



Which Covid Test should you buy ?

How is screening different from diagnostic testing? · Diagnostic testing: Diagnostic testing identifies current infection at the individual level and is performed when a person has signs or symptoms of infection, or when a person is asymptomatic but has recent known or suspected exposure. Most tests the FDA has authorized are for diagnosing SARS-CoV-2 in people suspected of COVID-19 by their health care provider, whether they are symptomatic. Some diagnostic tests are authorized for use only in symptomatic individuals. · Screening testing: Screening testing looks for individual infections in a group even if there is no reason to suspect those individuals are infected. Screening involves testing asymptomatic individuals who do not have known or suspected exposure to COVID-19 to make individual decisions based on the test results. The FDA has authorized some tests for screening.

Why are there different claims for how a test is used? Test developers decide the use they will seek to have authorized by the FDA. The FDA cannot compel developers to create tests, and the FDA does not decide the type of test, the use, or the price of tests that developers request to be authorized. Test developers gather evidence to support their test's use and submit this evidence to the FDA. When the FDA issues an emergency use authorization (EUA) for a test, it means that the FDA reviewed scientific and clinical evidence to determine that the test may be effective when used as authorized, such as to diagnose individuals with SARS-CoV-2. If the data provided for FDA review demonstrate that the test may be effective for testing certain individuals (e.g., individuals suspected of COVID-19) but is not effective for testing others (e.g., all individuals), the FDA generally includes an explicit limitation in the labeling regarding those other individuals. So, for tests authorized for use on a specific population (e.g., individuals suspected of COVID-19), the lack of a limitation in the labeling regarding use on other populations generally means that evidence to support a broader use (e.g., testing all individuals) was not provided to the FDA for review. This should be considered by health care providers who choose to order authorized tests for individuals who fall outside the test authorization.

Re Above:

Currently 225 Molecular Tests(a few screening tests available), 32 lab tests, 15 Antigen Tests (most popular for screening)

Critical Questions:

- Prescription required or not required.
- Results: Immediate (15 minutes or less) or can wait, can send away to a lab, etc.
- Symptoms or exposure required to test or can test(screen) under any circumstances.
- Test administered by healthcare practitioner or self-administered(at home, at job site, at restaurant or venue). This can have a 2nd criterion: Healthcare practitioner administered or self-administered(this can be a manager, lay person, usher at a church etc. etc.)
- Made in USA or ok if not Made in USA.
- Quantities needed 1M+ (Likely need to work with one of the big players and they are likely not made in the USA)
- Prices are set by Manufacturers, have volume discounts, and range from single digits to \$30+