



TaqPath COVID-19 CE-IVD RT-PCR Kit

A real-time PCR multiplex diagnostic solution for COVID-19

In response to the current coronavirus (SARS-CoV-2, the virus that causes COVID-19) outbreak, Thermo Fisher Scientific has worked rapidly to develop a new multiplex real-time RT-PCR diagnostic kit to enable clinical and public health laboratories to quickly diagnose COVID-19 caused by SARS-CoV-2 infection. The Applied Biosystems™ TaqPath™ COVID-19 CE-IVD RT-PCR kit has obtained CE-IVD marking.

The kit performance was established using nasopharyngeal and oropharyngeal swabs, nasopharyngeal aspirates, and bronchoalveolar lavage (BAL) only. Nasal swabs and mid-turbinate swabs are considered acceptable, however performance with these specimen types has not been established.

Features of the TaqPath COVID-19 CE-IVD RT-PCR Kit

- **Speed.** Detection using real-time PCR to diagnostic report generation for up to 382 samples in less than 2 hours.
- **Sensitivity.** Assays cover all of the SARS-CoV-2 genomes of high sequence quality and complete sequence length that are currently available through the GISAID Initiative.
- **Specificity.** Assays target genomic regions of the SARS-CoV-2 genome that are not present in other coronaviruses (e.g., SARS, MERS, bat SARS-like coronavirus, etc.).
- **Ease of Use.** COVID-19 Interpretive Software automatically converts genetic analysis data into diagnosis, helping reduce risk of user interpretation error.



Intended use of the products mentioned in this workflow graphic vary. For specific intended use statements please refer to the instructions for use.

Required workflow components for the *in vitro* diagnosis of COVID-19 in less than 2 hours.

The required workflow consists of real-time RT-PCR genetic analysis and automated translation of data into patient diagnosis.

The TaqPath COVID-19 CE-IVD RT-PCR Kit contains:

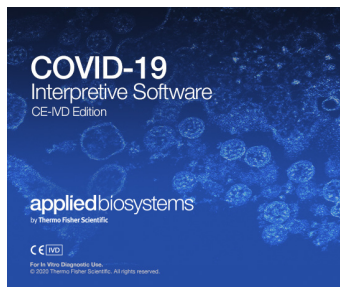
- TaqPath COVID-19 RT-PCR Kit, 1,000 reactions including the multiplex assay and an IPC
- TaqPath COVID-19 Control, positive control of SARS-CoV-2
- TaqPath COVID-19 Control Dilution Buffer
- TaqPath 1-Step Multiplex Master Mix (No ROX)
- Interpretive software package insert providing instructions to download the instructions for use

This kit is required for use with a range of validated Applied Biosystems™ real-time PCR instruments, as listed in the ordering table below.

Existing users of approved Applied Biosystems Real-Time PCR Instruments will need to install the COVID-19 Interpretive Software prior to running the kit.

Contact our local support team following the instruction below, and they will help you download and install the new software.

1. Go to thermofisher.com/contactus
2. Select “Instrument Service” as category
3. Enter instrument name and select your country
4. Call the local number displayed on the screen



The COVID-19 Interpretive Software helps your lab decrease analysis and interpretation time and reduce risk of user interpretation error:

- Automatically interpret genetic analysis results from the TaqPath COVID-19 CE-IVD RT-PCR Kit
- Following instrument data analysis, the COVID-19 Interpretive Software performs a QC check against all controls on the plate
- Software generates a report for each specimen
- COVID-19 Interpretive Software download is available upon kit purchase

Ordering information

Product	Components	Cat. No.
TaqPath COVID-19 CE-IVD RT-PCR Kit, 1,000 rxns	TaqPath COVID-19 Assay Multiplex 1,000X (1,500 µL) 1 tube	A48067
	MS2 phage - 10 tubes (1 mL)	
	Insert with electronic documentation instructions	
	IVT RNA Control - 10 tubes (10 µL) (spec. : 10 ⁴ copies/µL)	
TaqPath COVID-19 Control	Dilution Buffer for the IVT RNA Control - 10 tubes (250 µL)	
TaqPath COVID-19 Control Dilution Buffer	4X RT-qPCR mix - 1 bottle (10 mL)	
TaqPath 1-Step Multiplex Master Mix (No ROX)		
7500 Fast Real-Time PCR System	Laptop/desktop	4351106/4351107
7500 Fast Dx Real-Time PCR System	Laptop/desktop	4406984/4406985
7500 Real-Time PCR System	Desktop	4351105
QuantStudio 5 Real-Time PCR System, 96-well	0.1 mL	A28138
	0.2 mL	A28139
QuantStudio 5 Dx Real-Time PCR System, 96-well	0.2 mL, laptop	A32005
QuantStudio 5 Real-Time PCR System, 384-well	Laptop/desktop	A28570/A28575
QuantStudio 7 Flex Real-Time PCR System, 384-well block	Laptop/desktop	4485695/4485701

To order any of these products, please contact your local sales representative.

* Authorized laboratories using the TaqPath COVID-19 CE-IVD RT-PCR Kit will perform the TaqPath COVID-19 CE-IVD RT-PCR Kit as outlined in the Instructions for Use. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized assay and authorized reagent required to perform the TaqPath COVID-19 CE-IVD RT-PCR Kit are not permitted.

To learn more and for a full list of products to perform the required workflow, go to thermofisher.com/covid19CEIVD

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