### **applied**biosystems

# TaqMan<sup>™</sup> SARS-CoV-2 Fast PCR Combo Kit 2.0

#### **USER GUIDE**

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A.0	27 April 2021	New document.

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### **Product information**

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**IMPORTANT!** Before using this product, read and understand the information in the "Safety" appendix in this document.

### **Product description**

The TaqMan<sup>™</sup> SARS-CoV-2 Fast PCR Assay 2.0, packaged as part of the TaqMan<sup>™</sup> SARS-CoV-2 Fast PCR Combo Kit 2.0, is a multiplex real-time RT-PCR assay for the detection of SARS-CoV-2 viral RNA in human raw saliva samples.

The assay requires the following components:

- TaqMan<sup>™</sup> SARS-CoV-2 Fast PCR Combo Kit 2.0, includes the following components:
  - TaqMan<sup>™</sup> SARS-CoV-2 Fast PCR Assay 2.0—Multiplexed assays that contain primer and probe sets specific to the following targets (see Table 1):
    - SARS-CoV-2 ORF1a
    - SARS-CoV-2 N gene
    - SARS-CoV-2 ORF1b
    - RNase P (human sample collection control)
  - TaqMan<sup>™</sup> SARS-CoV-2 Plus Control—RNA control that contains targets specific to the SARS-CoV-2 genomic regions targeted by the assays and RNase P
  - TagMan<sup>™</sup> SARS-CoV-2 Control Dilution Buffer Dilution buffer for the control
  - SalivaReady<sup>™</sup> Solution—Lysis buffer
- TaqPath<sup>™</sup> 1-Step Multiplex Master Mix (No ROX<sup>™</sup>)

Table 1 Dyes, targets, and quenchers

Dye	Target	Quencher
FAM <sup>™</sup> dye	SARS-CoV-2 ORF1a	
VIC <sup>™</sup> dye	SARS-CoV-2 N gene	None <sup>[1]</sup>
ABY <sup>™</sup> dye	SARS-CoV-2 ORF1b	Noner
JUN <sup>™</sup> dye	RNase P	

<sup>[1]</sup> The TaqMan<sup>™</sup> SARS-CoV-2 Fast PCR Combo Kit 2.0 probes contain QSY<sup>™</sup> quenchers, which do not fluoresce. Select 'None' for Quencher in the instrument set up procedure (see "Set up and run the real-time PCR instrument" on page 14).

For catalog numbers and storage conditions, see "Contents and storage".

**IMPORTANT!** It is the responsibility of the laboratories using the TaqMan<sup>™</sup> SARS-CoV-2 Fast PCR Assay 2.0 to design and validate their own experimental design and analysis parameters.

### Contents and storage

Table 2 TaqMan<sup>™</sup> SARS-CoV-2 Fast PCR Combo Kit 2.0, 1,000 reactions (Cat. No. A51607)

Component	Amount	Storage
TaqMan <sup>™</sup> SARS-CoV-2 Fast PCR Assay 2.0	1 × 1 mL	–30°C to −10°C
TaqMan <sup>™</sup> SARS-CoV-2 Plus Control	10 × 10 μL	≤ -20°C
TaqMan <sup>™</sup> SARS-CoV-2 Control Dilution Buffer	10 × 250 μL	–30°C to −10°C
SalivaReady <sup>™</sup> Solution	1 × 20 mL	-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.

**IMPORTANT!** The customer is responsible for performing all of the necessary validations to run this assay.

Item	Source		
Real-time PCR instrument and software			
An Applied Biosystems <sup>™</sup> real-time PCR instrument compatible with the four dyes listed in Table 1 on page 5.			
<ul> <li>The assay has been tested with the following instruments:</li> <li>Applied Biosystems<sup>™</sup> QuantStudio<sup>™</sup> 5 Real-Time PCR Instrument, 96-well, 0.2-mL block</li> <li>Applied Biosystems<sup>™</sup> QuantStudio<sup>™</sup> 7 Flex Real-Time PCR Instrument, 384-well block</li> </ul>	Contact your local sales office		
(Recommended) QuantStudio <sup>™</sup> Design and Analysis Software v2.5 or later <sup>[1]</sup>	thermofisher.com/qpcrsoftware		
Equipment			
Laboratory freezers  • −30°C to −10°C  • ≤ −70°C <sup>[2]</sup>	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 <sup>™</sup> 96-Well Thermal Cycler, 0.2-mL block	4375786, or equivalent		
Reagents and consumables			
TaqPath <sup>™</sup> 1-Step Multiplex Master Mix (No ROX <sup>™</sup> )	<ul> <li>A28522 (5 × 1 mL)</li> <li>A28523 (1 × 10 mL)</li> </ul>		

#### (continued)

Item	Source	
Nuclease-free Water (not DEPC-Treated)	<ul><li>AM9938 (1 x 100 mL)</li><li>AM9932 (1 x 1,000 mL)</li></ul>	
Reservoir for multichannel pipettes	MLS	
Sterile aerosol barrier (filtered) pipette tips	thermofisher.com/pipettetips	
MicroAmp <sup>™</sup> Optical 96-Well Reaction Plate, 0.2 mL	<ul> <li>4306737 (with barcode)</li> <li>4326659 (with barcode)</li> <li>N8010560 (without barcode)</li> <li>4316813 (without barcode)</li> </ul>	
MicroAmp <sup>™</sup> Optical 384-Well Reaction Plate	<ul> <li>4309849 (with barcode)</li> <li>4326270 (with barcode)</li> <li>4343814 (with barcode)</li> <li>4343370 (without barcode)</li> </ul>	
MicroAmp <sup>™</sup> Clear Adhesive Film	4306311	
MicroAmp <sup>™</sup> Optical Adhesive Film	4311971, 4360954	
MicroAmp <sup>™</sup> Adhesive Film Applicator	4333183	
MicroAmp <sup>™</sup> Optical Film Compression Pad <sup>[3]</sup>	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) <sup>[4]</sup>	thermofisher.com	

<sup>[1]</sup> Use of QuantStudio<sup>™</sup> Design and Analysis Software v2.5 is recommended, but not required. It is the responsibility of the laboratories using the assay to design and validate their own experimental design and analysis parameters.

<sup>[2]</sup> If needed for long-term saliva storage.

<sup>[3]</sup> Recommended for use with the QuantStudio™ 5 Real-Time PCR Instrument, 96-well, 0.2-mL block.

<sup>[4]</sup> Only needed if using 384-well plates.

## 2

### Methods

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### **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 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
- 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 21).

### Guidelines for sample collection and storage

• Collect saliva sample in a collection device with a leak-proof, screw-top lid.

**IMPORTANT!** Do not collect saliva using a device that contains preservative solution.

Collect a minimum of 1 mL saliva.

- IMPORTANT! Collect saliva samples according to the instructions provided with your collection device. We recommend that you follow best practices to minimize the presence of inhibitors in the saliva:
  - At least 30 minutes before collection, clean the mouth. Swish water for 10 seconds, then swallow to remove debris.
  - After cleaning the mouth, avoid eating, drinking, smoking, using chewing tobacco, chewing gum, brushing teeth, and using mouthwash or other foreign substances until the sample is collected to ensure reliable results.
  - During collection, allow saliva to passively pool in the mouth, then drool into the collection device. Do not cough while performing collection, and ensure that the sample is free of phlegm or other debris.

Note: Laboratories are responsible for validation of their sample collection procedure.

• Store raw saliva samples according to the procedure established by your laboratory. For long-term storage, freeze raw saliva samples at -80°C. Avoid multiple freeze-thaw cycles.

### Prepare saliva samples



**WARNING!** Saliva samples have the potential to transmit infectious diseases. Use safe laboratory procedures established based on your laboratory's risk assessment. These may include wearing personal protective equipment (PPE) and handling samples in a BSL-2 biological safety cabinet.

**IMPORTANT!** Saliva samples can contain high amounts of inhibitory compounds that can affect real-time RT-PCR results. Laboratories are responsible for validating their sample collection and preparation procedures for use with the assay.

#### Before you begin

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

#### Prepare the samples

- For the required number of samples, add 20 µL of SalivaReady<sup>™</sup> Solution to each well of a new 0.2 mL 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<sup>™</sup> Solution.

- 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 <sup>[1]</sup>	1

<sup>[1]</sup> 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.

If necessary, the sealed plate may be stored at 4°C until used for real-time RT-PCR.

### **Prepare RT-PCR reactions**

#### **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 or a cold block 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 TaqMan<sup>™</sup> SARS-CoV-2 Plus Control to a working stock:
  - a. Pipet 120.0 µL of TaqMan<sup>™</sup> SARS-CoV-2 Control Dilution Buffer into a microcentrifuge tube, then add 2.0 µL of TaqMan<sup>™</sup> SARS-CoV-2 Plus Control. Mix well, then centrifuge briefly.
  - b. Pipet 120.0 µL of TaqMan<sup>™</sup> SARS-CoV-2 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 <i>n</i> samples plus 2 controls <sup>[1]</sup>	Volume for 94 samples plus 2 controls <sup>[1]</sup>
TaqPath <sup>™</sup> 1-Step Multiplex Master Mix (No ROX <sup>™</sup> ) (4X)	5.0 μL	5.5 x (n + 2) μL	528.0 μL
TaqMan <sup>™</sup> SARS-CoV-2 Fast PCR Assay 2.0 (20X)	1.0 µL	1.1 x (n + 2) μL	105.6 μL
Total Reaction Mix volume	6.0 μL	_	633.6 μL

<sup>[1]</sup> All volumes include 10% overage for pipette error.

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

	Volume per reaction		
Component	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 <sup>™</sup> Solution)	14.0 µL	_	_
Positive Control (diluted TaqMan™ SARS-CoV-2 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<sup>™</sup> 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<sup>™</sup> 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.

### Chapter 2 Methods Prepare RT-PCR reactions

- c. Add 14.0 µL of the diluted TaqMan<sup>™</sup> SARS-CoV-2 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<sup>™</sup> Optical Adhesive Film.

**IMPORTANT!** When applying the MicroAmp<sup>™</sup> 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  $1,400 \times g$  to remove bubbles and to collect the liquid at the bottom of the reaction plate.

**Note:** Bubbles might be present in some wells after centrifugation. Surface bubbles dissipate during PCR cycling and do not impact results.

#### 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 TaqMan<sup>™</sup> SARS-CoV-2 Plus Control to a working stock:
  - a. Pipet 120.0 µL of TaqMan<sup>™</sup> SARS-CoV-2 Control Dilution Buffer into a microcentrifuge tube, then add 2.0 µL of TaqMan<sup>™</sup> SARS-CoV-2 Plus Control. Mix well, then centrifuge briefly.
  - b. Pipet 120.0 μL of TaqMan<sup>™</sup> SARS-CoV-2 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 <i>n</i> samples plus 2 controls <sup>[1]</sup>	Volume for 382 samples plus 2 controls <sup>[1]</sup>
TaqPath <sup>™</sup> 1-Step Multiplex Master Mix (No ROX <sup>™</sup> ) (4X)	5.0 μL	5.5 x (n + 2) μL	2,112.0 μL
TaqMan <sup>™</sup> SARS-CoV-2 Fast PCR Assay 2.0 (20X)	1.0 µL	1.1 x (n + 2) μL	422.4 μL
Total Reaction Mix volume	6.0 μL	_	2,534.4 μL

<sup>[1]</sup> All volumes include 10% overage for pipette error.

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

	Volume per reaction				
Component	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 <sup>™</sup> Solution)	14.0 μL	-	_		
Positive Control (diluted TaqMan <sup>™</sup> SARS-CoV-2 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<sup>™</sup> 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 TaqMan<sup>™</sup> SARS-CoV-2 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<sup>™</sup> Optical Adhesive Film.

**IMPORTANT!** When applying the MicroAmp<sup>™</sup> 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  $1,400 \times g$  to remove bubbles and to collect the liquid at the bottom of the reaction plate.

**Note:** Bubbles might be present in some wells after centrifugation. Surface bubbles dissipate during PCR cycling and do not impact results.

### Set up and run the real-time PCR instrument

Ensure that your real-time PCR instrument is calibrated for the dyes listed in step 2. See your instrument user guide for more information.

1. Set up the real-time PCR instrument with the following settings.

Analysis type: Standard curve

Run mode: Standard
Passive reference: None
Sample volume: 20 µL

2. Set up the following reporter dye and detector pairs.

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

3. Set up the thermal protocol for your instrument.

Table 3 Applied Biosystems<sup>™</sup> QuantStudio<sup>™</sup> 5 Real-Time PCR Instrument, 96-well, 0.2-mL block

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	40	

Table 4 Applied Biosystems<sup>™</sup> QuantStudio<sup>™</sup> 7 Flex Real-Time PCR Instrument, 384-well block

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	- 40	

4. Set up the optical filters for your instrument, if needed.

Table 5 PCR Filters for the QuantStudio<sup>™</sup> 7 Flex Real-Time PCR Instrument, 384-well block

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

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

5. Load the plate and start the instrument run.

**IMPORTANT!** We recommend to use a compression pad with the QuantStudio<sup>™</sup> 5 Real-Time PCR Instrument, 96-well, 0.2-mL block.

With correct usage the compression pad should maintain performance for a minimum of 20 PCR runs. Use of deteriorated compression pads may lead to volume leakage and failed reactions.

### Analyze data

**IMPORTANT!** It is the responsibility of the laboratories using the TaqMan<sup>™</sup> SARS-CoV-2 Fast PCR Assay 2.0 to design and validate their own experimental design and analysis parameters.

(Recommended) Use QuantStudio<sup>™</sup> Design and Analysis Software v2.5 or later for data analysis. For more information about using the software, see "Related documentation" on page 21.

- 1. In the QuantStudio<sup>™</sup> Design and Analysis Software v2 home screen, open the data file (EDS).
- 2. In the open data file, click **Actions** > Save As, then save the data file with a new name.

**Note:** QuantStudio<sup>™</sup> Design and Analysis Software v2 requires data files created on a QuantStudio<sup>™</sup> 5 Real-Time PCR System and QuantStudio<sup>™</sup> 7 Flex Real-Time PCR System to be saved as a new data file.

- 3. In the analysis settings, select automatic baseline with a start cycle of 5 and an end cycle of auto.
- 4. Set the appropriate threshold values for each target, as validated by your laboratory.

**IMPORTANT!** Do not use automatic threshold values.

5. Determine  $C_q$  cutoff values for each target for samples and controls.

**Note:** QuantStudio<sup> $^{\text{TM}}$ </sup> Design and Analysis Software v2 reports  $C_q$  values instead  $C_t$  values. The  $C_q$  values are equivalent to  $C_t$  values.

Analyze results according to analysis, interpretation, and QC parameters, as validated by your laboratory.

Contact Support for more information.



### 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.

### Appendix A Safety Chemical safety

### **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.



AVERTISSEMENT! PRÉCAUTIONS GÉNÉRALES EN CAS DE MANIPULATION DE PRODUITS CHIMIQUES. Pour minimiser les risques, veiller à ce que le personnel du laboratoire lise attentivement et mette en œuvre les consignes de sécurité générales relatives à l'utilisation et au stockage des produits chimiques et à la gestion des déchets qui en découlent, décrites ci-dessous. Consulter également la FDS appropriée pour connaître les précautions et instructions particulières à respecter :

- Lire et comprendre les fiches de données de sécurité (FDS) fournies par le fabricant avant de stocker, de manipuler ou d'utiliser les matériaux dangereux ou les produits chimiques. Pour obtenir les FDS, se reporter à la section « Documentation et support » du présent document.
- Limiter les contacts avec les produits chimiques. Porter des équipements de protection appropriés lors de la manipulation des produits chimiques (par exemple : lunettes de sûreté, gants ou vêtements de protection).
- Limiter l'inhalation des produits chimiques. Ne pas laisser les récipients de produits chimiques ouverts. Ils ne doivent être utilisés qu'avec une ventilation adéquate (par exemple, sorbonne).
- Vérifier régulièrement l'absence de fuite ou d'écoulement des produits chimiques. En cas de fuite ou d'écoulement d'un produit, respecter les directives de nettoyage du fabricant recommandées dans la FDS.
- · Manipuler les déchets chimiques dans une sorbonne.

- Veiller à utiliser des récipients à déchets primaire et secondaire. (Le récipient primaire contient les déchets immédiats, le récipient secondaire contient les fuites et les écoulements du récipient primaire. Les deux récipients doivent être compatibles avec les matériaux mis au rebut et conformes aux exigences locales, nationales et communautaires en matière de confinement des récipients.)
- · Une fois le récipient à déchets vidé, il doit être refermé hermétiquement avec le couvercle fourni.
- Caractériser (par une analyse si nécessaire) les déchets générés par les applications, les réactifs et les substrats particuliers utilisés dans le laboratoire.
- Vérifier que les déchets sont convenablement stockés, transférés, transportés et éliminés en respectant toutes les réglementations locales, nationales et/ou communautaires en vigueur.
- **IMPORTANT!** Les matériaux représentant un danger biologique ou radioactif exigent parfois une manipulation spéciale, et des limitations peuvent s'appliquer à leur élimination.

### Appendix A Safety Biological hazard safety

### 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
Veriti <sup>™</sup> Thermal Cycler User Guide	MAN0018441
QuantStudio <sup>™</sup> 3 and 5 Real-Time PCR Systems Installation, Use, and Maintenance Guide	MAN0010407
QuantStudio <sup>™</sup> 6 and 7 Flex Real-Time PCR Systems Maintenance and Administration Guide	4489821
QuantStudio <sup>™</sup> Design and Analysis Software v2 User Guide	MAN0018200

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  - Safety Data Sheets (SDSs; also known as MSDSs)

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

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