FAQ: Answers to Your Most Common Questions Regarding Commercially Available COVID-19 Tests and Testing at Duke Health

1. What are the main types of commercially available tests to diagnose COVID-19?

There are two main types of tests used to detect SARS-CoV-2, the virus that causes COVID-19. **Nucleic acid amplification tests (NAAT)** are also sometimes referred to as molecular tests, and use polymerase chain reaction (PCR) or similar technology to identify the presence of SARS-CoV-2 genetic material. A**ntigen tests** detect the presence of specific SARS-CoV-2 proteins.

Antibody tests are available to detect the body's immune response to SARS-CoV-2, but are not used for the diagnosis of COVID-19. See Question 6 for more information.

2. What types of SARS-CoV-2 diagnostic tests are available at Duke Health?

Duke Health currently performs two types of NAAT (molecular) tests. Duke Clinical Microbiology Laboratory staff perform PCR tests. Numerous test orderable names were created to assist the laboratory in prioritizing tests for various patient populations. The following test order names reflect PCR tests performed in the Clinical Microbiology Lab: Administrative Screen, Employee Screen, Inpatient Only, Outpatient (asymptomatic), Outpatient (symptomatic), Pre-procedural screen, Student Screen.

Outside of the laboratory, rapid/point-of-care testing is performed using the Abbott ID Now Platform, which is a rapid isothermal NAAT. The following test order names reflect the ID Now rapid isothermal NAAT test: CORONAVIRUS (COVID-19) SARS-COV-2 Rapid Test and POC CORONAVIRUS (COVID-19) SARS-COV-2 RAPID Test.

Duke Health does not currently perform rapid antigen tests at any of its clinical sites.

Symptoms?	*COVID / SARS-CoV-2 Test*	*Setting / Context*	*Infection Status & Isolation*
Symptomatic	Inpatient Only	• Inpatient or ED, expected to require admission	(*Symptomatic*) • Automatic "Suspected COVID-19" Status • Pre-checked Special Airborne Contact Isolation
	Outpatient	• Outpatient or ED, **not** expected to required admission • Preferentially run by Duke but may be diverted to LabCorp	
	Rapid / POC (Point-of-Care)	• Limited capacity – Use only in locations where POC testing devices deployed. • Need for rapid results to influence management disposition	(*Symptomatic Rapid/POC*) • **Order** Special Airborne Contact Isolation
Asymptomatic	Preoperative Screen	• Inpatient or outpatient • Level 5 or non-leveled surgical cases or other procedures requiring testing	(*Asymptomatic*) • No isolation required
	Administrative	• Inpatient or outpatient • Screening for administrative reason (e.g., clearance for SNF or dialysis) • Screening recovering patient for clearance of COVID-19	

Links to hospital-specific patient use cases:

Testing Guidance DRH
Testing Guidance DUH
Document Library > Periop & Pre-procedural

- ◯ COVID-19 RAPID + optional Isolation
- ◯ COVID-19 INPATIENT Only + Isolation
- ◯ COVID-19 OUTPATIENT + Isolation
- ◯ COVID-19 PRE-PROCEDURE Screen, No Isolation
  Nasopharyngeal Swab
- ◯ COVID-19 Administrative Testing Only, No Isolation

ID Now rapid molecular (NAAT)

In-laboratory PCR (NAAT)

DukeHealth

3. **Are there differences in test performance between the PCR and rapid molecular tests used at Duke Health?**

Yes. While both types of molecular tests are highly specific for SARS-CoV-2 virus (and therefore have a high positive predictive value), the ID Now POC/rapid molecular test has a slightly decreased sensitivity for SARS-CoV-2 (~85%) compared to the PCR assays (~90-95%). Thus, the negative predictive value of the POC/rapid molecular test is lower than for PCR tests, especially when the level of clinical suspicion (pre-test probability) for COVID-19 is high; negative results from any test assay should always be interpreted in the context of the clinical scenario.

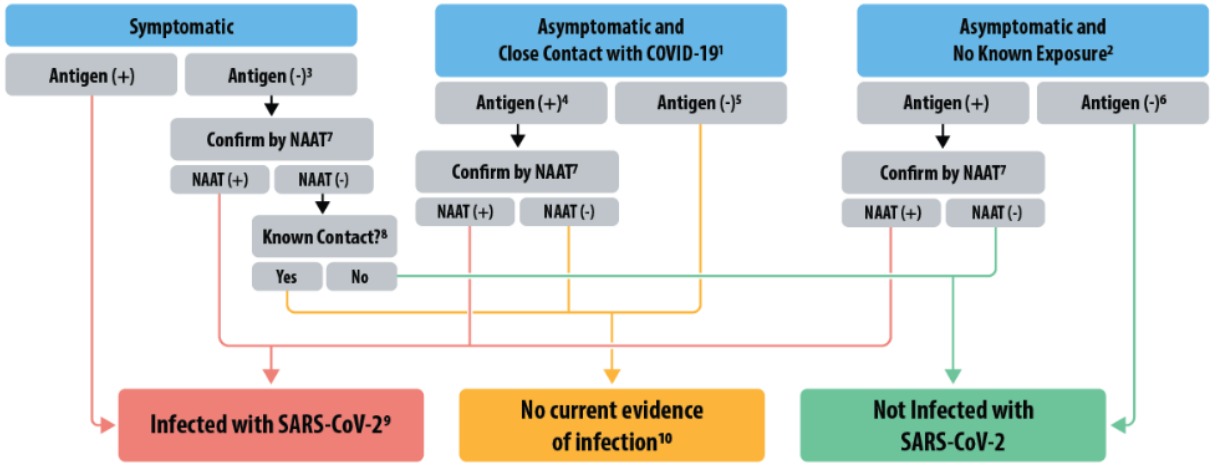
Follow these recommendations to optimize the usage and interpretation of COVID-19 tests:

- Use the POC test according to DUHS clinical guidance for the following scenarios:
    - Symptomatic patients only when test turnaround time < 1 hour is deemed necessary
    - Screening of asymptomatic patients according to our testing protocols (e.g., patients being admitted from the ED, labor and delivery, or with upcoming urgent surgical procedures)
- Interpret negative test results in the context of the clinical scenario, including symptom presentation, history of exposure, and confirmation or lack thereof of an alternate diagnosis. When there is high clinical suspicion for COVID-19 despite a negative test, continue Special Airborne Isolation and consider repeating a PCR test in 24 hours.

4. **How accurate are rapid antigen tests? How should clinicians interpret rapid antigen test results?**

Rapid antigen tests are not currently performed at any Duke Health site. However, they are inexpensive to perform and increasingly available at community testing locations including retail locations such as CVS. While the rapid result turnaround time is appealing for the purposes of contact tracing and quarantine of close contacts, rapid antigen tests have reduced sensitivity and specificity compared to nucleic acid amplification (NAAT)/molecular tests. Thus, rapid antigen tests have a greater potential for false negative and false positive results compared to NAATs, and the results should be interpreted in the context of the clinical scenario. Duke Health recommends following this algorithm published by CDC to aid in interpretation of rapid antigen tests.

Figure 1. Antigen Test Algorithm



Reference: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

5. How should clinicians interpret results of COVID-19 tests performed outside of Duke Health?

Clinicians should always confirm results of tests performed outside of Duke Health by requesting a copy of the official laboratory report and scanning into the patient's Duke medical record. Clinicians should determine the type of test performed (NAAT/molecular, rapid antigen) and interpret results based on the information contained in this document.

6. Are variant SARS-CoV-2 (COVID-19) Coronavirus strains detected by our current DUHS tests?

Yes. Most Coronavirus (COVID-19) SARS-CoV-2 nucleic acid detection tests are designed with multiple targets to minimize the risk of missing mutated strains (i.e., variants). The DUHS Clinical Microbiology Laboratory has confirmed that the B.1.1.7. UK variant is detected by all current DUHS COVID tests and will monitor detection of other variants as they arise and information is available. The FDA also monitors the performance of Emergency Use Authorized (EUA) COVID tests and public health laboratories conduct surveillance to monitor the spread of variant strains.

7. What is the clinical utility of SARS-CoV-2 Antibody Tests?

Antibody tests are useful for epidemiologic surveillance of immunity to SARS-CoV-2 on a population level. On the other hand, antibody tests are not recommended for routine clinical use at Duke Health. These tests detect the body's response to past SARS-CoV-2 infection, but are not recommended for use in the diagnosis of symptomatic infection, reinfection, or the determination of immune status of an individual patient. In select circumstances, the antibody response may be followed over time to confirm clinical infection when viral testing was non-confirmatory or in patients presenting with late complications of COVID-19 such as multisystem inflammatory syndrome in children.

References:

Centers for Disease Control and Prevention:

- Testing overview: https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html
- Antigen testing guidelines: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html
- Antibody testing guidelines: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html#anchor_1590264293982

Infectious Diseases Society of America (IDSA) COVID-19 Guidelines:

- Molecular diagnostic testing: https://www.idsociety.org/practice-guideline/covid-19-guideline-diagnostics/#toc-8
- Serology: https://www.idsociety.org/practice-guideline/covid-19-guideline-serology/