



TaqPath COVID-19 CE-IVD RT-PCR Kit

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

In response to the SARS-CoV-2 outbreak, Thermo Fisher Scientific worked rapidly to develop a 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. This kit is the Applied Biosystems™ TaqPath™ COVID-19 CE-IVD RT-PCR Kit, which has obtained CE-IVD marking.

The kit's performance was established using nasopharyngeal and oropharyngeal swabs, nasopharyngeal aspirates, bronchoalveolar lavage (BAL), and saliva specimen. Nasal swabs and midturbinate swabs are considered acceptable, but not tested specimen types.

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

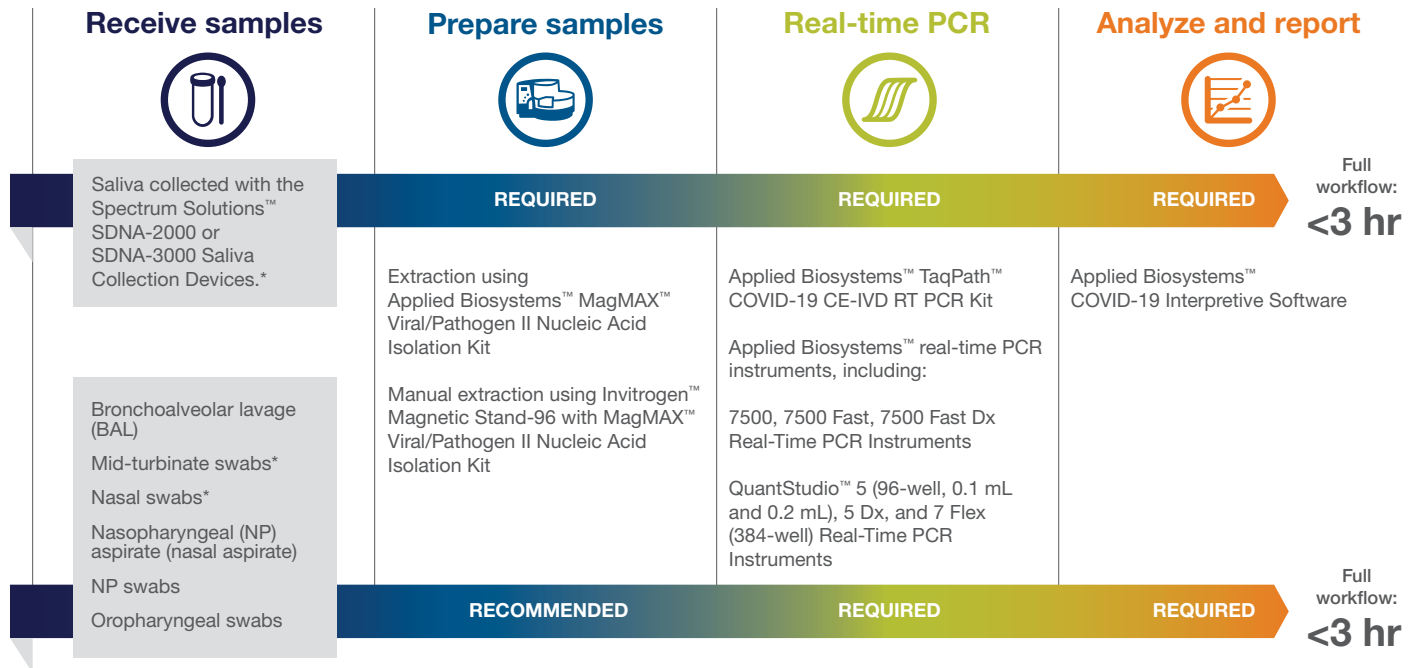
- Built-in redundancy (3 targets) compensates for emerging SARS-CoV-2 mutations and variants, helping provide confidence in your results
- Compatibility validated for use on some of the most-used real-time PCR instruments in the world
- Includes Applied Biosystems™ COVID-19 Interpretive Software CE-IVD Edition, which automatically converts genetic analysis data into a readable report, helping reduce risk of user interpretation error

S-gene advantage for potential early identification of B.1.1.529

This test uses a multi-target design that includes an S-gene target. If a sample with the 69-70del S-gene mutation is tested using the TaqPath COVID-19 CE-IVD RT-PCR Kit, it will result in an S-gene dropout. The European CDC and U.S. FDA have noted this pattern of detection may help with early identification of B.1.1.529.

(Reference: <https://www.ecdc.europa.eu/en/publications-data/threat-assessment-brief-rapid-increase-sars-cov-2-variant-united-kingdom>)

Workflow by sample type for the TaqPath COVID-19 CE-IVD RT-PCR Kit



* Regulatory authorizations vary by country. Saliva testing and workflow may not be applicable in all geographic areas. Check local authorities for status. Acceptable sample matrix. Performance not yet tested. Intended use of the products in this workflow may vary. Refer to the product instructions for use for details.

The required workflow components for the *in vitro* diagnosis of COVID-19 in less than 3 hours.

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

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

- TaqPath COVID-19 Assay Multiplex
 - Multiplex assays that contain three primer/probe sets targeting SARS-CoV-2 *orf1-ab*, S gene, and N gene
- MS2 Phage Control
- TaqPath COVID-19 Control Dilution Buffer
 - Dilution buffer to formulate the TaqPath COVID-19 Control
- TaqPath COVID-19 Control
 - RNA control specific to the SARS-CoV-2 genomic regions targeted by the assays
- TaqPath 1-Step Multiplex Master Mix (No ROX)
- Package insert
 - Provides instructions and links to download the Instructions for Use and the Applied Biosystems™ COVID-19 Interpretive Software CE-IVD Edition

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



Applied Biosystems COVID-19 Interpretive Software

Decrease analysis and interpretation time and help reduce risk of user interpretation error with the COVID-19 Interpretive Software CE-IVD Edition.

You may download the COVID-19 Interpretive Software upon kit purchase. Labs following the authorized workflow are required to complete an eLearning course and pass an exam to download. **Follow the instructions below to obtain the software from your local support team:**

- Go to thermofisher.com/contactus
- Select “Instrument Service” as category
- Enter product name or SKU and select your country
- Call the local number displayed on the screen

Ordering information

Product	Components	Cat. No.
TaqPath COVID-19 CE-IVD RT-PCR Kit, 1,000 reactions	TaqPath COVID-19 RT-PCR Kit	TaqPath COVID-19 Assay Multiplex 1,000X (1,500 µL), 1 tube MS2 phage: 10 tubes (1 mL) Insert with electronic documentation instructions
	TaqPath COVID-19 Control	IVT RNA Control: 10 tubes (10 µL) (spec.: 10 ⁴ copies/µL)
	TaqPath COVID-19 Control Dilution Buffer	Dilution Buffer for the IVT RNA Control: 10 tubes (250 µL)
	TaqPath 1-Step Multiplex Master Mix (No ROX)	RT-qPCR mix: 1 bottle (10 mL)
TaqPath COVID-19 CE-IVD RT PCR Kit, 100 reactions	TaqPath COVID-19 RT-PCR Kit	TaqPath COVID-19 Assay Multiplex 100X (150 µL), 1 tube MS2 phage: 1 tube (1 mL) Insert with electronic documentation instructions
	TaqPath COVID-19 Control	Dilution Buffer for the IVT RNA Control: 1 tubes (250 µL) IVT RNA Control: 1 tube (10 µL) (spec.: 10 ⁴ copies/µL)
	TaqPath 1-Step Multiplex Master Mix (No ROX)	RT-qPCR mix: 1 bottle (1 mL)
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 block	0.1 mL	A28138
	0.2 mL	A28139
QuantStudio 5 Dx Real-Time PCR System, 96-well block	0.2 mL, laptop	A32005
QuantStudio 7 Flex Real-Time PCR System, 384-well block	Laptop/desktop	4485695/4485701
Spectrum Solutions SDNA Molecular Diagnostic Saliva Collection Devices (SDNA-2000 or SDNA-3000)	Each	R13102

Note: Not all pack sizes may be marketed in your country. Consult your local Thermo Fisher Scientific representative for availability.

Delivered together in the same box.

 Learn more and get a full list of products to perform the required workflow at thermofisher.com/covid19ceivd

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