

# TESTING BASICS

## How do I know that the lab I am using will give me accurate results?

- COVID-19 testing must be conducted by a laboratory certified under the Clinical Laboratory Improvement Amendment (CLIA), which regulates laboratory testing. CLIA laboratories must be certified by the Center for Medicare and Medicaid Services (CMS) before they can accept human samples for diagnostic testing. COVID-19 testing must also be conducted under a specific Emergency Use Authorization (EUA) through the U.S. Food & Drug Administration (FDA). CLIA certified laboratories should be able to provide documentation on which COVID-19 EUA(s) they are using to customers. A list of all COVID-19 EUAs can be found on the FDA website.

Quality standards under different EUAs can vary, so it is important to understand what test results can and cannot tell you. Reviewing the sensitivity and specificity of a test can provide important information when selecting a COVID-19 test.

## What is test sensitivity?

- Sensitivity measures how often a test correctly generates a positive result. A test with 90% sensitivity will correctly return a positive result 90% of the time and give a false negative result 10% of the time.

## What is test specificity?

- Specificity measures how often a test correctly generates a negative result. For example, if a test has a 90% specificity then 90% of people will truly test negative while 10% will have a false positive result. The higher the sensitivity and specificity of a test the less false positives and false negatives will be reported.

## How do I know the test the laboratory offers is a good test?

- The QVL provides information on the EUA that each laboratory is using and also the sensitivity and specificity of that test. The laboratory will provide you with more information regarding their test upon request.

## What type of test is right for me?

- There are three primary types of COVID-19 tests:
  - A PCR test is a diagnostic test which detects viral RNA, and positive results indicate an active COVID-19 infection. PCR tests are the primary method for diagnosing COVID-19 cases.
  - Antigen testing is a point of care test that detects viral proteins to diagnose current infection, but has lower sensitivity which means it can result in larger numbers of false negative results. Therefore, antigen testing is only recommended for symptomatic infections by the CDC.
  - Serological tests detect antibodies to the COVID-19 virus, and indicate a past COVID-19 infection or exposure. Serological tests are not diagnostic.

## DISCLAIMER

The contents of this FAQ are not medical advice and should not be treated as a substitute for direct communication with a medical professional. If you have any questions or concerns, you should contact a medical professional.



## What does a COVID-19 result mean?

- A positive COVID-19 PCR result means that a person has an active infection at the time of testing.
- A negative result indicates that that person does not have an active infection, but because there is always a potential for false negatives, it does not entirely rule out COVID-19 infection. Therefore, if a negative result seems inconsistent with an individual's symptoms and/or exposure history, consultation with a healthcare professional is recommended, and patients should continue to self-isolate.
- An inconclusive result indicates that not enough viral RNA was detected to reach a positive threshold, but could mean that the patient has an early infection. Therefore an inconclusive result should typically be treated as presumptive positive, and re-testing is recommended.

## What type of collection device do I need?

- The COVID-19 Specimen Acceptability and Testing Availability Table outlines the various specimen types available and recommended for testing.

## What laboratory can I use?

- The Qualified Vendor List (QVL) provides a list of laboratories that offer COVID-19 testing with which the State of Missouri currently has active contracts. The laboratory list provides information on what specimen type the laboratory will accept and what type of test they are using. The list is not comprehensive, but local governments can utilize the state's contracts to procure tests at the listed rates.

## What is the Qualified Vendor List (QVL)?

- The State of Missouri's QVL is a list of laboratories that have responded to a request for quotes process through the State of Missouri and have reported to the State that they have met the minimum EUA and CLIA requirements. This list of laboratories provide molecular PCR COVID-19 testing and their pricing and test offerings are available for review. This list is not comprehensive of labs that perform COVID-19 testing. However, information regarding the laboratories on the QVL is readily available and local governments can use the state's contracts to procure testing at the rates described on the QVL, available here: <https://bit.ly/2OQeJ0n>

## Where do I get specimen collection kits?

- The laboratory you choose to work with should provide you with the components needed for test collection including swabs, and transport media along with instructions on how to ship/deliver back to the laboratory. Due to potential supply chain issues, an inventory of FEMA supplies are available at the MSPHL if needed. Online orders for testing materials can be placed here: <https://bit.ly/2CxLI7i>

## What if I have questions or concerns about the consistency, reliability, or quality of the laboratory results?

- If there is ever a question regarding a
- laboratory result you should first consult with the laboratory regarding the test result. If you see a pattern of inconsistencies or have concerns with the reliability or quality of the laboratory you are using, please reach out to the DHSS CLIA licensing office at 573-751-6318 and report your concerns.