At-home testing and COVID-19
February 16, 2021

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 about the 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. Some tests are now authorized for at-home collection and testing, and these tests include antigen tests and nucleic acid amplification tests, or molecular tests.

2. As these tests hit the market what do consumers look for?
   Accuracy (sensitivity and specificity) is important, but it is often challenging to identify a test’s true performance using only marketing materials and the limited information available from the validation study submitted to the FDA. Often scientific literature using post-market studies provides the most informative data on the performance of at-home tests. These studies are beginning to demonstrate that the performance of at-home tests varies substantially between manufacturers. But the tests are so new that the data is still being generated.

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 several at-home tests currently authorized by the FDA for emergency use (EUA) 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. One such molecular test recently received EUA from the FDA for at-home use. Others have been submitted to the FDA and are awaiting evaluation and EUA. There are several highly anticipated novel rapid test methods in development, that are expected to be available within the next few months.

   The most basic form of rapid antigen test for home use currently available is the lateral flow immunoassay. Essentially these are just like over-the-counter pregnancy tests. The basic principle is that the consumer swabs their own nose, then places the swab into the testing device with some liquid buffer. Like pregnancy tests, there is a line or colored area that appears in the display window if SARS-CoV-2 antigen is present, indicating a positive result. One at-home method uses a cell phone to read and record the results using a special app on the phone.

5. Can they be trusted?
   It is already well known that rapid tests are less sensitive than nucleic acid amplification tests like RT-PCR that are 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. At-home tests’ sensitivity is best in samples with a high amount of virus, and these samples are presumed to be from individuals who are more likely to be shedding a large amount of virus and potentially most contagious. The CDC has recommendations on how

Many authorities believe that the lower sensitivity of the rapid tests will be outweighed by the benefits of accessibility, rapid results and identification of individuals with high viral loads. For these reasons, the US government has invested millions of dollars in these rapid tests.

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? Several at-home tests 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 and is like at-home pregnancy tests. A similar Abbott BinaxNOW card test recently received FDA EUA for at-home use.

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 health care settings. For example, some POC COVID tests rely on tabletop instruments that health care 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 like a highly sensitive RT-PCR. Therefore, manufacturers will have data on test performance that is reviewed by the FDA prior to EUA. It is also important to consider the use case for these tests. Sometimes, at-home tests are promoted for use as screening tests, but they are designed and marketed as diagnostic tests. These different use cases can alter the positive and negative predictive values associated with interpreting the results. The FDA EUA documentation clearly states the conditions in which the use of the test is approved, such as in symptomatic or asymptomatic patients, patients suspected of being infected etc. It is important to know the specifics of the use authorization and any use limitations or recommendations the FDA has made.

8. Should you follow up an at-home test with a confirmatory test? Several of the rapid methods and at-home tests are considered “presumptive” and not definitive. The FDA has also recently modified their initial recommendations on several rapid tests to indicate the results are presumptive. For presumptive results the manufacturer’s instructions generally state that confirmatory testing should be performed.
if necessary, for medical decision making. At-home test manufacturers recommend consulting with a physician if the patient is symptomatic regardless of test result. Based on clinical information the provider will determine the need for a confirmatory test and clinical follow up.

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-home 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. Clinicians frequently ask us questions as they are questioned by their patients. This will be especially true with at-home tests for SARS CoV-2.

Currently there is very limited availability of at-home tests in the United States. At least one test requires a physician’s prescription or order. Another test will be available by mail only. This is an evolving situation and patients and the public should visit sites from the FDA and CDC for up-to-date information.