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Appropriate Use of Point-of-Care (POC) Tests for SARS-CoV-2

This document provides general guidance for healthcare providers considering the addition of POC tests for SARS-CoV-2 into their clinical workflow. Specifically, this information is intended to (1) assist ACPHD-sponsored COVID-19 testing sites that wish to incorporate POC tests as an option, and (2) guide clinicians, laboratorians, and administrators who want to consider rapid POC testing as part of screening testing strategies in schools, workplaces, or correctional facilities.

The document is *not* intended to guide Long Term Care Facilities, which should continue to follow applicable local, state, and federal regulations.

Several point-of-care (POC) tests are now available for SARS-CoV-2. These tests use various technologies and are described in more detail in the ACPHD COVID-19 Laboratory Testing Guidance for Clinicians. None of the tests are FDA approved, but all have emergency use authorizations (EUAs) from the FDA as diagnostic tests to detect current infection with SARS-CoV-2 (see *In Vitro* Diagnostics EUAs for a complete list). The most commonly used POC tests include:

Point-of-Care Tests to Detect SARS-CoV-2		
Technology	**Test name**	**Authorized Use Under FDA EUA**
RT-PCR	Cepheid Xpert® Xpress SARS-CoV-2 Test	Testing in individuals suspected of COVID-19 by their healthcare provider
Isothermal NAAT	Abbott ID NOW	Diagnostic testing within the first 7 days of symptom onset
Antigen test (detects nucleocapsid protein)	BD (Becton Dickinson) Veritor System	Diagnostic testing within the first 5 days of symptom onset
	Quidel Sofia 2 SARS Antigen FIA	Diagnostic testing within the first 5 days of symptom onset
	LumiraDx SARS-CoV-2 Ag Test	Diagnostic testing within the first 12 days of symptom onset
	Abbott BinaxNOW COVID-19 Ag Card	Diagnostic testing within the first 7 days of symptom onset

Considerations for using point-of-care testing platforms

When interpreting POC tests results, clinicians should consider the sensitivity and specificity of the testing platform, the purpose of testing (e.g., for clinical diagnosis, cohorting decisions among high-risk patients, or screening of asymptomatic workers or students), and the pretest probability

that a patient is infected with SARS-CoV-2. Pretest probability[1] is increased (1) when the individual has symptoms of COVID-19 , (2) when the individual has had close contact, during the prior 14 days, with a person known to have COVID-19 , and (3) when the individual resides in or frequently visits either a setting experiencing an outbreak or a community where prevalence is high.

The sensitivity and specificity of the Cepheid Xpert® Xpress SARS-CoV-2 test are similar to those of RT-PCR tests performed in moderate to high complexity CLIA laboratories. Positive and negative tests using this assay are generally reliable and may not require confirmation centrally at a reference laboratory.

Whereas the specificities of the Abbott ID NOW and the antigen tests named above are high, their sensitivities are generally lower than the Cepheid Xpert® Xpress and molecular tests (RT-PCR or TMA platforms) performed centrally (i.e., not at point-of-care). Negative results using these assays should be considered "presumptive negatives." The decision to accept a presumptive negative result, or to confirm it using a molecular test in a moderate to high complexity laboratory, requires clinical discretion and depends upon the pretest probability that the individual is infected as well as the purpose for which the test was ordered.

For example, a presumptive negative result in a healthcare provider working at a facility experiencing an outbreak should probably be confirmed with a molecular test; a presumptive negative result in an asymptomatic child with no known exposures, who is undergoing routine screening testing at school, probably does not require confirmation especially if community prevalence is low. Conversely, when using any of the point-of-care tests, a positive result in the

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*In summary, when using any of the POC tests **except** the Cepheid Xpert Xpress, confirmation with a centrally performed NAAT, such as a RT-PCR, should be considered:*

For a negative result when pretest probability is **HIGH** (patient with symptoms, OR known exposure, OR living in or frequently visiting a setting experiencing an outbreak or a community where prevalence is high); and

For a positive result when pretest probability is **LOW** (individuals with no symptoms, no known exposures, not living in or frequently visiting a setting experiencing an outbreak, and living in a community where prevalence is low).

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[1] The CDC defines pretest probability as the "probability of a patient having an infection before the test result is known; based on the proportion of people in a community with the disease at a given time (prevalence) and the clinical presentation of the patient."

setting of low pretest probability may warrant confirmation with a molecular test. Whenever a decision is made to perform confirmatory testing, the individual undergoing confirmatory testing should be considered infectious and isolated while awaiting confirmatory test results.

These principles may be operationalized using the algorithms listed below and illustrated in the Appendices as follows:

Appendix	**Intended audience for this algorithm**
Appendix A	Community testing sites using the Abbott ID NOW
Appendix B	Community testing sites using a rapid point-of-care (POC) antigen test
Appendix C	All sites introducing POC testing to screen asymptomatic groups with low pretest probability

Use of tests for clinical diagnostic purposes at ACPHD-sponsored community testing sites

Abbott ID NOW (isothermal NAAT)

When the Abbott ID NOW (isothermal NAAT) is available, persons presenting for testing at ACPHD-sponsored community testing sites will be categorized according to their pretest probability of SARS-CoV-2 infection (see **Appendix A**).

- Persons with **LOW** pretest probability may be tested using the Abbott ID NOW (isothermal NAAT), but all **positive** results must be confirmed using a centrally run RT-PCR.
- Persons with **HIGH** pretest probability may also be tested using the Abbott ID NOW, but **negative** results in this group must be confirmed centrally using a non-POC NAAT, such as RT-PCR.

Rapid POC Antigen tests

ACPHD views the use of antigen tests as appropriate for diagnostic testing in individuals who present *during the period following symptom onset* as allowed under their respective EUAs (see table above). **Negative** tests in these individuals require confirmation with a non-POC NAAT, such as RT-PCR, run centrally by the lab.

When a rapid POC antigen test is available, persons presenting for testing at ACPHD-sponsored community testing sites will be categorized according to the presence or absence of symptoms (see **Appendix B**).

- Persons who are symptomatic within the period allowed under the available test's FDA Emergency Use Authorization (EUA) (see table above) will be tested using a POC antigen test. Positive results will be accepted, but negative results require confirmation by a centrally run RT-PCR.
- Persons who are asymptomatic, or whose symptoms have been present longer than the period allowed under the FDA EUA, will be tested using a centrally performed RT-PCR.

Use of point-of-care tests with stable groups of asymptomatic people

Available POC tests for SARS-CoV-2 have not been widely used for screening groups of asymptomatic individuals who may have unrecognized exposures, but whose pretest probability is thought to be low. Currently, the test performance, when used in this way, has not been well characterized (see *Quality Assurance* section below). Providers and organizations developing protocols for asymptomatic screening should keep abreast of current validation studies and modify their protocols accordingly.

Groups of individuals who are closely associated and frequently in contact with each other – such as staff and residents in congregate living settings, groups of employees working together at the same site, or staff and students of a particular school – may be effectively screened periodically using centrally run molecular tests, such as RT-PCR, if the turnaround time is rapid (e.g., 24 hours). However, when the availability of such tests is limited, or the turnaround time is long, screening testing protocols may fail to identify and isolate infectious individuals quickly enough to limit spread within the group.

Because of their low cost, portability, and rapid turnaround time, rapid POC tests may be preferred for frequent, periodic screening testing[2] in some settings. The lower sensitivity of these tests is offset by the frequency of their use, permitting the detection of transmissible virus during the viral load spike beginning just before and continuing for a few days after symptom onset, if symptoms occur. A team of epidemiologists at the Harvard Chan School of Public Health has advocated for the frequent, even daily, use of less sensitive tests (see NEJM Perspective), with rapid turnaround time, in order to identify infectious individuals quickly, so they can be isolated, contacts traced, and chains of transmission disrupted. The graph in Appendix D illustrates how frequent testing may offset the disadvantage of using tests with lower analytic sensitivity in this setting.

[2] Screening testing for SARS-CoV-2 is intended to identify infected persons who are asymptomatic and without known or suspected exposure to SARS-CoV-2. Screening testing is performed to identify persons who may be contagious so that measures can be taken to prevent further transmission. For further information, click here.

"Screening testing" of stable groups with low pretest probability

In certain settings, such as schools or some places of employment, health screening protocols will exclude all individuals with symptoms, as well as anyone who should be in quarantine because of close contact with a COVID-19 case within the prior 14 days. Assuming that community prevalence is also low, protocols for on-site screening testing will therefore include only individuals whose pretest probability is LOW.

If a POC test with somewhat lower sensitivity, such as the Abbott ID NOW or a rapid antigen test, is deployed for screening testing in this setting of low pretest probability:

- Negative results may be accepted even though they are "presumptive", but
- Positive results should be confirmed centrally with a molecular test, such as RT-PCR, and the individual should be isolated while awaiting confirmatory test results (see **Appendix C**).

Testing in congregate settings with higher pretest probability

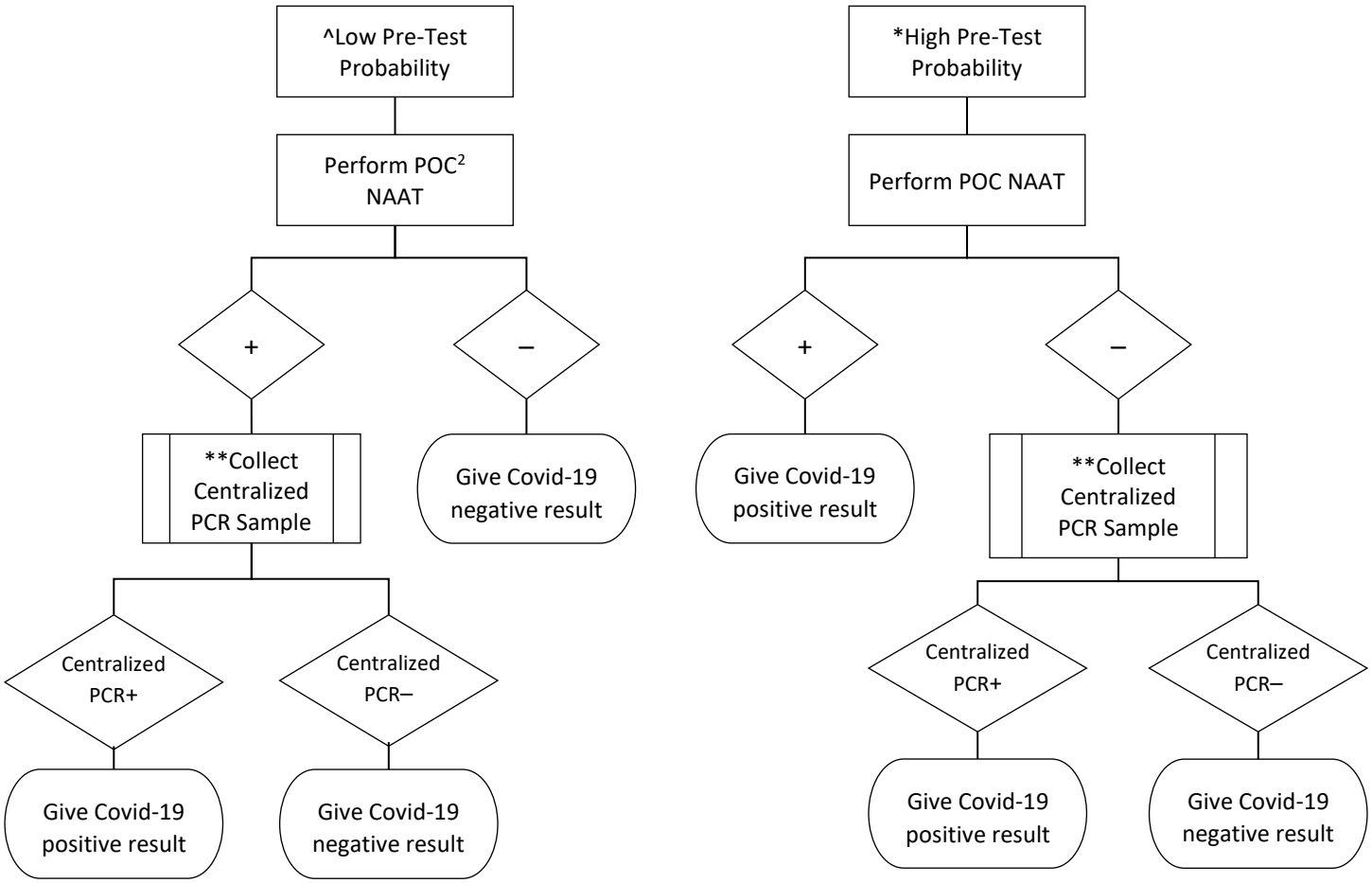
Screening testing protocols in closed congregate settings, such as prisons, must be flexible and consider the presence or absence of cases, persons with symptoms compatible with COVID-19, or known exposures in the setting. In most instances, if such a facility introduces POC testing, the facility should follow the algorithm either in Appendix A or Appendix B, depending on the type of POC test that is available. If it can be verified that ALL persons in the congregate setting have low pretest probability, a strategy of frequent testing using a POC test, as described in Appendix C, may be considered.

Quality Assurance

The implementation of quality assurance (QA) and quality improvement (QI) strategies (i.e., concurrently running a centrally performed molecular assay for a finite cohort of patients who are also tested at POC) is an essential and required activity when introducing a new POC test into any setting for clinical diagnostic or screening purposes. Every site introducing any new POC test should implement a QA/QI strategy to ensure the accuracy and reliability of these new POC tests in the particular setting. The state of Nevada provided one real-world example demonstrating the importance of QA strategies, when they identified an overall 60% false positivity rate when two new antigen tests were introduced into Skilled Nursing Facilities. This information need not discourage facilities from utilizing the new POC tests but underscores the essential requirement for careful introduction, including QA/QI strategies to verify their reliability.

Appendix A[3]

A Risk-Stratified Covid-19 Testing Algorithm for Community Testing Sites For use with Abbott ID NOW (Point-of-Care isothermal NAAT[1])



Notes: Any positive result would prompt contact tracing, quarantine, etc.
[1]NAAT = Nucleic Acid Amplification Test
[2]POC = point of care
^Low pre-test probability = no symptoms, no history of close contact with a known COVID+ person in the prior 14 days, AND not living in or frequently visiting a setting with an outbreak
*High pre-test probability = any symptoms, OR history of close contact with a known COVID+ person in the prior 14 days, OR living in or frequently visiting a setting with an outbreak
**Pending central lab PCR results, patient should self-isolate

[3] Adapted from algorithms developed by Tri Do, MD, MPH, FACP, AAHIVS, Medical Director, Community Health Center Network, San Leandro, CA

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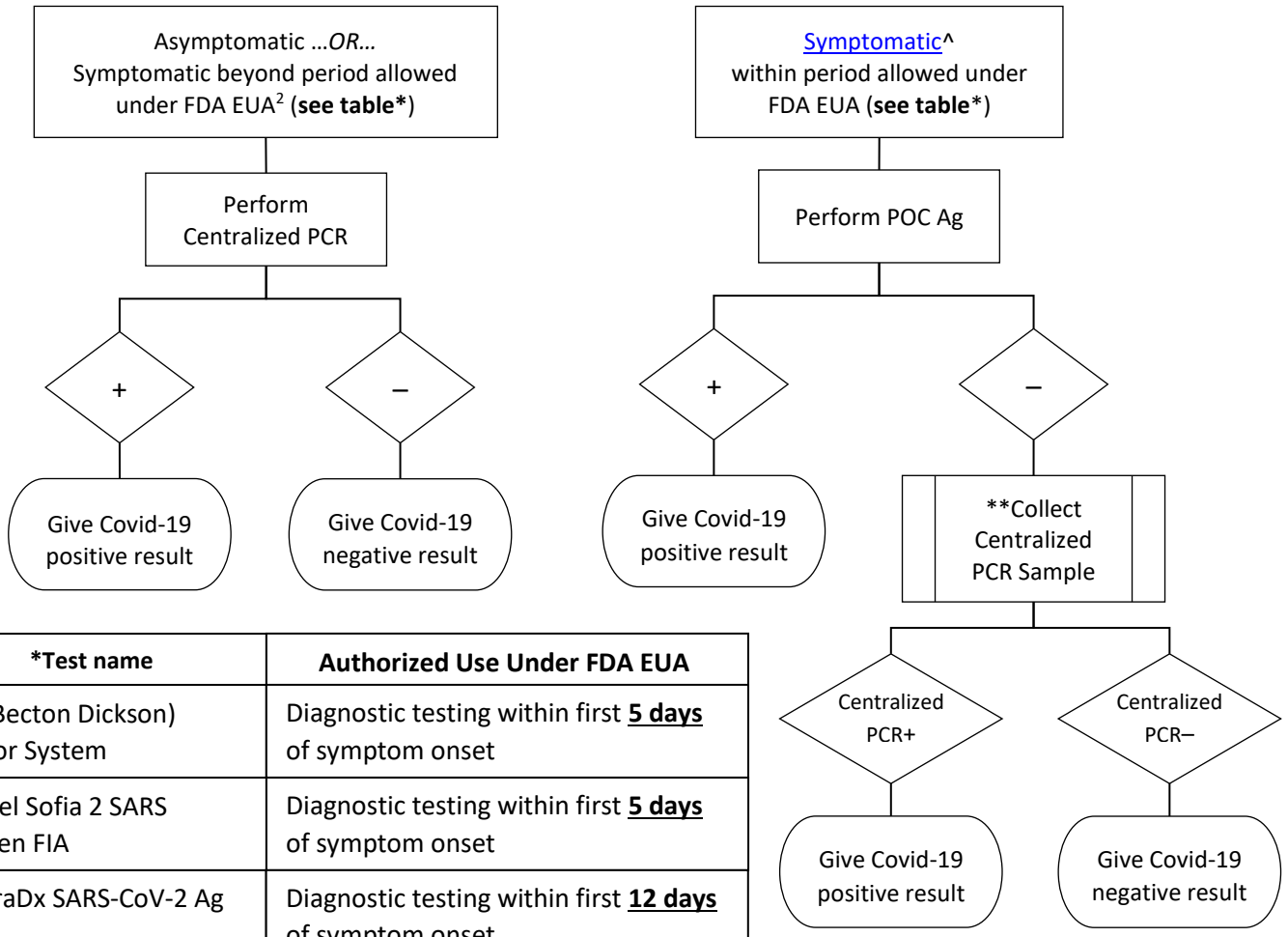
Appendix B[4]

A Risk-Stratified Covid-19 Hybrid Testing Algorithm
Centralized PCR vs. Rapid POC[1] Antigen Test



*Test name	Authorized Use Under FDA EUA
BD (Becton Dickson) Veritor System	Diagnostic testing within first **5 days** of symptom onset
Quidel Sofia 2 SARS Antigen FIA	Diagnostic testing within first **5 days** of symptom onset
LumiraDx SARS-CoV-2 Ag Test	Diagnostic testing within first **12 days** of symptom onset
Abbott BinaxNOW COVID-19 Ag Card	Diagnostic testing within first **7 days** of symptom onset

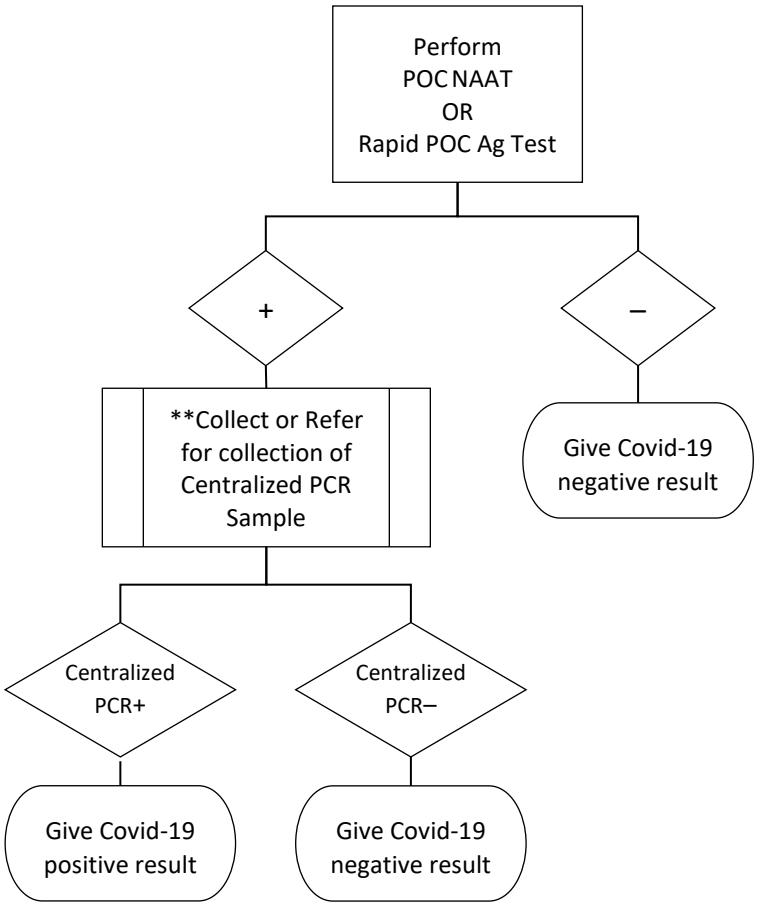
Notes: Any positive result would prompt contact tracing, quarantine, etc.
[1]POC = point of care.
[2]EUA = Emergency Use Authorization
^See CDC Symptom List
** Pending centralized lab PCR results, patient should self-isolate

[4] Adapted from algorithms developed by Tri Do, MD, MPH, FACP, AAHIVS, Medical Director, Community Health Center Network, San Leandro, CA

Appendix C

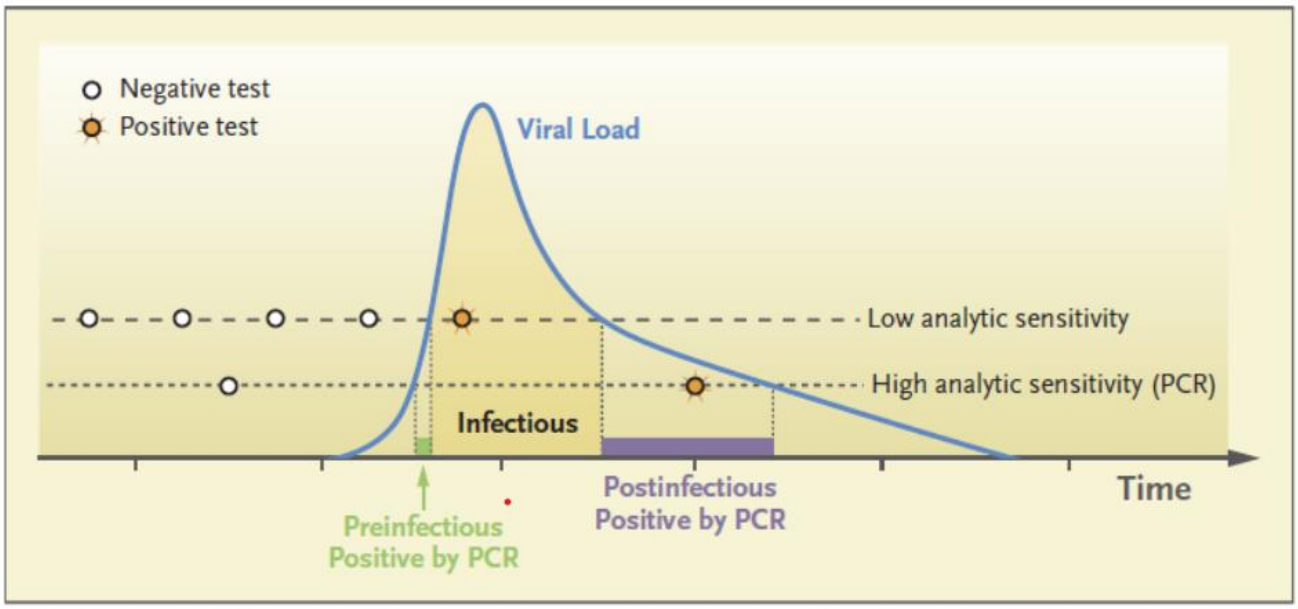
Testing Among Stable Groups of Individuals with ^Low Pre-Test Probability
For use with Abbott ID NOW (Point-of-Care isothermal NAAT[1]) or Rapid POC[2] Antigen Test

The strategy described in this algorithm is expected to be most effective when testing is performed frequently (e.g. twice a week). Please note that the use described here falls outside the FDA Emergency Use Authorizations for these tests.



Notes: Any positive result would prompt contact tracing, quarantine, etc.
[1]NAAT = Nucleic Acid Amplification Test
[2]POC = point of care
^Low pre-test probability = no symptoms, no history of close contact with a known COVID+ person in the prior 14 days, AND not living in or frequently visiting a setting with an outbreak
**Pending central lab PCR results, patient should self-isolate. PCR should be collected as soon as possible, but always within 48 hours of positive POC test.

Appendix D[5]



High-Frequency Testing with Low Analytic Sensitivity versus Low-Frequency Testing with High Analytic Sensitivity.

A person's infection trajectory (blue line) is shown in the context of two surveillance regimens (circles) with different analytic sensitivity. The low-analytic-sensitivity assay is administered frequently and the high-analytic-sensitivity assay infrequently. Both testing regimens detect the infection (orange circles), but only the high-frequency test detects it during the transmission window (shading), in spite of its lower analytic sensitivity, which makes it a more effective filter. The window during which polymerase chain reaction (PCR) detects infections before infectivity (green) is short, whereas the corresponding postinfectious but PCR-detectable window (purple) is long.

[5] Mina MJ, Parker R, Larremore DB. "Rethinking Covid-19 Test Sensitivity — A Strategy for Containment." The New England Journal of Medicine, Massachusetts Medical Society, Sep. 30, 2020.