

TaqPath COVID-19 Combo Kit

An end-to-end, 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, real-time PCR multiplex diagnostic kit to enable clinical and public health laboratories to quickly diagnose COVID-19 caused by SARS-CoV-2 infection.*

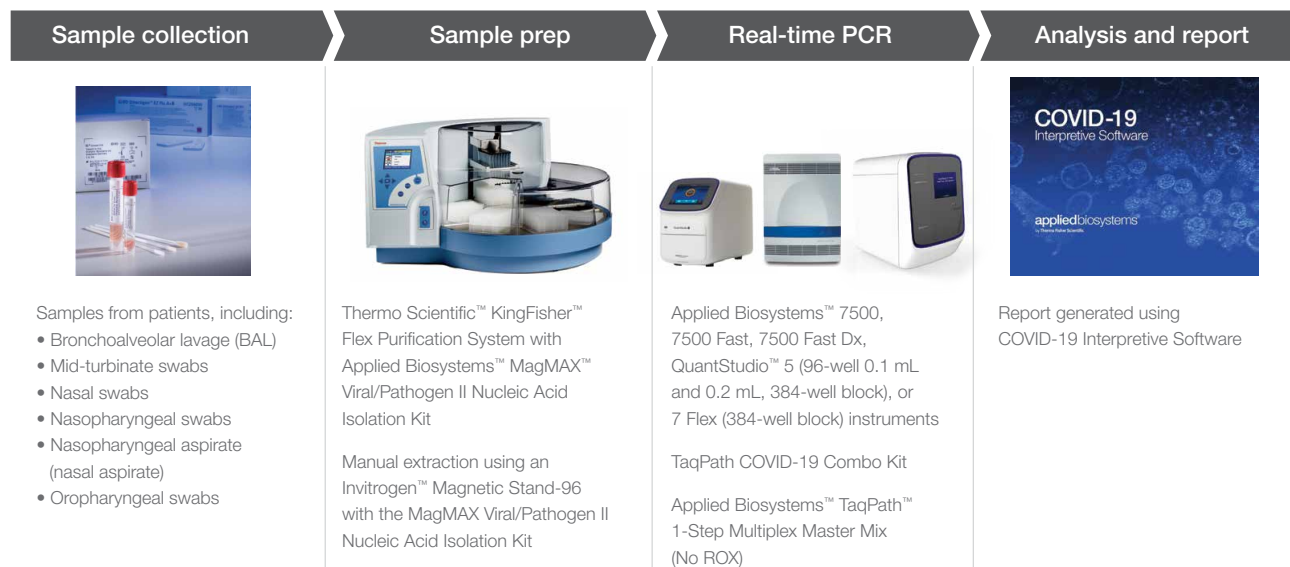
The Applied Biosystems™ TaqPath™ COVID-19 Combo Kit is a fast, highly sensitive *in vitro* diagnostic solution that contains both the assays and controls needed for the real-time PCR detection of RNA from SARS-CoV-2.

Features of the TaqPath COVID-19 Combo Kit

- Complete workflow enabling clinical laboratories to evaluate 94 specimens in under 3 hours, or 382 specimens in under 6.5 hours, with a single Thermo Scientific™ KingFisher™ purification system and Applied Biosystems™ real-time PCR system combination

(when additional approved instruments are utilized, throughput can increase significantly) (Figure 1)

- Targeted specificity to 100% of currently available complete genomes for SARS-CoV-2
- Assays target spike (S) protein and nucleocapsid (N) protein regions having higher specificity and exhibiting lower risk for mutation
- Applied Biosystems™ COVID-19 Interpretive Software, which automatically converts genetic analysis data into diagnosis, helping reduce risk of user interpretation error
- Six approved specimen types, requiring only 200 to 400 µL of sample: bronchoalveolar lavage (BAL), mid-turbinate swabs, nasal swabs, nasopharyngeal swabs, nasopharyngeal aspirate (nasal aspirate), and oropharyngeal swabs



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

Figure 1. End-to-end workflow for the *in vitro* diagnosis of 94 specimens in under 3 hours, or 382 specimens in under 6.5 hours, using a single KingFisher purification system and Applied Biosystems real-time PCR system combination.

The TaqPath COVID-19 Combo Kit contains 1,000 reactions for maximum throughput. Each kit includes:

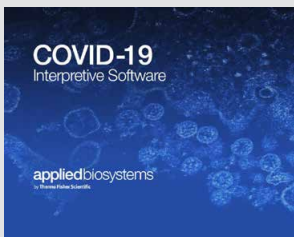
- TaqPath RT-PCR COVID-19 Kit
 - Three coronavirus genes: *orf-1ab*, gene for the S protein, and gene for the N protein
 - MS2 phage control
- TaqPath COVID-19 Control Kit
 - COVID-19 control RNA (*orf-1ab*, gene for the S protein, and gene for the N protein)
 - TaqPath COVID-19 Control Dilution Buffer

This Kit has been approved for use on the following Applied Biosystems™ real-time PCR instruments:

- QuantStudio™ 5 Real-Time PCR Systems (96-well 0.1 mL and 0.2 mL, 384-well block)
- QuantStudio™ 7 Flex Real-Time PCR System (384-well block)
- 7500 Fast Dx Real-Time PCR System
- 7500 Fast Real-Time PCR System
- 7500 Real-Time PCR System

Existing users of these systems will need to install the latest COVID-19 Interpretive Software prior to running the kit. Contact our technical support team using the information below, and they will help you download and install the new software.

Questions? Contact
or email instrumentservices@thermofisher.com



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 Combo 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

Ordering information

Product	Components	Quantity	Cat. No.
TaqPath COVID-19 Combo Kit, 1,000 reactions	TaqPath RT-PCR COVID-19 Kit (1,000 reactions)	1,000 reactions	A47814
	TaqPath COVID-19 Control (2 tubes)		
	TaqPath COVID-19 Control Dilution Buffer (2 tubes)		
	IFU Mini Booklet		
TaqPath 1-Step Multiplex Master Mix (No ROX)		10 mL	A28523

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

* Authorized laboratories using the TaqPath COVID-19 Combo Kit will perform the TaqPath COVID-19 Combo Kit as outlined in the 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 Combo Kit are not permitted.



Learn more and see a full list of products for the workflow at thermofisher.com/COVID19

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For Emergency Use Authorization (EUA) Only. For Prescription Use Only. For *In Vitro* Diagnostic Use.

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