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). 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 Department of Health and Mental Hygiene (NYC Health Department) and New York State (NYS) Department of Health is revised.

**Important Points**

- No test is accurate all of the time; false positive and false negative test results will occur. 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 how likely it is that the person may have COVID-19, which is affected by factors including whether they have symptoms compatible with COVID-19, had a recent exposure to someone with COVID-19, previously had a positive diagnostic test for SARS-CoV-2, and their COVID-19 vaccination status. For more information, see *IV Diagnostic Test Performance and Characteristics and Pre-Test Probability*.
- Avoid testing individuals who 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, use clinical judgement to guide decision-making, which may include performing additional SARS-CoV-2 testing.
- See the NYC Health Department’s website ([here](#)) for testing recommendations for unvaccinated and fully vaccinated persons.
II. Testing Basics

Currently Available SARS-CoV-2 Test Types

- **Diagnostic (viral) tests**
  - **Molecular tests**, which directly detect and amplify specific fragments of viral RNA using nucleic acid amplification (NAA) tests, are recommended for diagnosing current SARS-CoV-2 infections.
  - **Antigen tests**, which detect viral surface proteins, can also diagnose acute infection but are generally less sensitive than molecular tests.

- **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-CoV-2. 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 NYS Limited Services Laboratory permit from the Clinical Laboratory Evaluation Program (CLEP) and a CLIA Certificate of Waiver. To date, the FDA has authorized NAA, antigen and serology tests for SARS-CoV-2 testing in CLIA-waived point-of-care settings.

On June 24, 2021, Governor Cuomo ended the state of emergency, declared on March 7, 2020, and COVID-19 related Executive Orders have expired. As a result:

- Clinical laboratories with a temporary NYS clinical laboratory permit are no longer permitted to perform COVID-19 testing on specimens from NYS, even if they hold a CLIA certificate. See [here](#) for information on how to apply for a permit.
- **Remote supervision** of COVID-19 testing in a clinical is no longer permitted. Clinical laboratories are required to have laboratory practitioners appropriately supervised in accordance with the requirements set out in [10 NYCRR § 58-1.3](#).
- **Licensed pharmacists** are no longer considered qualified health care professionals for purposes of directing a limited service laboratory (LSL) to perform COVID-19, influenza or respiratory syncytial virus testing. Any facility with an LSL must have a director who meets the definition of a qualified health care professional pursuant to Section 571(6) of the NYS Public Health Law (qualified health care professionals include a physician, dentist, podiatrist, physician assistant, specialist assistant, nurse practitioner, or midwife, licensed and registered with the NYS Education Department). However, pursuant to the federal Public Readiness and Emergency Preparedness (PREP) Act, pharmacists may continue to order and administer COVID-19 tests.
Clinical laboratories are no longer permitted to operate temporary collection stations (also known as patient service centers or PSC) to collect specimens from individuals for COVID-19 testing without NYS Department of Health approval. Application materials and additional information can be found here.

Questions related to these changes can be directed to clep@health.ny.gov.

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

Dozens of antigen and NAA-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.

<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>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>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>Prescription only</td>
<td>No</td>
<td>NAA</td>
</tr>
</tbody>
</table>
**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 indeterminant) 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 isolate and encourage them to inform their household and other close contacts of their possible exposure, so that they can quarantine and get tested.

**EUAs**
Use only tests with an EUA 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. For each test, it is important for clinicians to review the EUA documentation, particularly the Instructions for Use documents to understand the specific performance characteristics. Also, there are test-specific informational documents that must be provided to patients.

**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 NAA 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. Further, 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 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 counsel patients with symptoms to 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.

NAA RT-PCR COVID-19 tests are based on the amplification and detection of targeted viral genetic material. The cycle threshold, or Ct value, is a count of the number of cycles needed to amplify the genetic material to a detectable level. Specimens with lower amounts of viral RNA require more cycles (a higher Ct value) to amplify it to a detectable level, while specimens containing a larger amount of viral RNA need fewer amplification cycles (a lower Ct value) to detect a positive result.

Although there is a relationship between Ct values and the amount of virus in a specimen, Ct value is affected by several factors and therefore is not a direct measure of a person’s viral load or infectiousness. Aside from viral load, factors that affect Ct value include type of specimen collected, quality and timing of specimen collection, and sample degradation due to improper storage or handling.

For more information see:
- Ct Values: What They Are and How They Can Be Used (APHL)
- The use of SARS-CoV-2 PCR cycle threshold (Ct) values for clinical decision-making (IDSA/Association for Molecular Pathology)

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. Antigen tests perform best in symptomatic people shortly after symptom onset. Specimens collected either before symptom onset or later in the course of infection, may not have detectable levels of antigen, resulting in a negative test result.

Antigen tests are considered specific for the virus when used as designated in the Instructions for Use but are generally 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.

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 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 outbreak response (for example, in congregate settings). Many antigen tests were developed for and evaluated on symptomatic people early in the clinical course, and there was limited data to guide their use for screening asymptomatic people with no known exposure to COVID-19. However recent studies led the FDA to expand EUAs for several antigen tests that perform well when used as a screening tool among asymptomatic individuals when done in succession, or serially. See the FDA FAQ for additional information.

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.

For more information on use of antigen tests in congregate and community settings:
- CDC - Interim Guidance for Rapid Antigen Testing for SARS-CoV-2

For guidance regarding the use of antigen tests for screening asymptomatic persons:
- Association of Public Health Laboratories (APHL) - Considerations for Implementation of SARS-CoV-2 Rapid Antigen Testing
- CDC - Considerations for Use of SARS-CoV-2 Antigen Testing in Nursing Homes

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 viral tests for diagnosing active (current) SARS-CoV-2 infection. 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.

Currently available serology tests are insufficient to determine immune status (i.e., 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.

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. The Pfizer-BioNTech, Moderna, and Johnson & Johnson COVID-19 vaccines use the spike protein to generate an immune response; therefore, a positive serologic test for spike
protein IgM/IgG could indicate previous infection and/or vaccination. Therefore, depending on the assay, a positive result may not be able to 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. If it is necessary to evaluate an individual with history of COVID-19 vaccination for previous SARS-CoV-2 infection, an antibody test specifically evaluating IgM/IgG to the nucleocapsid protein should be used.

See FDA’s 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, 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 nine 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-CoV-2. 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. The pre-test probability is the probability that a patient is infected with SARS-CoV-2.

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.
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.

**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)

- **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.

- 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.

**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 [CDC Guidance](https://www.cdc.gov), 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 reduce the risk of nosocomial transmission

Providers and facilities should consider using NAA-based tests for screening; however, SARS-CoV-2 antigen tests may be more feasible for some facilities or screening programs. Routine antigen testing of people 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 exposure are encouraged to confirm positive antigen results with an NAA-based test, as outlined above.

### False SARS-CoV-2 Diagnostic (Viral) Test Results - Key Points

- **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 (including those who are fully vaccinated) who interacts with other people, especially infected household members, runs a daily risk of acquiring COVID-19. This risk increases in crowded places, in confined spaces (especially indoors), with close contact, and when protective actions (such as physical distancing, mask use, and hand hygiene) are not followed.

- **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**, 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, such as the presence of non-specific antibodies (such as rheumatoid factor) or a highly viscous specimen.
### SARS-CoV-2 Diagnostic (Viral) Test Comparison Summary

<table>
<thead>
<tr>
<th>Molecular Tests</th>
<th>Antigen Tests</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Test Methodology</strong></td>
<td>Lateral flow immunoassay to detect viral surface proteins</td>
</tr>
<tr>
<td>Amplify specific fragment of viral RNA using nucleic acid amplification (NAA). Examples include:</td>
<td></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>
<tr>
<td><strong>Specimen Types</strong></td>
<td></td>
</tr>
<tr>
<td>Nasopharyngeal, oropharyngeal, or nasal swab; saliva; lower respiratory tract specimens</td>
<td>Nasopharyngeal or nasal swab</td>
</tr>
<tr>
<td><strong>Authorized for Point-of-Care (POC) or At-Home Test Kit Options?</strong></td>
<td></td>
</tr>
<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>
<tr>
<td><strong>Turn-Around Time for Results</strong></td>
<td></td>
</tr>
<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>
<tr>
<td><strong>Performance Characteristics</strong></td>
<td></td>
</tr>
<tr>
<td>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 prevalence of COVID-19 in their community</td>
<td></td>
</tr>
</tbody>
</table>
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.

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 CDC rapid antigen testing guidelines for more discussion.

<table>
<thead>
<tr>
<th>Positive Test Result Interpretation</th>
<th>Negative Test Result Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>High pre-test probability:</td>
<td>High pre-test probability:</td>
</tr>
<tr>
<td>A positive result indicates SARS-CoV-2 RNA was detected. The patient is considered infected and contagious and should be managed appropriately.</td>
<td>In most cases a positive result indicates SARS-CoV-2 antigens were detected. The patient is considered infected and contagious and managed appropriately.</td>
</tr>
<tr>
<td>Low pre-test probability:</td>
<td>Low pre-test probability:</td>
</tr>
<tr>
<td>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>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>

<table>
<thead>
<tr>
<th>Considerations for Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>High pre-test probability:</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td>Low pre-test probability:</td>
</tr>
<tr>
<td>A negative result is likely a true negative.</td>
</tr>
</tbody>
</table>
NAA-based testing is recommended for the following:
- People with symptoms of COVID-19
- Close contacts of someone with COVID-19
- 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

Antigen-based testing is recommended for the following:
- People with symptoms of COVID-19, within 5 to 12 days of onset (varies by test)
- Close contacts of someone with COVID-19

These tests are not intended for asymptomatic people. 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.

The NYC Health Department may change recommendations as the situation evolves. 8.15.21