

At-home testing and COVID-19 October 6, 2020

1. What does “at-home” testing mean?

"At-home" testing in the strictest sense refers to a test where the consumer performs the test and obtains the result "at-home". There is some confusion on this term "at-home testing" because there are some tests that are approved for "at-home" collection, but the sample itself is sent to a central laboratory facility for actual testing, so in this situation the patient does not perform the test themselves and does not obtain the result themselves at home. The best analogy for true at-home testing is an over-the-counter pregnancy test, where the consumer performs the test themselves and obtains the results at home.

Currently, there are no true at-home tests authorized for emergency use by the Food and Drug Administration (FDA) for COVID (only at-home collection is currently authorized for some manufacturers' collection devices) but true at-home testing is being developed.

2. As these tests hit the market what do consumer's look for?

It is best to look for a test that is relatively accurate and manufactured by a reputable company with experience in rapid laboratory diagnostics. However, it will be challenging to know which tests perform better than others until they've been in use by the public for some time, so that data can be accumulated to better understand which tests are less accurate than others.

3. Is specimen collection important and why?

Yes, specimen collection is important and therefore it's important for consumers to carefully follow the directions provided by the manufacturer. Errors in the collection or testing process can lead to false results; for example, if an inadequate amount of sample is collected on a swab then there is a higher likelihood for a false negative.

4. How do all these different kinds of tests work?

There are multiple companies working on at-home tests using different technologies. Most rapid tests are designed to detect SARS-CoV-2 antigens, or protein segments; however, there are some companies working on rapid at-home tests that detect the genetic material (RNA) of the virus. The most basic form of rapid antigen test that could be used at home is a lateral flow immunoassay. Essentially these are just like over-the-counter pregnancy tests. The basic principle is that the consumer would swab their own nose, then place the swab into the testing device with some liquid buffer. Like pregnancy tests, there would be a line that appears in the display window if SARS-CoV-2 antigen is present, indicating a positive result.

5. Can they be trusted?

It is already well known that rapid tests are less accurate than the gold standard RT-PCR tests performed in clinical laboratories. However, the large advantage of rapid tests is that they can increase accessibility and frequency of testing and can provide results more quickly to allow for rapid quarantine of positive individuals. It is also important to note that rapid tests work well to identify individuals with high levels of virus, who are presumed to be more likely to be contagious. On the other hand, the gold standard method is so sensitive that it detects low levels of viral genetic material in individuals who are no longer contagious, which is not practically useful when trying to quickly identify people who are likely to be contagious to prevent further spread. Therefore, it is thought that the lower accuracy of rapid tests will be outweighed by the benefits of accessibility, rapid results, and identification of individuals with high viral loads.



6. What's the difference between an "at-home" test and a point-of-care (POC) test that you get in a doctor's office, hospital, pharmacy, or is there?

Currently there are no at-home tests authorized by the FDA; however, in theory at-home tests will rely on the same types of testing principles as the currently-authorized POC tests that are used in doctor's offices, hospitals, and pharmacies. For example, the Abbott BinaxNOW antigen card is a lateral flow immunoassay authorized for health care settings only and is like at-home pregnancy tests. However, one potential difference is that at-home tests must be simple and easy to use, whereas that may not always be the case for POC tests used in healthcare settings. For example, some POC COVID tests rely on tabletop instruments that healthcare personnel are trained to operate; these types of instruments are too expensive and complex to distribute for at-home testing purposes.

7. How do you gauge these tests?

Test performance is typically gauged by comparing it to a gold standard method, in this case RT-PCR. Therefore, manufacturers will have data on test performance that is reviewed by the FDA prior to emergency use authorization. Additionally, as mentioned above, tests can be gauged based on the reputation of the manufacturer and whether they have a track record and experience in rapid laboratory diagnostics.

8. How and should you follow up with a confirmatory test?

Rapid methods are considered "presumptive" and not definitive. For presumptive results such as this, the manufacturers' instructions generally state that confirmatory testing should be performed if necessary for medical decision making.

9. What is the CAP watching for when it comes to these tests?

The CAP has no official role in evaluating at-home testing and it is unclear how "at-home" tests will be reported for public health purposes. As laboratorians we are always interested in test performance on our patients, especially how testing at homes affects them because they frequently compare at-home tests with our laboratory analysis. For this reason, we keep abreast of developments and performance of at-home tests and how they compare to our laboratory-based tests. Clinician frequently ask us questions as they are questioned by their patients. This will be especially true with at-home tests for SARS CoV-2.