

Frequently asked questions

General

Where can I find more information about the Sherlock™ CRISPR SARS-CoV-2 kit?

Find kit details at www.unitedPPEAmerica.com.

What is an EUA approved test for COVID-19?

An EUA approved test is a test that has received Emergency Use Authorization (EUA) from the US Food and Drug Administration (FDA), and may be used during the COVID-19 pandemic.

Scientific

Is the Sherlock™ CRISPR SARS-CoV-2 assay a PCR test?

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

Can the Sherlock™ CRISPR SARS-CoV-2 kit be used to detect 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.

Technical

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.

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Can I use the Sherlock™ CRISPR SARS-CoV-2 kit at home?

No, this kit is for laboratory use only.

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

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

Can the Sherlock™ CRISPR SARS-CoV-2 kit be used to detect 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.

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

No. Sample pretreatment is not required prior to using the Sherlock™ CRISPR SARS-CoV-2 kit on clinical specimens.

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.

How long does the Sherlock™ CRISPR SARS-CoV-2 test take to generate a result?

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

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

Following sample extraction, setup time is approximately 30 minutes.

How many patient samples can be processed by the Sherlock™ CRISPR SARS-CoV-2 kit?

Thirty-three (33) patient samples can be processed with this kit.

I do not have a BioTek NEO2 microplate reader. Can I use an alternative device to run the Sherlock™ CRISPR SARS-CoV-2 test?

The FDA Emergency Use Authorization requires the use of the BioTek® NEO2 microplate reader; however, any microplate fluorescence reader with a filter to do dual wavelengths and kinetic readings will be able to read as well.

Is the Sherlock™ CRISPR SARS-CoV-2 kit available for sale or use outside the USA?

Yes, please contact www.unitedppeamerica.com for purchases outside the USA

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, Sherlock Biosciences has received FDA Emergency Use Authorization (EUA) for its kit. This authorization is given at the FDA's discretion and is limited in duration to the time that FDA feels that conditions exist to justify the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19.

Is the Sherlock™ CRISPR SARS-CoV-2 kit only for sale to CLIA labs?

Yes, the Sherlock™ CRISPR SARS-CoV-2 kit is for sale only to CLIA labs certified to perform high complexity tests.

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

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

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.

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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.

What instruments are required to run the Sherlock™ CRISPR SARS-CoV-2 kit?

The Sherlock™ CRISPR SARS-CoV-2 kit requires a heat block capable of maintaining 61°C and a BioTek model NEO2 microplate reader running Gen5 3.08 software, capable of fluorescence detection at 37°C (ex/em 490 nm/520 nm). 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 setup, and a heat block with a heated lid capable of maintaining 61°C or a PCR instrument with a heated lid) are required.

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What is CRISPR and how does it work?

CRISPR (**C**lustered **R**egularly **I**nterspaced **S**hort **P**alindromic **R**epeats) are repetitive regions of DNA, originally discovered in bacteria that serve as a primitive form of an immune system. When CRISPR and the downstream regions of DNA (termed “spacer” regions and originally 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 gets activated and cleaves the targeted nucleic acid.

What is SHERLOCK?

SHERLOCK (**S**pecific **H**igh sensitivity **E**nzymatic **R**eporter **u**n**L**O**C**King) 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 that signature, the CRISPR enzyme gets activated and releases a detectable fluorescent signal.

What is the Limit of Detection of the Sherlock™ CRISPR SARS- CoV-2 kit?

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.

What is the sensitivity and specificity of the Sherlock™ CRISPR SARS-CoV-2 assay?

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

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