

## FAQ on Saliva-Based Testing for COVID-19 Surveillance

### ■ *Is this test authorized by the FDA?*

Yes. This particular saliva-based test is intended for use under the Food and Drug Administration's Emergency Use Authorization #200090 authorized on April 10, 2020. This is the only saliva test and saliva collection device that is FDA-authorized for self-collection in the U.S. at this time.

<https://www.fda.gov/media/137773/download>.

### ■ *How accurate is this test?*

This test is comparable in accuracy to the more invasive nasal swab test and is recommended by our state health officials. The assay can detect the virus down to fewer than 10 copies per milliliter of saliva, which is highly sensitive. In practice, 98% of test results are either positive or negative, with only 2% being inconclusive.

The sequences that help to detect the virus (primers) match the viral sequences almost 100% of the time, which ensures that the test is specific only to the 3 selected viral genes, which in combination are only found in the SARS-CoV-2 virus. These are the same selected viral genes tested for in the nasopharyngeal swab PCR test.

This saliva-based test is not an antibody test. It is a PCR test.

### ■ *Should I consider antibody testing instead of this?*

A COVID-19 antibody test is a blood test that can tell if you previously had COVID-19 and have since recovered. The test involves having your blood drawn at a healthcare facility. It checks for the presence of a particular antibody your body makes when it's fighting the virus. These antibodies appear in your bloodstream after you've been infected.

An antibody test is **not** the same as a nasal swab or saliva-based PCR test and **does not** check for the presence of the virus that causes COVID-19. You should not get an antibody test if you're currently experiencing symptoms of COVID-19 or need to know if you are **currently** infected.

The global scientific and medical community still has much to discover and learn about the virus and its resulting disease. For the individual patient, an antibody test is currently unlikely to change your medical management or what precautions you need to use such as physical distancing or masking in public.

At this time, the antibody test is most useful to understand how much the disease has spread in the community and potentially predict if a second surge of cases is likely to occur. The results may also help develop new treatments and even a vaccine.

One challenge with current antibody tests is that there is a high likelihood (almost 50% for some tests) of having a "false positive" result. This means the test will be positive when the person has never had the disease. This is true for all COVID-19-related antibody tests, including very good ones.

### ■ *How often should an individual be tested?*

The scientific and medical community believe most who are infected with COVID-19 are asymptomatic or may not show any known symptoms of an infection. This saliva-based PCR test will confirm infection between 2 and 28 days since exposure to the virus.

A negative test confirms that the individual has not been infected and is "safe" as long as they continued to maintain vigilance from the time they took the test to receiving the results. A positive test means that the individual should isolate and monitor symptoms.