



Rapid Antigen Test Guidance

UPDATED: October 21, 2021

Introduction:

The State of Maine is distributing rapid point-of-care (POC) antigen (Ag) tests, Abbott BinaxNOW COVID-19 Ag Card and AccessBio CareStart™ Antigen Rapid Diagnostic Test. This guidance describes the conditions for receiving and using the State-distributed Ag tests and was initially issued on October 29, 2020 and was previously updated on November 9, 2020, December 15, 2020, January 25, 2021, May 27, 2021, August 30, 2021, and September 29, 2021. It may be further updated as circumstances and science evolve.

The Maine Department of Health and Human Services (DHHS) is distributing Rapid Antigen tests, as they are received, in periodic installments in two ways. First, it is working with Walgreens to make Ag tests accessible to residents across the State of Maine at its drive-through sites. Second, it will distribute Ag Cards to facilities not directly receiving them from the Federal government that agree to the terms described in this guidance. Since demand may exceed supply, DHHS is prioritizing facilities that use them for high-risk populations, in high-risk settings, or where access to COVID-19 testing is otherwise limited.

Maine DHHS Guidance on Use of Rapid Antigen (Ag) Testing

- **Approved Uses:** Given the limited test experience, constrained supplies, and current FDA approval for use of Rapid Ag tests, Maine DHHS is currently limiting use of this test to the following situations:
 1. Adults and children who have [symptoms consistent with COVID-19](#) and are within the first seven days of onset of symptom onset.
 2. Serial testing—defined as antigen testing daily or every other day—of asymptomatic unvaccinated adults who have been identified as a [close contact of a confirmed COVID-19 case](#). Using this approach, serial testing of asymptomatic adults with negative results could support the ability of those adults to maintain their core roles and potentially avoid workforce shortages. Maine CDC approval is not required for this testing. **(Updated 1/25/21)**
 3. One time testing of asymptomatic fully vaccinated individuals who have been identified as a close contact of a confirmed case, administered between day 5 and 7 following exposure. **(Updated 10/21/21)**
 4. Surveillance testing—defined as antigen testing two times per week—of asymptomatic unvaccinated adults who are at higher risk of contracting COVID-19 as a result of working or being in a high transmission setting, such as healthcare, hospitality and service, or environments where individuals are in close proximity to each other or are interfacing with the public. Using this approach, twice weekly

- testing using BinaxNOW could serve as a surveillance tool to ensure an individual has not contracted the virus. School-Based BinaxNOW testing guidance is available on the Maine Department of Education [website](#). (Updated 5/27/21)
5. Part of a surveillance testing plan for licensed nursing facilities or congregate care settings as specified in guidance issued by the Department and follow the approved uses outlined in “Revised Guidance for Staff Testing and Community Engagement.” [Testing and Community Engagement Guidance](#) (Updated 5/5/21)
- **Specimen collection:** The following methods may be used for anterior nares specimen collection for Rapid Ag testing:
 1. Individuals 6 years and older may conduct self-swabbing that is supervised by an individual who is [appropriately trained](#) on the process for specimen collection for Rapid Ag testing. (Updated 5/27/21)
 2. Children under 6 years old may have the specimen collected by a parent or guardian under the supervision of an individual who is appropriately trained on the process for specimen collection, or by a health care provider who is [appropriately trained](#) to conduct anterior nares swabbing. (Updated 5/27/21)

Maine DHHS Requirements for Facilities to Use Rapid Ag Tests:

Maine DHHS has outlined six core requirements that facilities need to meet to receive and use state-supplied Rapid Ag tests:

1. The facility is not currently receiving Rapid Ag tests from the federal government and will let DHHS know if it starts to receive them from the federal government.
2. The facility agrees to use the tests in accordance with Maine DHHS Guidance, which may be updated based on evolving science.
3. The facility 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. (Updated 11/09/20)
4. The facility must complete the online training modules to ensure the test is used in a manner consistent with the manufacturer’s instructions. BinaxNOW training is available at: [Abbott BinaxNOW Online Training](#). CareStart training is available at: [CareStart Ag Test Instructional Video](#). (Note: CareStart tests can be conducted with a Nasopharyngeal (NP) or an Anterior Nasal (AN) collection method).
5. The facility must immediately report all 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: the REDCap electronic reporting portal. The facility must report all negative, positive, and inconclusive test results within 24 hours. (Updated 11/09/20)
6. The facility 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.

Clinical Considerations for Use Rapid Ag Testing and Use of Reflex PCR Testing:

1. Use of Rapid Antigen cards to test adults and children who exhibit [symptoms suggestive of COVID-19 infection](#):
 - A negative Ag 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. A confirmatory PCR test should be considered in such situations.
 - A positive Ag test result in a symptomatic individual indicates that the individual is a probable case. **(Updated 12/15/20)**
 - Any facilities with three positive tests in a 14-day period from different households should send at least the first three positive antigen tests out for confirmatory PCR testing. This may indicate an outbreak in the facility. **(Updated 2/12/21)**

2. Serial testing—defined as antigen testing daily or every other day—of asymptomatic adults who have been identified as a close contact of a confirmed COVID-19 case (no Maine CDC approval required) **(Updated 1/25/21)**:
 - An asymptomatic adult who has been identified as a close contact of a confirmed COVID-19 case and a negative Ag test may work only on the day of the negative result with proper personal protective equipment and symptom monitoring. **(Updated 01/25/21)**
 - A positive Ag test result indicates that the adult is a probable case.

3. Surveillance testing—defined as antigen testing two times per week—of asymptomatic adults (no Maine CDC approval required) **(Updated 5/27/21)**:
 - A negative Ag test result suggests that the individual does not have COVID-19 at the time the test was taken.
 - A positive Ag test result indicates that the individual is a probable case.

Supply and Distribution of Ag Test:

Facilities that would like to use the Ag Cards must apply using the [Maine DHHS online application form](#). Given limited supply, the Department cannot fulfill all requests and will prioritize those facilities that will be offering testing to high-risk populations, in high-risk settings, or serve populations otherwise lacking access to testing. Of note, organizations should order Ag Card tests in batches of 20 because tests are packaged in a “kit” that includes 20 or 40 test cards along with the necessary test controls and reagent and cannot be split. **(Updated 11/09/20)**

Procedure for Specimen Collection:

- The Ag test can be used to test nasal swab samples directly using a dual nostril collection. Collection requires inserting the swab into the nostril exhibiting the most visible drainage, or the nostril that is most congested if drainage is not visible. The individual collecting the sample uses gentle rotation, pushing the swab until resistance is met at the level of the turbinates (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.

- Please follow the manufacturer’s guidelines for testing the sample. Refer to either Abbott’s BinaxNOW instructions or AccessBio’s CareStart instructions depending on the type of Rapid Ag test being used.

Storage and Stability:

Ag Tests come in a test “Kit” which includes individually wrapped Test Cards containing the test strip, the collection swabs, and 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, it cannot be used once the date has passed the expiration date marked on the packaging. In some instances, kits manufactured in early 2021 have an expiration date that has been extended. For more information on which lot numbers are eligible for this extension, please reference the Maine CDC [website](#). 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. **(Updated 5/27/21)**

Updates:

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

Appendices:

- **Appendix A: Directions for Completing CLIA Certificate of Waiver Application Needed to Conduct Point-of-Care COVID-19 Testing (Updated 8/30/2021)**
- **Appendix B: Maine CDC Point-of-Care Test Reporting (REDCap reporting system)**

(Continue on to next page for Appendices)

Appendix A: Directions for Completing CLIA Certificate of Waiver Application Needed to Conduct Point-of-Care COVID-19 Testing: November 6, 2020

NOTE: Full information on how to obtain a CLIA Certificate of Waiver can be found in the CMS document, “How to Obtain a CLIA Certificate of Waiver: <https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/howobtaincertificateofwaiver.pdf>

Key steps for this completing the application CLIA Certificate of Waiver required to obtain and use the Abbott BinaxNOW COVID-19 Antigen Cards are outlined below:

1. Get the “CMS Certificate of Waiver Form 116”, which can be completed either as a fillable PDF form, or on paper. You can get the form in any of the following ways:
 - See PDF version of the form, attached to this email
 - Download the form from www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms116.pdf
 - Contact Maine CLIA program: CLIALAB.DHHS@Maine.gov. (Updated 8/30/21)
2. If you plan to complete the form electronically, download the PDF application and save it to your computer; if you plan to complete it on paper, print off the application. Note, the application is 9 pages long, but the application itself is comprised of the first 4 pages; the remaining pages are instructions for filling out the application.
3. **Complete the form using the following steps:**

Section I. General Information

- Check box for “Initial Application”
- “CLIA Identification Number”: leave blank
- “Facility Name: Enter name of your organization
- “Federal Tax Identification Number”: Enter Federal Tax ID # for your organization
- “Email address”: Enter email for you or the primary care contact at your organization
- “Telephone No.”: Enter phone for you or primary care contact at your organization
- “Fax No.”: Enter Fax for your organization
- “Facility Address”: Enter physical location for address where testing will be done
- “Mailing/Billing Address” Enter if different from your physical address
- “Corporate Address”: Enter if different from Facility Address
- “Name of Service Director”: Name of person responsible for testing at your facility

Section II. Type of Certificate Requested:

- Check “Certificate of Waiver”

Section III. Type of Laboratory

- Check the type of facility that best reflects your entity, or enter description under “Other”

Section IV. Hours of Laboratory Testing

- Enter the hours and days that anticipate doing testing at your facility (best estimate is OK)

Section V. Multiple Sites

- Select “No” if planning to do testing only at your site
- Select “Yes” if planning to do testing at multiple sites in your organization, and complete remaining questions in this section

Section VI. Waived Testing

- Write in “COVID-19 Ag Card to test for detection of SARS-CoV-2”
- **Estimated Total Annual Test:** Fill in your best estimate of the total number of tests you predict you will be conducting annually volume at your site. You can estimate based on the number of tests received or a percentage of your population.

Section VII. Skip

Section VIII. Skip

Section IX. Type of Control:

- Check the box that best describes the ownership type of your organization

Section X. Director Affiliation with Other Laboratories

- If the individual overseeing this testing site is also overseeing other CLIA Waived sites, please list the sites.

Signature

- Print the name and include signature for person most responsible for planned testing at your facility

Send your completed application via email (attach completed PDF) or paper to Maine’s CLIA program director:

CliaLab.DHHS@maine.gov (Updated 12/15/20)

Division of Licensing & Regulatory Services

41 Anthony Avenue, Station #11

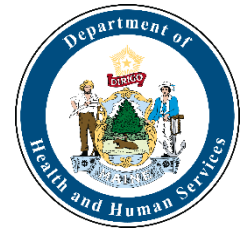
Augusta, ME 04333-0011

FAX: (207) 287-9304

[Fee: Note there is a \$180 fee required for acquiring a CLIA Certificate of Waiver, but that should NOT be sent with this initial application. The state will send you an invoice for the fee once your application is reviewed and processed.]

(Continue on to next page for additional Appendix)

Appendix B: 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 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.

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 Maggie Bordeau, 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

“AccessBio CareStart” 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):

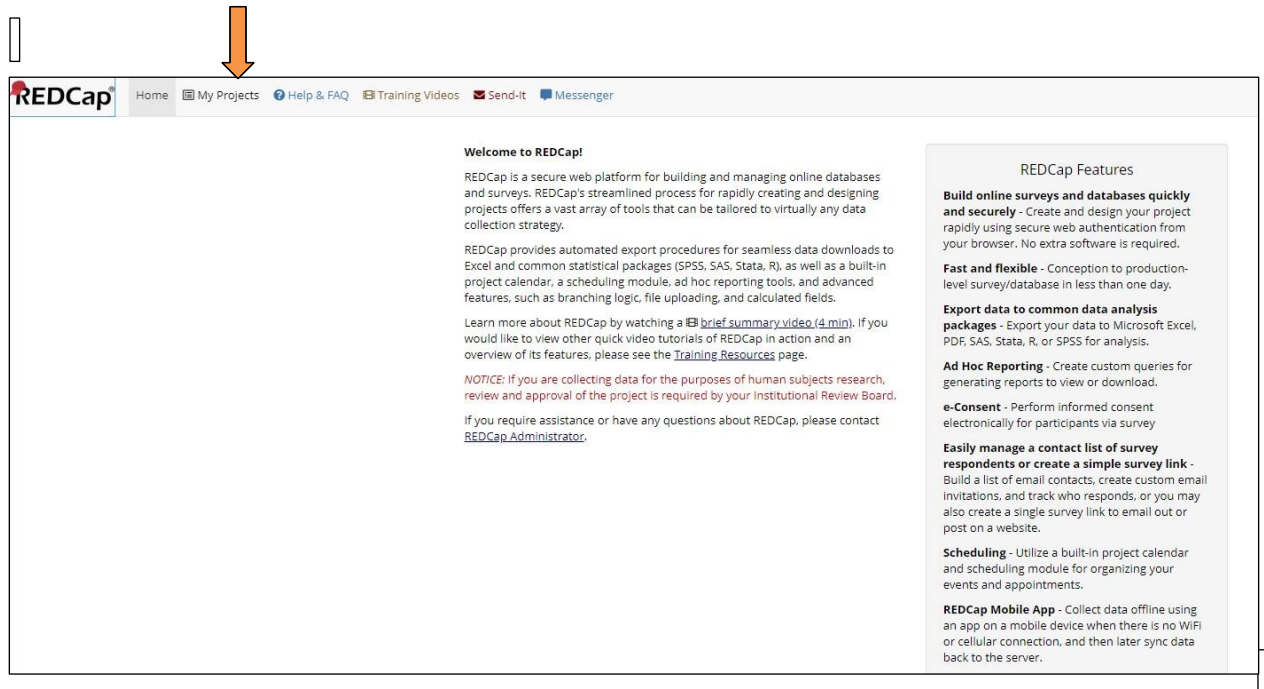
- First name
- Middle initial
- Last name
- Date of birth
- Sex
- Ethnicity
- Race
- Patient address
- Patient phone number
- Specimen collection date (all results must be reported within 24 hours)
- Specimen source
- Test results
- Comments (clinical/laboratory information about the patient).

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 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

Department of Health and Human Services
Maine Center for Disease Control and Prevention

Point of Care Result Reporting PID: 39

Project Home

The tables below provide general dashboard information, such as a list of all users with access to this project, general project statistics, and upcoming calendar events (if any).

Current Users (7)		Project Statistics	
User	Expires	Records in project	Total: 27 / In group: 0
coronavirus (Corona Virus)	never	Most recent activity	11-04-2020 14:24
holly.howieson (Holly Howieson)	never	Space usage for docs	0.06 MB
jenna.strathdee (Jenna Strathdee)	never		
meccdc:redcap (MeCDC REDCap)	never		
sara.robinson (Sara Robinson)	never		
trevor.brown (Trevor Brown)	never		
trevorbrown (Trevor Brown)	never		

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 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	I (American Indian or Alaska Native) A (Asian) B (Black or African American)

		P (Native Hawaiian or Other Pacific Islander) W (White) O (Other Race/Multiracial) U (Unknown)
poc_pt_ethnicity	Patient Ethnicity	H (Hispanic) NH (Not Hispanic) U (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	NP (Nasopharyngeal) OP (Oropharyngeal) AN (Anterior Nares) MT (Nasal Mid-turbinate) B (Blood) OTH (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	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