Frequently Asked Questions (FAQs)

TaqPath COVID-19 Combo Kit

Applied Biosystems™ TaqPath™ COVID-19 Combo Kit (Cat. No. A47814) and United States (US) Food and Drug Administration (FDA) Emergency Use Authorization (EUA) workflow components.

1. What instruments, consumables, and reagents do I need for the SARS-CoV-2 RNA detection test? Where can I find the full list of EUA products and protocols?

Go to thermofisher.com/COVID19EUA to see the workflow outlining the instruments, consumables, and reagents required to run a SARS-CoV-2 RNA detection experiment.

2. What instruments are approved under the EUA?

The TaqPath COVID-19 Combo Kit is currently approved for use with the Thermo Scientific™ KingFisher™ Flex Magnetic Particle Processor, all Applied Biosystems™ 7500 systems and QuantStudio™ 5 Real-Time PCR Systems (0.1 mL, 0.2 mL, and 384-well block), and the QuantStudio™ 7 Flex Real-Time PCR System (384-well block).

3. What specimen types can be tested with the SARS-CoV-2 RNA detection test?

The TaqPath COVID-19 Combo kit is currently approved for use with viral RNA extracted from these six specimen types: bronchoalveolar lavage (BAL), mid-turbinate swabs, nasal swabs, nasopharyngeal swabs, nasopharyngeal aspirate (nasal aspirate), and oropharyngeal swabs.

4. What comes in the TaqPath COVID-19 Combo kit? Is the master mix included or does it need to be purchased separately?

The Applied Biosystems™ TaqPath™ 1-Step Multiplex Master Mix will need to be purchased separately. The TaqPath COVID-19 Combo Kit includes two kits:

TaqPath RT-PCR COVID-19 Kit

- Assays targeting regions of three coronavirus genes: orf-1ab, gene for the S protein, gene for the N protein
- MS2 phage control

TaqPath COVID-19 Control Kit

- Contains COVID-19 control RNA (orf-1ab, gene for the S protein, and gene for the N protein)
- TaqPath COVID-19 Control Dilution Buffer

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5. **What is the sensitivity and specificity of the TaqPath COVID-19 Combo kits?**

You can find a detailed writeup of the performance characteristics used to assess analytical performance and clinical performance of the TaqPath COVID-19 Combo Kit in the **Instructions for Use**. These include: limit of detection (10 genomic copy equivalents (GCE)/reaction), reactivity (homology of assay designs to known SARS-CoV-2 genomes), interfering substances analysis (no false positive results were observed for any of the substances and concentrations tested), cross-reactivity (in silico analysis of 43 organisms for potential cross-reactivity or interference), and clinical evaluation of 60 contrived positive and 60 negative specimens to evaluate kit performance. These characteristics taken together help to confirm that the test performs as expected.

6. **Can you provide any details on how Thermo Fisher completed their validation and limit of detection (LOD) studies?**

Viral RNA and MS2 were added to each sample after the addition of the Proteinase K, magnetic beads, and binding solution. GCE/mL and GCE/reaction calculations were based on the 400 µL specimen input volume, 50 µL elution volume, and 5 µL template input volume (assuming 100% extraction efficiency). For our 1X LOD, we spiked 100 copies of the RNA into the prep (100 copies/400 µL) for a theoretical RNA concentration of 2 copies/µL in the eluate. Final concentration in the reaction = 5 µL x 2 copies/µL = 10 copies/reaction. Additional details can be found in the **Instructions for Use** under "Performance characteristics".

7. **What genes are targeted and why is it important to have 3 targets in the assay?**

The TaqPath COVID-19 Combo kit targets regions of three coronavirus genes: orf-1ab, the gene for the S protein, and the gene for the N protein. These target areas are specific to the SARS-CoV-2 virus, reducing the risk of detecting other coronaviruses. They also exhibit lower mutation entropy. Lastly, our assay continues to maintain targeted specificity to 100% of currently available complete genomes for SARS-CoV-2. Being an RNA virus, SARS-CoV-2 is more susceptible to mutations which can impact the efficiency of the assay.

8. **What sample collection swabs would you recommend for same day transport and processing?**

The **Instructions for Use** (IFU) only specify specimen types: Upper respiratory specimens (such as nasopharyngeal, oropharyngeal, nasal, and mid-turbinate swabs, and nasopharyngeal aspirate) and bronchoalveolar lavage (BAL). The language in our product IFU was developed with the support of the FDA to enable customers to have flexibility in the choice of storage components utilized. This means that the choice of one storage matrix over another does not impact compliance with the product IFU. This allows labs to have flexibility based on availability of storage media and vials that conform with information posted on the FDA website. It is important to note that 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. We did not validate any specific transport and storage solution; your lab is responsible for choosing and verifying the transport media you have selected and complying with manufacturer guidance for the storage media and vial you intend to use. You can find further guidance on alternatives to viral transport medium (VTM) or universal transport medium (UTM) that the FDA believes to be appropriate on their **website**.

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9. Does each individual component have its own expiration date, or does the entire kit have the same expiration date?

Each component has an expiration date and each outer box has an expiration date. PCR reagents have a date 12 months from manufacturing, while the control and control buffer have 9 months of shelf life from date of manufacture.

10. Will the SARS-CoV-2 positive control work with assays from other manufacturers?

Our positive control sequence is designed specifically for the target regions in our assay only. We have not tested our control with assays from other manufacturers.

11. Is the MS2 phage control infectious? Can you share the concentration of the MS2 phage?

The MS2 control is a critical internal control for the test and although not infectious to humans, laboratories should always employ universal precautions in the handling of all samples and reagents. The MS2 phage is active and can infect its host; hosts are Escherichia coli and other members of the Enterobacteriaceae. The MS2 concentration is proprietary.

12. What if I switch out a component or step of the EUA workflow?

We cannot support the use of any products that are not listed in the protocol. This includes any workflow changes (automation, liquid handling, etc.). Any deviation from the FDA-approved protocol is considered off-label use and invalidates compliance with the IFU. Customers should consult the FDA on requirements and regulations around this. To view the most recent EUA documentation from the FDA, please visit the **website**.

13. Why is RNaseP not used in your TaqPath COVID-19 Combo Kits?

By design, our kit does not have a sample adequacy control (SAC). That is usually an assay for a human target (i.e., RNaseP). We see a high degree of variation with the 16S RNaseP assay which makes the use of it as a SAC unreliable.

14. Can I make a change to the protocol for the TaqPath COVID-19 Combo Kit?

Any changes to the protocol are considered off-label use and invalidate compliance with the IFU.

15. What is the difference between the original MagMAX Viral/Pathogen kit (Cat. No. A42352, A48310) and the MagMAX Viral/Pathogen II kit (Cat. No. A48383)?

There are two key differences:

- A proprietary raw material in the bead component. The chemistry driving the RNA to the beads is identical and the nucleic acid binding capacity provides similar/equivalent results between the two products.
- The MagMAX Viral/Pathogen II kit (Cat. No. A48383) is only available in bulk format; there is no 100-reaction option for this kit.

16. Is MagMAX Viral/Pathogen II kit compatible with the TaqPath COVID-19 Combo Kit?

Yes. You can use the MagMAX Viral/Pathogen II kit just as you would use the MagMAX Viral/Pathogen with the TaqPath COVID-19 Combo Kit. When using the 200 µL sample input protocol, please note that the eluate input into the PCR will be changed to 10 µL (5 µL eluate input when using 400 µL).

17. How is efficiency improved with MagMAX Viral/Pathogen II kit?

The MagMAX Viral/Pathogen II kit protocol is faster and more flexible. It reduces the number or wash steps from 3 to 2 and sample input from 400 to 200 µL, allowing double the amount of purified RNA and resulting in more tests.

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18. In the COVID-19 interpretive Software, are there specific plate positions that must be used for positive and negative controls? Will interpretative software consider replicates? If not, what would you recommend in case of a discrepancy?

Controls can be placed anywhere on the plate. They need to be assigned and defined correctly for the interpretive software. The interpretive software cannot process replicate samples. If a customer chooses to run replicate samples, the wells must be labeled differently (e.g., Sample 1a, Sample 1b, instead of two wells labeled "Sample 1").

19. How is the report generated for the TaqPath COVID-19 Combo kit?

The report is generated using the COVID-19 Interpretive Software. It will:

- Automatically interpret genetic analysis results from the TaqPath COVID-19 Combo Kit
- Perform a QC check against all controls on the plate following instrument data analysis
- Generate a report for each specimen

20. How can I obtain software for the TaqPath COVID-19 Combo Kit?

To obtain the software, contact your local support team or look up the local service phone number on the website (see below).

Go to **thermofisher.com/contactus**

- In the Step One pane, click Instrument Service.
- In the Step Two pane, enter the name of your real-time PCR instrument, then select your location from the dropdown list.
- To obtain the software, call the local service phone number that is displayed on the screen.

21. Can I use synthetic RNA from another company with your TaqPath COVID-19 Combo Kit?

You must use the TaqPath COVID-19 Positive Control as the positive control with the kit.

22. When using the TaqPath COVID-19 Combo Kit, can you install the interpretive software on the instrument computer?

No, the interpretive software must be installed on a separate computer that meets the specifications in the Quick Reference Guide.

23. When using the TaqPath COVID-19 Combo Kit, how important is it to vortex the reaction plate?

It is extremely important to thoroughly mix and spin down the RT-PCR reaction plate. The Applied Biosystems™ TaqPath™ 1-Step Multiplex Master Mix (No ROX) is a 4x master mix and is extremely viscous. If the plate is not mixed sufficiently, this can cause optical mixing in the early cycles of the qPCR that can invalidate the run.

24. What plastics are compatible with my KingFisher instrument?

Please refer to the **KingFisher plastics for SARS-CoV-2 testing guide** to identify the right plastics for your KingFisher instrument.

25. Do you have any recommendations for SARS-CoV-2 viral inactivation?

We have general recommendations for viral inactivation that can be found in our **application note** on this topic.

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TaqPath COVID-19 Combo Kit: For In Vitro Diagnostic Use. For Prescription Use Only. For Emergency Use Authorization (EUA) Only.
Intended use of other products mentioned in this document may vary. For specific intended use statements please refer to the instructions for use.

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