



## **Rapid Antigen Testing Guidance For School-Based Testing April 6, 2022**

### **Introduction:**

The State of Maine is distributing point-of-care (POC) rapid antigen tests to PreK-12 schools. These tests are the Abbott BinaxNOW COVID-19 Ag Card.

Starting in April 2022, Maine DHHS, with the support of U.S. Department of Health and Human Services, will provide schools with a one-time allotment of at-home COVID-19 antigen test kits to distribute to students and staff. These tests include the Siemens [CLINITEST Rapid COVID-19 Antigen Self-Test](#), [Abbott BinaxNOW Self-tests](#), or [OraSure InteliSwab rapid tests](#). This guidance may be updated as circumstances and science evolve.

### **Maine DHHS Requirements for PreK-12 Schools to Use POC BinaxNOW COVID-19 Ag Cards in the School Setting:**

Maine DHHS has outlined the following six core requirements that schools need to meet to receive and use state-supplied tests:

1. The school or school administrative unit (SAU) agrees to use the tests in accordance with Maine DHHS Guidance, which may be updated based on circumstances and evolving science.
2. The school or SAU has either a valid Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. To obtain a CLIA Certificate of Waiver, organizations must complete an application ([CLIA Waiver Application Form](#)) and upon approval will be invoiced a \$180 fee. More information on applying for a CLIA Certificate is available on the [CMS CLIA website](#) or see [Appendix A](#) in this document for a step-by-step guide on completing the CLIA Certificate of Waiver application for BinaxNOW testing.
3. The school or SAU must complete the online training modules to ensure the POC test is used consistent with the manufacturer's instructions. That training is available at: [Abbott BinaxNOW Online Training](#)
4. The school or SAU should have a process to obtain parent/staff [consent for testing](#).
5. The school or SAU must immediately report all positive results to the Maine Center for Disease Control and Prevention (CDC) by enrolling in and using the Maine CDC Point-of-Care Test Reporting System (REDCap): The REDCap electronic reporting portal. The facility must report positive results within 24 hours.

6. The school or SAU must have a way to contact each person with test results. At a minimum, positive and inconclusive results should be relayed by telephone or in person. Negative results could be shared by email or text message.

### **Maine DHHS Guidance on Use of POC BinaxNOW COVID-19 Ag Cards in the School Setting:**

Maine DHHS is currently only using this test in the following situations in the school setting.

1. Students and staff who have [symptoms consistent with COVID-19](#) during the school day and are within the first seven days of symptom onset.
  - A positive result in a symptomatic individual indicates that the individual is highly likely to have COVID-19.
  - A negative result is strongly suggestive that the individual does not have COVID-19. However, an individual who has a known COVID-19 exposure, and/or who continues to have symptoms consistent with COVID-19 should be further evaluated by their health care provider. Serial antigen testing or a confirmatory PCR test may be considered in such situations.

### **Maine DHHS Guidance on Uses of Antigen Self-Tests:**

While Maine DHHS is making antigen self-tests available to schools for direct distribution to students and staff, the department acknowledges that students and staff have access to antigen self-tests from other sources, including local pharmacies, the federal free at-home covid test program and the State of Maine's Project Access Covid Tests. The following guidance should be applied to all self-tests.

1. Testing of students and staff who develop symptoms consistent with COVID-19 while at home. Under this approach, students and staff would self-test when symptoms develop. Individuals may wish to test serially, meaning every 1-2 days, while symptoms persist if initial self-test is negative.
  - A positive self-test suggests that the individual is highly likely to have COVID-19 and should isolate and follow [Maine CDC guidelines](#).
  - A negative self-test result is strongly suggestive that the individual does not have COVID-19. However, an individual who has a known COVID-19 exposure, and/or who continues to have symptoms consistent with COVID-19 should be further evaluated by their health care provider. A confirmatory PCR test may be considered in such situations. Individuals may wish to test serially, meaning every 1-2 days, while symptoms persist if initial self-test is negative. Symptomatic students and staff should follow school guidelines regarding when it is safe to return to school.
2. Serial testing of asymptomatic unvaccinated students and staff in public and private PreK-12 schools who have been identified as a close contact of a confirmed COVID-19 case.

- As detailed by the U.S. CDC, under [this approach](#), asymptomatic, unvaccinated students and staff with negative results can be present at school but must quarantine from the community. They must wear a well-fitting mask at all times for 10 days following the COVID-19 exposure when around others indoors, except while eating or drinking. These tests should be self-administered or administered by the parent or guardian before the individual goes to school.
  - A negative self-test result suggests that the student or staff member does not have COVID-19 at the moment the test was taken. But because these individuals, by definition, have a known COVID-19 exposure, those who have any symptoms consistent with COVID-19 may not work whatsoever and should be placed in isolation. Additionally, they should be further evaluated by their healthcare provider, and a confirmatory PCR test should be considered.
  - In general, children who have previously tested positive for COVID-19 and who can wear a mask should not be retested for 90 days following the date of the positive test result, and do not need to quarantine if exposed again during this time period. However, a child who develops new onset of symptoms consistent with COVID-19 infection during the 90-day period following the initial positive test collection date should be retested. The child should follow guidance outlined above in the section addressing isolation.
3. Testing of students and staff following a 5-day vacation period with testing occurring prior to the start of school and again 3 to 5 days afterward. Under this approach, students and staff would self-test after a 5-day or longer vacation break. Testing twice within a one-week period would increase the likelihood of identifying cases following a vacation period.
- A positive self-test result in an asymptomatic individual indicates that the individual is highly likely to have COVID-19 and should isolate.
  - A negative self-test result in an asymptomatic individual indicates the individual does not have COVID-19 at the moment the test was taken.

**Storage and Stability:**

Please review individual manufacturer’s guidelines on storage and stability of tests.

[BinaxNOW COVID-19 Ag CARD](#)

[CLINITEST Rapid COVID-19 Antigen Self-Test](#)

**Resources:**

- [Directions for completing CLIA Certificate of Waiver for Schools](#)
- [Sample Consent Form](#)

- [Standard Operating Procedure for Responding to a Positive Case](#)

**Appendices:**

- **Appendix A: Maine CDC Point-of-Care Test Reporting (REDCap reporting system)**

*(Continue on to next page for Appendices)*



## Maine CDC Point of Care Test Reporting

Maine CDC requests that all Point of Care (POC) tests are reported through the REDCap online reporting system. Facilities that use the BinaxNOW COVID-19 Antigen test must report all results through REDCap. Results of every test conducted must be reported via the online reporting tool within 24 hours. This includes negative, positive, and inconclusive test results. After facilities/organizations register as reporting organizations, they will be sent a unique link that is tied to their facility and CLIA license or waiver. *Facilities/organization should not register more than one time.* If your facility/organization misplaces the link to submit POC results, email [redcap.dhhs@maine.gov](mailto:redcap.dhhs@maine.gov) to obtain the unique URL/link.

## Registration

Each facility/organization that will use the REDCap reporting system needs to register at [https://redcap.link/MECDC\\_POC\\_Registration](https://redcap.link/MECDC_POC_Registration).

The facility will need to identify one individual to be the reporter. This can be anyone (Infection Control, Nurse, Admin, Director etc.) who would be able to answer questions about the facility if there is a question about a submission. They will need to provide their name, telephone number, and email address. This information can be edited in the survey form for individual submissions if desired. Maine CDC also needs the following information about the facility/organization (these fields are required, and registrations will not be approved if any of this information is missing):

- Facility/organization name
- Provider name (may use medical director or if you plan to use the Standing Order please enter Isaac Benowitz, MD)
- CLIA Number (it can be looked up using the [U.S. CDC CLIA Lookup Tool](#) or the [CMS CLIA Lookup Tool](#))
- Address (physical location of the facility)
- Phone Number
- Facility Type (select from one of the dropdown options or choose other and specify the type of facility)

If your facility/organization will be running more than 20 samples a day and would like a .csv upload option, select Yes for the “Does your facility expect to frequently upload more than 20 results per day” question.

You will be asked to provide “COVID Testing Information.” For the “POC Testing Device Name (Manufacturer)” please indicate the platform you are using such as “Abbott BinaxNOW” or

“Cepheid” In the next selection menu for POC tests, please only select whichever tests your facility may perform. After you have completed this form and you have verified its accuracy, you can press Submit. *This form should only be completed once for each facility/organization.*

After submitting the registration survey, you will get a confirmation that the submission was successful. Maine CDC will review the information and when approved you will receive an automated email with a unique URL link that will be used every time to enter results from all POC tests including positives, negatives, and inconclusive results. Facilities/organizations should expect to receive their custom link within two (2) business days. This link will not change and will be tied to your specific facility/organization. When you click on the link, it will automatically populate the Facility Reporting information into the form for reporting of POC results.

## Entering Single Lab Reports

When submitting results to Maine CDC, you will need the following pieces of information from each person that was tested using a POC Test (including positive, negative, and inconclusive test results):

- First name
- Middle initial
- Last name
- Date of birth
- Sex
- Ethnicity
- Race
- Patient address
- Patient phone number
- Specimen collection date (all results must be reported within 24 hours)
- Specimen source
- Test results
- Comments (clinical/laboratory information about the patient).

It is important that after you enter in all the appropriate information that you verify the accuracy in the “Verify Lab Submission” section at the bottom of the form. This section will auto-populate as you enter data into each field. Please do not hit submit until the entry is complete and you have verified all of the information at the bottom of the survey. These are official infectious disease records with Maine CDC and should be treated as such regarding accuracy and completeness. All information submitted via this form is covered by Maine CDC confidentiality rule(s) and law(s) including [22 MRSA Chapter 250](#).

Once submitted, the information is automatically processed directly into Maine CDC’s National Electronic Disease Surveillance System. If you identify an error after submission, please contact [redcap.dhhs@maine.gov](mailto:redcap.dhhs@maine.gov) to correct the issue.

## CSV uploads (Batch uploading)

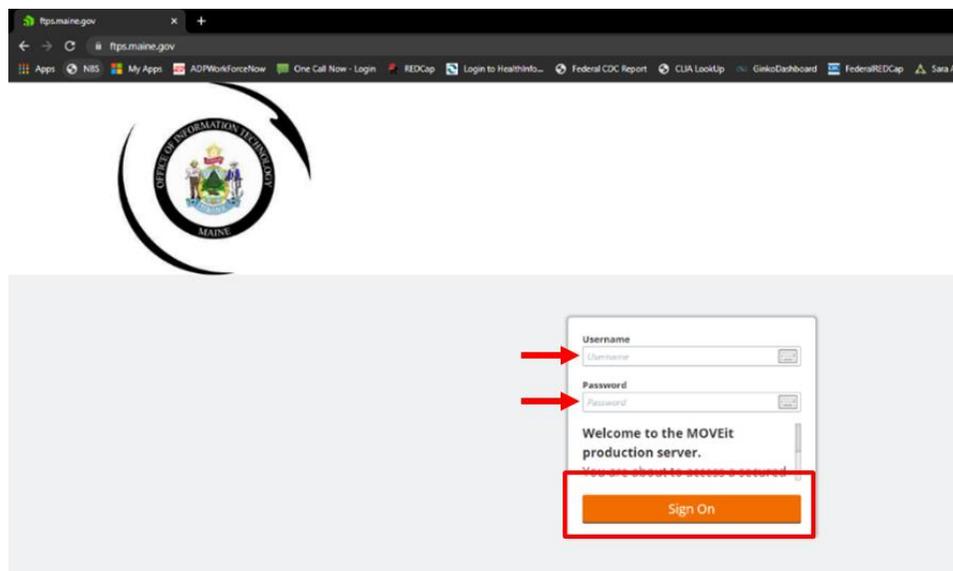
If you indicated that your facility/organization will routinely conduct more than 20 tests per day, you will receive a second email that has information about an FTP account for uploading batches of results. This email will include a username, a password, and a template CSV file. To batch upload a set of results follow these steps:

Record each test on one row of a CSV file with columns matching those in the template (one row per test). Please refer to the Appendix I for information about how values of each column should be coded. In order to route the file to appropriate system, name your file using format:  
*FacilityName\_POC\_mmdyyyy.csv.*

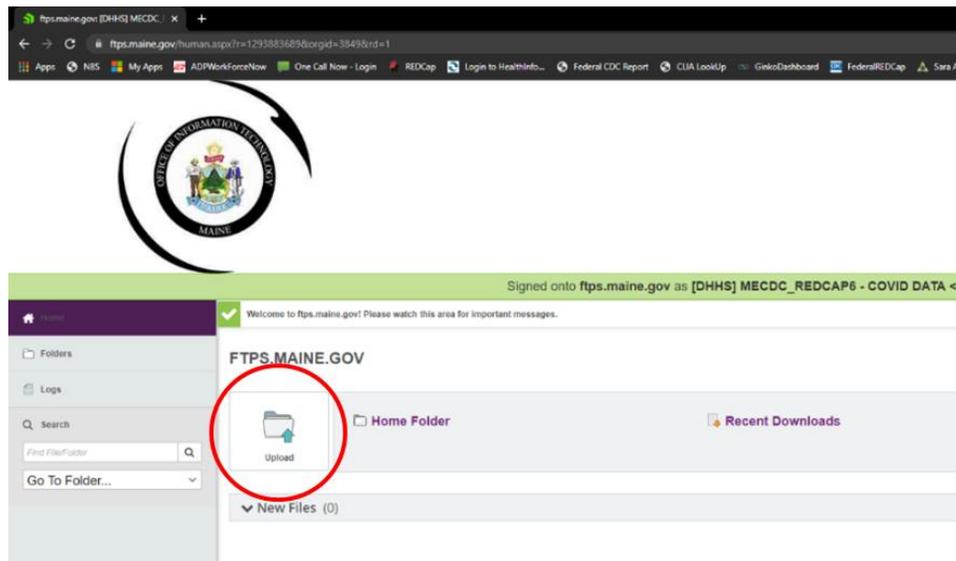
- For example, a file reported from Bedrock Medical Center on 09/01/2021 should be named BedrockMedicalCenter\_POC\_09012021.csv
- The precise formatting of your organization/facility's name will be provided to you. The only part of the file name that should change between submissions is the date.

After recording the tests you need to report in a .csv file and saving the file with the appropriate name, upload it by following the steps below:

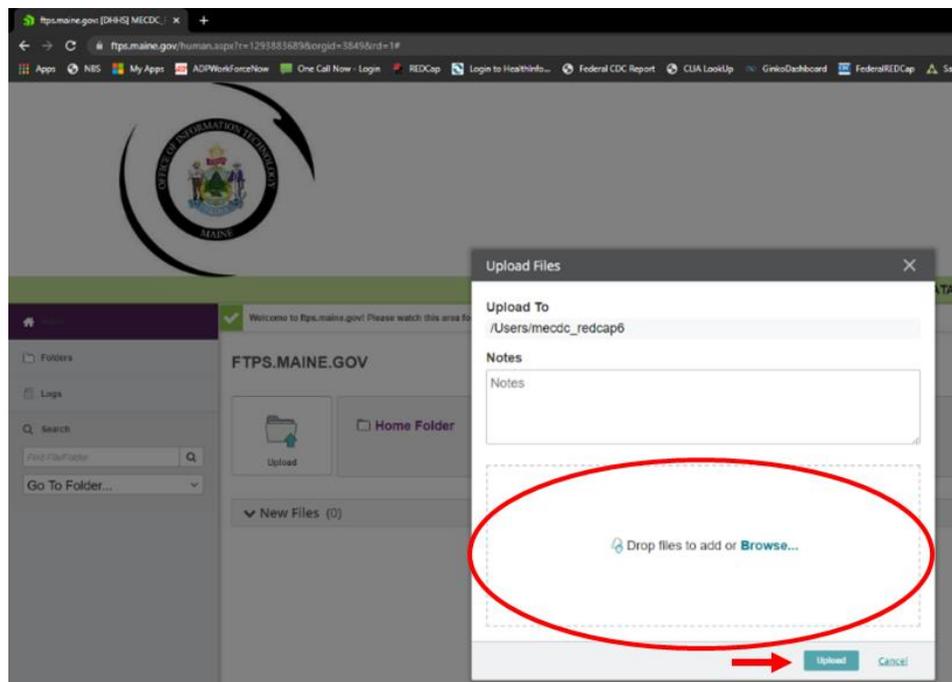
1. Go to <https://ftps.maine.gov/> and log in using the username and password sent to you in the FTP email.



2. Click Upload.

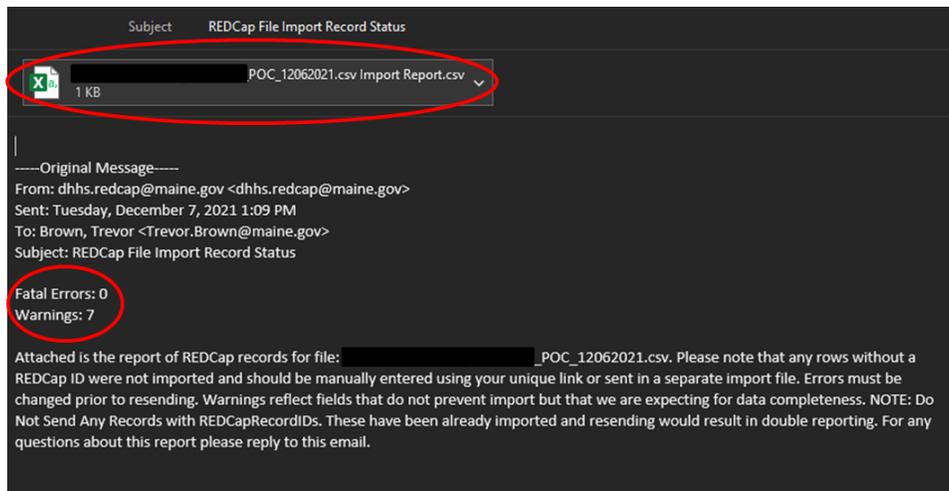


3. Drag and drop, or browse, to upload files.



4. After uploading a file, an email will be sent acknowledging Maine CDC's receipt of the data and detailing any data quality issues that the system encountered. Warnings are issues that should

be corrected for future submissions, but that did not prevent Maine CDC from importing a record. Fatal errors on the other hand indicate records that Maine CDC was unable accept because of critical data issues. These issues must be corrected and resubmitted in a new file that does not contain any records that were previously accepted. Records that cause fatal errors are not considered to have been reported until they are resubmitted, and the resubmission is accepted. The CSV file attached to this email contains detailed information describing problems encountered with any records that caused warnings and/or fatal errors. Please note that depending current testing volume it may take several hours to process a batch upload and send this email.



	A	B	C	D
1	REDCap Converted Record ID	Original Record ID	Errors and Warnings	Date Record Imported
2	714958	[redacted]	Warning: Missing Patient Sex, Warning: Missing Patient Race, Warning: Missing Patient Ethnicity, Warning: Missing Testing Device Name	12/7/21 12:08
3	714961	[redacted]	Warning: Missing Patient Sex, Warning: Missing Patient Race, Warning: Missing Patient Ethnicity, Warning: Missing Testing Device Name	12/7/21 12:08
4	714965	[redacted]	Warning: Missing Patient Sex, Warning: Missing Patient Race, Warning: Missing Patient Ethnicity, Warning: Missing Testing Device Name	12/7/21 12:08
5	714971	[redacted]	Warning: Missing Patient Sex, Warning: Missing Patient Race, Warning: Missing Patient Ethnicity, Warning: Missing Testing Device Name	12/7/21 12:08
6	714976	[redacted]	Warning: Missing Patient Sex, Warning: Missing Patient Race, Warning: Missing Patient Ethnicity, Warning: Missing Testing Device Name	12/7/21 12:08
7	714978	[redacted]	Warning: Missing Patient Sex, Warning: Missing Patient Race, Warning: Missing Patient Ethnicity, Warning: Missing Testing Device Name	12/7/21 12:08
8	714983	[redacted]	Warning: Missing Patient Sex, Warning: Missing Patient Race, Warning: Missing Patient Ethnicity, Warning: Missing Testing Device Name	12/7/21 12:08

If you have any questions, email [redcap.dhhs@maine.gov](mailto:redcap.dhhs@maine.gov) for assistance. This guide may be updated periodically and is current as of 01/28/2022.

## Appendix I: CSV File Data Dictionary

Files must be coded *exactly* as specified in the data dictionary. If the variables have coded values, the codes are in bold with a description of the code in parenthesis.

Variable Name	Variable Description	Acceptable values
record_id	Record ID Number	Free Text
redcap_data_access_group		LEAVE BLANK
redcap_add_timestamp	Survey Start Time	LEAVE BLANK
poc_date_received_ph	Date of Report	MM/DD/YYYY
poc_disease_event	Disease Name	COVID-19
poc_reporter_name	Reporter Name	Free Text
poc_reporter_phone	Reporter Phone	10 Digit Number
poc_reporting_fac_clia	Facility CLIA number	Free Text
poc_reporting_fac_name	Reporting Facility Name	Free Text
poc_dr_name	Provider Name	Free Text
poc_fac_name	Facility/Practice Name	Free Text
poc_dr_st1	Facility Street Address	Free Text
poc_dr_st2	Facility Street Address 2	Free Text
poc_dr_city	Facility City	Free Text
poc_dr_st	Facility State	ME
poc_dr_zip	Facility Zip Code	5 Digit Number (Set Excel cell format to "Zip Code" to retain leading zeros)
poc_dr_ph	Facility Phone Number	10 Digit Number
poc_fac_type	Facility Type	EMS Corrections Hospital Pharmacy Provider Office School Swab and Send University/College Urgent Care Other
poc_pt_fname	Patient First Name	Free Text
poc_pt_mname	Patient Middle Initial	Free Text
poc_pt_lname	Patient Last Name	Free Text
poc_date_of_birth	Patient Date of Birth	MM/DD/YYYY
poc_sex	Patient Sex	Male Female Other

poc_pt_race	Patient Race	<b>I</b> (American Indian or Alaska Native) <b>A</b> (Asian) <b>B</b> (Black or African American) <b>P</b> (Native Hawaiian or Other Pacific Islander) <b>W</b> (White) <b>O</b> (Other Race/Multiracial) <b>U</b> (Unknown)
poc_pt_ethnicity	Patient Ethnicity	<b>H</b> (Hispanic) <b>NH</b> (Not Hispanic) <b>U</b> (Unknown)
poc_pt_st1	Patient Street Address	Free Text
poc_pt_st2	Patient Street Address 2	Free Text
poc_pt_city	Patient City	Free Text
poc_pt_st	Patient State	Two Letter State Abbreviation
poc_pt_zip	Patient Zip	5 Digit Number (Set Excel cell format to "Zip Code" to retain leading zeros)
poc_pt_phone	Patient Phone Number	10 Digit Number
poc_order_num	Test ID/Accession #	Free Text
poc_collect_date	Specimen Collection Date	MM/DD/YYYY
poc_spec_source	Specimen Source	<b>NP</b> (Nasopharyngeal) <b>OP</b> (Oropharyngeal) <b>AN</b> (Anterior Nares) <b>MT</b> (Nasal Mid-turbinate) <b>B</b> (Blood) <b>OTH</b> (Other, please specify)
poc_spec_source_oth	Specimen Source Other, please specify	Free Text
poc_date_verified	Resulted Date	MM/DD/YYYY
poc_device_ag	If using an antigen POC test, Antigen device manufacturer (required if reporting an antigen test otherwise leave blank); use same response for poc_device_manufacturer and poc_device_dropdown	<b>1</b> (Abbott BinaxNOW COVID-19 Ag Card) <b>2</b> (Access Bio CareStart COVID-19 Antigen test) <b>3</b> (BD Veritor System for Rapid Detection of SARS-CoV-2) <b>4</b> (Celltrion DiaTrust COVID-19 Ag Rapid Test) <b>5</b> (Ellume COVID Antigen Test) <b>6</b> (GenBody COVID-19 Ag) <b>7</b> (InBios SCoV-2 Ag Detect Rapid Test)

		<b>8</b> (Luminostics Clip COVID Rapid Antigen Test) <b>9</b> (LumiraDx SARS-CoV-2 Ag Test) <b>10</b> (OraSure InteliSwab COVID-19 Rapid Test Pro) <b>11</b> (PHASE Sceintific INDICAID COVID-19 Rapid Antigen Test) <b>12</b> (Quidel QuickVue SARS Antigen Test) <b>13</b> (Quidel Sofia SARS Antigen FIA) <b>14</b> (Salofa Oy Sienna-Clarity COVID-19 Antigen Rapid Test Cassette) <b>15</b> (OraSure InteliSwabs COVID-19 Rapid Antigen Test)
poc_device_pcr	PCR device manufacturer (required if reporting a PCR test otherwise leave blank); use same response for poc_device_manufacturer and poc_device_dropdown	<b>1</b> (Abbott ID NOW COVID-19) <b>2</b> (BioFire Respiratory Panel 2.1-EZ) <b>3</b> (Bio-Rad Reliance SARS-CoV-2) <b>4</b> (Cepheid Xpert Omni SARS-CoV-2) <b>5</b> (Cepheid Xpert Xpress SARS-CoV-2 test) <b>6</b> (Cue COVID-19 Test for Home and OTC Use) <b>7</b> (Lucira CHECK-IT COVID-19 Test Kit) <b>8</b> (Lucira COVID-19 All-In-One Test Kit) <b>9</b> (Mesa Biotech Accula SARS-Cov-2 Test) <b>10</b> (Roche cobas SARS-CoV-2) <b>11</b> (Visby Medical COVID-19 Point of Care Test) <b>12</b> (New England Biolabs Colorimetric LAMP)
poc_testname	Test Name	94500_6_COVID19_PCR 94558_4_COVID19_Antigen
poc_result	Test Result	Positive Negative Indeterminate

hospitalized	Was the patient currently hospitalized?	y (Yes) n (No) u (Unknown)
healthcare	Does the patient work in healthcare??	y (Yes) n (No) u (Unknown)
responder	Is the patient a first responder?	y (Yes) n (No) u (Unknown)
congregate	Does the patient live in a congregate setting?	y (Yes) n (No) u (Unknown)
symptoms	Was the patient symptomatic?	y (Yes) n (No) u (Unknown)
symptom_date	Symptom onset date	MM/DD/YYYY (leave blank if asymptomatic)
poc_unit	Result Unit	LEAVE BLANK
poc_ref_range	Result Reference Range	LEAVE BLANK
poc_notes	Comments	Free Text
poc_survey_duration_sec	Administrative variable	LEAVE BLANK
poc_ph1600_complete	Complete indicator	0 (Incomplete) 1 (Unverified) 2 (Complete)
import_to_nbs	Administrative variable	LEAVE BLANK
import_to_nbs_timestamp	Administrative variable	LEAVE BLANK
administrative_use_only_complete	Administrative variable	LEAVE BLANK