



ARIZONA DEPARTMENT OF HEALTH SERVICES

Facilities performing laboratory tests for COVID-19, including facilities using Point-of-Care (POC) devices such as FDA-authorized antigen diagnostic tests, are required to report results to public health, pursuant to [Arizona Administrative Code R9-6-204](#) and the federal [COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115](#). Reporting to ADHS meets both state and federal requirements. Laboratory is defined in [A.R.S. § 36-451\(4\)](#).

●

As of April 4, 2022, COVID-19 test reporting requirements in Arizona depend on a) what type of test you are using, and b) whether your facility has a Clinical Laboratory Improvement Amendments (CLIA) certificate of waiver or is CLIA-certified to perform moderate- or high-complexity tests. Test results must be reported within 24 hours of test completion.

- Facilities that are conducting testing under a **CLIA certificate of waiver** are now required to only report **POSITIVE** COVID-19 test results at this time.
- Facilities that are **CLIA-certified to perform moderate- or high-complexity testing** must report **ALL** test results (i.e., positive, negative, inconclusive) from COVID-19 NAAT testing (e.g., RT-PCR), and only **POSITIVE** results from other tests.

The following test products are considered COVID-19 NAAT tests:

- Abbott ID NOW COVID-19 Test
- Accula™ SARS-CoV-2 Rapid PCR Test
- BioFire® Respiratory Panel
- Cepheid® Xpert® Xpress SARS-COV-2/Flu/RSV Rapid Test
- Cobas® SARS-CoV-2 & Influenza A/B Assay
- Lucira™ COVID-19 All-In-One Test Kit
- SalivaDirect™ COVID-19 Test

The reporting procedures described below are intended for facilities using POC devices to test for COVID-19, but that may have limited technical or database support. This document instructs on how to securely send the results to ADHS, satisfying state requirements.

- Please note, this reporting method applies only to COVID-19 test results obtained using an on-site POC testing instrument.
 - Specimens collected from staff, residents, or others and sent off-site to another laboratory for COVID-19 testing **do not need to be reported through this process.**
- Facilities that prefer to meet laboratory reporting requirements by submitting COVID-19 results electronically via a standardized spreadsheet should review the [Flat File Guidance for Facilities using Point-of-Care \(POC\) Testing Devices](#). Flat File is an alternative to the web entry form and to electronic submission of results via Health Level Seven (HL7) messages. Facilities may choose whichever mechanism best suits their needs. Further

details on all acceptable laboratory reporting mechanisms are available on the [COVID-19 Lab Resources webpage](#).

A Clinical Laboratory Improvement Amendment (CLIA) Certificate of Waiver, or another form of CLIA certification, is required for facilities performing COVID-19 POC testing, and must be obtained before testing begins. Please see the ADHS [CLIA Information for Point-of-Care Testing](#) on the [Laboratory Licensure & Certification webpage](#) if you need further information about obtaining CLIA certification. The facility's CLIA Certificate of Waiver Number is required for reporting testing results.

OVERVIEW OF REPORTING PROCESS USING THE WEB ENTRY FORM

1. Complete the online [Facility Registration Form for Reporting COVID-19 Point-of-Care Diagnostic Testing](#) to enroll your facility for reporting results using this process. **This form needs to be completed only one time per licensed facility type.**
2. Following registration approval, instructions for accessing the *COVID-19 Results Reporting Form for Point-of-Care Testing* will be sent to your facility, using the email addresses provided during registration. This reporting form is where you will enter the required information about the individual tested and their test results. Please note, the form needs to be completed for each individual for whom you are reporting a result.
3. Questions concerning this process can be directed to reportingquestions@azdhs.gov. Please do NOT send patient information in your communications.

THINGS TO CONSIDER BEFORE YOU BEGIN (for all reporting methods)

- Identify 1–2 people to be point-of-contact(s) for your facility, and be prepared to provide their contact information in the event ADHS needs to follow up on reported information.
- Know the [CLIA Certificate Number for your facility](#). This will be required for each test result being reported. Additional information on obtaining a CLIA Certificate Number or for questions regarding current CLIA Certificates can be found on the [ADHS CLIA Information for Point-of-Care Testing](#) page.
- Know the POC platform your facility is using. There are [many POC platforms available](#), with additional platforms under development.
- Know what type of specimen is collected for each patient tested. Examples include Nasopharyngeal (NP) Swab or Nasal Swab. Additional sample types and explanations can be found on [CDC's Guidelines for Collecting, Handling, and Testing Clinical Specimens](#) webpage.
- Have a standard procedure in place for recording patient demographic information (name, date of birth, sex, address (including county of residence), phone number, race and ethnicity) and testing information (specimen collection date, test results and result date). This information will be needed when reporting to ADHS.
- Have a standard procedure available for identifying whether each person tested is a staff member of the facility or a resident of the facility.

Douglas A. Ducey | Governor Cara M. Christ, MD, MS | Director

- Have a standard procedure available for notifying each person tested of their results and guardians/family, as necessary.

Skilled nursing facilities (SNFs) must meet the reporting requirements for the State of Arizona as well as for the Centers for Medicare and Medicaid Services (CMS). If your facility is reporting in the NHSN COVID-19 test module, ADHS needs to conduct data validation to make sure the reports coming from NHSN are meeting the Arizona reporting requirements for your facility.

- Please make sure your facility is reporting all positive test results to both reporting methods (POC web entry and NHSN) paying special attention to the collection & result dates.
- To meet the state requirements, reports from tests performed at your facility still need to be submitted through the POC web entry until you receive communication from ADHS indicating you passed the validation.