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

New information and questions from healthcare providers have occasioned the development of this addendum to Alameda County's guidance entitled *Appropriate Use of Point-of-Care (POC) Tests for SARS-CoV-2*. The algorithms in that document remain valid. The guidance and algorithms in this addendum are intended to clarify and supplement the original guidance.

Data from a recent UCSF study support the notion that the Abbott BinaxNOW COVID-19 Ag Card (the "BinaxNOW") has acceptable sensitivity and specificity for detecting SARS-CoV-2 in individuals who are most likely to be infectious, *regardless of the presence or absence of symptoms at the time of testing*. For this reason, the BinaxNOW rapid antigen test may warrant broader utilization when turnaround time for non-POC NAATs (such as RT-PCR) is prolonged and rapid public health and infection control decisions are critical. A study from Pima County, Arizona found lower sensitivity overall using the BinaxNOW compared with RT-PCR; however, sensitivity was higher among individuals, both symptomatic and asymptomatic, who had positive viral cultures and thus might have been more infectious. Although it is important to recognize that results of these studies should not be extrapolated to other POC antigen testing platforms, questions have naturally arisen about how ACPHD's POC testing protocols might be appropriately modified to account for these new data.

In addition, the CDC has also published guidance on use of antigen testing generally. This guidance includes a role for off-label use of antigen testing in individuals who are asymptomatic with a known close contact to someone with COVID-19 – individuals who are described by CDC as having "moderate" pretest probability.

Finally, some providers have inquired about how best to interpret and/or to report discordant test results (e.g., patients with positive antigen test and negative RT-PCR on samples collected within 48 hours of each other). Appropriate actions following discordant test results are suggested in the algorithms that follow. *Laboratory providers* are reminded to report all COVID-19 test results (positive or negative), even if two different tests produce discordant results. This reporting requirement also applies to any provider who is performing point-of-care testing under a CLIA waiver. *Healthcare providers* must report all laboratory-confirmed cases of COVID-19 within 24 hours, by completing a COVID-19-specific Confidential Morbidity Report (CMR). The CMR may be sent by fax to (510) 273-3944, or by secure email to COVIDreport@acgov.org. Detailed description of these reporting requirements may be found here. Laboratories and healthcare providers are asked to report discordant test results by email to CovidReport@acgov.org .

The following guidance is intended to address these questions in the context of specific scenarios involving several patient populations.

Introduction to Scenarios

In general, antigen (Ag) tests should NOT be used off label for *clinical diagnostic purposes* in **asymptomatic individuals with low pre-test probability**[1], because (1) they are expected to yield an unacceptably high rate of false positive results, and (2) their low sensitivity in this population risks false negative results in infected individuals whose viral load is low, either very early in the course of infection or following the resolution of symptoms. These individuals should be tested by a NAAT (such as RT-PCR) instead, because NAATs generally have higher sensitivity than antigen tests. Appendix B, in the original document linked above, describes appropriate testing strategies for this population.

However, when pretest probability is moderate or high, the rapid turnaround time for antigen tests and their ability to detect most patients with high viral loads make them an attractive and practical tool to facilitate rapid decisions about isolation, quarantine and cohorting that could have significant public health impacts. With this in mind, this document introduces options for using antigen tests off label in the following circumstances:

	Description	Relates to Appendix:
1	Testing asymptomatic individuals with known close contact – Moderate pretest probability	N/A
2	Testing symptomatic AND asymptomatic individuals during an outbreak in a congregate setting when RT-PCR turnaround time is prolonged	B
3	Testing symptomatic AND asymptomatic individuals when community prevalence is high and RT-PCR turnaround time is prolonged	B

Two remaining scenarios are introduced at the request of healthcare providers to address:

	Description	Relates to Appendix:
4	Discordant test results (antigen positive, RT-PCR negative) in symptomatic persons	B
5	POSITIVE antigen tests in asymptomatic persons participating in a periodic screening testing protocol, NOT in the context of an outbreak	C

[1] 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 *or a community with high prevalence*.

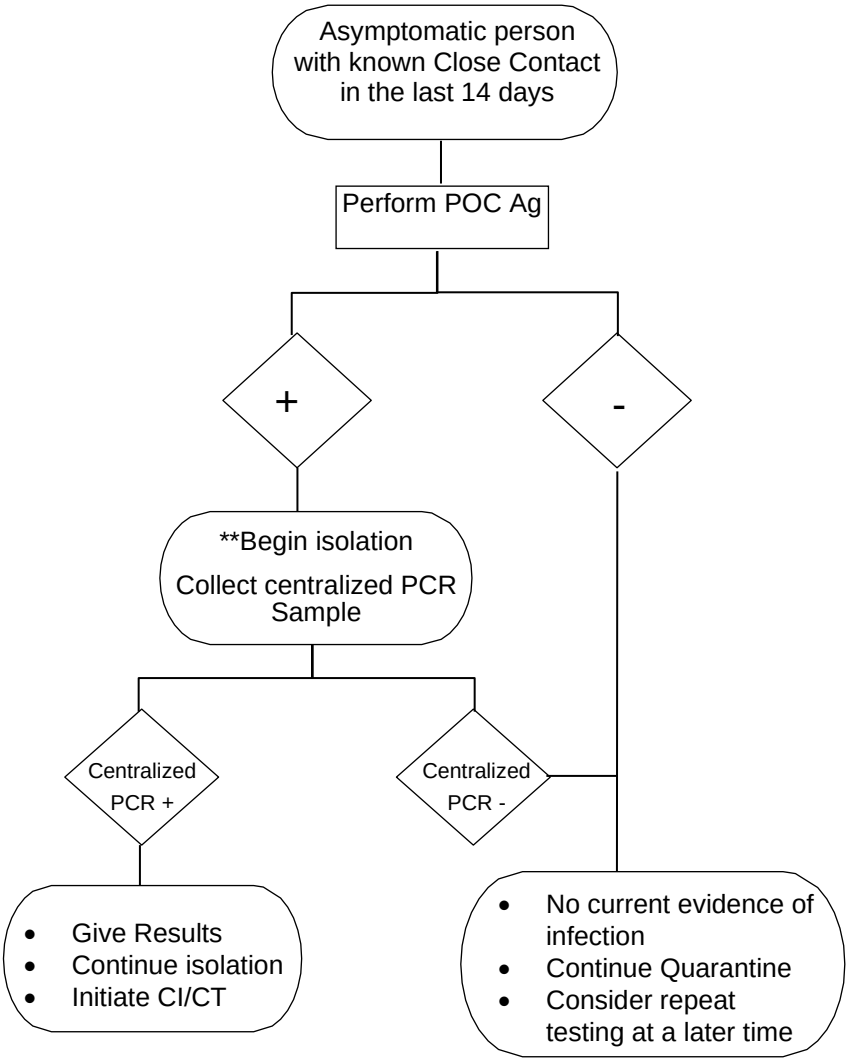
Scenario 1

Testing asymptomatic individuals with known close contact - Moderate pretest probability

Testing asymptomatic close contacts is an off-label use for antigen tests. However, the CDC has described this group as having 'moderate' pretest probability and has established an algorithm for antigen testing in this population. The following algorithm describes this use of POC antigen tests.

CDC recommends confirmatory testing by PCR of all positive antigen tests in this population. However, some facilities may choose to forgo PCR confirmation of positive antigen tests if their internal quality assurance analyses have confirmed a low rate of false positive antigen results.

Please note: In this scenario, healthcare providers should consider performing a NAAT (e.g., RT-PCR) first if short turnaround time is available, if the person cannot be safely and effectively quarantined, or if there are anticipated barriers to confirmatory testing. Persons testing negative should still complete the appropriate quarantine (see blanket quarantine order of the Alameda County Health Officer).

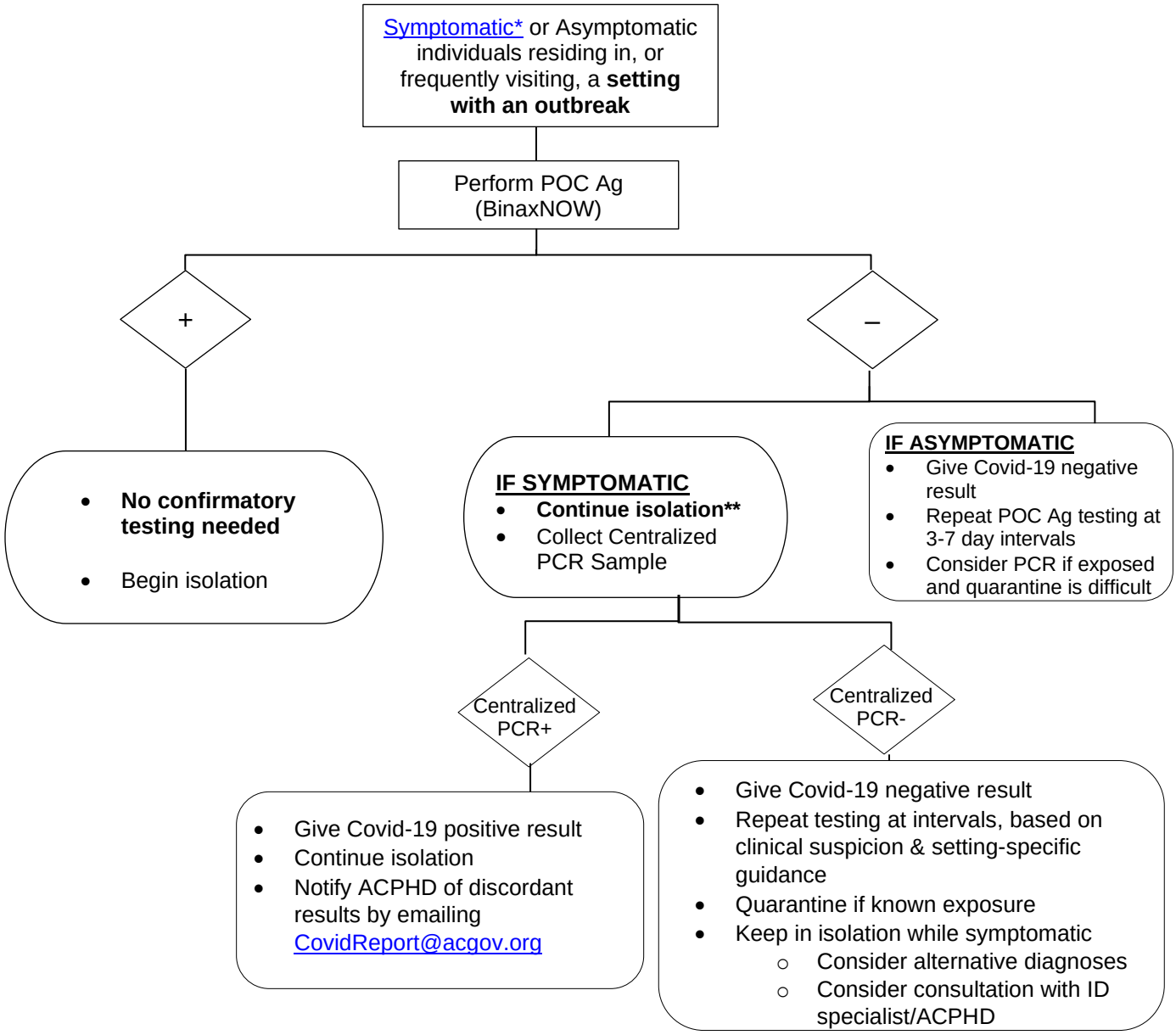


**Pending central lab PCR results, patient should self-isolate. PCR should be collected as soon as possible, but always within 48 hours of positive POC test.

Scenario 2 – Relates to Appendix B

Testing symptomatic AND asymptomatic individuals during an outbreak in a congregate setting when RT-PCR turnaround time is prolonged (e.g., >48 hours)

In congregate settings **experiencing an outbreak**, the algorithm in Appendix B may be used when turnaround time for RT-PCR tests is acceptable (e.g., 24-48 hours). However, **when turnaround time for RT-PCR testing is unacceptable**, the following modified algorithm may be utilized with the Abbott BinaxNOW COVID-19 Ag Card*** (the "BinaxNOW") in an attempt to facilitate rapid decisions about isolation and cohorting:

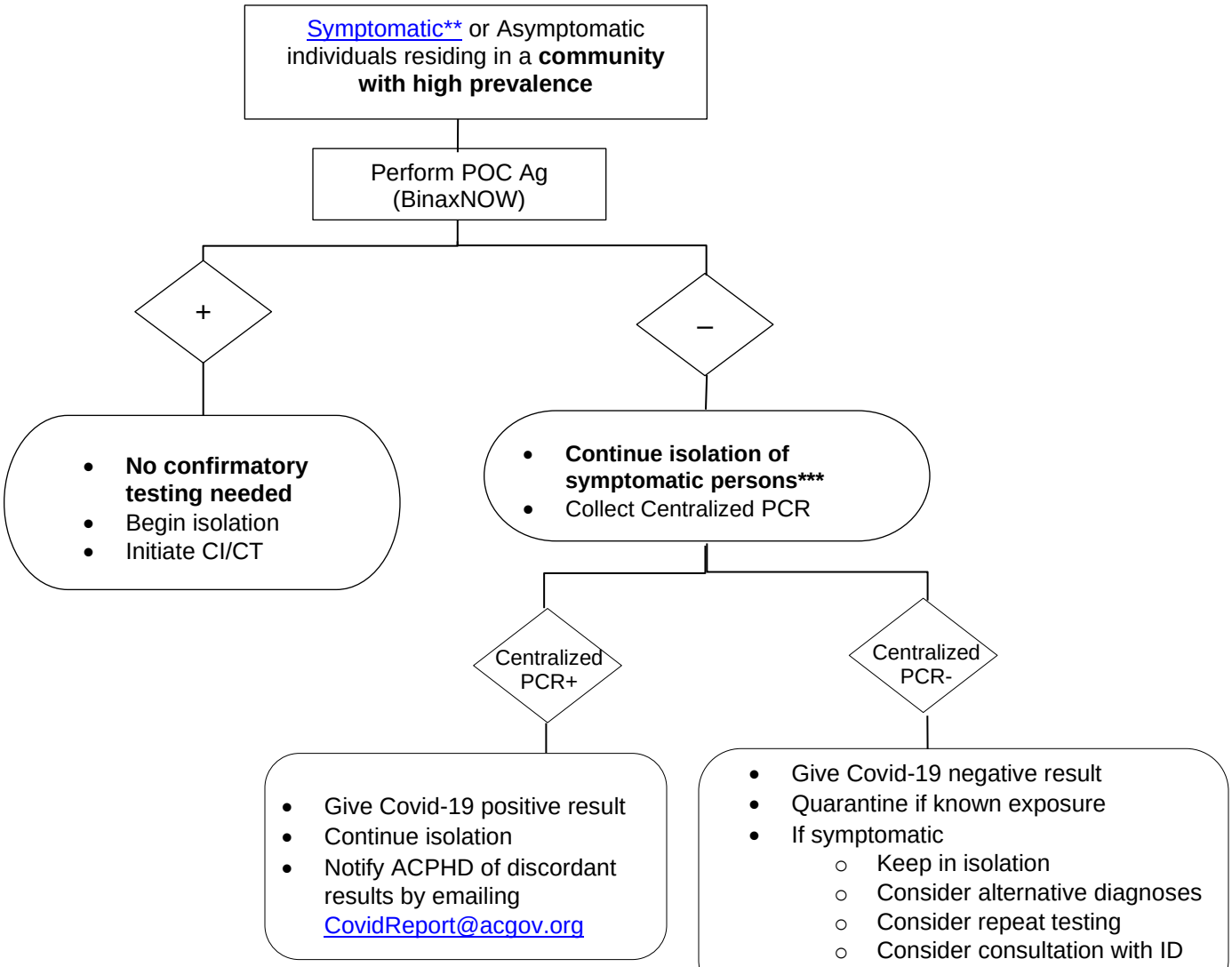


*Symptomatic individuals should be isolated (or excluded from work) immediately.
**Pending central lab PCR results, individual should self-isolate. PCR should be collected as soon as possible, but always within 48 hours of positive POC test.
*** Current data support the use of the BinaxNOW off label in this way. If medical literature in the future supports the use of other antigen assays in a similar manner, this algorithm may be modified accordingly.

Scenario 3 – Relates to Appendix B

Testing symptomatic AND asymptomatic individuals when community prevalence is high and RT-PCR turnaround time is prolonged (e.g., >48 hours)

CDC has defined community prevalence as "low" when NAAT positivity over the last 14 days is less than 5% OR when there are fewer than 20 new cases of COVID-19 per 100,000 persons with in the last 14 days*. When community prevalence is low and turnaround time for RT-PCR tests is acceptable (e.g., 24-48 hours), the algorithm in Appendix B should be used. However, when community prevalence exceeds these thresholds and **turnaround time for RT-PCR testing is unacceptable**, the following modified algorithm may be utilized with the Abbott BinaxNOW COVID-19 Ag Card**** (the "BinaxNOW") in attempt to facilitate rapid decisions about isolation and quarantine:

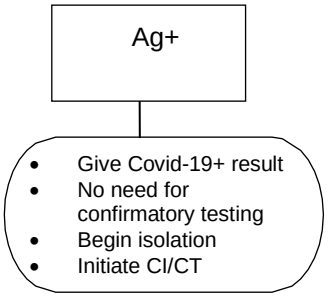


*For easy comparison with county metrics, this correlates to 1.4 cases per 100,000 per day.
**Symptomatic individuals should be isolated (or excluded from work or school) immediately.
***Pending central lab PCR results, individual should self-isolate. PCR should be collected as soon as possible, but always within 48 hours of positive POC test.
**** Current data support the use of the BinaxNOW off label in this way. If medical literature in the future supports the use of other antigen assays in a similar manner, this algorithm may be modified accordingly.

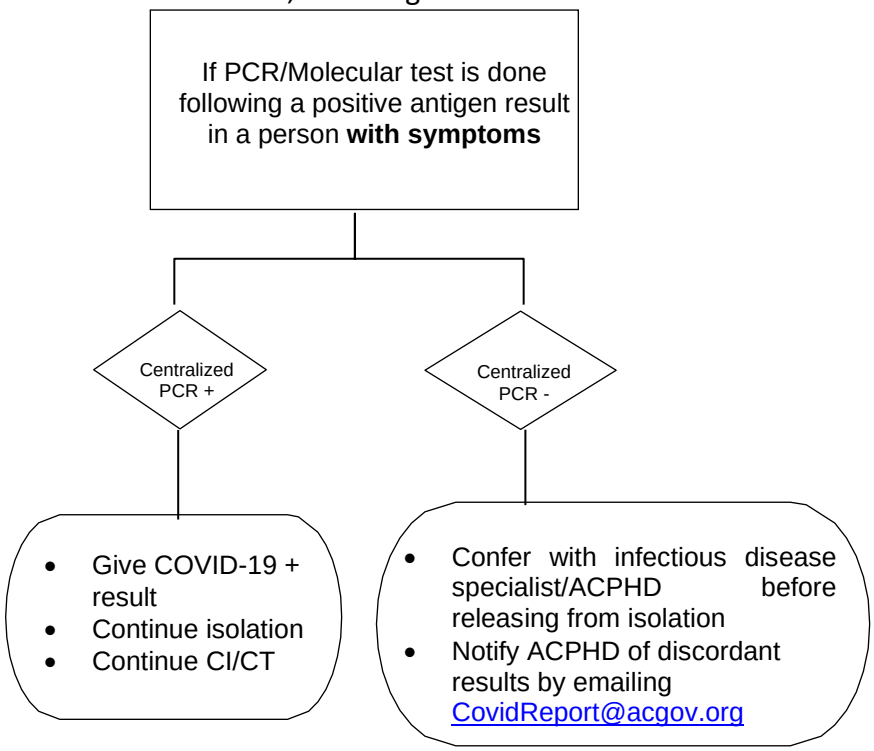
Scenario 4 - Relates to Appendix B

Discordant test results (antigen positive, RT-PCR negative) in symptomatic persons

For POSITIVE antigen tests in symptomatic persons tested within the timeframe allowed under FDA EUA (e.g., within 7 days of symptom onset for Abbott BinaxNOW COVID-19 Ag Card):

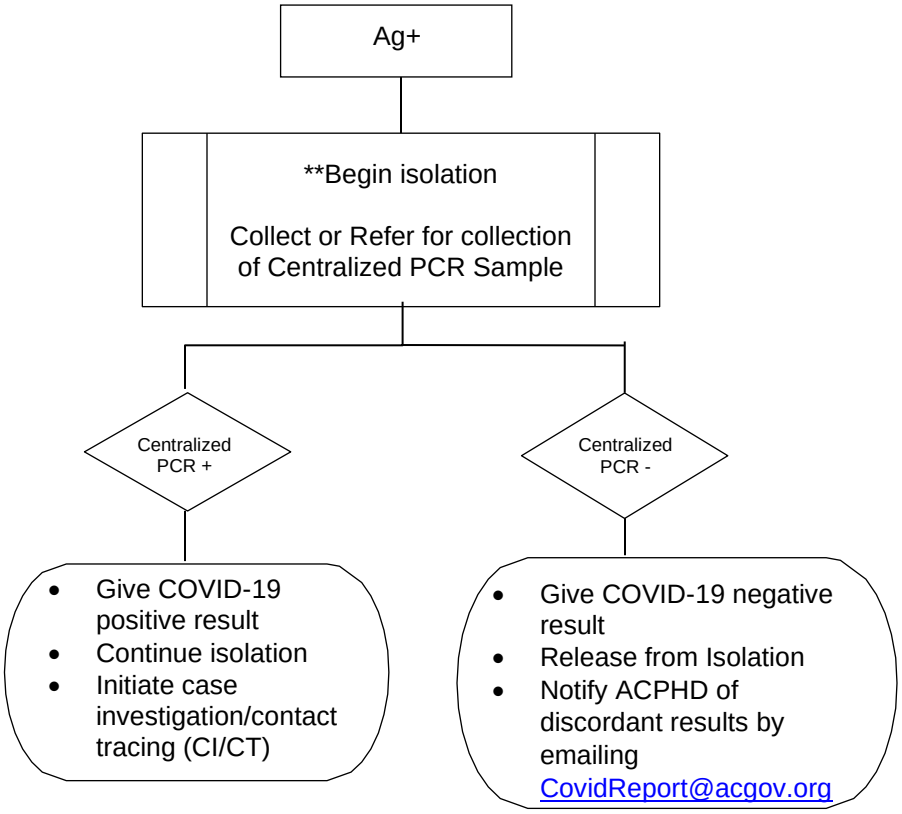


The following algorithm applies to the scenario in which a confirmatory PCR test is performed following a positive antigen test result in a person with symptoms. **Please note that confirmatory testing with PCR or other molecular test (NAAT) is NOT needed or recommended in this situation.** Antigen tests perform well in symptomatic persons, with positive results having high specificity. However, false positives may occur, typically due to technical errors. Also, laboratories and clinics may perform PCRs in tandem with antigen tests from time to time, as part of quality assurance and improvement activities. This algorithm describes the appropriate clinical actions in this situation, including the scenario when test results are discordant.



Scenario 5 - Relates to Appendix C

For POSITIVE antigen tests in asymptomatic persons participating in a periodic screening testing protocol (e.g., twice a week), NOT in the context of an outbreak, this algorithm applies:



Please note: In this context, negative antigen test results do NOT need to be confirmed by PCR. HOWEVER, if a PCR is performed and is positive (i.e., tests results are discordant) BOTH the negative antigen test and the positive PCR test results should be reported. Because the PCR is a more sensitive assay, the positive result may indicate either very early infection or a prior resolving infection, with viral load too low to be detected by the antigen assay.

**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.