

1. Do we report all tests that are done or just those that are positive for Covid-19?  
(submitted by: W.S.)
  - a. *All testing is reported. A positive result is immediately reported to the Local Health Department.*
  
2. Are we required just the antigen tests, or PCR tests that we may do, or do PCR tests (because they are not rapid and determined in a lab), it is the lab's responsibility?  
(submitted by: K.R.)
  - a. *All testing is reported. The organization that performs the test and generates a result is the organization responsible for reporting.*
  
3. If you test asymptomatic patients with rapid antigen test and it is positive, confirmatory PCR testing is recommended. Do we wait for the PCR confirmatory test before reporting to the health dept? (submitted by: M.B.)
  - a. *No, you must report the results of all tests performed in-house. Understand that a positive antigen test in an asymptomatic patient with no known exposure will not be enumerated as probable case. So, if the PCR test (reported by the performing laboratory) confirms a negative test PCR test result, the suspected case will be marked as Not a Case that was originally reported from the positive Antigen test.*
  
4. If only testing M-F, do we have to send aggregate counts on weekends? (submitted by: M.B.)
  - a. *Yes, the public health order requires daily submissions. However, if you miss a day, you can report any latent reports the next day by selecting the appropriate date of results. This is to say you can report multiple dates of testing on any given day should this need occur.*
  
5. I assume we are exempted from reporting testing that is "not reportable" under FDA/CMS guidance (e.g. surveillance testing using NON-CLIA certified labs- <https://www.cms.gov/files/document/clia-university-lab-testing.pdf>) (submitted by: R.P.)
  - a. *If surveillance testing is being performed as described in this Q&A, then, correct, you would not need to report as you would not be operating under a CLIA waiver; however, if there is any notification of results reported, then the institution must apply for a CLIA Waiver or utilize another laboratory to conduct the testing.*

6. Can you share link to the Guidance for electronic submission doc within this chat? (submitted by: M.B.)
  - a. <https://odh.ohio.gov/wps/portal/gov/odh/know-our-programs/Electronic-Laboratory-Reporting/COVID-19-Reporting>
7. When you set up account, can it be done by anyone or does it need to be clinicians performing testing? (submitted by: S.R.)
  - a. *Any public citizen may create a user account.*
8. For educational facilities, what surveillance testing is required? (submitted by: E.D.)
  - a. *Ohio's Responsible Restart Guidelines for Higher Education <https://coronavirus.ohio.gov/static/responsible/Screening-Testing.pdf> required all institutions of higher education to have a comprehensive testing and screening program for symptomatic students and strongly recommends the implementation of a comprehensive testing and screening program for asymptomatic students. Considerations for developing a comprehensive testing and screening program for asymptomatic students are contained in the guidelines.*
9. If we ultimately use an antigen test other than Abbott Binax Now, will this be the same reporting required? (submitted by K.G.)
  - a. *The same reporting is required for all testing solutions used now and in the future.*
10. We are an educational institution but a regional hospital is administering the test, holds the CLIA waiver and will do the reporting. Do they report based on our institution or the hospital? (submitted by: K.G.)
  - a. *They will report based on their laboratory as the sending CLIA and performing CLIA but will provide the institution as the ordering facility and ordering provider.*
11. We have yet to begin using the BinaxNOW tests...do we need to register anyway or wait until we implement usage of the tests? Additionally, do we enter data each day—even if we do not utilize tests on a given date? (submitted by J.F.)
  - a. *You can register your laboratory as early as you want. There is no need to start reporting until you start testing though. Yes, for aggregate counts submissions, the public health order requires daily submissions.*
12. I test once a week. What do I do the other days? (submitted by: multiple participants)
  - a. *You will report the aggregate counts daily by 11 am ET for all testing performed the previous day. If no testing was performed, you will enter 0s into the designated tabs.*

13. Please confirm. We offer PCR testing but just collect specimens and mail back to vendor. The receiving lab reports to state health departments. Do we have any additional reporting responsibilities? (submitted by K.M.)
- For this question the answer is "no". We caution that the institution should ensure methods are in place to report positive results to the local health department.*
14. ...we offer PCR & Antigen testing regularly, antibody testing as indicated by our medical providers (infrequently at present). What steps do we need to take to get all 3 tabs? (submitted by M.B.)
- If Higher Education Institutions have the capacity to offer all three testing types, there will be no disabling of tabs for this facility type. So, this will not be an issue. Other institutions not offering these additional test types will have to enter 0s into the tabs that are not applicable to them. In the future, we may try to have a feature enhancement to the web portal to designate the applicable tabs by location, but this will be substantial work effort.*
15. If a patient is considered a "probable cause" and reported to LHD and the patient wants and gets a negative test, we are not supposed to send to LHD? (submitted by L.D.)
- Any positive tests must be reported to ODH electronically (or faxed to the LHD until the electronic file is approved). Understand, a case investigation will occur by local public health and if that patient is asymptomatic and has no known exposure to a confirmed case, this patient will not be counted as a probable case.*
16. To clarify, are colleges/universities required to ONLY report on tests that are conducted by the institution? What about testing done by outside agencies or community partners (those labs are likely already reporting)? (submitted by: J.F.)
- The organization that performs the test and generates a result is the organization responsible for reporting.*
17. We are only planning on testing one day per week < we have a small population. Will that create any concerns if not reporting daily. (submitted by: V.L.)
- You must report aggregate counts daily. Line level results can be reported just on testing days for COVID-19 reporting only.*
18. We are partnering with a healthcare institution for CLIA certificate, would the health system report or can I have access to report for the antigen testing done for our students? (submitted by V.L.)
- The organization that performs the test and generates a result is the organization responsible for reporting. No other organization should report.*

19. Can you explain the CLIA certificate/waiver? (submitted by K.R.)

Sites of administrations

The BinaxNOW test is authorized for point-of-care use in settings operating under a [Clinical Laboratory Improvement Amendments \(CLIA\)](#) Certificate of Waiver, Certification of Compliance, or Certificate of Accreditation.<sup>1</sup>

The application to apply for a CLIA certification or waiver can be found [here](#) and additional support can be provided by contacting Abbott support or by contacting Phil Ennen of Ohio's testing team at [Philip.Ennen@insurance.ohio.gov](mailto:Philip.Ennen@insurance.ohio.gov). Once a testing site has identified a laboratory director and provided all required information on the application, a CLIA number will be assigned and the site can begin testing for COVID-19<sup>2</sup>.

20. Is there a written version of this material somewhere to review? (submitted by L.R.)

- a. [ODH Electronic Laboratory Reporting \(ELR\) webpage](#)
- b. Direct [download file](#)
- c. Line level results must be [reported](#) electronically to ODH within 24 hours of case identification.
- d. Aggregate counts must be [reported](#) daily by 11 a.m. ET for the previous day of testing.

21. How do we backfill test reporting? (submitted by K.B.)

- a. *Once registered, alert the ODH personnel that you need to provide backfill and we will send you the spreadsheet. It is also attached for your review.*

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<sup>1</sup> <https://www.cms.gov/files/document/qso-20-21-clia.pdf-0>

<sup>2</sup> <https://odh.ohio.gov/wps/portal/gov/odh/know-our-programs/lab-certification-clia/laboratorycertificationCLIA>