I. Background

The SARS-CoV-2 testing landscape is continually changing as new tests receive an emergency use authorization (EUA) from the Food and Drug Administration (FDA). Molecular, antigen, antibody and next generation sequencing tests are now available and additional technologies are anticipated.

This document provides an overview of SARS-CoV-2 tests with a focus on the use and interpretation of diagnostic (viral) tests. It will be updated as new tests and performance data become available, and as guidance from the Centers for Disease Control and Prevention (CDC), FDA, New York City (NYC) Department of Health and Mental Hygiene and New York State (NYS) Department of Health is revised.

Important Points

- No test is accurate all of the time, and false positive and false negative test results will occur. As the prevalence of COVID-19 declines in a community, the proportion of positive diagnostic test results that are falsely positive will increase. When deciding whether to administer a COVID-19 diagnostic test, which type of test to administer, and how to interpret the test result, it is important to consider a person’s susceptibility to infection and if the person presents with COVID-19 like illness, had a recent exposure to someone with COVID-19, previously had a positive diagnostic test for SARS-CoV-2, and received COVID-19 vaccination. For more information, see IV Diagnostic Test Performance and Characteristics and Pre-Test Probability.

- Avoid testing individuals who are fully vaccinated or have had a positive SARS-CoV-2 diagnostic test in the preceding 3 months unless there is clinical suspicion of COVID-19. If a positive diagnostic test is reported for a person for whom there is low clinical
suspicion (e.g., is asymptomatic), use clinical judgement to guide decision-making, which may include performing additional SARS-CoV-2 testing.

II. Testing Basics

Currently Available SARS-CoV-2 Test Types

- **Diagnostic (viral) tests** – molecular and antigen tests.
  - Molecular tests, which directly detect and amplify specific fragments of viral RNA using nucleic acid amplification tests (NAAT), are recommended for diagnosing current SARS-CoV-2 infections.
  - Antigen tests, which detect viral surface proteins, can also diagnose acute infection but are less sensitive and specific than molecular tests, especially when the likelihood of someone having SARS-CoV-2 infection is low (for example, when asymptomatic or no recent exposure to someone with COVID-19) and the prevalence of COVID-19 in the community is low.

- **Serologic tests** – detect antibodies made by the immune system in response to SARS-CoV-2 infection, which is suggestive of previous infection or a response to COVID-19 vaccination.

- **Next generation sequencing test** – detects T-cells which are part of the adaptive immune response and can assess recent or prior infection with SARS-CoV2. This type of test is not widely available.

Point-of-Care and At-Home COVID-19 Tests

Point-of-care (POC) tests are assays that can be conducted in a Clinical Laboratory Improvement Amendments (CLIA)-waived setting or facility outside of a clinical laboratory (such as an outpatient clinic, doctor’s office, nursing home, worksite, school or mobile testing site). To use POC tests, facilities must have a New York State [Limited Services Laboratory permit](#) from the [Clinical Laboratory Evaluation Program (CLEP)](#) and a CLIA Certificate of Waiver. To date, the FDA has authorized NAAT, antigen and serology tests for SARS-CoV-2 testing in CLIA-waived point-of-care settings.

It is critically important that testing sites observe best practices for handling patient specimens by safely following appropriate [Universal Precautions](#) guidelines. In addition, staff performing POC tests must be adequately trained to safely and accurately perform the test following the manufacturer’s Instructions for Use to obtain accurate results. The [NYS Wadsworth Center website](#) provides guidance on the operation of COVID-19 testing. For additional information on POC testing, see [CDC Guidance for SARS-CoV-2 POC Testing](#).

As of April 20, 2021, approximately 50 antigen and NAAT-based tests and one serologic test have been given an [EUA](#) by the FDA for at-home collection of samples, which are then shipped to a laboratory for processing. An increasing number of tests that can be performed at home (without the need for sending samples to a laboratory) are receiving EUAs. Some of these at-home tests are available for over-the-counter (OTC) purchase and some require a prescription. Most of these tests are authorized for use in individuals with symptoms of COVID-19 or who
were recently exposed to someone with COVID-19; however, a growing number of tests are also being authorized for routine screening of asymptomatic individuals.

### Reporting SARS-CoV-2 Test Results

Results from SARS-CoV-2 tests performed in a clinical laboratory are reported electronically directly from the laboratory to the NYC and NYS Health Departments. However, SARS-CoV-2 POC test results and at-home test kit results (positive, negative, and indeterminate) must be reported by providers and facilities via the Electronic Clinical Laboratory Reporting System (ECLRS) within 24 hours of receiving a result. Providers should instruct patients who test positive on an at-home test kits to appropriately isolate and encourage them to inform their household contacts and any other close contacts of their possible exposure, so that they can quarantine and get tested, if not fully vaccinated (if fully vaccinated, they should get tested only if symptomatic and isolate while waiting for their test results).

### EUAs

Use only tests with an EUA from the FDA for patient care. A wide variety of SARS-CoV-2 NAA, antigen, and serologic tests now have EUAs and are listed on the FDA website. There are test-specific informational documents that must be provided to providers and patients. For each

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<table>
<thead>
<tr>
<th>At Home Test Kit</th>
<th>Available over the counter?</th>
<th>Can it be used as a screening test</th>
<th>Antigen or NAA based test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ellume COVID-19 Home Test</td>
<td>Yes</td>
<td>Yes</td>
<td>Antigen</td>
</tr>
<tr>
<td>Abbott BinaxNOW COVID-19 Antigen Self Test</td>
<td>Yes</td>
<td>Yes</td>
<td>Antigen</td>
</tr>
<tr>
<td>Abbott BinaxNOW COVID-19 Ag Card Home Test</td>
<td>No, prescription only</td>
<td>Yes</td>
<td>Antigen</td>
</tr>
<tr>
<td>Abbott BinaxNOW COVID-19 Ag Card 2 Home Test</td>
<td>yes</td>
<td>yes</td>
<td>Antigen</td>
</tr>
<tr>
<td>Quidel QuickVue At-Home OTC COVID-19 Test</td>
<td>Yes</td>
<td>Yes</td>
<td>Antigen</td>
</tr>
<tr>
<td>Quidel QuickVue At-Home COVID-19 Test</td>
<td>No, prescription only</td>
<td>No</td>
<td>Antigen</td>
</tr>
<tr>
<td>Cue COVID-19 Test for Home and Over The Counter (OTC) Use</td>
<td>Yes</td>
<td>Yes</td>
<td>NAA</td>
</tr>
<tr>
<td>Lucira CHECK-IT COVID-19 Test Kit</td>
<td>Yes</td>
<td>Yes</td>
<td>NAA</td>
</tr>
<tr>
<td>Lucira COVID-19 All-In-One Test Kit</td>
<td>No, prescription only</td>
<td>No</td>
<td>NAA</td>
</tr>
</tbody>
</table>
test, it is important for clinicians to review the EUA documentation, particularly the Instructions for Use documents to understand the specific performance characteristics.

III. Additional Detail on SARS-COV-2 Test Types

Molecular Tests
Molecular tests detect the unique genetic sequence of the SARS-CoV-2 virus using NAAT procedures, such as real-time reverse transcription polymerase chain reaction (rRT-PCR) or other amplification methods (e.g., transcription-mediated amplification (TMA) or loop-mediated isothermal amplification (LAMP)). Most NAA tests are of moderate or high complexity and must be run in a laboratory. However, some are authorized to be conducted in POC and home settings.

Laboratory-based NAA tests are the most accurate tests for diagnosing current SARS-CoV-2 infection. They are considered very sensitive and specific. However, their sensitivity is affected by the timing of testing, sampling technique and sample type. Furthermore, not all NAA tests have equivalent performance, so it is important for providers to be familiar with the characteristics of the specific test that is being used. NAA tests currently available for use in the POC setting may be less sensitive than laboratory-based NAA tests.

In addition to the limited test performance data provided by the manufacturer in the EUA documentation, the FDA has published comparative performance data of NAA against a standard reference panel.

Interpretation of NAA test results:
- Positive NAA test result generally confirms a SARS-CoV-2 infection. Note: NAA tests may remain persistently positive for prolonged periods (up to 12 weeks or longer) after a patient has recovered from COVID-19, due to prolonged presence of non-viable RNA (see CDC Decision Memo). rRT-PCR can detect levels of viral nucleic acid that cannot be cultured, suggesting that the presence of viral nucleic acid does not always indicate contagiousness.
- Negative NAA tests must be interpreted in the context of the exposure history and clinical presentation. False-negative tests have been documented, especially early in the clinical course (see Variation in False-Negative Rate of rRT-PCR–Based SARS-CoV-2 Tests by Time Since Exposure).

Laboratory turn-around time (TAT) for NAA test results should be less than 48 hours. However, results can be delayed if laboratories are experiencing high volumes of specimens or shortages of reagents. Providers should be aware of current TAT and make sure patients with symptoms isolate while waiting for their test result. Currently available POC NAA tests results have a TAT as short as 15 to 45 minutes. See FDA list of NAA tests with EUAs for more information on the performance and use of specific authorized tests.
Antigen Tests
Antigen tests detect the presence of SARS-CoV-2 viral surface proteins, which indicate current viral infection and can identify individuals during their infectious period. There are a number of available SARS-CoV-2 antigen tests with an EUA and designed for use in a CLIA-waived setting. The main advantages of POC antigen tests are that their results are available within 15 to 45 minutes, they are relatively simple to perform and they are less expensive than NAA tests.

Antigen tests are considered specific for the virus when used as designated in the Instructions for Use but are less sensitive than most NAA tests. See FDA’s list of EUAs for Antigen Tests for more information about the performance and use of specific authorized tests.

Antigen tests can supplement other testing methodologies, especially in settings where NAA testing capacity is limited or testing results are delayed, and can add both clinical and infection control value by enabling the prompt identification of SARS-CoV-2 infection to expedite response in outbreak settings (for example, in congregate settings). Many antigen tests were developed for and evaluated on symptomatic persons early in the clinical course, and there was limited data to guide their use for screening asymptomatic persons with no known exposure to COVID-19. However recent studies led the FDA to expand EUAs for several antigen tests which perform well when used as a screening tool among asymptomatic individuals when done in succession, or serially. See the FDA FAQ for additional information.

Both false-positive and false-negative results have been reported for antigen tests. For this reason, confirmatory NAA testing at a clinical laboratory is needed when:

- An individual with a high pre-test probability (such as a person with symptoms of COVID-19 or recent exposure to SARS-CoV-2, especially in a setting with widespread community transmission or an outbreak setting) has a negative rapid antigen test result
- An individual with a low pre-test probability (such as a person who is asymptomatic with no recent exposure to SARS-CoV-2, especially when there is limited-to-no community transmission) has a positive rapid antigen test result

Confirmatory NAA testing should be done within 48 hours of initial specimen collection, and the individual should be directed to isolate at home while awaiting NAA results. Ideally, two specimens should be collected (nasal swab for the antigen test and a nasopharyngeal swab for laboratory-based NAA test) at the same patient encounter when antigen tests are being used in the outpatient setting.

See NYC Health Department’s 2020 Health Advisory #39 titled, Proper Use and Interpretation of SARS-CoV-2 Antigen Tests, for more information.

Guidelines released by the CDC outline scenarios where antigen tests may be considered for screening asymptomatic persons. To learn more, see:

- Association of Public Health Laboratories (APHL) - Considerations for Implementation of SARS-CoV-2 Rapid Antigen Testing
- CDC - Interim Guidance for Rapid Antigen Testing for SARS-CoV-2
Serology Tests

Serology tests detect waning or past SARS-CoV-2 virus infection indirectly, by measuring the antibody response to the virus. Serologic tests should not replace diagnostic viral tests for diagnosing active (current) SARS-CoV-2 infection. Currently available serology tests are also insufficient to determine immune status (whether the patient is protected from future infection) following SARS-CoV-2 infection or COVID-19 vaccination, or to assess the need for vaccination in an unvaccinated person. See FDA list of EUA authorized serology tests and performance information. For more information see Section VI. Interpretation of SARS-CoV-2 test results in vaccinated persons.

CDC Recommendations for Use of Serologic Tests include:

- To help establish a diagnosis when a patient presents with late complications of COVID-19 illness, such as multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A), or signs or symptoms of late sequelae of COVID-19.
- To support diagnosis of acute COVID-19 illness for persons who present late. For persons who present 9 to 14 days after illness onset, serologic testing can be offered in addition to recommended testing for viral detection. This will improve diagnostic accuracy at a time in the clinical course when the sensitivity of viral detection is decreasing and the antibody response is increasing.

For more information, see:

- CDC Interim Guidelines for COVID-19 Antibody Testing
- Infectious Diseases Society of America (IDSA) Guidelines on the Diagnosis of COVID-19: Serologic Testing
- FDA Serology/Antibody Test FAQs

Next Generation Sequencing Test

At this time there is only one next generation sequencing (NGS) test with an EUA. This NGS detects T-cells that are part of the adaptive immune response and can assess recent or prior infection with SARS-CoV2. This test may not be able to show current infection because it can take several days after infection to develop an adaptive T cell immune response and the immune response may last longer than the COVID-19 infection.

IV. Diagnostic Test Performance and Characteristics and Pre-Test Probability

Decisions regarding which SARS-CoV-2 diagnostic test to use and how to interpret test results should take the accuracy of the test and pre-test probability into account.

There are concerns that false negative results may occur with molecular tests if a mutation occurs in the part of the SARS-CoV-2 genome assessed by that test. Most molecular tests use multiple genetic targets to determine a final result and therefore are less likely to be impacted
by increased prevalence of genetic variants. For more information about the use of specific tests impacted by genetic variation see the FDA website.

**Interpretation of SARS-CoV-2 Diagnostic (Viral) Test Results – Key Points**

- **Accuracy of test results** is affected by:
  - Sensitivity and specificity of the test
  - Whether the test is used as directed in the EUA
  - Proper administration of the test, including specimen collection methods
  - Timing in relation to onset of symptoms, if present

- **The pre-test probability** is the probability that a patient is infected with SARS-CoV-2. Factors that increase the pre-test probability of infection include:
  - Symptoms of COVID-19
  - History of exposure to someone with COVID-19 in the past 14 days
  - Residence or work in a setting with an ongoing outbreak or high incidence of COVID-19

- **When the pre-test probability is high:**
  - A positive viral test result is likely to indicate current infection with SARS-CoV-2.
  - A negative viral test result should be interpreted in the context of the exposure history and clinical presentation. If result was from an antigen test or POC NAA, conduct confirmatory NAA testing at a clinical laboratory within 48 hours of the initial specimen.

- **When the pre-test probability is low:**
  - A negative viral test result is likely to be a true result.
  - A positive viral test result should be interpreted in the context of the exposure history and clinical presentation. If result was from an antigen test, conduct confirmatory NAA testing at a clinical laboratory within 48 hours of the initial specimen collection.

- **Note that if more than 48 hours separate the two specimen collections, or if there have been opportunities for new exposures, a NAA should be considered a separate test rather than a confirmatory test.**

V. **Considerations for Testing Persons Without Symptoms or a Known Exposure to SARS-CoV-2**

Due to uncertainties in test performance in asymptomatic individuals and those who have a lower likelihood of having been exposed to SARS-CoV-2, clinical judgment should be used to determine if a person with a questionable test result may warrant additional NAA testing at a clinical laboratory. There are some situations where testing people without symptoms or a known exposure (i.e., screening) can play an important role in viral transmission reduction.

**Screening for** SARS-CoV-2 is intended to identify infections among people who have no symptoms and no known recent exposure to SARS-CoV-2 to reduce community transmission.
Screening is not recommended for most asymptomatic persons who have been fully vaccinated or asymptomatic persons who tested positive on a COVID-19 diagnostic test in the three months following their date of symptom onset (or date of first positive test if they had no symptoms). Screening is currently being conducted in several NYC settings in accordance with NYS Department of Health guidance, including:

- Nursing homes and other congregate residential settings that serve people with an increased risk for severe COVID-19, or where spread could occur rapidly due to proximity of residents, and test results can inform immediate decisions regarding the need to isolate residents to prevent ongoing spread
- Schools and other educational settings
- Newly admitted patients in health care facilities (to prevent persons who are entering a facility from spreading the infection to staff or other patients)

Providers and facilities should consider using NAA-based tests for screening, however SARS-CoV-2 antigen tests may be the most feasible option for some facilities or screening programs. Routine antigen testing of persons within a closed congregate setting, such as a long-term care facility or a correctional facility, has been suggested by the CDC as a potential strategy to rapidly identify cases of SARS-CoV-2 infection to prevent further transmission in the facility. CDC cites modeling evidence showing that outbreak control depends largely on the frequency of testing and the speed of reporting and is only marginally improved by high test sensitivity.

The Centers for Medicare and Medicaid Services (CMS) has stated that, for the duration of the COVID-19 public health emergency, they will exercise enforcement discretion and not cite facilities with a CLIA certificate of waiver when SARS-CoV-2 POC antigen tests are performed on asymptomatic individuals. Providers who screen individuals with no COVID-19 symptoms and no known recent exposure are encouraged to confirm positive antigen results with an NAA-based test, as outlined above.

When Testing Asymptomatic Persons Without a Known Exposure – Interpretation and Patient Management

- It is important to emphasize that negative test results only indicate that the test did not detect the virus at the time the test was taken. When there is widespread community transmission, any person who interacts with other people, especially infected household members, runs a daily risk of acquiring COVID-19. This daily risk increases in crowded places, in confined spaces (especially indoors), with close contact, and when protective actions (such as maintaining physical distancing, correctly using face coverings when around others, frequent hand hygiene) are not followed. A negative test does NOT mean the person can safely ignore physical distancing and face covering requirements.

- A false negative result in a person with a high pre-test probability can happen if an infected individual is still incubating the infection or as detectable levels of antigen begin to decline (i.e., if the test was done too early or late in the course of the infection), or if the test simply fails to detect the SARS-CoV-2 virus.

- A false positive test result, as has been seen most often in asymptomatic individuals who have no recent exposure to SARS-CoV-2 (low pre-test probability), can occur as a result of test interference from patient-specific factors, such as the presence of non-specific antibodies (such as rheumatoid factor) or a highly viscous specimen.
<table>
<thead>
<tr>
<th>Test Methodology</th>
<th>Antigen Tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amplify specific fragment of viral RNA using nucleic acid amplification (NAA). Examples include:</td>
<td>Lateral flow immunoassay to detect viral surface proteins</td>
</tr>
<tr>
<td>▪ Reverse-transcription real time polymerase chain reaction (rRT-PCR)</td>
<td></td>
</tr>
<tr>
<td>▪ Transcription mediated amplification (TMA)</td>
<td></td>
</tr>
<tr>
<td>▪ Isothermal amplification method including LAMP, NEAR, etc., which are ultrafast NAA</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Specimen Types</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Refer to the manufacturer for acceptable sample type(s) for each test</td>
<td></td>
</tr>
<tr>
<td>Nasopharyngeal, oropharyngeal, or nasal swab; saliva; lower respiratory tract specimens</td>
<td>Nasopharyngeal or nasal swab</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Authorized for Point-of-Care (POC) or At-Home Test Kit Options?</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Most are not, but some are. To use POC tests, facilities must have a NYS Limited Services Laboratory permit from the Clinical Laboratory Evaluation Program (CLEP) and a CLIA Certificate of Waiver.</td>
<td>Yes. To use POC tests, facilities must have a NYS Limited Services Laboratory permit from the Clinical Laboratory Evaluation Program (CLEP) and CLIA Certificate of Waiver.</td>
</tr>
<tr>
<td>Home test kits include home collection tests kits for which specimens are sent to a laboratory and those that are performed at home.</td>
<td>Home test kits include home collection tests kits for which specimens are sent to a laboratory and those that are performed at home.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Turn-Around Time for Results</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Laboratory-based NAA: less than 48 hours (but may be longer if the laboratory is experiencing a backlog or reagents are in short supply)</td>
<td>POC tests range from 15 to 30 minutes.</td>
</tr>
<tr>
<td>POC tests and home test kits performed at home range from 15 to 45 minutes.</td>
<td>Home test kits performed at home range from 15 to 45 minutes.</td>
</tr>
</tbody>
</table>
Performance Characteristics
No test is 100% accurate. Test results should always be interpreted in the context of the pre-test probability, which is informed by the clinical presentation, exposure history of the person being tested, and the prevalence of COVID-19 in their community.

<table>
<thead>
<tr>
<th>Laboratory-based NAA tests have high sensitivities and specificities. They are the most accurate tests available for clinical diagnostic detection of SARS-CoV-2. Current NAA POC tests and home test kits performed at home use a methodology that is different from rRT-PCR and may be less sensitive.</th>
<th>Antigen tests are less sensitive than NAA tests. Antigen levels in specimens collected more than 5 to 7 days after the onset of symptoms may drop below the limit of detection of the test leading to a negative test result, while NAA-based testing may still detect viral RNA. It may be necessary to confirm an antigen test result with a NAA test if the result is inconsistent with the clinical context. See <a href="https://www.cdc.gov/coronavirus/2019-ncov/testing/rapid-ag/">CDC rapid antigen testing guidelines</a>.</th>
</tr>
</thead>
</table>

Positive Test Result Interpretation

<table>
<thead>
<tr>
<th>High pre-test probability: A positive result indicates SARS-CoV-2 RNA was detected. The patient is considered infected and contagious and should be managed appropriately.</th>
<th>High pre-test probability: In most cases a positive result indicates SARS-CoV-2 antigens were detected. The patient is considered infected and contagious and managed appropriately.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low pre-test probability: While uncommon, false positive results have been reported with NAA tests. If a false positive is suspected, repeat NAA testing and direct patient to isolate while awaiting NAA result.</td>
<td>Low pre-test probability: May be a false positive result and confirmatory testing by NAA is needed. Direct the patient to isolate while awaiting confirmatory test results.</td>
</tr>
</tbody>
</table>

Negative Test Result Interpretation

<table>
<thead>
<tr>
<th>High pre-test probability: A negative result is likely to be a true negative; however, if based on clinical judgment there is reason to suspect SARS-CoV-2 infection, repeat NAA testing and direct patient to isolate while awaiting NAA result.</th>
<th>High pre-test probability: May be a false negative and should be confirmed with a laboratory-based NAA test within 48 hours of the initial specimen collection and direct patient to isolate while awaiting NAA result.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low pre-test probability: A negative result is likely a true negative.</td>
<td>Low pre-test probability: A negative is likely to be a true negative and confirmatory testing not needed unless clinical judgment deems it important for patient management or infection control.</td>
</tr>
</tbody>
</table>
### Considerations for Use

<table>
<thead>
<tr>
<th>NAA-based testing is recommended for the following:</th>
<th>Antigen-based testing is recommended for the following:</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Persons with symptoms of COVID-19</td>
<td>▪ Persons with symptoms of COVID-19, within 5 to 12 days of onset (varies by test)</td>
</tr>
<tr>
<td>▪ Close contacts of someone with COVID-19</td>
<td>▪ Close contacts of someone with COVID-19</td>
</tr>
<tr>
<td>▪ For people without symptoms living or working in a high-risk setting (such as a skilled nursing facility) or who are identified as part of outbreak response</td>
<td>These tests are not intended for asymptomatic persons. However, due to their rapid turn-around time and ease of use, they may be useful as for routine screening of residents and staff of congregate settings or individuals who reside or work in a setting or area with an outbreak or increased prevalence of COVID-19, and must always be done in conjunction with NAA-based test confirmation.</td>
</tr>
</tbody>
</table>

### VI. Interpretation of SARS-CoV-2 test results in vaccinated persons

Prior receipt of a COVID-19 vaccine authorized for use in the U.S. will not affect the results of SARS-CoV-2 NAA or antigen tests. Natural SARS-CoV-2 infection results in antibodies against viral protein antigens including the nucleocapsid (N) and spike (S) proteins, including the receptor binding domain (RBD) of the S protein, whereas vaccines currently authorized for use in the U.S. elicit antibodies against the S protein or the RBD. For current FDA-authorized serologic tests, it has not been established specifically which antibodies these tests detect, and therefore if positive, they cannot be used to differentiate between natural infection or vaccination. Additionally, this means it is also possible the test may have a negative result in a person who received COVID-19 vaccine.

### VII. Additional Information and Guidance

- New York State Wadsworth Center:
  - [Coronavirus Testing Guidance](#) on testing, pooling results, and handling specimens.
- Centers for Disease Control and Prevention:
  - [Interim Guidance for Antigen Testing for SARS-CoV-2](#)
  - [Considerations for Use of SARS-CoV-2 Antigen Testing in Long Term Care Facilities](#)
  - [Interim Guidelines for COVID-19 Antibody Testing](#)
  - [Overview of Testing for SARS-CoV-2 (COVID-19)](#)
- Food and Drug Administration:
FAQs on Testing for SARS-CoV-2
SARS-CoV-2 Reference Panel Comparative Data

- World Health Organization:
  - Antigen-Detection in the Diagnosis of SARS-CoV-2 Infection Using Rapid Immunoassays
- Interpreting a COVID-19 Test Result (Watson and Brush, BMJ, May 2020)
- Harvard University Center for Systems Biology:
  - COVID-19 Diagnostics in Context
- American Society for Microbiology:
  - Why Pre-Test Probability Matters

The NYC Health Department may change recommendations as the situation evolves.  6.1.21