



## Abbott BinaxNOW Ag Test Card Guidance For School-Based Testing October 21, 2021

### Introduction:

The State of Maine is distributing rapid point-of-care (POC) antigen (Ag) tests to Pre-K-12 schools. These tests are the Abbott BinaxNOW COVID-19 Ag Card ("Ag Cards"). This guidance describes the conditions for receiving and using the State-distributed Ag Cards in the Pre-K through 12 school setting. It may be further updated as circumstances and science evolve.

### BinaxNOW COVID-19 Ag Card - Background:

- The BinaxNOW COVID-19 Ag Card is approved by the Food and Drug Administration (FDA) for use in the detection of COVID-19 in individuals who are suspected of COVID-19 because of the acute presentation of [symptoms consistent with COVID-19](#) and who are within the first seven days of onset of symptoms. More information on the [BinaxNOW COVID-19 Ag Card test is available from FDA](#)
- Notwithstanding the Emergency Use Authorization (EUA), Federal officials have also recommended the test be used among asymptomatic individuals; however, less is known about the efficacy of its use in asymptomatic individuals. There are settings where antigen testing in asymptomatic individuals may be appropriate to support education and school sponsored activities.

### Maine DHHS Guidance on Use of BinaxNOW COVID-19 Ag Card Testing in the School Setting

- **Approved Uses:** Maine DHHS is currently limiting use of this test to the following situations in the school setting. A school does not need to offer testing in all of these approved uses; they are options.
  1. Adults and children who have [symptoms consistent with COVID-19](#) and are within the first seven days of symptom onset.
    - A positive Ag Card test result in a symptomatic individual indicates that the individual is highly likely to have COVID-19.
    - A negative BinaxNOW test result is strongly suggestive that the individual does not have COVID-19. However, an individual in a high-risk setting, who has a known COVID-19 exposure, and/or who continues to have symptoms suggestive of COVID-19 should be further evaluated by their personal health care provider. A confirmatory PCR test may be considered in such situations.

2. Serial testing of asymptomatic unvaccinated staff in public and private Pre-K-12 schools who have been identified as a [close contact of a confirmed COVID-19 case](#). Under this approach, asymptomatic adults with serially negative results can maintain their core roles and not quarantine, potentially avoiding workforce shortages.
  - A negative BinaxNOW Ag Card test result suggests that the adult 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. Symptomatic close contacts should be further evaluated, and a confirmatory PCR test should be considered.
  - An asymptomatic adult who has been identified as a close contact of a confirmed COVID-19 case and a negative BinaxNOW Ag Card test may work only on the day of the negative BinaxNOW result with proper personal protective equipment and symptom monitoring.
3. Screening testing of all participating unvaccinated students and adults immediately prior to a school-sponsored event, such as graduation or prom. Under this approach, schools may limit participation to asymptomatic individuals who screen negative using the Ag Card. Screening under this approach does not replace local public health mitigation policies, such as masking and physical distancing.
  - A positive Ag Card test result in an asymptomatic individual indicates that the individual is highly likely to have COVID-19 and would not participate in or attend the school sponsored event.
  - Testing should occur no more than 6 hours before a scheduled event to ensure any infectious individual can be identified as close to the event as possible.
4. Twice-weekly testing of all unvaccinated students and supervising adults participating in school-sponsored extracurricular activities, such as performing arts and sports. Under this approach, schools may limit participation in these activities to those with negative results. Twice-weekly testing would not replace local public health mitigation policies, such as masking, physical distancing, and symptom screening.
5. Screening of unvaccinated 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, unvaccinated students and staff would be screened using an Ag Card following a longer vacation break, as rates of transmission increase following a period of vacation and travel. Screening students twice within a one-week period would increase the likelihood of identifying cases that result from exposure during the break.
  - Testing should occur prior to the start of school and again 3 to 5 days afterward.
  - A positive Ag Card test result in an asymptomatic individual indicates that the individual is highly likely to have COVID-19 and would not attend school.

6. One time testing of unvaccinated individuals identified as close contacts—student or staff—before they begin their quarantine. This would be used if a person is not enrolled in pooled testing, is identified as a close contact, and is unvaccinated. After testing, they would need to leave school to begin their quarantine period. Schools may offer additional testing to these individuals 3-7 days following exposure, so long as quarantined individuals do not physically enter the school building, for example by using a drive-through method. Testing of quarantined individuals does not shorten or alter their quarantine status.
7. One time testing of identified close contacts—students or staff—who are fully vaccinated within 5-7 days following exposure. An individual may or may not be enrolled in pooled testing, is identified as a close contact of a confirmed case and is fully vaccinated. The Maine CDC, following U.S. CDC Guidance, recommends that fully vaccinated individuals identified as a close contact do not need to quarantine, but should be tested 5-7 days following exposure.
8. Screening of individuals who are members of a positive pool, as outlined in the [Maine K-12 Pooled Testing Guidance](#).

**Note:** An individual is considered vaccinated 14 days after receiving their final vaccine dose.

### **Maine DHHS Requirements for Pre-K-12 Schools to Use BinaxNOW:**

Maine DHHS has outlined the following seven core requirements that schools need to meet to receive and use state-supplied BinaxNOW COVID-19 Ag Cards:

1. The school agrees to use the tests in accordance with Maine DHHS Guidance, which may be updated based on evolving science.
2. The school or school administrative unit(SAU) has either a valid CLIA (Clinical Laboratory Improvement Amendments) 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 must complete the BinaxNOW online training modules to ensure the test is used consistent with the manufacturer’s instructions. That training is available at: [Abbott BinaxNOW Online Training](#)
4. Have a process to obtain parent/staff [consent for testing](#).
5. The school must immediately report all results—positive and negative—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 all negative, positive, and inconclusive test results within 24 hours.

6. The school must be prepared to direct individuals to a [testing site](#) and/or identify a health care provider to order a confirmatory PCR test when indicated.
7. The school must have a way to contact each person with test results. At a minimum, positive results should be relayed by telephone or in person. Negative results could be shared by email or text message.

**Specimen collection:** The following methods may be used for anterior nares specimen collection for BinaxNOW Ag testing:

1. Any child physically able to may conduct self-swabbing that is supervised by an individual who is [appropriately trained](#) on the process for specimen collection for BinaxNOW Ag testing so long as they are able.

### **Supply and Distribution of BinaxNOW Ag Cards:**

Schools that would like to use the BinaxNOW Ag Cards must apply using the [Maine DHHS online application form](#). NOTE: BinaxNOW test cards come in kits (40 cards per kit) schools should order kits based on school population and use. Round up to meet the kit definition. Kits cannot be split and should be stored and used per BinaxNOW guidance. Schools should place an order at least 7 days prior to the date they are needed for testing.

### **Procedure for BinaxNOW Specimen Collection and Testing:**

- The BinaxNOW COVID-19 Ag Card can be used to test nasal swab samples directly using a dual nostril collection. The individual collecting the sample uses gentle rotation, pushing the swab until resistance is met at the level of the turbinate (less than one inch into the nostril) and then rotates the swab 5 times or more against the nasal wall and then slowly removes from the nostril. Using the same swab, the individual repeats sample collection in the other nostril.
- To perform the test following specimen collection from the patient, 6 drops of extraction reagent from a dropper bottle are added to the top hole of the swab well. The patient sample is inserted into the test card through the bottom hole of the swab well, and firmly pushed upwards until the swab tip is visible through the top hole. The swab is rotated 3 times clockwise and the card is closed, bringing the extracted sample into contact with the test strip. Test results are interpreted visually at 15 minutes based on the presence or absence of visually detectable pink/purple colored lines. Results should not be read after 30 minutes.
- Prior to beginning the testing process, the test administrator should put on Personal Protective Equipment (PPE), including surgical mask and eye protection in accordance with CDC guidance, followed by sanitizing hands and putting on clean gloves. PPE does not need to be changed between each test, unless any piece becomes visibly soiled.

### **Storage and Stability:**

Each BinaxNOW Ag Tests comes in a test “Kit” which includes 40 individually wrapped cardboard, book-shaped hinged Test Cards containing the test strip, as well as 40 collection

swabs, and one 10mL bottle of extraction reagent. Kits must be stored at 2-30°C. Ensure all test components are at room temperature before use.

The test is stable until the expiration date marked on the outer packaging and containers; however, Abbott extended the expiration from six months to nine months in March of 2021. Some kits manufactured prior to this extension may be used beyond their listed expiration period. For identification of which kits this may apply to, please reference the attached document. ([Abbott BinaxNOW Shelf-Life Guidance](#) ) Facilities that are unable to use their allotment prior to expiration may transfer the tests to another facility to reduce waste. The receiving facility must adhere to all the guidelines outlined in this document.

### **Updates:**

Please note that this Guidance will continue to be reviewed and may be updated once there is additional data on the BinaxNOW Ag Test Card, including its uses and efficacy, and as requests are approved.

### **Resources:**

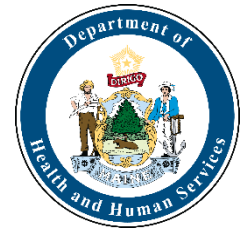
- [Directions for completing CLIA Certificate of Waiver for Schools](#)
- [Sample Consent Form](#)
- [Standard Operating Procedure for Responding to a Positive Case](#)

### **Appendices:**

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

*(Continue on to next page for Appendices)*

## Appendix A: Maine CDC Point-of-Care Test Reporting: November 6, 2020



### 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 Siiri Bennett, 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):

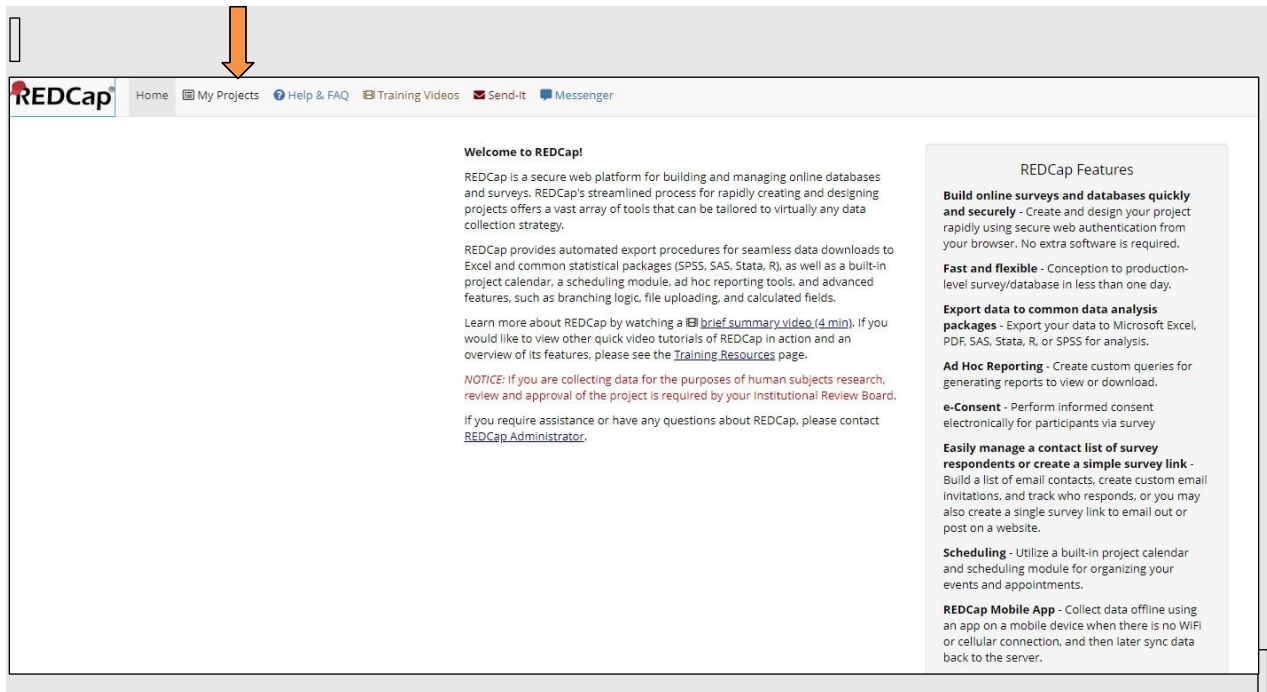
- First name
- Middle initial
- Last name
- Date of birth
- Sex
- Ethnicity
- Race
- Patient address
- Patient phone number
- Specimen collection date (all results must be reported within 24 hours)
- Specimen source
- Test results
- Comments (clinical/laboratory information about the patient).

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](#).

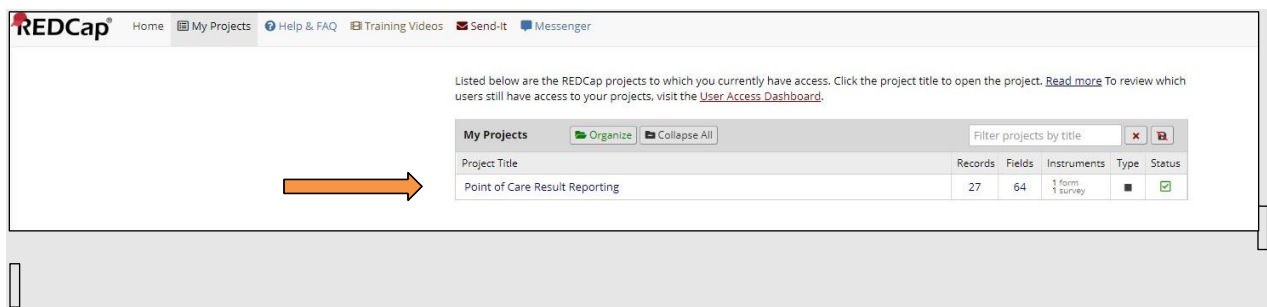
Once submitted, the information is automatically processed directly into Maine CDC’s National Electronic Disease Surveillance System. If you identify an error after submission, please contact [redcap.dhhs@maine.gov](mailto:redcap.dhhs@maine.gov) to correct the issue.

## CSV uploads

If you indicated that your facility/organization will routinely test more than 20 samples a day, you will get a second email that has information about a REDCap account. This email includes your username and a link to set a password and log in. Once you set your password you will see the REDCap homepage screen. Click on the My Projects tab.



Click on the Point of Care Result Reporting Project



On the left-hand side, click on the Data Import Tool



The screenshot shows the REDCap interface for a project titled "Point of Care Result Reporting" (PID: 39). The interface is divided into a left sidebar and a main content area. The sidebar contains navigation options such as "My Projects", "REDCap Messenger", "Project Home and Design", "Data Collection" (showing "No records"), "Applications" (with "Data Import Tool" and "Field Comment Log" links), and "Reports". An orange arrow points to the "Data Import Tool" link. The main content area features the "Department of Health and Human Services" logo and the "Maine Center for Disease Control and Prevention" name. Below this, the "Project Home" section provides general dashboard information, including a list of users with access to the project and project statistics.

Current Users (7)	
User	Expires
coronavirus (Corona Virus)	never
holly.howieson (Holly Howieson)	never
jenna.strathdee (Jenna Strathdee)	never
meccdc:redcap (MeCDC REDCap)	never
sara.robinson (Sara Robinson)	never
trevor.brown (Trevor Brown)	never
trevorbrown (Trevor Brown)	never

Project Statistics	
Records in project	Total: 27 / In group: 0
Most recent activity	11-04-2020 14:24
Space usage for docs	0.06 MB

A sample completed template is available as a .csv file for reference. Many of the fields can be pre-populated for your facility/organization simplifying future data entry. The .csv file data dictionary is included as Appendix I.

If you need a new template, click on the Download your Data Import Template link. If you already have the data ready, scroll to the bottom and verify the information in the questions in the green box.

- Record format: verify if your data is in rows or columns
- Format for date and datetime values: select if your dates start with the month or the day
- Allow blank values to overwrite existing saved values? No (keep as default)
- Name the imported records automatically? Yes (keep as default)

Click the Choose File button and navigate to where your file is saved. Click on Upload File once your file name appears.

**Instructions:**

- 1.) Click the link below to download your data import template as a CSV (comma delimited) file. Save it locally to your computer and then open it to begin filling it with the data you wish to import.
  - [Download your Data Import Template \(with records in rows\)](#)
  - OR
  - [Download your Data Import Template \(with records in columns\)](#)
- 2.) In each column of the Data Import Template file that you downloaded, place the data for each record that you wish to import. Once all your data has been added, save the file.
  - Be sure not to change the Variables/Field Names in the file or an error may occur.
  - All multiple choice fields (e.g., dropdown, radio) must have the raw coded value (rather than the choice label) entered in those cells, or else it cannot be processed. These can be found in the [Codebook](#).
  - Any empty rows or columns in the file can be safely deleted before importing the file. Doing this reduces the upload processing time, especially for large projects.
- 3.) Click the 'Browse' or 'Choose File' button below to select the file on your computer, and upload it by clicking the 'Upload File' button.
- 4.) Once your file has been uploaded, the data will NOT be immediately imported but will be displayed and checked for errors to ensure that all the data is in correct format before it is finally imported into the project.

**Record format:** The file to be uploaded has its records stored as separate

**Format for date and datetime values:**

**Allow blank values to overwrite existing saved values?**

**Name the imported records automatically (force record auto-numbering)?**

**Upload your CSV file:**

No file chosen

If there is an error in the file, REDCap will give you an error message and tell you what the error is, and what column or row the error is in.

**Point of Care Result Reporting** PID 39

**Data Import Tool**

**Record format:** The file to be uploaded has its records stored as separate

**Format for date and datetime values:**

**Allow blank values to overwrite existing saved values?**

**Name the imported records automatically (force record auto-numbering)?**

**Upload your CSV file:**

No file chosen

**Errors were detected in the import file that prevented it from being loaded.**

There is 1 error (shown in red in the error table below) in this dataset. Please correct any errors and upload the file again.

ERROR DISPLAY TABLE			
Record	Field Name	Value	Error Message
5-1	poc_sex	M	The value is not a valid category for poc_sex

If the file is uploaded successfully, you will get a confirmation that the data was uploaded and is available for review.

**Data Import Tool**

Record format: The file to be uploaded has its records stored as separate

Format for date and datetime values:

Allow blank values to overwrite existing saved values?

Name the imported records automatically (force record auto-numbering)

Upload your CSV file:

No file chosen

**Your document was uploaded successfully and is ready for review.**  
 You are now required to view the Data Display Table below to approve all the data before it is officially imported into the project. Follow the instructions below.

**Instructions for Data Review**

The data you uploaded from the file is displayed in the Data Display Table below. Please inspect it carefully to ensure that it is all correct. After reviewing it, **click the 'Import Data' button at the bottom of this page** to import this data into the project.

**KEY for Data Display Table below**

Black text = New Data
Gray text = Existing data (will not change)
(Red text) = Data that will be overwritten
Red box = error
Orange box = warning

Once you have reviewed the data, click the Import Data button at the bottom of the page. If the import is successful, you will get a notification that records were created.

**Import Successful!** 2 records were created or modified during the import.

The data you uploaded from the file was successfully imported into the project. If you wish to import more data, you may use the box above to select another file on your computer.

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 the date in the footer.

## Appendix I: CSV File Data Dictionary

Required fields are highlighted in blue. If the variables has 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_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
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
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_manufacturer	Device manufacturer	Free Text
poc_testname	Test Name	94500_6_COVID19_PCR 94558_4_COVID19_Antigen 94564_2_COVID19_AB_IgM 94563_4_COVID19_AB_IgG 94547_7_COVID19_AB_IgGlgM 94562_6_COVID19_AB_IgA 94762_2_COVID19_Total_AB
poc_result	Test Result	Positive Negative Indeterminate
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	<b>0</b> (Incomplete) <b>1</b> (Unverified) <b>2</b> (Complete)
import_to_nbs	Administrative variable	LEAVE BLANK

import_to_nbs_timestamp	Administrative variable	LEAVE BLANK
administrative_use_only_complete	Administrative variable	LEAVE BLANK