

## Food and Beverage Industry COVID-19 Test Method Factsheet

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### Introduction

As the virus, SARS-CoV-2, which is causing the COVID-19 pandemic, continues to spread, there is increased need for the food and beverage industry to implement employee COVID-19 testing protocols. It should be recognized that testing provides a snapshot of COVID-19 incidence at a single point in time and should not be used as a “silver-bullet” solution for COVID-19 control and monitoring in food companies.

### Types of COVID-19 Tests Available<sup>1</sup>

There are two main types of tests currently being used: 1) molecular tests for evaluating whether an individual has an active SARS-CoV-2 infection and 2) serological or antibody tests for determining if an individual had an infection in the past. Molecular-based testing, identifies either the genetic material of SARS-CoV-2 or specific molecules that make up other parts of this virus. Serological testing measures the presence or concentration of antibodies developed in response to infection by a virus. *All COVID-19 testing should be conducted (or supervised) and interpreted by trained medical personnel with knowledge of the limitations of the individual tests used.*

### *Molecular Testing*

The most common molecular-based tests detect viral genetic material (ribonucleic acid (RNA)); such tests include nucleic acid amplification tests (NAAT), with polymerase chain reaction (PCR) tests being one sub-type. Another type of molecular test detects other components of the virus's structure, typically antigens found in or attached to the viral envelope. Molecular tests for COVID-19 involve analysis of samples typically collected directly from a patient's respiratory system (e.g. nasal or throat swab) for the presence of SARS-CoV-2 RNA. These tests can detect SARS-CoV-2 genetic material or other molecules in individuals who are infected by the virus, whether symptomatic or not, and are the ideal method for diagnosing persons with COVID-19. The U.S. Food and Drug Administrations (FDA) approves molecular based tests for SARS-CoV-2, ensuring they meet the Emergency Use Authorization (EUA) statutory standard and yield highly accurate results.

### *Serological Testing*

Serological tests, also referred to as antibody tests, measure the presence or concentration of antibodies in a person's blood serum or plasma. Antibodies are proteins that help fight off infections. Serological tests evaluate the body's immune response to an infection, rather than detecting the virus itself, and are typically performed to determine if a person has had a past exposure. Serological tests that rely on detecting the body's immune response are less accurate for evaluating an individual's current infection status as compared to molecular tests that can identify material from the virus itself.

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<sup>1</sup> For more information, see FDA's [FAQs on Diagnostic Testing for SARS-CoV-2](#). (Accessed April 28, 2020)

One of the body's initial immune system responses to infection by pathogenic organisms, including SARS-CoV-2, is the production of Immunoglobulin M (IgM) antibodies. These antibodies serve as a part of the immune system's attack on the invading virus. The presence of IgM antibodies in the blood may indicate that the person tested has an active infection or has had a recent infection. Because IgM antibodies take time to build up in the body, a negative serological test result for IgM antibodies does not necessarily mean that someone is not currently infected; it could just mean that there is not sufficient IgM in the person's blood to be detected using serological testing at that point in time. Over time, the body then begins to develop Immunoglobulin G (IgG) antibodies, which are more specific to the particular infecting virus. Available serological or antibody-based tests for COVID-19 are designed to detect either IgG alone or both IgM and IgG.

Results of a serological test should not be used as a measure of a person's current COVID-19 infection status. If a serological test is used in the early stages of infection with SARS-CoV-2, even though the person may be infected and contagious (actively shedding the virus), the body may not yet be producing antibodies or the level of antibodies produced may not be high enough to be detected. In addition, antibodies related to COVID-19 can remain in the body after infection is over and someone is no longer contagious. This illustrates the limits of serological test effectiveness for diagnosing *active infection* with COVID-19. In fact, FDA specifically says that serology or antibody tests alone should not be used to diagnose COVID-19.

Serological testing *may* be useful in indicating recent *past* infection. However, it is not yet known how long SARS-CoV-2-specific IgM and IgG antibodies remain in the blood after infection, to what extent these antibodies confer immunity and, if so, how long that immunity persists, therefore, these tests need to be interpreted with great caution and knowledge of each test and its limitations. ***Due to these limitations, use of serologic testing by the food industry is not generally recommended, although may be of value to the public health sector.***<sup>2, 3</sup>

#### Determining When and Who to Test

To learn if a person may have a current infection, diagnostic tests are used, but not everyone needs this test. According to the Centers for Disease Control and Prevention (CDC) guidance, testing should only be done in certain situations, under the direction of a physician and in coordination with local and state public health agencies.<sup>4</sup>

#### Instances Where Testing **Might** be Appropriate

- When the entire community is being tested as part of a community-wide surveillance effort. In this scenario, the testing would NOT be limited to only company employees and is typically performed by or in coordination with the state or local health department.

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<sup>2</sup> For the medical and public health community, appropriately validated serology tests, when used broadly in population studies, can be useful in, among other things, understanding how many people have been infected or exposed, how long antibodies remain in previously infected people, how far the pandemic has progressed, and used to identify candidates for donating plasma to help treat those with COVID-19. (FDA; <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2#5ea1d48ac547a>) (Accessed April 30, 2020)

<sup>3</sup> CDC; COVID-19 Serology Surveillance Strategy <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/serology-surveillance/index.html> (Accessed April 30, 2020)

<sup>4</sup> CDC; Evaluating and Testing Persons for Coronavirus Disease 2019 (COVID-19) <https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html> (Accessed April 30, 2020)

- To aid a company in making its decision about the return to work for an employee with confirmed or suspected COVID-19. In this case, if testing is conducted, a molecular-based test looking for active COVID-19 infection by the virus, rather than serological testing, should be used.<sup>5</sup>
- In situations when a company will have employees traveling to isolated or remote sites where physical distancing, immediate access to healthcare and other factors may necessitate testing.
- When an individual has had a known close contact or exposure to the virus and is showing COVID-19 symptoms<sup>6</sup>, and after consultation with the attending physician or local public health authorities.

*Instances Where Testing Might **NOT** be Appropriate*

- Testing all employees, regardless of exposure risk, unless it is part of a community-wide surveillance effort. CDC prioritizes COVID-19 testing for hospitalized patients, healthcare facility workers, residents in long-term care facilities and persons identified through public health cluster and selected investigations.
- Testing employees who are not showing symptoms and have not had close contact exposure to the virus or infected individuals, unless recommended by public health or medical professionals.

*Follow-up to Testing and Final Thoughts*

Individual establishments should use science-based approaches to assess risk and determine if there is a need for employee screening, testing and work restrictions. To help guide company decisions in response to development of symptoms associated with COVID-19 and/or testing outcomes among employees, see the related industry guidance found on the FeedingUS.org website: [Covid-19 Employee Symptoms/Testing Status-Based Decision Tool For Food Facilities](#)

Please remember that anytime an employee exhibits symptoms of COVID-19, the employee should be sent home from work and required to follow up with his or her physician or healthcare provider. *Any and all of the above-mentioned testing should be performed (or overseen/supervised) and interpreted by trained medical/pharmacy personnel and in consultation with state and local public health agencies.* Regardless of whether an establishment chooses to test its employees in certain scenarios, the establishment should refer to [CDC guidance](#) for when employees can discontinue isolation and return to work.

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*DISCLAIMER: The purpose of this Factsheet is to summarize and simplify for the general food and beverage industry COVID-19 test and testing information provided to the public by the U.S. Centers for Disease Control and Prevention (CDC), the U.S. Food and Drug Administration (FDA) and collected through other knowledgeable sources, based on the authors best understanding. The authors do not intend for this Factsheet to constitute medical or legal advice or to serve as a substitute for official U.S. government guidance cited herein. As the CDC, FDA and/or other agencies issue more guidance about*

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<sup>5</sup> CDC offers isolation discontinuation guidance with or without having to test, accessible here: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html> (Accessed April 30, 2020)

<sup>6</sup> CDC; Symptoms of Coronavirus. <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html> (Accessed April 30, 2020)

COVID-19 tests and testing, portions of this Factsheet may become incorrect. The authors strongly urge companies to consult with their medical and/or legal advisors, in addition to the most recent agency guidance, before conducting any testing activities.

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