with live influenza B virus strain B/Wisconsin/1/2010 (Victoria lineage) (QuantStudio™ 5 Real-Time PCR Instrument, 96-well, 0.2-mL block)

Concentration	Replicate	C_t value		Interpretation	% Positive
		Flu B	MS2		
1,000 GCE/mL	1	38.07	24.67	Positive	100%
	2	42.63	24.80	Positive	
	3	39.47	24.76	Positive	
	4	37.73	24.70	Positive	
	5	38.52	24.87	Positive	
	6	39.56	24.52	Positive	
	7	37.83	24.39	Positive	
	8	38.27	24.54	Positive	
	9	38.08	24.50	Positive	
	10	38.87	24.76	Positive	
	11	41.83	24.81	Positive	
	12	37.29	24.96	Positive	
	13	37.71	25.00	Positive	
	14	37.45	24.88	Positive	
	15	38.61	24.69	Positive	
	16	38.48	24.62	Positive	
	17	38.37	24.70	Positive	
	18	38.67	24.64	Positive	
	19	40.73	24.96	Positive	
	20	38.99	24.82	Positive	

Table 15 LoD results

Virus	Limit of Detection (7500 Fast Dx Real-Time PCR Instrument)		Limit of Detection (QuantStudio™ 5 Real-Time PCR Instrument, 96-well, 0.2-mL block)	
SARS-CoV-2 isolate USA-WA1/2020	100 GCE/mL	0.16 $TCID_{50}$/mL	100 GCE/mL	0.16 $TCID_{50}$/mL
Influenza A virus strain A/Perth/16/2009 (H3N2)	200 GCE/mL	2.49×10^{-3} $TCID_{50}$/mL	200 GCE/mL	2.49×10^{-3} $TCID_{50}$/mL
Influenza A virus strain A/Brisbane/59/2007 (H1N1)	500 GCE/mL	1.59×10^{-3} $TCID_{50}$/mL	500 GCE/mL	1.59×10^{-3} $TCID_{50}$/mL
Influenza B virus strain B/Florida/04/2006 (Yamagata lineage)	500 GCE/mL	5.88×10^{-2} $TCID_{50}$/mL	500 GCE/mL	5.88×10^{-2} $TCID_{50}$/mL
Influenza B virus strain B/Wisconsin/1/2010 (Victoria lineage)	1,000 GCE/mL	5.60×10^{-3} $TCID_{50}$/mL	1,000 GCE/mL	5.60×10^{-3} $TCID_{50}$/mL

Reactivity (Inclusivity)

In silico analysis was performed in January 2021, using at least 309,579 complete SARS-CoV-2 genomes in GISAID and GenBank databases. Based upon BLAST analysis, the TaqPath™ COVID-19, FluA, FluB Combo Kit maps with 100% homology to 99.67% and 96.61% of known SARS-CoV-2 isolates in GenBank and GISAID databases, respectively. The coverage of GISAID isolates improves to 99.02% if B.1.1.7 lineage sequences containing the ΔH69/V70 deletion in the S gene are removed from the analysis. Mapping was deemed successful for a given isolate if at least one SARS-CoV-2 target showed 100% identity.

In silico analysis was performed in August 2020, using 32,460 full-length segment 7 sequences from human influenza A isolates from NCBI Influenza Virus Sequence Database and 30,858 human influenza A segment 7 sequences (2009 to 2020) from the GISAID database. Influenza A assay primer/probes had 100% homology to 88% of known strains/isolates of influenza A analyzed as of August 2020.

Functional testing was also performed for the following 10 influenza A strains, starting at 3X LoD (1,500 GCE/mL for H1N1 strains and 600 GCE/mL for H3N2 strains, based on the results of the LoD study described in Table 15 on page 41). The lowest concentration tested that produced Positive results for 3 of 3 replicates is indicated.

Table 16 Influenza A strains (7500 Fast Dx Real-Time PCR Instrument and QuantStudio™ 5 Real-Time PCR Instrument, 96-well 0.2-mL block)

Strain	Lowest concentration tested Positive for 3 of 3 replicates	
	GCE/mL	$TCID_{50}$/mL or $CEID_{50}$/mL
H1N1/Georgia/M5081/2012	1,500 GCE/mL	4.78×10^{1} $TCID_{50}$/mL
H1N1/New Caledonia/20/99	1,500 GCE/mL	7.44×10^{-2} $TCID_{50}$/mL
H1N1/Puerto Rico/08/1934	1,500 GCE/mL	Unknown
H1N1/Solomon Islands/3/2006	1,500 GCE/mL	5.40×10^{1} $CEID_{50}$/mL
H1N1/California/04/2009	4,500 GCE/mL	4.20×10^{0} $TCID_{50}$/mL
H3N2/Wisconsin/15/2009	600 GCE/mL	Unknown
H3N2/Switzerland/9715293/2013	600 GCE/mL	$\geq 1.15 \times 10^{-4}$ $CEID_{50}$/mL[1]
H3N2/Wisconsin/67/2005	600 GCE/mL	3.23×10^{-2} $TCID_{50}$/mL
H3N2/Aichi/2/68	600 GCE/mL	Unknown
H3N2/Hong Kong/8/68	600 GCE/mL	Unknown

[1] Certificate of Analysis for this strain lists concentration as $\geq 5 \times 10^{3}$ $CEID_{50}$/mL.

In silico analysis was performed in August 2020, using 8,660 full-length segment 7 sequences from human influenza B isolates from NCBI Influenza Virus Sequence Database and 12,577 human influenza B segment 7 sequences (2009 to 2020) from the GISAID database. Influenza B assay primer/probes had 100% homology to 41% of known strains/isolates of influenza B analyzed as of August 2020.

Functional testing was also performed for the following 5 influenza B strains, starting at 3X LoD (1,500 GCE/mL for Yamagata-, unknown-, and mixed-lineage strains, and 3,000 GCE/mL for Victoria-lineage strains, based on the results of the LoD study described in Table 15 on page 41) . The lowest concentration tested that produced Positive results for 3 of 3 replicates is indicated.

Table 17 Influenza B strains (7500 Fast Dx Real-Time PCR Instrument and QuantStudio™ 5 Real-Time PCR Instrument, 96-well 0.2-mL block)

Strain	Lowest concentration tested Positive for 3 of 3 replicates	
	GCE/mL	$TCID_{50}$/mL
Unknown Lineage/Taiwan/2/62	1,500 GCE/mL	Unknown
Mixed Lineage/Malaysia/2506/2004	1,500 GCE/mL	1.09×10^{-2} $TCID_{50}$/mL
Victoria/Colorado/06/2017	3,000 GCE/mL	1.91×10^{-2} $TCID_{50}$/mL
Yamagata/Massachusetts/02/2012	1,500 GCE/mL	7.41×10^{-2} $TCID_{50}$/mL
Yamagata/Brisbane/03/2007	1,500 GCE/mL	3.50×10^{-1} $TCID_{50}$/mL

Competitive interference

Negative NP specimens were pooled and spiked with the indicated strains of SARS-CoV-2 (USA-WA1/2020), influenza A (A/Brisbane/59/07), or influenza B (B/Florida/04/06) virus in combinations where at least one virus was present at a low concentration and the other at a high concentration and were processed through the TaqPath™ COVID-19, FluA, FluB Combo Kit workflow.

Table 18 7500 Fast Dx Real-Time PCR Instrument

Combination	Target 1		Target 2		Target 3		Mean C_t (n=3) (Number detected/number tested)			
	Virus	Conc.	Virus	Conc.	Virus	Conc.	SARS-CoV-2 (VIC)	FluA (FAM)	FluB (ABY)	MS2 (JUN)
SARS-CoV-2^{lo} FluA^{hi}	SARS-CoV-2	0.48 $TCID_{50}$/mL	Flu A	10^5 $TCID_{50}$/mL	N/A	N/A	30.9 (3/3)	7.5 (3/3)	46.0 (0/3)	22.5 (3/3)
FluA^{lo} SARS-CoV-2^{hi}	Flu A	4.78×10^{-3} $TCID_{50}$/mL	SARS-CoV-2	10^5 $TCID_{50}$/mL	N/A	N/A	13.6 (3/3)	33.4 (3/3)	46.0 (0/3)	22.6 (3/3)
SARS-CoV-2^{lo} FluB^{hi}	SARS-CoV-2	0.48 $TCID_{50}$/mL	Flu B	10^5 $TCID_{50}$/mL	N/A	N/A	30.7 (3/3)	46.0 (0/3)	15.4 (3/3)	21.7 (3/3)
FluB^{lo} SARS-CoV-2^{hi}	Flu B	0.18 $TCID_{50}$/mL	SARS-CoV-2	10^5 $TCID_{50}$/mL	N/A	N/A	13.7 (3/3)	46.0 (0/3)	34.6 (3/3)	22.1 (3/3)
FluA^{lo} FluB^{hi}	Flu A	4.78×10^{-3} $TCID_{50}$/mL	Flu B	10^5 $TCID_{50}$/mL	N/A	N/A	46.0 (0/3)	34.5 (3/3)	15.5 (3/3)	21.0 (3/3)
FluB^{lo} FluA^{hi}	Flu B	0.18 $TCID_{50}$/mL	Flu A	10^5 $TCID_{50}$/mL	N/A	N/A	46.0 (0/3)	7.0 (3/3)	33.5 (3/3)	21.8 (3/3)
FluA^{lo}	Flu A	4.78×10^{-3} $TCID_{50}$/mL	N/A	N/A	N/A	N/A	46.0 (0/3)	33.8 (3/3)	46.0 (0/3)	22.4 (3/3)
SARS-CoV-2^{lo}	SARS-CoV-2	0.48 $TCID_{50}$/mL	N/A	N/A	N/A	N/A	31.3 (3/3)	46.0 (0/3)	46.0 (0/3)	22.6 (3/3)
FluB^{lo}	Flu B	0.18 $TCID_{50}$/mL	N/A	N/A	N/A	N/A	46.0 (0/3)	46.0 (0/3)	34.4 (3/3)	22.3 (3/3)
SARS-CoV-2^{lo} FluA^{lo} FluB^{lo}	SARS-CoV-2	0.48 $TCID_{50}$/mL	Flu A	4.78×10^{-3} $TCID_{50}$/mL	Flu B	0.18 $TCID_{50}$/mL	30.8 (3/3)	33.9 (3/3)	34.6 (3/3)	23.1 (3/3)

Table 19 QuantStudio™ 5 Real-Time PCR Instrument 96-well, 0.2-mL block

Combination	Target 1		Target 2		Target 3		Mean C_t (n=3) (Number detected/number tested)			
	Virus	Conc.	Virus	Conc.	Virus	Conc.	SARS-CoV-2 (VIC)	FluA (FAM)	FluB (ABY)	MS2 (JUN)
SARS-CoV-2^lo FluA^hi	SARS-CoV-2	0.64 $TCID_{50}$/mL[1]	Flu A	10^5 $TCID_{50}$/mL	N/A	N/A	32.1 (3/3)	8.1 (3/3)	46.0 (0/3)	23.7 (3/3)
FluA^lo SARS-CoV-2^hi	Flu A	6.36×10^{-3} $TCID_{50}$/mL[1]	SARS-CoV-2	10^5 $TCID_{50}$/mL	N/A	N/A	15.1 (3/3)	33.0 (3/3)	46.0 (0/3)	24.1 (3/3)
SARS-CoV-2^lo FluB^hi	SARS-CoV-2	0.48 $TCID_{50}$/mL	Flu B	10^5 $TCID_{50}$/mL	N/A	N/A	32.3 (3/3)	46.0 (0/3)	16.2 (3/3)	22.9 (3/3)
FluB^lo SARS-CoV-2^hi	Flu B	0.18 $TCID_{50}$/mL	SARS-CoV-2	10^5 $TCID_{50}$/mL	N/A	N/A	14.7 (3/3)	46.0 (0/3)	35.7 (3/3)	23.9 (3/3)
FluA^lo FluB^hi	Flu A	4.78×10^{-3} $TCID_{50}$/mL	Flu B	10^5 $TCID_{50}$/mL	N/A	N/A	46.0 (0/3)	35.2 (3/3)	16.5 (3/3)	22.8 (3/3)
FluB^lo FluA^hi	Flu B	0.18 $TCID_{50}$/mL	Flu A	10^5 $TCID_{50}$/mL	N/A	N/A	46.0 (0/3)	7.2 (3/3)	36.5 (3/3)	23.5 (3/3)
FluA^lo	Flu A	6.36×10^{-3} $TCID_{50}$/mL[1]	N/A	N/A	N/A	N/A	46.0 (0/3)	33.5 (3/3)	46.0 (0/3)	24.1 (3/3)
SARS-CoV-2^lo	SARS-CoV-2	0.64 $TCID_{50}$/mL[1]	N/A	N/A	N/A	N/A	32.4 (3/3)	46.0 (0/3)	46.0 (0/3)	24.4 (3/3)

Table 19 QuantStudio 5 Real-Time PCR Instrument 96-well, 0.2-mL block *(continued)*

Combination	Target 1		Target 2		Target 3		Mean C_t (n=3) (Number detected/number tested)			
	Virus	Conc.	Virus	Conc.	Virus	Conc.	SARS-CoV-2 (VIC)	FluA (FAM)	FluB (ABY)	MS2 (JUN)
FluB[lo]	Flu B	0.18 $TCID_{50}$/mL	N/A	N/A	N/A	N/A	46.0 (0/3)	46.0 (0/3)	36.1 (3/3)	24.2 (3/3)
SARS-CoV-2[lo] FluA[lo] FluB [lo]	SARS-CoV-2	0.48 $TCID_{50}$/mL	Flu A	4.78×10^{-3} $TCID_{50}$/mL	Flu B	0.18 $TCID_{50}$/mL	32.1 (3/3)	34.8 (3/3)	35.9 (3/3)	24.2 (3/3)

[1] This virus combination produced 3/3 Positive at 3X LoD, but the shift in mean C_t versus 3X LoD alone was greater than 1.5. Therefore, the combination was repeated with the low-concentration virus at 4X LoD.

No competitive interference was detected at the 3X LoD level for the following viral combinations:

- SARS-CoV-2 (0.48 $TCID_{50}$/mL) and FluB (10^5 $TCID_{50}$/mL)
- FluB (0.18 $TCID_{50}$/mL) and SARS-CoV-2 (10^5 $TCID_{50}$/mL)
- FluA (4.78×10^{-3} $TCID_{50}$/mL) and FluB (10^5 $TCID_{50}$/mL)
- FluB (0.18 $TCID_{50}$/mL) and FluA (10^5 $TCID_{50}$/mL)
- SARS-CoV-2 (0.48 $TCID_{50}$/mL), FluA (4.78×10^{-3} $TCID_{50}$/mL), and FluB (0.18 $TCID_{50}$/mL)

No competitive interference was detected at the 3X LoD level for the following viral combinations (7500 Fast Dx Real-Time PCR Instrument only):

- SARS-CoV-2 (0.48 $TCID_{50}$/mL) and FluA (10^5 $TCID_{50}$/mL)
- FluA (4.78×10^{-3} $TCID_{50}$/mL) and SARS-CoV-2 (10^5 $TCID_{50}$/mL)

No competitive interference was detected at the 4X LoD level for the following viral combinations (QuantStudio™ 5 Real-Time PCR Instrument 96-well, 0.2-mL block only):

- SARS-CoV-2 (0.64 $TCID_{50}$/mL) and FluA (10^5 $TCID_{50}$/mL)
- FluA (6.36×10^{-3} $TCID_{50}$/mL) and SARS-CoV-2 (10^5 $TCID_{50}$/mL)

Cross-reactivity

Functional testing was performed using the following microorganisms at the indicated concentrations. No cross-reactivity with the microorganisms tested was observed for SARS-CoV-2, influenza A virus, influenza B virus, or the MS2 Phage Control with the TaqPath™ COVID-19, FluA, FluB Combo Kit at the concentrations tested.

Table 20 Cross-reactivity testing results

Organism	Equivalent concentration tested	Number detected / number tested
Bacillus anthracis	2.9×10^8 GCE/mL	0/3
Bordetella pertussis	1.1×10^6 CFU/mL	0/3
Chlamydia psittaci	1.5×10^5 GCE/mL	0/3
Chlamydophila pneumoniae	1.1×10^6 CFU/mL	0/3
Corynebacterium diphtheriae	1.1×10^6 CFU/mL	0/3
Coxiella burnetii	2.6×10^5 GCE/mL	0/3
Haemophilus influenzae	1.1×10^6 CFU/mL	0/3
Legionella non-pneumophila *(Legionella longbeachae)*	1.1×10^6 CFU/mL	0/3
Legionella pneumophila	1.1×10^6 CFU/mL	0/3
Leptospira interrogans	1.7×10^8 GCE/mL	0/3

Table 20 Cross-reactivity testing results *(continued)*

Organism	Equivalent concentration tested	Number detected / number tested
Moraxella catarrhalis	4.2×10^8 GCE/mL	0/3
Mycobacterium tuberculosis	7.9×10^6 GCE/mL	0/3
Mycoplasma pneumoniae	1.1×10^6 CFU/mL	0/3
Neisseria elongata	1.1×10^6 CFU/mL	0/3
Neisseria meningitidis	1.1×10^6 CFU/mL	0/3
Pseudomonas aeruginosa	1.1×10^6 CFU/mL	0/3
Staphylococcus aureus	1.1×10^6 CFU/mL	0/3
Staphylococcus epidermidis	1.1×10^6 CFU/mL	0/3
Streptococcus pneumoniae	3.8×10^8 GCE/mL	0/3
Streptococcus pyogenes	4.2×10^8 GCE/mL	0/3
Streptococcus salivarius	1.1×10^6 CFU/mL	0/3
Adenovirus	1.1×10^5 $TCID_{50}$/mL	0/3
Enterovirus	1.1×10^5 $TCID_{50}$/mL	0/3
Human coronavirus 229E	1.1×10^5 $TCID_{50}$/mL	0/3
Human coronavirus NL63	4.0×10^4 $TCID_{50}$/mL	0/3
Human coronavirus OC43	1.1×10^5 $TCID_{50}$/mL	0/3
Human metapneumovirus	1.1×10^5 $TCID_{50}$/mL	0/3
Influenza C virus	1.1×10^5 $TCID_{50}$/mL	0/3
MERS Coronavirus	Unknown[1]	0/3
Parainfluenza 1 virus	1.1×10^5 $TCID_{50}$/mL	0/3
Parainfluenza 2 virus	1.1×10^5 $TCID_{50}$/mL	0/3
Parainfluenza 3 virus	1.1×10^5 $TCID_{50}$/mL	0/3
Parainfluenza 4 virus	1.1×10^5 $TCID_{50}$/mL	0/3
Parechovirus	1.1×10^5 $TCID_{50}$/mL	0/3
Respiratory Syncytial Virus A	1.1×10^5 $TCID_{50}$/mL	0/3
Respiratory Syncytial Virus B	1.1×10^5 $TCID_{50}$/mL	0/3
Rhinovirus	1.1×10^5 $TCID_{50}$/mL	0/3
Candida albicans	1.1×10^6 CFU/mL	0/3

Table 20 Cross-reactivity testing results *(continued)*

Organism	Equivalent concentration tested	Number detected / number tested
Pneumocystis carinii (Substituted for *Pneumocystis jirovecii)*	1.1 × 10^6 CFU/mL	0/3
Pooled human nasal wash	14% v/v	0/3

[1] The concentration was not provided by the vendor. The concentration tested was unknown.

Additional testing was performed to assess the impact of most of the organisms listed above at the indicated concentrations on the detection of MS2 Phage Control.

Chlamydophila pneumoniae and *Coxiella burnetii* were not tested in the presence of the MS2 Phage Control.

None of the organisms that were tested had a significant impact on the MS2 Phage Control C_t except for *Streptococcus pneumoniae* gDNA when tested directly in PCR without extraction, which produced an approximately 4–5-fold C_t increase in the mean C_t. Dilution of *S. pneumoniae* gDNA by 1:10 eliminated the inhibition on both of the real-time PCR instruments.

Instrument	Equivalent concentration	Mean C_t for MS2 Phage Control (n=3)	Δ C_t
7500 Fast Dx Real-Time PCR Instrument	3.8 × 10^8 GCE/mL	29.09	4.99
	3.8 × 10^7 GCE/mL	23.88	–0.22
	3.8 × 10^6 GCE/mL	23.94	–0.16
	3.8 × 10^5 GCE/mL	24.07	–0.03
	0 GCE/mL	24.10	N/A
QuantStudio™ 5 Real-Time PCR Instrument	3.8 × 10^8 GCE/mL	29.85	4.13
	3.8 × 10^7 GCE/mL	25.57	–0.15
	3.8 × 10^6 GCE/mL	25.69	–0.03
	3.8 × 10^5 GCE/mL	25.91	0.19
	0 GCE/mL	25.72	N/A

Interfering substances

Pooled negative NP specimens were spiked with SARS-CoV-2 (USA-WA1/2020), influenza A (A/Brisbane/59/07), or influenza B (B/Florida/04/06) viruses at 3X LoD and run in triplicate for each of the 10 potentially interfering substances and one no-interferent control on the 7500 Fast Dx Real-Time PCR Instrument and the QuantStudio™ 5 Real-Time PCR Instrument 96-well 0.2-mL block.

Interference was not observed for mucin, blood, corticosteroid nasal spray, nasal gel, homeopathic allergy relief nasal spray, throat lozenges, Oseltamivir, antibiotic ointment, and systemic antibiotics at the concentrations tested. Afrin™ Original nasal spray showed interference at 10% v/v; the highest concentrations that did not produce interference for any viral target were 0.6% and 1.3% for the 7500 Fast Dx Real-Time PCR Instrument and the QuantStudio™ 5 Real-Time PCR Instrument, respectively.

Table 21 Interfering substances (7500 Fast Dx Real-Time PCR Instrument)

Interfering substance	Final concentration in sample	Agreement with expected results					
		SARS-CoV-2		Flu A		Flu B	
		Percent agreement	Number of positive / Number tested	Percent agreement	Number of positive / Number tested	Percent agreement	Number of positive / Number tested
None	N/A	100%	3/3	100%	3/3	100%	3/3
Mucin: bovine submaxillary gland, type I-S	0.1 mg/mL	100%	3/3	100%	3/3	100%	3/3
Blood (human)	1% v/v	100%	3/3	100%	3/3	100%	3/3
Nasal sprays or drops—Afrin™ Original	0.6% v/v	100%[1]	3/3	100%[1]	3/3	100%[2]	3/3
Nasal corticosteroids—Flonase™	5 µg/mL	100%	3/3	100%	3/3	100%	3/3
Nasal gel—NeilMed™ Nasogel™	1% w/v	100%	3/3	100%	3/3	100%	3/3
Homeopathic allergy relief medicine—NatraBio Allergy Relief	10% v/v	100%	3/3	100%	3/3	100%	3/3
Throat lozenges, oral anesthetic and analgesic—Chloraseptic™	1% w/v	100%	3/3	100%	3/3	100%	3/3

Table 21 Interfering substances (7500 Fast Dx Real-Time PCR Instrument) *(continued)*

Interfering substance	Final concentration in sample	Agreement with expected results					
		SARS-CoV-2		Flu A		Flu B	
		Percent agreement	Number of positive / Number tested	Percent agreement	Number of positive / Number tested	Percent agreement	Number of positive / Number tested
Oseltamivir phosphate	33 µg/mL	100%	3/3	100%	3/3	100%	3/3
Antibiotic, nasal ointment—Bactroban™	5 µg/mL	100%	3/3	100%	3/3	100%	3/3
Antibacterial, systemic—Tobramycin	0.6 mg/mL	100%	3/3	100%	3/3	100%	3/3

[1] All replicates tested at 10%, 5%, and 2.5% were undetected.
[2] All replicates tested at 10%, 5%, 2.5%, and 1.3% v/v were undetected.

Table 22 Interfering substances (QuantStudio™ 5 Real-Time PCR Instrument, 96-well, 0.2-mL block)

Interfering substance	Final concentration in sample	Agreement with expected results					
		SARS-CoV-2		Flu A		Flu B	
		Percent agreement	Number of positive / Number tested	Percent agreement	Number of positive / Number tested	Percent agreement	Number of positive / Number tested
None	N/A	100%	3/3	100%	3/3	100%	3/3
Mucin: bovine submaxillary gland, type I-S	0.1 mg/mL	100%	3/3	100%	3/3	100%	3/3
Blood (human)	1% v/v	100%	3/3	100%	3/3	100%	3/3
Nasal sprays or drops—Afrin™ Original	1.3% v/v	100%[1]	3/3	100%[1]	3/3	100%[1]	3/3
Nasal corticosteroids—Flonase™	5 µg/mL	100%	3/3	100%	3/3	100%	3/3
Nasal gel—NeilMed™ Nasogel™	1% w/v	100%	3/3	100%	3/3	100%	3/3

Table 22 Interfering substances (QuantStudio 5 Real-Time PCR Instrument, 96-well, 0.2-mL block) *(continued)*

Interfering substance	Final concentration in sample	Agreement with expected results					
		SARS-CoV-2		Flu A		Flu B	
		Percent agreement	Number of positive / Number tested	Percent agreement	Number of positive / Number tested	Percent agreement	Number of positive / Number tested
Homeopathic allergy relief medicine—NatraBio Allergy Relief	10% v/v	100%	3/3	100%	3/3	100%	3/3
Throat lozenges, oral anesthetic and analgesic—Chloraseptic™	1% w/v	100%	3/3	100%	3/3	100%	3/3
Oseltamivir phosphate	33 µg/mL	100%	3/3	100%	3/3	100%	3/3
Antibiotic, nasal ointment—Bactroban™	5 µg/mL	100%	3/3	100%	3/3	100%	3/3
Antibacterial, systemic—Tobramycin	0.6 mg/mL	100%	3/3	100%	3/3	100%	3/3

[1] All replicates tested at 10%, 5%, and 2.5% were undetected.

Clinical evaluation

A clinical evaluation study was carried out to evaluate the performance of the TaqPath™ COVID-19, FluA, FluB Combo Kit using archived nasopharyngeal specimens.

The following specimens were tested:

- 51 NP specimens positive for SARS-CoV-2
- 59 NP specimens negative for SARS-CoV-2
- 56 NP specimens positive for influenza A virus
- 104 NP specimens negative for influenza A virus
- 36 NP specimens positive for influenza B virus
- 124 NP specimens negative for influenza B virus

Samples were tested using the TaqPath™ COVID-19, FluA, FluB Combo Kit as well as the following comparator tests:

- Comparator for SARS-CoV-2: FDA EUA-Authorized Molecular SARS-CoV-2 Assay
- Comparator for influenza A/B virus: FDA-cleared Molecular Influenza A+B Assay

Samples were extracted using the MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit for testing with TaqPath™ COVID-19, FluA, FluB Combo Kit or 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 23 Clinical evaluation study for SARS-CoV-2 (7500 Fast Dx Real-Time PCR Instrument)

TaqPath™ COVID-19, FluA, FluB Combo Kit	Comparator assay		
	SARS-CoV-2 Positive	SARS-CoV-2 Negative	Total
SARS-CoV-2 Positive	49	0	49
SARS-CoV-2 Negative	2	59	61
Total	51	59	110

PPA: 96.1% (95% CI: 86.5% LCL - 99.5% UCL)

NPA: 100% (95% CI: 93.9% LCL - 100.0% UCL)

Table 24 Clinical evaluation study for SARS-CoV-2 (QuantStudio™ 5 Real-Time PCR Instrument, 96-well, 0.2-mL block)

TaqPath™ COVID-19, FluA, FluB Combo Kit	Comparator assay		
	SARS-CoV-2 Positive	SARS-CoV-2 Negative	Total
SARS-CoV-2 Positive	49	0	49
SARS-CoV-2 Negative	2	59	61
Total	51	59	110

PPA: 96.1% (95% CI: 86.5% LCL - 99.5% UCL)

NPA: 100% (95% CI: 93.9% LCL - 100.0% UCL)

Table 25 Clinical evaluation study for Flu A (7500 Fast Dx Real-Time PCR Instrument)

TaqPath™ COVID-19, FluA, FluB Combo Kit	Comparator assay		
	Flu A Positive	Flu A Negative	Total
Flu A Positive	54	1	55
Flu A Negative	2	103	105
Total	56	104	160

PPA: 96.4% (95% CI: 87.7% LCL - 99.6% UCL)

NPA: 99.0% (95% CI: 94.8% LCL - 100.0% UCL)

Table 26 Clinical evaluation study for Flu A (QuantStudio™ 5 Real-Time PCR Instrument, 96-well, 0.2-mL block)

TaqPath™ COVID-19, FluA, FluB Combo Kit	Comparator assay		
	Flu A Positive	Flu A Negative	Total
Flu A Positive	53	1	54
Flu A Negative	3	103	106
Total	56	104	160

PPA: 94.6% (95% CI: 85.1% LCL - 98.9% UCL)

NPA: 99.0% (95% CI: 94.8% LCL - 100.0% UCL)

Table 27 Clinical evaluation study for Flu B (7500 Fast Dx Real-Time PCR Instrument)

TaqPath™ COVID-19, FluA, FluB Combo Kit	Comparator assay		
	Flu B Positive	Flu B Negative	Total
Flu B Positive	33	4	37
Flu B Negative	3	120	123
Total	36	124	160

PPA: 91.7% (95% CI: 77.5% LCL - 98.2% UCL)

NPA: 96.8% (95% CI: 91.9% LCL - 99.1% UCL)

Table 28 Clinical evaluation study for Flu B (QuantStudio™ 5 Real-Time PCR Instrument, 96-well, 0.2-mL block)

TaqPath™ COVID-19, FluA, FluB Combo Kit	Comparator assay		
	Flu B Positive	Flu B Negative	Total
Flu B Positive	33	4	37
Flu B Negative	3	120	123
Total	36	124	160

PPA: 91.7% (95% CI: 77.5% LCL - 98.2% UCL)

NPA: 96.8% (95% CI: 91.9% LCL - 99.1% UCL)

C_t cutoff values for assay targets

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

Table 29 Assay C_t cutoff values

Sample or Control	Target	C_t cutoff
Positive Control	MS2	Valid C_t values are >37
	Flu A and Flu B targets	Valid C_t values are ≤45
	SARS-CoV-2 targets	Valid C_t values are ≤37
Negative Control	MS2	Valid C_t values are ≤32
	Flu A and Flu B targets	Valid C_t values are >45
	SARS-CoV-2 targets	Valid C_t values are >37
Clinical samples	MS2	Valid C_t values are ≤32[1]
	SARS-CoV-2 targets	Positive C_t values are ≤37
	Flu A and Flu B targets	Positive C_t values are ≤45

[1] If any of the viral targets is positive, the C_t for MS2 can be >32.

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)*, 5th Edition, HHS Publication No. (CDC) 21-1112, Revised December 2009; found at:
  https://www.cdc.gov/labs/pdf/CDC-BiosafetymicrobiologicalBiomedicalLaboratories-2009-P.pdf
- World Health Organization, *Laboratory Biosafety Manual*, 3rd Edition, WHO/CDS/CSR/LYO/2004.11; found at:
  www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf

Documentation and support

Related documentation

Document	Publication Number
Applied Biosystems™ 7500 Fast Dx Real-Time PCR Instrument Reference Guide	4406991
QuantStudio™ 3 and 5 Real-Time PCR Systems Installation, Use, and Maintenance Guide	MAN0010407
MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit (automated extraction) User Guide	MAN0018073
Thermo Scientific™ KingFisher™ Flex User Manual	N07669
Pathogen Interpretive Software Installation Quick Reference	MAN0019535

Customer and technical support

For additional documentation and information about this kit, visit: **https://www.thermofisher.com/covid19flu**

For download instructions for the software, see "Obtain the software" on page 27.

Refer to the Read Me file 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**.

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applied biosystems PRODUCT INFORMATION SHEET

TaqPath™ COVID-19, FluA, FluB Combo Kit

Multiplex real-time RT-PCR test for the detection and differentiation of SARS-CoV-2, influenza A, and influenza B RNA

Catalog Number A49868

Pub. No. 100097258 Rev. B

You are receiving TaqPath™ RT-PCR COVID-19, FluA, FluB Kit components that may state that they have not been reviewed by the FDA and that review under the EUA program is pending. Please note that the TaqPath™ RT-PCR COVID-19, FluA, FluB Kit and all of its components, including software, have now received Emergency Use Authorization by the FDA. The labeling on the components you are receiving may not yet have been updated to reflect this change in regulatory status. You may use these kits just as you would the emergency use authorized-labeled kits as per the intended use.

Intended Use

The TaqPath™ COVID-19, FluA, FluB Combo Kit is a multiplex real-time RT-PCR test intended for the simultaneous qualitative detection and differentiation of RNA from the SARS-CoV-2, influenza A, and/or influenza B viruses in nasopharyngeal swab and anterior nasal swab specimens collected from individuals suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high-complexity tests.

The TaqPath™ COVID-19, FluA, FluB Combo Kit is intended for use in simultaneous detection and differentiation of SARS-CoV-2, influenza A, and/or influenza B nucleic acid in clinical specimens and is not intended to detect influenza C virus. The SARS-CoV-2, influenza A, and influenza B RNA is generally detectable in upper respiratory samples during the acute phase of infection.

Positive results are indicative of active infection but do not rule out bacterial infection or co-infection with other pathogens not detected by the test. Clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. The agent detected may not be the definite cause of disease.

Laboratories within the United States and its territories are required to report all SARS-CoV-2 results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2, influenza A, and/or influenza B infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and/or epidemiological information.

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

Instructions for Use/Interpretation/Limitations

The *TaqPath™ COVID-19, FluA, FluB Combo Kit Instructions for Use* (Pub. No. MAN0019582) can be downloaded from the following link:

https://www.thermofisher.com/covid19flu

If you require arinted 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 test 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 test has been authorized only for the detection of nucleic acid from SARS CoV-2, influenza A virus, and influenza B virus and not for any other viruses or pathogens.

The emergency use of this test 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

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

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Obtain the software

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

- Applied Biosystems™ Pathogen Interpretive Software
- SAE Administrator Console Dx

To obtain the software, contact your local instrument service team. Go to **http://www.thermofisher.com/educationconnect**. Access the e-learning course by entering the subscription code *C19FAFBCKEUAPIS10*

Contents and storage

Table 1 TaqPath™ COVID-19, FluA, FluB Combo Kit, 1,000 reactions (Cat. No. A49868)

Component	Contents	Amount	Storage
TaqPath™ RT-PCR COVID-19, FluA, FluB Kit, 1,000 reactions	TaqPath™ COVID-19, FluA, FluB RT-PCR Assay Multiplex	1,500 µL	–30°C to –10°C
	MS2 Phage Control	10 × 1,000 µL	–30°C to –10°C
TaqPath™ COVID-19, FluA, FluB Control		10 × 10 µL	≤ –70°C
TaqPath™ Control Dilution Buffer		10 × 250 µL	–30°C to –10°C

Customer and technical support

For additional documentation and information about this kit, visit: **https://www.thermofisher.com/covid19flu**. For download instructions for the software, see "Obtain the software" on page 2. Refer to the Read Me file provided with the Pathogen Interpretive 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 customer is responsible for compliance with regulatory requirements that pertain to their procedures and uses of the instrument.
The information in this guide is subject to change without notice.
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Revision history: Pub. No. 100097258

Revision	Date	Description
B	14 January 2021	• Updated labeling for Emergency Use Authorization, added limitations, and added information about kit components that might not have an Emergency Use Authorization label. • Removed licensing information. • Updated instructions to obtain the software.
A	19 October 2020	New document.

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