Centers for Disease Control and Prevention

Coronavirus Disease 2019 (COVID-19)

Frequently Asked Questions on COVID-19 Testing at Laboratories

1. Where do **public health laboratories** get access to testing kits to detect the viru that causes Coronavirus Disease 2019 (COVID-19)?

a. CDC provides the test kits for public health laboratories (PHLs) to perform real-time RT-polymerase chain reactio (rRT-PCR) detection of the SARS-CoV-2 virus (the virus that causes COVID-19) in respiratory specimens. CDC rece Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA) on February 4, 2020 for use o rRT-PCR test to detect the virus in upper and lower respiratory specimens. These test kits are available through International Reagent Resource (IRR) . For over ten years, CDC has provided test kits and reagents to PHLs through the IRR. This resource was established to support state and local public health laboratories, Departmer Defense laboratories, and other qualified laboratories participating in public health surveillance and studies. Cli and commercial laboratories conducting COVID-19 testing access test reagents from commercial reagent manufacturers which have received EUA from the FDA. Genomic RNA material for validation purposes can be obtained from BEI Resources as indicated in question 7 below.

2. What is the CDC's International Reagent Resource (IRR)?

a. The International Reagent Resource (IRR) was established by the Centers for Disease Control and Prevention (CD to provide registered users with reagents, tools and information for studying and detection of Influenza and oth pathogens, including the SARS-CoV-2 virus that causes Coronavirus Disease 2019 (COVID-19). The IRR acquires, authenticates, and produces reagents that scientists need to carry out basic research and develop improved diagnostic tests, vaccines, and detection methods. By centralizing these functions within the IRR, access to and of these materials in the scientific and public health community is monitored and quality control of the reagents assured. The International Reagent Resource is managed under a CDC contract by American Type Culture Collection (ATCC).

3. What reagents do **public health laboratories** need to perform testing to detect the virus that causes Coronavirus Disease 2019 (COVID-19)?

a. Public health laboratories in the U.S. performing COVID-19 testing of respiratory specimens are provided the following reagents from the CDC's International Reagent Resource (IRR):

    i. Equipment and Extraction Kits – These kits are used in the preparation of specimens
        1. QIAGEN with QIAmp DSP Viral RNA Mini Kit (obtained from IRR)
        2. QIAGEN EZ1 Advanced XL with EZ1 DSP Virus Kit (obtained from IRR)
        3. QIAGEN QIAcube with QIAmp DSP Viral RNA Mini Kit (obtained from IRR))
        4. Roche MagNA Pure LC with Total Nucleic Acid Kit

5. Roche MagNA Pure Compact with Nucleic Acid Isolation Kit I
6. Roche MagNA Pure 96 with DNA and Viral NA Small Volume Kit

ii. rRT-PCR Test Kits (CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel) – These kits include vials of test reag that detect the virus that causes COVID-19 in respiratory specimens (obtained from IRR)

iii. Reagents –
1. Master Mix Kits (rRT-PCR Enzyme Mastermix (TaqPath™ 1-Step RT-qPCR Master Mix, CG) – These kits contain the enzymes and other components needed to run the PCR test. (obtained from IRR)
2. Human Specimen Control (HSC) (obtained from IRR)
3. EUA Positive Control (obtained from IRR)

4. How do clinicians get access to COVID-19 testing?

a. As availability of diagnostic testing for COVID-19 increases, clinicians will be able to access laboratory tests for diagnosing COVID-19 through clinical laboratories performing tests authorized by FDA under an Emergency Use Authorization (EUA). Clinicians should consult with the laboratories that routinely perform their diagnostic servic to see how best to access testing for COVID-19.

b. A list of Coronavirus Disease 2019 (COVID-19) Emergency Use Authorizations provided by FDA are available at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#coronavirus2019

c. Clinicians are also able to access laboratory testing through public health laboratories in their A list of available public health laboratory testing locations is provided by the Association of Public Health Laboratories (APHL) . Questions about testing can be directed to a clinician's state health department.

5. Where can additional information about laboratory testing guidance from CDC found?

a. CDC has published the following interim guidelines, but this is a very dynamic response so please check CDC's website for the most up to date information:
i. Frequently Asked Questions about Biosafety and COVID-19
ii. 2019-nCoV Real Time RT-PCR Diagnostic Panel Instructions for Use
iii. Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Patients Under Investigatio for 2019-nCoV
iv. Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with 2019-nCo

6. Where do clinical and commercial laboratories get access to testing supplies to detect the virus that causes Coronavirus Disease 2019 (COVID-19)?

a. FDA

7. Where do test developers get the genomic RNA needed to validate test performance for FDA?

a. Currently, genomic RNA material can be used for validation purposes at biosafety level 2 laboratories (BSL-2). Genomic RNA material is available through BEI Resources . Registration with BEI Resources is required to request SARS-CoV-2 materials.BEI Resources is prioritizing and fast tracking all SARS-CoV-2 registrations with a 1

72-hour turnaround time for all SARS-CoV-2 related registrations. Please contact BEI Resources at contact@beiresources.org or 1-800 359-7370 for questions.

b. Developers are required to sign a material transfer agreement prior to the release of materials.

c. All BEI Resources reagents are provided worldwide. There is no cost for the reagents themselves. However, ship and handling charges may apply.

d. If a kit to detect the virus (SAR-CoV-2) is needed, then contact IRR as indicated in FAQ#1 above.

8. What is the NIH's BEI Resources Repository?

a. BEI Resources Repository was established by the National Institute of Allergy and Infectious Diseases **at National Institutes of Health** to provide reagents, tools and information for studying Category A, B, and C priority pathogens, emerging infectious disease agents, non-pathogenic microbes and other microbiologica materials of relevance to the research community including diagnostic developers. Centralizing these functions within BEI Resources facilitates access to these materials by the scientific community and ensures quality contro the reagents.

Page last reviewed: March 10