CORONA**VI**RUS **D**ISEASE (COVID-19)

Testing for SARS-CoV-2 (Lab Diagnosis of COVID-19)

Trinity Health

Audience: Providers, Clinicians, Lab Leaders and Colleagues
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UNIVERSAL: This guide should be used for all COVID patients regardless of Ministry COVID Levels

What's New/Updated: Added FDA recommendations for use of at-home antigen test by patients, information about testing persons after recovery from COVID-19, added links to guides on testing based on community transmission rate, corrected links to guides that have been archived and removed details related to testing of persons who are fully vaccinated or up-to-date.

Alert: Considerations When SARS-CoV-2 Testing Demand is Exceeding Supply:

1. Pivot to batch, molecular testing methods and platforms, when applicable;
    - Option 1: Use in-house batch testing platforms (e.g., Abbott Alinity M/M2000, Hologic Panther, NeuMoDx, etc.). Note, turn-around time (TAT) for results typically = 1-2 days
        - Patient populations to consider moving to batch testing:
            - Preoperative testing of patient for whom overnight stay is anticipated (result can be from up to 3 days prior to date of surgery)
            - Outpatient procedure: schedule so result is available prior to date of procedure or do not order if patient is not at high-risk post-procedure pulmonary or cardiac complication.
            - Patients seen in the Emergency Department but stable to be sent home to recover
    - Option 2: Send specimens to Reference Lab (e.g., Warde Lab, Quest, LabCorp, etc.) – TAT approx. 3 days
2. Consider use of rapid antigen testing (e.g., BD Veritor, Abbott BinaxNow, Quidel), if available, for on-site rapid screen using the decision support grid below:
    - For patient with symptoms of possible COVID-19 antigen test is reasonably accurate. Use for these patients can lessen demand for rapid molecular test.
3. In house Batch Testing Impacted, Pivot to Reference Lab:
    - Considerations for use of reference lab would mean longer TAT, e.g., result might not be available within 3 days prior to the operative procedure but can be considered if testing capacity is severely limited

Decision Support Grid for Contingency Response if Availability of Molecular Test for SARS-CoV-2 (RT-PCR or Abbott ID Now) is in Limited Supply

Patient Populations	Primary	Secondary
Person under investigation (PUI) for possible COVID-19 needing inpatient admission - after evaluation in ED or direct admit	RT-PCR or **Abbott ID Now (AIDN)**	Ag
OB patient presenting for delivery: Symptomatic & Asymptomatic	RT-PCR or **AIDN**	Ag
Behavioral health admission – Symptomatic & Asymptomatic	RT-PCR or **AIDN**	Ag
Emergent Surgery - unknown status	RT-PCR or **AIDN**	Ag
Healthcare personnel (HCP) - symptomatic	**Ag**	**AIDN**
HCP - Asymptomatic with high-risk exposure	RT-PCR or **AIDN**	Ag
Patients without symptoms requiring inpatient admission with overnight stay for surgical procedure; pre-operative screening	RT-PCR or **AIDN**	Ag
Patients without symptoms - direct admit or admission from ED for care unrelated to COVID-19	RT-PCR or **AIDN**	Ag
Pre-procedure screening (endoscopy of respiratory tract or upper GI, colonoscopy)	**Ag**	**AIDN**
Pre-procedure screening; provision of AGP as part of procedure is anticipated	**Ag**	**AIDN**
Hospital Based ambulatory / drive through testing for PUI	**Ag**	**AIDN**

Trinity Health Primary: ideal test method to use Secondary: If primary is limited or unavailable, use listed alternative test method

Diagnostic Testing for SARS-CoV-2 in Persons with Symptoms and Suspected of COVID-19

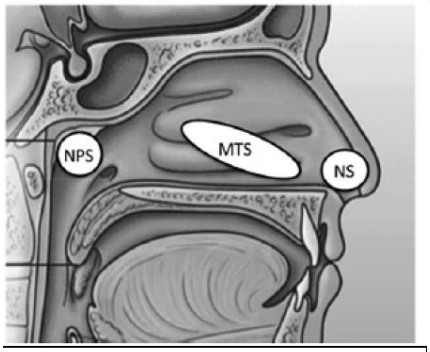
Authorized assays for viral testing include those that detect SARS-CoV-2 nucleic acid or antigen. Viral (nucleic acid or antigen) tests check samples from the respiratory system (such as nasal or oral swabs or saliva) to determine whether an infection with SARS-CoV-2, the virus that causes COVID-19, is present.[1] Viral tests are recommended to diagnose acute infection of both symptomatic and asymptomatic individuals, to guide contact tracing, treatment options, and isolation requirements Some tests are point-of-care tests, meaning results may be available at the testing site in less than an hour. Other tests must be sent to a laboratory, a process that may take at least 1-3 days.

- ☐ **Molecular, RNA nucleic acid amplification test (NAAT) is the gold standard and should be used for identification and confirmation of infection in symptomatic persons suspected of COVID-19.**

For initial diagnostic testing for SARS-CoV-2, the virus that causes COVID-19 the FDA has identified the following as appropriate types of specimens[2]. Important: follow the instructions for use for the specific test method being used that has an approved FDA EUA.

- ☐ Nasopharyngeal (NP) specimen collected by a health care professional (HCP)
- ☐ Oropharyngeal (OP) specimen collected by an HCP using a swab;
- ☐ Mid-turbinate specimen collected by an HCP or by onsite self-collection using a specialized, flocked tapered swab; or
- ☐ Anterior nares specimen collected by an HCP or by onsite self-collection using a flocked swab, round foam swab, or spun fiber swab. For anterior nares specimen collection, a swab with a full-sized tip (OP-type swab) is generally preferred over a swab with a mini-tip (NP-type swab).
- ☐ Other types of specimens, e.g. saliva, based on FDA EUA instructions

Figure 1. Illustration of locations for collecting specimens for testing.



Sampling Locations: NPS, Nasopharyngeal swab; MTS, midturbinate swab; NS, nasal swab. (From Frazee et al., 2018)

- Personnel should adhere to standard procedures associated with other respiratory pathogens, such as seasonal influenza and other human coronaviruses, when they transport specimens within a facility. Refer to CDC recommendations for more details on biosafety practices for specimens.[3]

Interpretation and Use of Cycle Threshold (Ct) Values

Many but not all molecular test methods that use polymerase chain reaction (PCR) to amplify viral RNA also include a cycle threshold (Ct) value. The result the provider will see from an ordered test will be whether viral RNA is detected or not (qualitative). Occasionally a provider may be interested in the Ct value. Generally, the more template (e.g., SARS-CoV-2) that is in the original sample, the fewer the cycles that are needed before the target is detected and crosses this threshold. A lower value suggests there is a higher viral load (quantitative). The following are some key aspects about Ct values and this link will take you to FAQs about Ct values; faqs-for-pcr-ct-value-testing.pdf (trinity-health.org)

- A lower Ct value suggests a higher viral load more often seen in those with acute infection. The Ct value also can be helpful in determining if someone who had initial infection develops new onset of symptoms weeks to months later. If tested again and the Ct is high, it may just be residual viral RNA and the symptoms may be from another cause. [see also: testing-algorithm-flu-reinfection.pdf (trinity-health.org)]
    - **Note**: The precise threshold between low (e.g., <33) or high (≥ 33) Ct value varies by brand of molecular test. The Clinical lab can provide this level of detail based on what test method is in use. In addition, a high Ct can be seen if the person is tested very early during acute infection.
- Ct values are **not** standardized across specimen sources, testing platforms, or laboratories. Therefore, they are not be routinely included in results of molecular tests that detect SARS-CoV-2.
- If a provider is interested in the Ct value for a test they ordered, they should consult their ministry's infectious disease specialist to assist with interpretation and application to the specific case. If an infectious disease specialist is not available and the result may impact a time sensitive need, the ordering provider should contact the Clinical Director of the performing lab and request the Ct value.

SARS-CoV-2 Testing

- Anyone with symptoms of COVID-19, regardless of vaccination status, should receive a viral test as soon as possible.

- Asymptomatic Health Care Professionals, **regardless of vaccination status** who have had close contact with someone with COVID-19 without wearing appropriate PPE must have a series of two viral tests for SARS-CoV-2 infection. In these situations, testing is recommended as soon as possible after the date of exposure and at least 5 days after exposure. The exceptions to the series of two tests are:
    - Notification of close contact was received at day 5 or later after exposure
    - Initial test detected SARS-CoV-2

  See also the Colleague Exposure Assessment Tool for more details.

- People who have had SARS-CoV-2 infection in the last 90 days do not need to be tested if they remain asymptomatic, including those with a known contact. See also testing-algorithm-flu-reinfection.pdf (trinity-health.org)

- When choosing which test to use, it is important to understand the purpose of the testing (diagnostic or screening), performance of the test within the context of the level of community transmission, need for rapid results and other considerations.

- In healthcare facilities with an outbreak of SARS-CoV-2, recommendations for viral testing HCP, residents, and patients (regardless of vaccination status) remain unchanged.

- In nursing homes with an outbreak of SARS-CoV-2, HCP and residents, regardless of vaccination status, should have a viral test every 3-7 days until no new cases are identified for 14 days.

- Hospitals and dialysis facilities with an outbreak of SARS-CoV-2 should follow current recommendations for viral testing potentially exposed HCP and patients, regardless of vaccination status.

- The CDC has developed an online COVID-19 Viral Testing Tool that is an interactive web tool designed to help both healthcare providers and individuals understand COVID-19 testing options. This tool helps healthcare providers quickly access the most relevant, actionable information to determine what type(s) of COVID-19 testing they should recommend to patients. The tool helps individuals determine what type of test they should seek. After test results are in, the tool can help interpret test results and guide next steps. The version of this tool for providers is available at; Guidance for Healthcare Workers about COVID-19 (SARS-CoV-2) Testing | CDC

- Testing persons who have recently tested positive, and recovered from COVID-19:
    - If someone has had exposure to someone with COVID-19 and is asymptomatic, but has had COVID-19 within the past 30 days, testing to identify a new infection is generally not recommended. If someone has become newly symptomatic after having had COVID-19 within the past 30 days, antigen tests should be used to identify a new infection. If they test negative, the antigen test should be repeated per FDA guidance.
    - If someone had exposure to another person with COVID-19, but the exposed individual has had COVID-19 within the past 30-90 days, consider using antigen tests (rather than an NAAT, such as a PCR test) to identify a new infection. They should not test until at least 5 days after their exposure. Whether they are symptomatic or asymptomatic, if they test negative with an antigen test, they should repeat the antigen test as recommended by FDA guidance.

Links to Care Setting Specific Guides Involving Testing:

Refer to the following guidance that are specific to certain care settings that include specifics related to testing:

- pace-admission-guidance.pdf (trinity-health.org)
- placement-of-patients-in-skilled-nursing-facilities.pdf (trinity-health.org)
- hosp-op-mgmt-pts-wo-placement.pdf (trinity-health.org)

Screening of Asymptomatic Populations at Higher Risk of Having or Transmitting SARS-CoV-2:

Recent experience with outbreaks in nursing homes and those in need of urgent scheduled or unscheduled care, e.g., pregnant women, emergent surgery, has identified some frequently do not report typical symptoms such as fever, cough and shortness of breath; some may not report any symptoms. Unrecognized asymptomatic and pre-symptomatic infections likely contribute to transmission in these and other health care settings. Therefore, screening of those not listed in the priorities listed above are increasingly important and providers are requesting testing be made available. In addition, circulation of variants of SARS-CoV-2 can infect those who are fully vaccinated therefore this guide has added thresholds related to level of activity in the community served by the ministry to allow flexibility in screening testing based on local experience.

Persons who have a known, close contact exposure to someone with suspected or confirmed COVID-19 should get tested 5 days after the exposure. Refer to colleague-exposure-assessment-tool.pdf (trinity-health.org) for additional details on timing of testing and management of colleague based on the results.

Admission & Pre-Procedure Testing Among Fully Vaccinated Persons [See Table 1]:

Operational considerations may impact a ministry's testing approach and the following are examples of such considerations:

- **Ministry Patient Care Unit Design -**
  A ministry with a large number of semi-private rooms may desire a more conservative testing approach that includes testing patients who are fully vaccinated compared to ministry that has all or mostly private rooms.
  - **Note:** Testing on admission protocol should remain for patients who are unvaccinated or if vaccine status cannot be verified to assure patients co-located in semi-occupancy rooms are negative for SARS-CoV-2.
- **Use of Incidence & Trends of Cases of SARS-CoV-2 Among the Population Served to Determine Scope of Screening Testing of those Without Symptoms.**

- Scope of screening testing of patients needing admission to acute care ministries or those scheduled for outpatient procedures and other care are based on the COVID-19 transmission rate for the community served. Refer to the following guides for their application to the transmission rate that applies to the population at any particular moment in time:
  - Inpatient admissions:
    - screening-testing-high.pdf (trinity-health.org)
    - screening-testing-moderate.pdf (trinity-health.org)
    - screening-testing-low.pdf (trinity-health.org)
  - Preoperative or pre-procedure:
    - pre-procedural-testing-high.pdf (trinity-health.org)
    - pre-procedural-testing-moderate.pdf (trinity-health.org)
    - pre-procedural-testing-high.pdf (trinity-health.org)

See also **Table 1. Use of Rates of Community Transmission to Guide Inclusion of Fully Vaccinated in Screening Testing**:

NOTE: Asymptomatic community members that wish to be tested should be referred to their primary care providers office, or to an available community testing provider. They should not be sent to the emergency room for testing.

Table 1. Use of Rates of Community Transmission to Guide Inclusion of Fully Vaccinated in Screening Testing:

Refer to the System Office COVID Dashboard		Screening Testing for Fully Vaccinated Persons	
Total new cases per 100,000 persons in the past 7 days	Percentage of molecular (RT-PCR) tests that are positive during the	At Admission	Pre-procedure, Outpatient
<10 (**low level of community transmission**)	< 5%	Optional/Based on clinical judgement	Optional/Based on clinical judgement
≥10 to < 50 (**moderate level of community transmission)**	≥ 5 to Less than 8%	Test those who will be placed in semi-occupancy room, for placement in a non-COVID unit, or providers ordering based on clinical judgement. For admissions requiring an overnight stay for an operative procedure, test within 3 days prior to date of admission.	Test outpatients with higher risk for post-operative cardiac or pulmonary complications (See examples below) or for other clinical reason
≥ 50 to <100 (**substantial level of community transmission)**	≥ 8 to less than 10%	Test all inpatient admissions and for peroperative testing, within 3 days prior to date of admission when overnight stay is anticipated	Test all outpatients with higher risk for post-operative cardiac or pulmonary complications (See examples below) or for other clinical reason
≥ 100 (**high level of community transmission)**	≥ 10%	Test all inpatient admissions and for preoperative testing, test within 3 days prior to date of admission when an overnight stay is anticipated	Test all outpatients with higher risk for post-operative cardiac or pulmonary complications (See Table below) or for other clinical reason

NOTE: If the two indicators, new case rate and % of molecular tests, suggest different transmission levels, apply the higher level

Examples of Underlying Conditions & Types of Operative Procedures for Which Risk of Postoperative Complications is High (include but are not limited to):

Underlying Conditions/ Co-Morbidities	Operative Procedures
Diabetes	Cardiac Surgery
Recovering from prior severe COVID19; refer to testing-algorithm-flu-reinfection.pdf (trinity-health.org) for details on testing of these patients. Note: elective surgery for patients who've recovered should not be scheduled until at least 7 weeks after diagnosis unless the risks of deferring surgery outweigh the risk of postoperative morbidity or mortality associated with COVID-19.[11]	Thoracic Surgery
Chronic Lung Disease	Vascular surgery
Heart conditions (such as heart failure, coronary artery disease, cardiomyopathies or hypertension)	Neurosurgery
Need for emergency surgery	

Table 2. Recommended Testing of Asymptomatic Patient Populations who are at higher risk of having and/or transmitting COVID-19 disease who present to the hospital for non-COVID-19 related services; Timing & Method

Effective 8/10/2021*			Type of Test	
Patient Type	**Vaccination Status**	**When to Test**	**Rapid Testing**	**PCR Testing**
Pregnant women	NOT fully vaccinated[3] (or unknown)	Upon arrival for delivery	X	Use only if Rapid Test Not Available
	Fully-vaccinated[3]	Testing Not Indicated unless case rate is substantial or high		X
General Admissions No procedures planned	Fully-vaccinated[3]	Testing Not Indicated unless case rate is substantial or high		X
	NOT fully vaccinated[3] (or unknown)	Test on Admission. If applicable, test to assure patients co-located in semi-occupancy rooms are negative for SARS-CoV-2.	Use only if results needed urgently, otherwise use standard PCR	X
Admissions from Congregate Settings Such as Senior Residential Settings, Nursing Facilities, Assisted Living Facilities, Dialysis Centers, Correctional or Detention Facilities	NOT fully vaccinated[3] (or unknown)	Prior to placement in Observation, Extended Stay or Inpatient Admission	X[1, 2]	
	Fully-vaccinated[3]	Testing Not Indicated unless case rate is substantial or high		X
Surgical or Invasive Procedures **Overnight Stay Anticipated**	Fully-vaccinated[3]	Test only if case rate is substantial or high, is at high risk for post-operative cardiac/pulmonary complications, reports a recent high-risk exposure, or as ordered by the provider.		X
	NOT fully vaccinated[3] (or unknown)	Within 3 calendar days of the procedure	Use only if results needed urgently, otherwise use standard PCR	X
Surgical or Invasive Procedures **Overnight Stay NOT anticipated**	Regardless of Vaccination Status	Test only if case rate is substantial or high, at high risk for post-operative cardiac/pulmonary complications, reports of a recent high-risk exposure, or as ordered by the provider.		X
Pre-discharge to SNF and Assisted Living	Regardless of Vaccination Status	Start 3 days prior to transfer	Order as initial test if SNF has a 2 test requirement. Order second test using standard RT-PCR at least 24 hrs after initial	Use only if Rapid Test Not Available

Footnotes for Table 2:

1. If Rapid Test is Negative, perform a confirmatory Standard PCR Test

2. If Rapid Testing is Not Available, use a Standard PCR Test

3. A person is considered fully vaccinated if it has been 2 weeks after their second dose in a 2-dose series, such as the Pfizer or Moderna vaccines, or 2 weeks after a single-dose vaccine, such as Johnson & Johnson's Janssen vaccine.

Repeat Testing of Patients Who've Recovered from COVID-19

There is ongoing investigation of the correlation between detection of SARS-CoV-2 RNA and period of transmissibility (infectivity) for a person with COVID-19; evidence to date indicates transmissibility is significantly reduced after acute infection. Therefore, repeat molecular testing after either 10 days following onset of symptoms or from date of initial detection of viral RNA is **NOT** recommended due to the likelihood that such testing only detects remnant RNA and it is unlikely that the person can transmit infection to others *Symptom-based Criteria for Patient with initial symptoms of acute SARS-CoV-2*

  - At least 1 day (24 hours) has passed *since recovery* defined as resolution of fever without the use of fever-reducing medications **and** improvement in respiratory symptoms (e.g., cough, shortness of breath); **and**,
  - At least 10 days have passed *since symptoms first appeared*

- *Time-based strategy for Patient with no symptoms of acute SARS-CoV-2 but tested positive*
  - 10 days have passed since the date of their first positive COVID-19 diagnostic test, assuming they have not subsequently developed symptoms since their positive test. Note, because symptoms cannot be used to gauge where these individuals are in the course of their illness, it is possible that the duration of viral shedding could be longer or shorter than 10 days after their first positive test.

Patients meeting these criteria do NOT need another molecular test prior to any subsequent outpatient procedure or inpatient surgery requiring an overnight inpatient admission. The patient should be treated as having recovered from the COVID viral infection

Antigen Testing[4]

Antigen tests are designed to detect proteins from the virus that causes COVID-19 in respiratory specimens, for example nasal swabs. Antigen tests are very specific for the virus but are not as sensitive as molecular tests. This means that a positive result is accurate, but a negative result does not rule out infection.

- Sensitivity = 60-80% (varies by brand of antigen assay), when compared to an EUA molecular test that uses nucleic acid amplification test (NAAT) method.
- Specificity= 98-100%
- Specimen can be either a nasopharyngeal (NP) and nasal (NS) swab tested either directly or after the swabs have been added to either Copan UTM or the CDC's formulation of viral transport media (VTM)
- Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. See Table 1 for summary comparison of antigen to NAAT.

Positive antigen result - indicates that antigens from SARS-CoV-2 were detected, and the person tested is infected but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. If therapeutic or subsequent management actions are to be taken based on the positive result, providers should consider confirming the test result with a molecular test.

Negative antigen result- does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

When evaluating the results of an antigen test for SARS-CoV-2 consider the performance characteristics (e.g., sensitivity, specificity) and the instructions for use of the FDA-authorized test, and the prevalence of SARS-CoV-2 infection in that particular community (percent positivity rate over the previous 7–10 days or the number of cases in the community relative to the population size).

Confirmatory testing of a positive antigen test, when indicated, should take place as soon as possible, e.g. not longer than 48 hours after the initial antigen testing.

- If more than 48 hours separate the two specimen collections, or if there have been opportunities for new exposures, a laboratory-based NAAT should be considered a separate test – not a confirmation of the earlier test. If the results

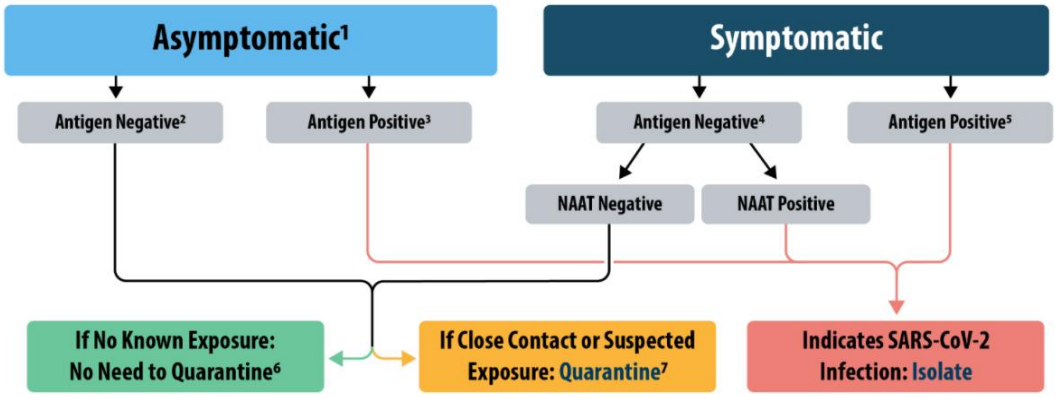
are discordant between the antigen test and the confirmatory NAAT, in general the confirmatory test result should be interpreted as definitive for the purpose of clinical diagnosis.

Examples of populations to screen using antigen tests:

- Testing of residents, colleagues and clinicians in skilled nursing facilities under requirements from state-specific executive orders.
- Point of care / timely screening of persons scheduled for medically necessary outpatient procedures that require use of aerosol generating procedures (AGPs)
- Prior to initiation of immunosuppressive therapy
    - Rationale: Use of antigen test for screening conserves limited quantity of molecular test methods

Testing a symptomatic person in a community setting using Antigen Test:

Figure 2. Antigen Test Algorithm for Community Settings



For more information see: CDC Antigen Testing Guidelines and Table 3.

At-home Testing

A health care provider might consider either an at-home collection kit or an at-home test if a patient has signs and symptoms of COVID-19 and cannot get tested by a health care provider. At-home collection kits and tests are available either by prescription or over the counter in a pharmacy or retail store without a prescription. Available at-home tests look for current infection. Since a prescription is not required for many of these tests, patients may choose to purchase and perform an at-home test without consulting a provider.

- Collection Kit – The specimen is collected in the home and the then the specimen is sent for testing in an outside laboratory. These can be either PCR or antigen tests depending on the manufacturer.
- Collection Kit with At-home Test – The specimen is collected, and the test is performed in the home. These typically use either molecular or antigen test method.

The FDA recommends patients perform repeat, or serial, testing following a negative result on any at-home COVID-19 antigen test, to reduce the risk an infection may be missed (false negative result). This should be done following a negative result whether or not you the person using an at-home test has COVID-19 symptoms.

- At-Home COVID-19 Antigen Tests-Take Steps to Reduce Your Risk of False Negative: FDA Safety Communication | FDA

After use of an at-home COVID-19 antigen test:

- If a patient reports a positive at home antigen test result initially or after a repeat test, the test detected the SARS-CoV-2 virus and most likely they have COVID-19.

- If a has a negative result, the test did not detect the SARS-CoV-2 virus at the time of that test.

    - If the patient has COVID-19 symptoms, providers should recommend they repeat the test again 48 hours after the first negative test, for a total of at least two tests. If the second test is negative but the patient is concerned they may still have COVID-19, their provider should recommend they test again 48 hours after the second test, consider getting a laboratory molecular-based test, or discuss this with their provider.

    - If the patient does not have COVID-19 symptoms and but believes they have had close contact exposure to COVID-19, they should repeat the test again 48 hours after the first negative test, then 48 hours after the second negative test, for a total of at least three tests.

    - If the patient gets a negative result on the third test but is still concerned that you could have COVID-19, they can test again, consider getting a laboratory molecular-based test, or discuss this with their health care provider.

    - A positive result on any repeat test with an at-home COVID-19 antigen test means the patient most likely has COVID-19 and should follow the CDC guidance for people with COVID-19.

The person must follow the manufacturer's instructions exactly, and in the order specified for these tests to perform correctly. The FDA issues emergency use authorizations (EUA) for SARS-CoV-2 tests and it is important to verify an EUA has been issued by the FDA to the manufacturer of the in-home test kit.

Once a person engages the health care system (MGPS, ED, etc.) and reports a positive at-home test, the test result should be confirmed using a standard molecular or antigen (antigen, if capacity of molecular tests are limited) test ordered by the provider and run by the Clinical Laboratory to confirm the patient's positive in-home test result. Prior to administering any EUA approved COVID-19 treatment, the diagnosis should be confirmed by lab testing that has FDA EUA. Providers may recommend treatment of a patient who reports positive at-home test who also has clinical symptoms of COVID-19 in addition to results of other laboratory or imaging tests while awaiting confirmation of the at-home test result.

If a colleague reports a positive COVID-19 at-home test, a standard, molecular or antigen (antigen, if capacity of molecular tests is limited) SARS-CoV-2 test should be performed to:

- Confirm the positive result
- Check for vaccination breakthrough in a vaccinated colleague (as applicable)

The test should be performed the same day or next day. See the Exposure Assessment Tool for more information.

Serological Antibody Test for SARS-CoV-2:

Serological tests such as serum levels of IgM and IgG antibody against SARS-CoV-2 are important for understanding the epidemiology of emerging human coronaviruses (hCoVs), including the burden and role of asymptomatic infections to be clinically useful as the supplemental tests to the nucleic acid test.[5]

The following is an important perspective and caution on interpretation and use of serologic testing from the IDSA.[6]

> *As serological testing for SARS-CoV-2 advances, there are multiple issues that need to be addressed, from test quality to interpretation. Unlike molecular tests for COVID-19 (e.g., PCR), antibody tests may be better suited for public health surveillance and vaccine development than for diagnosis.* ***The current antibody testing landscape is***

varied and clinically unverified, and these tests should not be used as the sole test for diagnostic decisions. *Further, until more evidence about protective immunity is available,*

- **serology results should not be used to make staffing decisions or**
- **decisions regarding the need for personal protective equipment**

Guiding Principles for Providers when Considering Serologic Testing for SARS-CoV-2:

- ✓ Person being tested understands their willingness to be tested is voluntary
- ✓ Providers ordering test are to provide consistent education to persons being tested on interpreting results – **patient (test subject) education is being developed and will be on COVID-19 web**
- ✓ Order testing that uses a platform (analyzer) that has demonstrated high specificity, ideally > 99%
- ✓ Goal for testing should be to improve colleague/patient health and safety and/or have operational implications
- ✓ Begin with testing groups/populations with medium or high prevalence of previous infection to minimize false positives
- ✓ Testing should be done that supports ongoing research, and understanding of value of serologic testing
- ✓ Testing can support identifying those who might donate convalescent plasma with understanding that agencies that collect plasma will repeat testing of potential donors with their method(s)

Key Populations to Consider for Serologic Testing:

- ☐ Patients and health care personnel (HCP), e.g. colleagues and clinicians who have recovered from confirmed COVID-19 infection
- ☐ HCP without any symptoms of COVID-19 but have or are caring for PUIs or those with COVID-19 in units or areas with high volume of patients, e.g., cohort unit, Fever and Upper Respiratory Infection (FURI) clinics, and/or Emergency Department
- ☐ Residents and colleagues in congregate living settings, especially skilled nursing and assisted living facilities, that have experienced outbreaks of COVID-19

The clinical application of serologic testing is still evolving, and the System's Clinical Lab leadership network is actively working on getting more experience with serologic diagnostics at a select number of RHMs. Serologic assays are more retrospective and timing of development of antibody typically is after initial detection of viral RNA using NAAT. (**See Figure 1**) There remain uncertainties like cross reactivity of IgG antibodies with other endemic hCoVs, relationship of antibody to RT-PCR detection of viral RNA, sensitivity and specificity of serology in populations that may have high or low prevalence of infection, etc.[5,6]

Figure 2. Sequence of Detection of SARS-CoV-2 using Laboratory Diagnostics

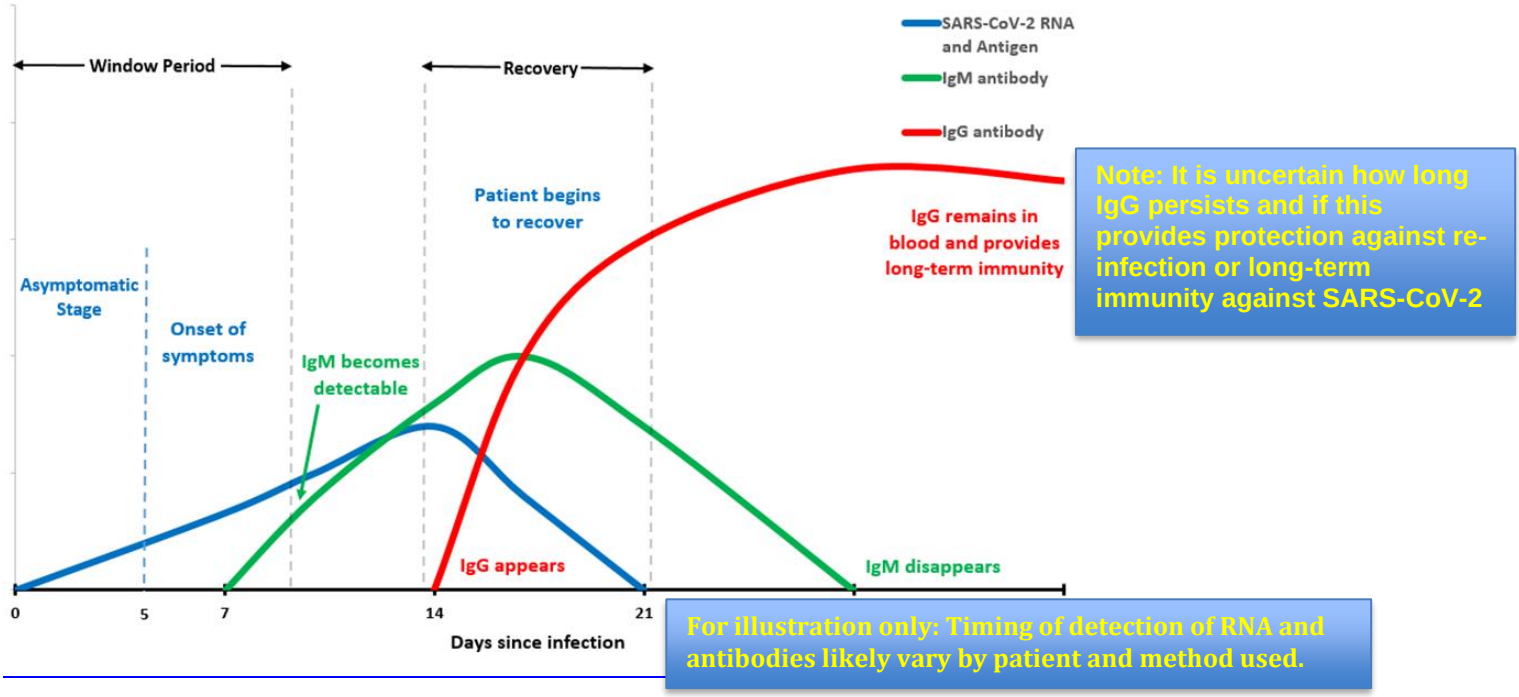


Table 3. Summary of Some Differences between Nucleic Acid Amplification Tests (NAATs) and Antigen Tests

	NAATs	Antigen Tests
Intended Use	Detect *current* infection	Detect *current* infection
Analyte Detected	Viral Ribonucleic Acid (RNA)	Viral Antigens
Specimen Type(s)	Nasal, Nasopharyngeal, Oropharyngeal, Sputum, Saliva	Nasal, Nasopharyngeal
Sensitivity	Varies by test, but generally high for laboratory-based tests and moderate-to-high for POC tests	Varies depending on the course of infections, but generally moderate-to-high at times of peak viral load*
Specificity	High	High
Test Complexity	Varies by Test	Relatively Easy to Use+
Authorized for Use at the Point-of-Care	Most are not, some are	Most are, some are not
Turnaround Time	Most 1–3 days. Some could be rapid 15 minutes.	Ranges from 15 minutes–30 minutes+
Cost/Test^	Moderate (~$75–$100/test)	Low (~$5–$50/test)
Advantages	Most sensitive test method available Short turnaround time for NAAT POC tests, but few available Usually does not need to be repeated to confirm results	Short turnaround time (approximately 15 minutes)+ When performed at or near POC, allows for rapid identification of infected people, thus preventing further virus transmission in the community, workplace, etc. Comparable performance to NAATs in symptomatic persons and/or if culturable virus present, when the person is presumed to be infectious
Disadvantages	Longer turnaround time for lab-based tests (1–3 days) Higher cost per test A positive NAAT diagnostic test should not be repeated within 90 days, since people may continue to have detectable RNA after risk of transmission has passed	May need confirmatory testing Less sensitive (more false negative results) compared to NAATs, especially among asymptomatic people

*The decreased sensitivity of antigen tests might be offset if the point-of-care antigen tests are repeated more frequently (i.e., serial testing at least weekly).

Definitions:

Close contact: means being within 6 feet of the person with COVID-19 for a cumulative total of 15 minutes or more over a 24-hour period during that person's potential period of transmission. The potential transmission period runs from 2 days before the person felt sick (or, for asymptomatic people, 2 days prior to test specimen collection) until the time the person is isolated.

Exposure criteria for health care personnel (HCP): HCP who were not wearing a respirator and any other required PPE described in PPE Guidebook and has been in close contact with the person with COVID-19**.**

Fully Vaccinated: A person is considered fully vaccinated if it has been 2 weeks after their second dose in a 2-dose series, such as the Pfizer or Moderna vaccines, or 2 weeks after a single-dose vaccine, such as Johnson & Johnson's Janssen vaccine.

References:

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10. CDC. Interim Public Health Recommendations for Fully Vaccinated People.