

FAQs

I. General

1. Where can I find info about the Sherlock™ CRISPR SARS-CoV-2 kit?
Please go to www.sherlock.bio or our US partner IDT www.idtdna.com

2. What is an EUA approved test for COVID19?
An EUA approved test is a test that has received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA), and may be used during the COVID19 pandemic.

3. Where can I purchase the Sherlock™ CRISPR SARS-CoV-2 kit?
Please contact our US partner IDT www.idtdna.com

4. How many patient samples can be processed by a kit?
Thirty-three (33) patient samples can be processed by this kit.

5. Is this kit only for sale to CLIA labs?
Yes, though academic labs may order this kit for research use only (RUO) purposes. However, priority is given to use for diagnostic purposes during the COVID-19 pandemic.

6. Can I use the Sherlock™ CRISPR SARS-CoV-2 kit at home?
No, this kit is for laboratory use only.

7. Is this kit available for sale or use outside the USA?
No, currently this kit is only registered for sale in the USA.

II. Scientific

1. What is SHERLOCK?
SHERLOCK (Specific High sensitivity Enzymatic Reporter unlocking) is a method for detection of nucleic acid targets. It works by amplifying genetic sequences and programming a CRISPR molecule to detect the presence of a specific genetic signature in a sample. When it finds those signatures, the CRISPR enzyme is activated and releases a detectable fluorescent signal.

2. What is CRISPR? How does it work?
CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats) are repetitive regions of DNA, originally discovered in bacteria, and serve as a primitive form of an immune system. When CRISPR and the downstream regions of DNA (termed the “spacer” region, originally regions taken from viral genomes) are transcribed, the

CRISPR element allows for the binding to Cas (CRISPR associated) enzymes. When the CRISPR-Cas complex binds to the region targeted by the spacer, the Cas enzyme is activated to cleave the targeted nucleic acid.

3. Is there any scientific literature on this technology?

Nucleic acid detection with CRISPR-Cas13a/C2c2. Gootenberg, J.S. et al. (2017). Science 356, 438-442. **Multiplexed and portable nucleic acid detection platform with Cas13, Cas12a, and Csm6.** Gootenberg, J.S. et al. (2017). Science 360, 439-444. **Nucleic Acid Detection of Plant Genes Using CRISPR-Cas13.** Abudayyeh, O.O. et al. (2019). The CRISPR Journal Volume 2, Number 3.

4. What is the Limit of Detection?

The Limit of Detection (LoD) is the lowest amount of target in a specimen that can be detected >95% of the time. It is also known as the analytical sensitivity. For the Sherlock™ CRISPR SARS-CoV-2 kit, the LoD is 6.75 copies/μL.

5. What is the sensitivity and specificity of the assay?

With contrived clinical samples, the positive percent agreement (PPA) and negative percent agreement (NPA) are 100%.

6. Is this a PCR test?

No, the Sherlock™ CRISPR SARS-CoV-2 kit is a molecular diagnostic that utilizes Loop Mediated Isothermal Amplification (LAMP) to amplify the targeted sequences.

7. Can this kit be used to detect a DNA, RNA or protein in a sample?

The Sherlock™ CRISPR SARS-CoV-2 kit detects SARS-CoV-2 viral genomic RNA in a clinical sample.

8. Has the Sherlock™ CRISPR SARS-CoV-2 kit been tested on patient samples?

No, the Sherlock™ CRISPR SARS-CoV-2 kit has not been tested on patient samples. The kit has been tested using contrived clinical samples (i.e. nasal swabs negative for COVID-19 that were spiked with varying concentrations of COVID-19 RNA).

9. What sample types can be used with the Sherlock™ CRISPR SARS-CoV-2 kit?

This kit can be used with nasal swab, nasopharyngeal swab, oropharyngeal swab, nasopharyngeal wash/aspirate or nasal aspirate and BAL specimens collected from symptomatic patients suspected of COVID-19 by their healthcare provider.

10. Is the Sherlock™ CRISPR SARS-CoV-2 kit quantitative?

No, the Sherlock™ CRISPR SARS-CoV-2 kit provides qualitative results only.

11. Should the Sherlock™ CRISPR SARS-CoV-2 kit be used for monitoring purposes?

The performance of the Sherlock™ CRISPR SARS-CoV-2 kit has not been established for monitoring treatment of SARS-CoV-2 patients; per the FDA Emergency Use Authorization, the kit may not be used for monitoring purposes.

12. Does the Sherlock™ CRISPR SARS-CoV-2 kit test if a patient has immunity?

No, the Sherlock™ CRISPR SARS-CoV-2 kit detects the presence of viral RNA in the patient sample. It does not test if a patient has immunity towards SARS-CoV-2.

13. Can the Sherlock™ CRISPR SARS-CoV-2 kit be used on human samples to diagnose viruses other than the SARS-CoV-2 virus?

No, the Sherlock™ CRISPR SARS-CoV-2 kit cannot be used to detect the presence of or to diagnose any other pathogens aside from SARS-CoV-2.

III. Technical

1. Is the Sherlock™ CRISPR SARS-CoV-2 kit FDA approved/cleared?

The Sherlock™ CRISPR SARS-CoV-2 kit has not been FDA cleared or approved, however, the kit has received FDA Emergency Use Authorization (EUA) and may be used during the COVID19 pandemic. This authorization is given at the FDA's discretion and is limited in duration to the time that FDA feels that conditions exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19.

2. What CLIA complexity is the Sherlock™ CRISPR SARS-CoV-2 kit?

The Sherlock™ CRISPR SARS-CoV-2 kit is a CLIA high complexity test. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

3. How long does the test take to generate a result?

Following sample extraction, a result can be generated in approximately 1 hour. Multiple samples can be processed simultaneously.

5. How long will it take a lab technician to set-up the Sherlock™ CRISPR SARS-CoV-2 kit?

Following sample extraction, set-up time is approximately 30 minutes.

8. What instruments do I require to run the Sherlock™ CRISPR SARS-CoV-2 kit? The Sherlock™ CRISPR SARS-CoV-2 kit requires a heatblock capable of maintaining 61°C and a BioTek model NEO2 microplate reader running Gen5 3.08 software and capable of fluorescence detection at 37°C (ex/em 490nm/520nm). Additionally, standard equipment found in molecular laboratories (vortexer, minicentrifuge, pipettes, Biosafety Cabinet Class II, for the extraction, PCR Workstations for each portion of the assay set up, Heat block with a heated lid capable of maintaining 61°C or PCR instrument with a heated lid) are required.

9. I do not have a BioTek NEO2 microplate reader, can I use an alternative device?

At present, the FDA Emergency Use Authorization, requires use of the BioTek NEO2 microplate reader.

10. Do I need to pretreat the sample prior to using it in the Sherlock™ CRISPR SARS-CoV-2 kit?

No sample pretreatment is required prior to using the Sherlock™ CRISPR SARS-CoV-2 kit on clinical specimens.

11. What controls should I use with the Sherlock™ CRISPR SARS-CoV-2 kit? Nuclease-free water is required for a negative control. Quantified, extracted viral genomic RNA is required for a positive control.