LHD Follow up & Entry of COVID-19 Antigen (Ag) labs in NC COVID

LHD Guidance:

The North Carolina Department of Health and Human Services and the Test Surge Workgroup have developed a flowchart on Using, Interpreting, & Responding to COVID-19 Antigen Tests to accompany the Department's Antigen Testing Guidance. The flowchart and guidance provide information for clinicians and laboratories. This LHD guidance providers additional information about management of antigen results in NC COVID and classification of cases.

Antigen test results are currently feeding into NC COVID via electronic reporting and positive results can also be entered manually. Negative antigen tests feed into NC COVID similar to negative molecular tests and should not enter your workflow.

All positive antigen tests should be entered into NC COVID and follow-up should be initiated as for a positive molecular test. Except in specific situations described below, a case with a positive antigen result should be classified as **probable,** consistent with the current CSTE COVID-19 case definition[1].

Examples from paper labs reporting for Ag tests:

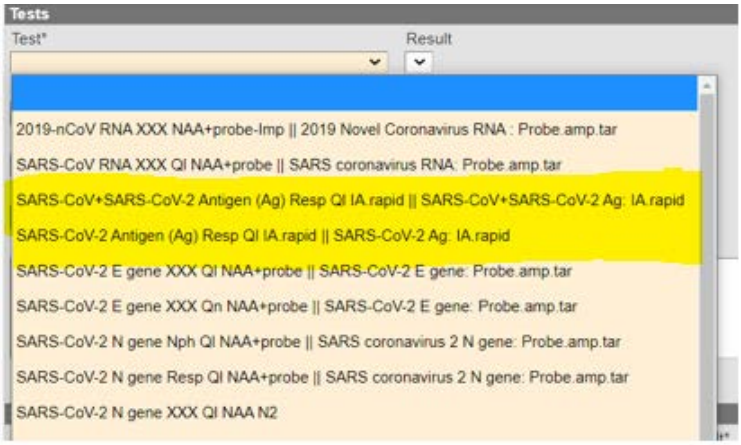
Test	Result
SVLUC Covid Ag	Positive

Test	Result
COVID-19 Antigen	Positive

NC COVID:

Lab Tab

Enter Antigen tests in the Lab Tab as follows:



[1] https://cdn.ymaws.com/www.cste.org/resource/resmgr/2020ps/Interim-20-ID-01_COVID-19.pdf

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There are two Ag test results to choose from in the picklist. Currently, the available testdevices should use the following selections:

Quidel Sofia 2 (COVID-19)

SARS-CoV+SARS-CoV-2 Antigen (Ag) Resp Ql IA.rapid || SARS-CoV+SARS-CoV-2 Ag: IA.rapid

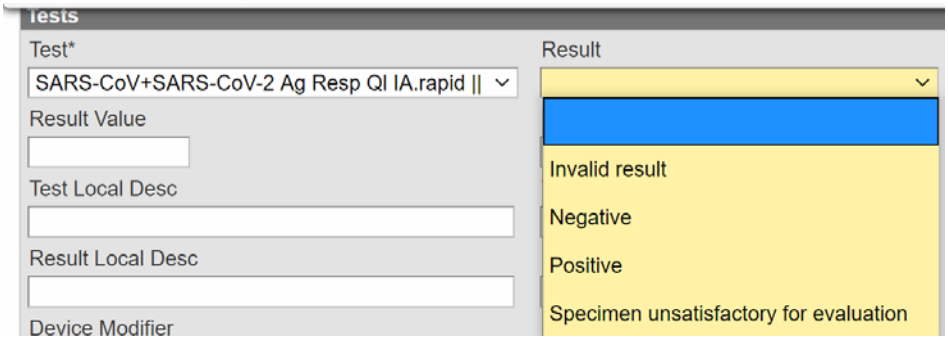
BD Veritor System for Rapid Detection of SARS-CoV-2

SARS-CoV-2 Antigen (Ag) Resp Ql IA.rapid || SARS-CoV-2 Ag: IA.rapid

Abbott BiNAXNow COVID Ag Card

SARS-CoV-2 Antigen (Ag) Resp Ql IA.rapid || SARS-CoV-2 Ag: IA.rapid

Then select the appropriate result as indicated on your paper lab result:



- An invalid, inconclusive, or unsatisfactory antigen test means a recommendation for retesting should be given to the patient by the ordering provider. As these results do not meet the case definition, the result should NOT be entered into NC COVID.
- A positive antigen result is considered a '**probable**' case and should receive the same follow up investigation as a PCR confirmed case and follow up PCR testing is only recommended for persons with no symptoms and no known risk exposures.
- A negative antigen result in a(n):
    - Symptomatic person is recommended for follow up testing with a PCR test due to the probability of a false negative.
    - Asymptomatic person with no known exposure does not require follow up PCR testing. As these results do not meet the case definition, the result should NOT be entered into NC COVID.

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Administrative package, Investigation Trail:

The classification status should appear as follows:

1. **Positive Ag lab result.** Conduct case investigation and Assign to the State with the classification status also as Probable.

    a. If the provider also conducts a PCR test that results as positive, this can be reported as a Confirmed case.

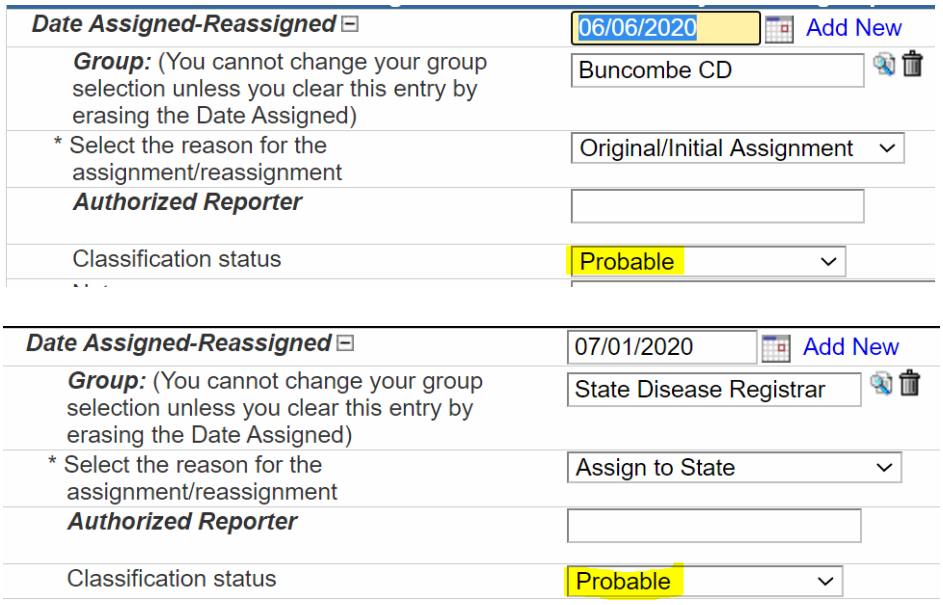
If a patient has a negative PCR result from a specimen collected within 48 hours of a specimen that was positive by antigen testing or rapid point of care isothermal amplification testing (e.g., Abbott ID Now)*, in order to determine case classification, you **MUST** confirm and document if the patient is

1. Part of an outbreak
2. Is symptomatic
3. Has a known risk exposure (ex. close contact to a confirmed case)

- If answers to any of the questions above are YES, then this is a PROBABLE case and requires follow up, regardless of the negative PCR result.
- If answers to all of the questions above are NO, then the event can be closed as DOES NOT MEET CRITERIA and submitted to the State. No additional case follow-up is routinely recommended, although additional testing or control measures may be recommended by the LHD depending on the specific situation.

*Not applicable to rapid point of care PCR test (ex. Cepheid)

<u>Example Investigation Trail with +Ag test submitted to the State</u>



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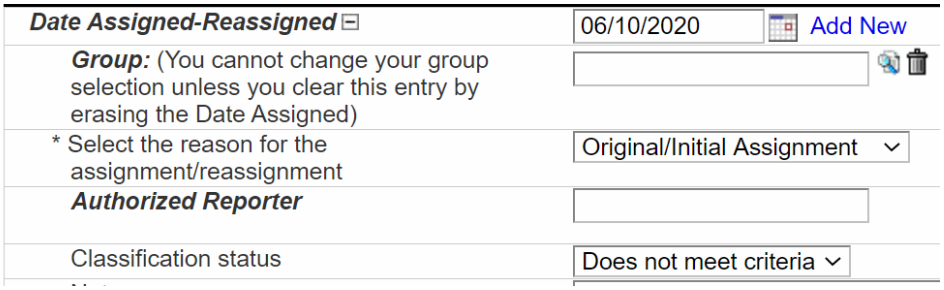
2. **Negative Ag lab result.** (or +Ag lab result, -PCR and meets the criteria above in 1a to be does not meet criteria). The LHD does not need to manually enter negative results into NCCOVID. Any negative results that come into NCCOVID via ELR will be automatically closed as the classification of "Does Not Meet" by the NCCOVID system. The LHD does NOT need to do anything with these events.

   Example Investigation Trail with -Ag test



3. **Invalid or Unsatisfactory Ag lab result**. You are not required to manually enter these. If these results feed in via ELR, they will feed in with the classification status of Under Investigation. **If the provider also conducts a PCR test that results as positive, this can be reported as a Confirmed case. If the PCR test results Negative or the provider does not retest, update the classification status to Does Not Meet Criteria and submit to the State with the same classification.

   Example Investigation Trail with Invalid Ag test submitted to the State