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Abbott BinaxNOW Ag Test Card Guidance

UPDATED: August 30, 2021

Introduction:

The State of Maine is distributing rapid point-of-care (POC) antigen (Ag) tests, Abbott BinaxNOW COVID-19 Ag Card ("Ag Cards"). This guidance describes the conditions for receiving and using the State-distributed Ag Cards and was initially issued on October 29, 2020 and was previously updated on November 9, 2020, December 15, 2020, January 25, 2021, and May 27, 2021. 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
- The Maine Department of Health and Human Services (DHHS) is distributing Ag Cards, as they are received, in periodic installments in two ways. First, it is working with Walgreens to make Ag Cards 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 BinaxNOW COVID-19 Ag Card Testing

- **Approved Uses:** Given the limited test experience, constrained supplies, and current FDA approval for use of BinaxNOW Ag Card 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 adults who have been identified as a close contact of a confirmed COVID-19 case. Using this approach, serial BinaxNOW 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. Surveillance testing—defined as antigen testing two times per week—of asymptomatic unvaccinated adults a 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)**

4. Part of a surveillance testing plan for licensed nursing facilities or congregate care settings as specified in guidance issued by the Department on February 1, 2021 and follow the approved uses outlined in "Revised Guidance for Staff Testing and Community Engagement." (Revised Guidance for LTC and Congregate Settings) **(Updated 2/12/21)**

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

Maine DHHS has outlined six core requirements that facilities need to meet to receive and use state-supplied BinaxNOW COVID-19 Ag Cards:

1. The facility is not currently receiving BinaxNOW Ag Cards 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 BinaxNOW online training modules to ensure the test is used in a manner consistent with the manufacturer's instructions. That training is available at: Abbott BinaxNOW Online Training
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 of BinaxNOW COVID-19 Ag Card Testing and Use of Reflex PCR Testing:

1. Use of BinaxNOW COVID-19 Ag Card to test adults and children who exhibit symptoms suggestive of COVID-19 infection:
   - 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. A confirmatory PCR test should be considered in such situations.
   - A positive Ag Card 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 BinaxNOW Ag Card test may work only on the day of the negative BinaxNOW result with proper personal protective equipment and symptom monitoring. **(Updated 01/25/21)**
   - A positive BinaxNOW 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 BinaxNOW Ag Card test result suggests that the individual does not have COVID-19 at the moment the test was taken.
   - A positive BinaxNOW test result indicates that the individual is a probable case.

Supply and Distribution of BinaxNOW Ag Cards:

Facilities that would like to use the BinaxNOW 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. Facilities are encouraged to work with their respective professional or membership associations to support logistics coordination and distribution of test cards. Of note, organizations should order BinaxNOW Ag Card tests in batches of 40 because tests are packaged in a "kit" that includes 40 test cards along with the necessary test controls and reagent and cannot be split. **(Updated 11/09/20)**

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. 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.

- 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.

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, 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 the BinaxNOW Ag Test Card, including its 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)

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

(including BinaxNOW COVID-19 Antigen Card Tests)

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. **<u>Complete the form using the following steps</u>**:

   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 "Abbott BinaxNOW 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 BinaxNOW Ag 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)

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 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):

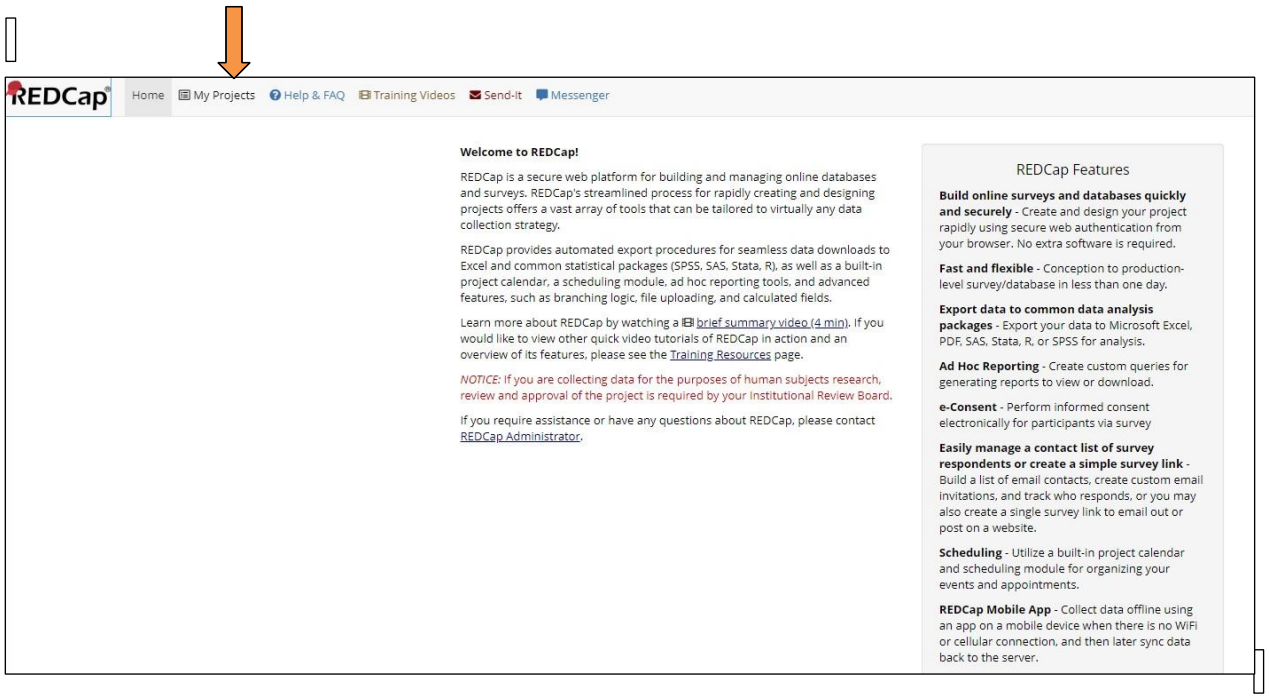
- First name
- Middle initial
- Last name
- Date of birth
- Sex
- Ethnicity
- Race
- Patient address
- Patient phone number
- Specimen collection date (all results must be reported within 24 hours)
- Specimen source
- Test results
- Comments (clinical/laboratory information about the patient).

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.

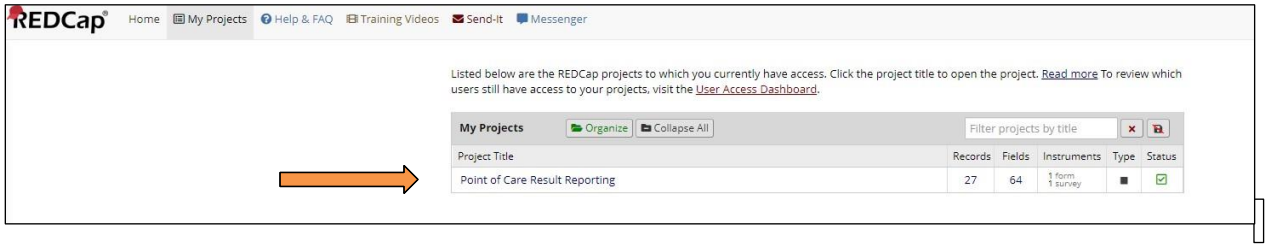
Once submitted, the information is automatically processed directly into Maine CDC's National Electronic Disease Surveillance System. If you identify an error after submission, please contact redcap.dhhs@maine.gov to correct the issue.

CSV uploads

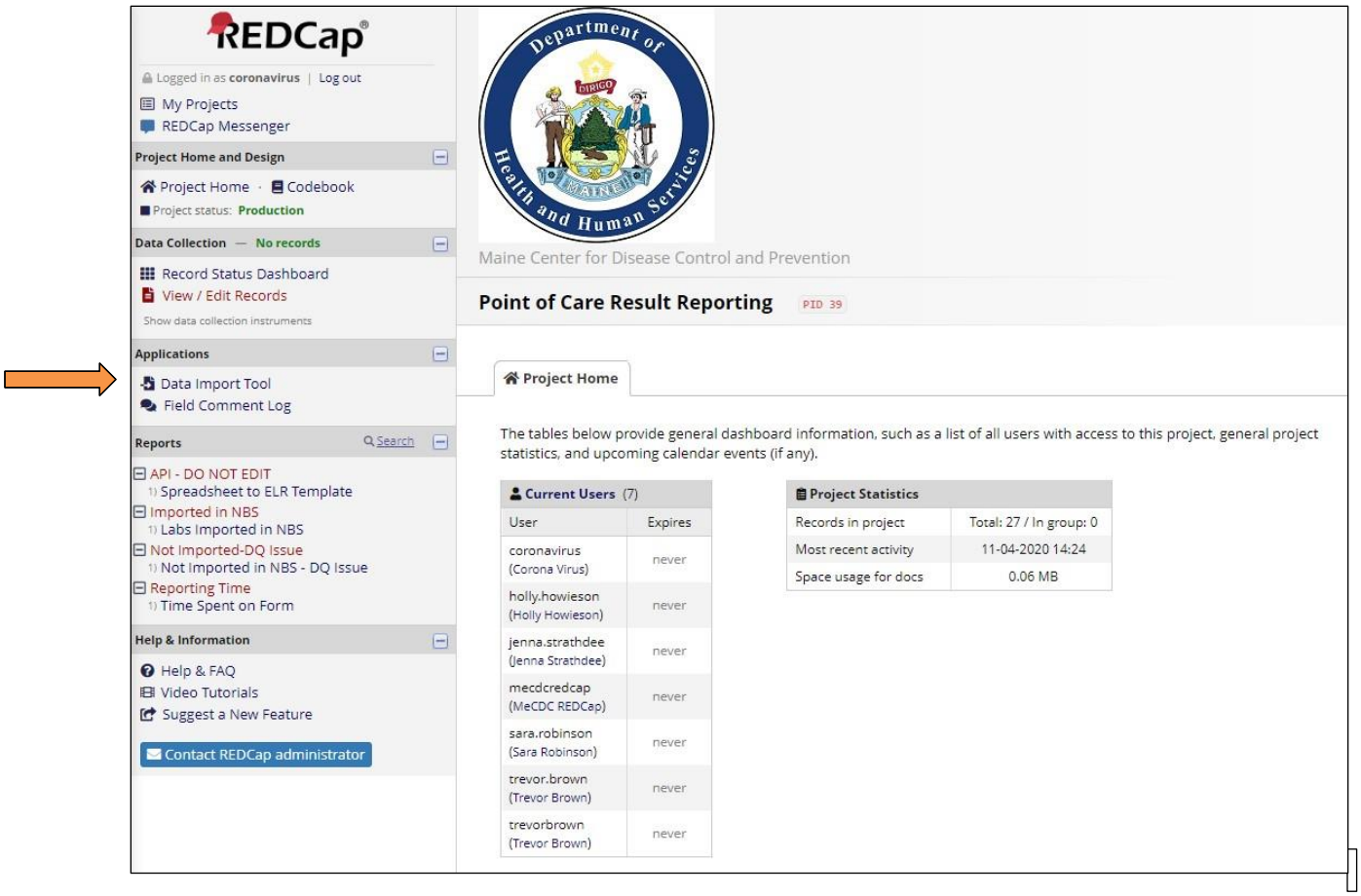
If you indicated that your facility/organization will routinely test more than 20 samples a day, you will get a second email that has information about a REDCap account. This email includes your username and a link to set a password and log in. Once you set your password you will see the REDCap homepage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

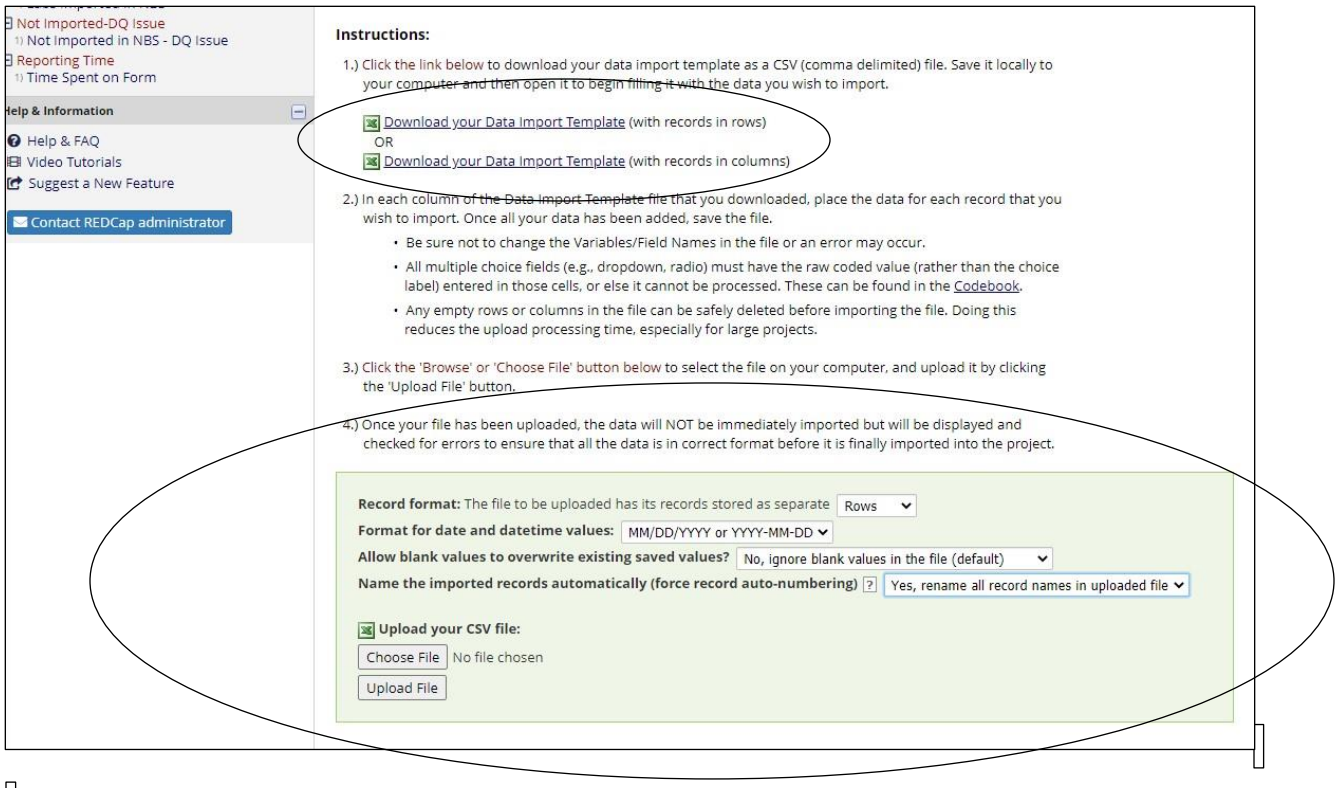


A sample completed template is available as a .csv file for reference. Many of the fields can be pre-populated for your facility/organization simplifying future data entry. The .csv file data dictionary is included as Appendix I.

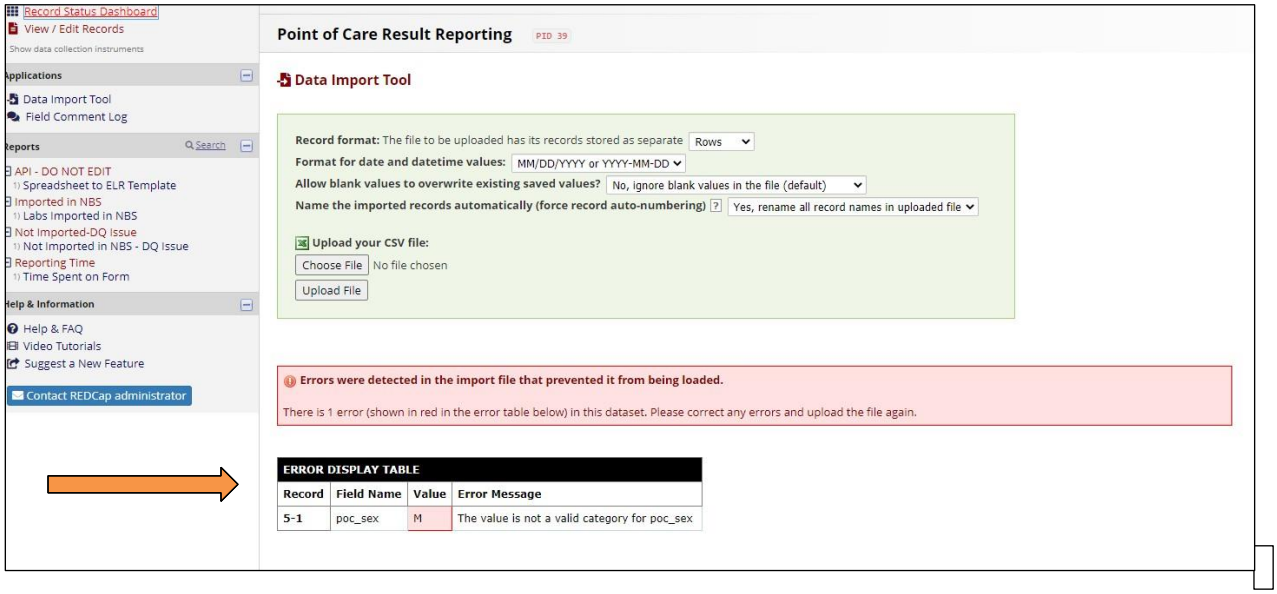
If you need a new template, click on the Download your Data Import Template link. If you already have the data ready, scroll to the bottom and verify the information in the questions in the green box.

- 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.

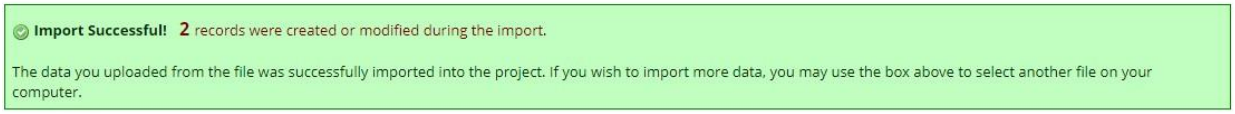


If there is an error in the file, REDCap will give you an error message and tell you what the error is, and what column or row the error is in.



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

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.



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_IgGIgM 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