Centers for Disease Control and Prevention (CDC)

National Center for Environmental Health (NCEH)

Division of Laboratory Sciences (DLS)

NEWBORN SCREENING AND
MOLECULAR BIOLOGY BRANCH
(NSMBB)

NEWBORN SCREENING QUALITY
ASSURANCE PROGRAM (NSQAP)
PORTAL

QUALITY CONTROL USER GUIDE

June 2021

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1. Introduction

The NSMBB Newborn Screening Quality Assurance Program (NSQAP) Portal has been designed to accept participant quality control (QC) data using two options: manual data entry and data upload. Participants are advised to consider their laboratory's internal workflow, processes, and needs, before choosing **one** of the two options for data submission. Additionally, participants are advised to consider the following before deciding on a data entry option:

- 1. Participants are permitted to only use one data entry option (manual or upload) per event.
- 2. If the upload option is chosen, data must be consolidated into a single template for upload. Participants are required to download the template, enter data from all QC programs into a single template file and save the file before uploading. If multiple uploads are performed, the previous file will be overwritten.
- The review feature enables participants to review and edit manually entered or uploaded data in the Portal directly from the review page.

The following pages describe how to enter data into the NSQAP Portal once a data entry option is chosen.

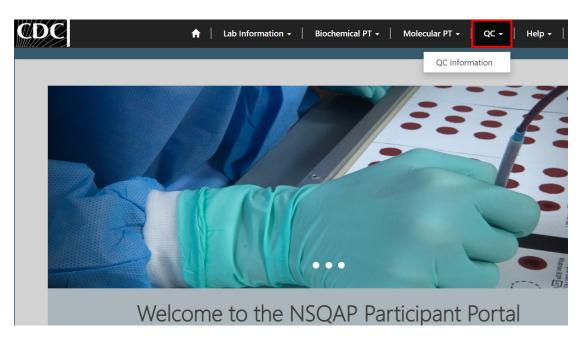
2. QC Manual Data Entry

QC Programs data can be manually entered into the NSQAP Portal from the QC Information section of the Portal.

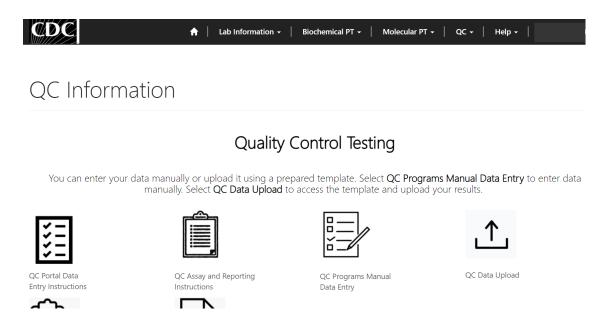
Note: If you choose to manually enter data, you cannot upload data to the Portal.

2.1 QC Information Homepage

1. Select the 'QC' button at the top of the page on the toolbar and select the 'QC Information' option.



2. This page serves as the homepage and resource for all QC related activities.



3. The QC Information homepage contains several icons that are used to navigate to the various QC sections within the NSQAP Portal.

QC Information

Quality Control Testing

You can enter your data manually or upload it using a prepared template. Select QC Programs Manual Data Entry to enter data manually. Select QC Data Upload to access the template and upload your results.



- 1. **QC Portal Data Entry Instructions** Downloadable Instructions for Completing Manual Data Entry in the NSQAP Portal.
- QC Assay and Reporting Instructions NSQAP QC Assaying and Reporting Instructions for QC Analytes
- 3. QC Programs Manual Data Entry —Page for Manually Entering QC Data into the Portal
- 4. **QC Data Upload** Homepage for Accessing Information for Uploading QC Program Data into the Portal
- 5. QC Manual Review Page for Reviewing QC Data Manually Entered into the Portal
- 6. **QC Manual Submit** Page for Submitting QC Data Manually Entered into the Portal
- 7. **QC Certification Information** NSQAP Report Forms and Certification Data Information

2.2 Manual Data Entry

1. Select the 'QC Programs Manual Data Entry' icon on the QC Information homepage.

QC Information

Quality Control Testing

You can enter your data manually or upload it using a prepared template. Select QC Programs Manual Data Entry to enter data manually. Select QC Data Upload to access the template and upload your results.



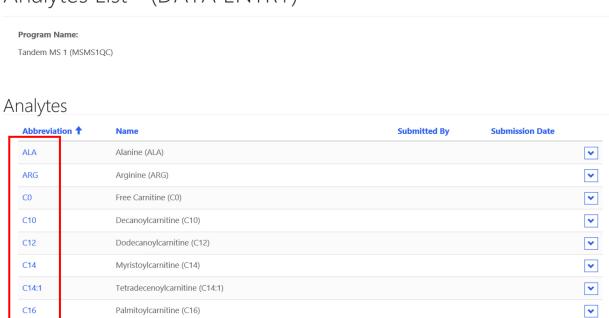
2. Select the QC Program by clicking on the program hyperlink.

QC Programs

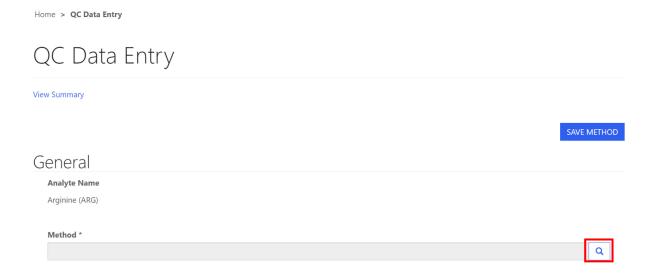
Program Name ↑	Created On
17 α-Hydroxyprogesterone + Total Galactose (17OHPQC and TGalQC)	3/5/2020 11:05 AM
Galactose-1-phosphate Uridyltransferase (GALTQC)	3/5/2020 11:05 AM
Immunoreactive Trypsinogen (IRTQC)	3/5/2020 11:05 AM
Lysosomal Storage Disorders (LSDQC)	3/5/2020 11:05 AM
Second-tier Congenital Adrenal Hyperplasia by LC-MS/MS (CAHQC)	3/5/2020 11:05 AM
Second-tier Maple Syrup Urine Disease and Phenylketonuria by LC-MS/MS (MSUD-PKUQC)	3/5/2020 11:05 AM
Second-tier Methylmalonic /Propionic Acidemia and Homocystinuria by LC-MS/MS (MMA-HCYQC)	3/5/2020 11:05 AM
Tandem MS 1 (MSMS1QC)	3/5/2020 11:05 AM
Thyroid-Stimulating Hormone (TSHQC)	3/5/2020 11:05 AM
Thyroxine (T4QC)	3/5/2020 11:05 AM

3. Select the Analyte by clicking on the analyte abbreviation hyperlink.

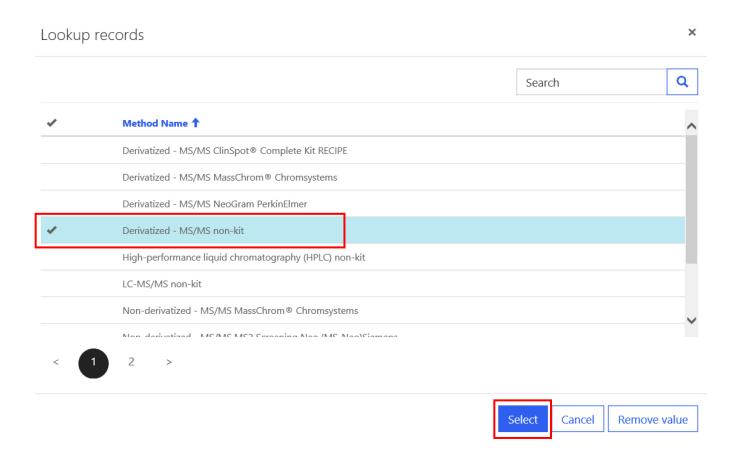
Analytes List - (DATA ENTRY)



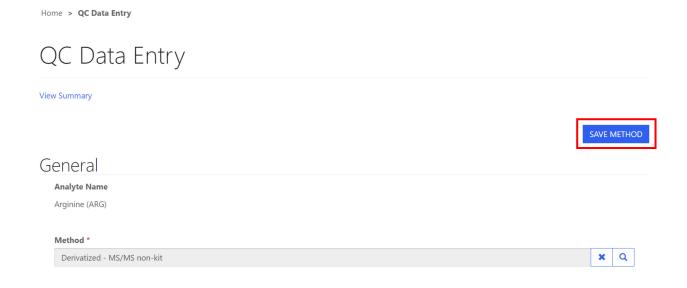
4. Select the 'Magnifying Glass' icon on the 'Method' field.



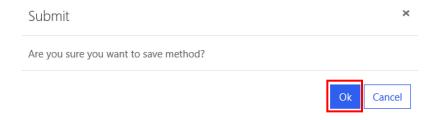
5. A new window will appear listing methods for the analyte. Click on the method, and the row will highlight with a check mark on the left side. Click the **'Select'** button at the bottom of the window to choose the method.



6. Select the 'Save Method' button to save the method for the analyte.



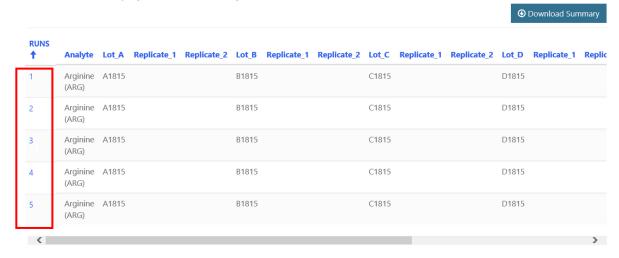
7. Select the 'OK' button when prompted "are you sure you want to save the method?".



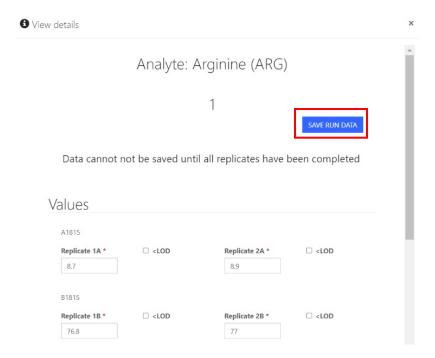
8. To add QC data, select the run hyperlink in the 'Runs' summary table.

Runs

The summary table will display data with two decimal places, regardless of the values entered. Results entered as <LOD will not be displayed in the summary table.



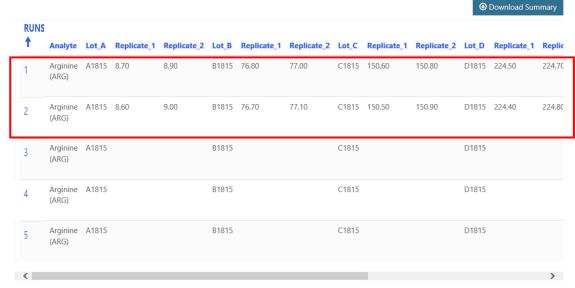
9. A data entry window will appear. Enter a quantitative value or select the <LOD checkbox for both replicates per lot then select the **'SAVE RUN DATA'** button.



NOTE: To save run data, both replicates must have a quantitative value or <LOD selected.

10. Data will appear in the summary table when the run is saved.

Runs The summary table will display data with two decimal places, regardless of the values entered. Results entered as <LOD will not be displayed in the summary table.



11. Analyte specific data can be entered, reviewed, and edited on this page.

NOTE: Export results to an Excel spreadsheet by selecting the 'Download Summary' button. (Optional)

Runs

The summary table will display data with two decimal places, regardless of the values entered. Results entered as <LOD will not be displayed in the summary table.



2.3 Review Manually Entered Data

All manually entered QC Programs data can be reviewed by accessing the 'QC Manual Review' page on the QC Information page.

1. Select the 'QC Manual Review' icon from the QC Information page.

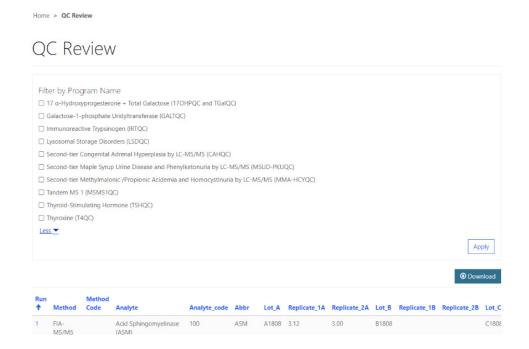


Quality Control Testing

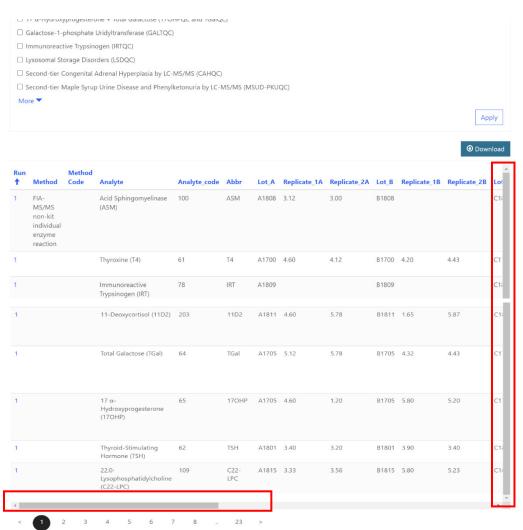
You can enter your data manually or upload it using a prepared template. Select **QC Programs Manual Data Entry** to enter data manually. Select **QC Data Upload** to access the template and upload your results.



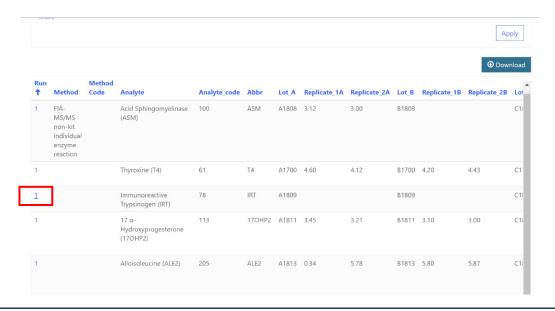
2. On the QC Manual Review page, results can be reviewed and edited.



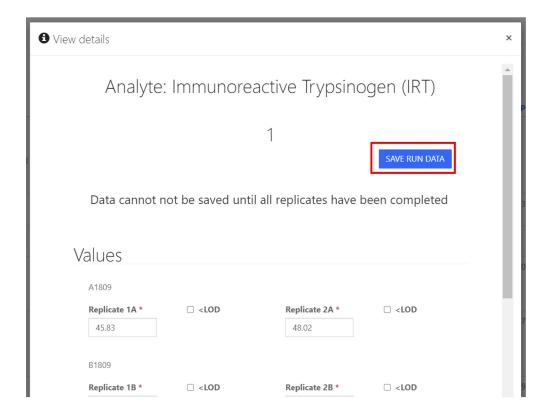
3. To review QC data, navigate through the results table using the navigation features located on the right side and the bottom of the table.



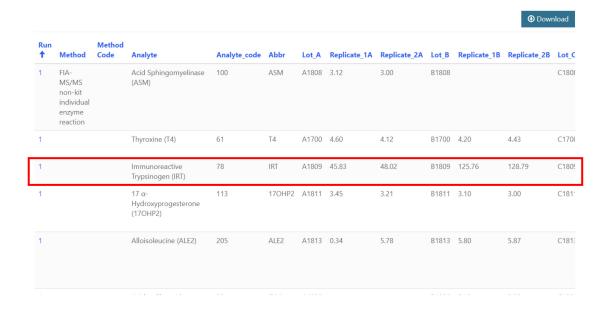
4. To edit data, select the hyperlinked run number of the row of interest.



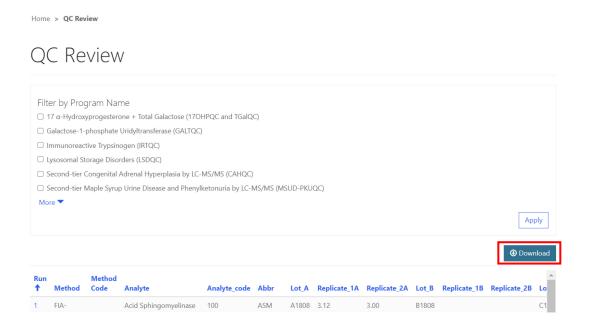
5. The analyte data entry page will appear. The data can be edited and saved.



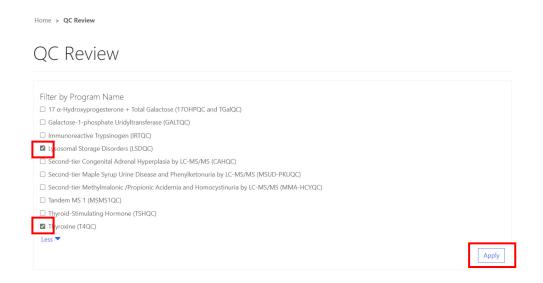
6. After selecting 'Save Run Data' you will be directed back to the QC Review page to continue reviewing your data.



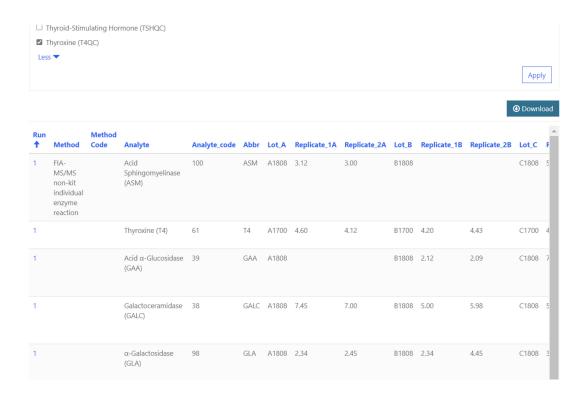
7. Review QC data offline by selecting 'Download' to generate an Excel spreadsheet of the data entered.



8. QC data can be filtered by program. Check the box(es) next to all relevant program names then select 'Apply'.



9. The data table will then update based on the filters chosen.



2.4 Submit Manually Entered Data

1. After reviewing data, navigate to the 'QC Manual Submit' page on the 'QC Information' page to submit all data at once.

QC Information

Quality Control Testing

You can enter your data manually or upload it using a prepared template. Select QC Programs Manual Data Entry to enter data manually. Select QC Data Upload to access the template and upload your results.





Instructions

QC Manual Submit

QC Assay and Reporting





QC Programs Manual Data Entry





QC Certification Information

2. Select 'Submit".

Home > QC Submission Webpage - Manual

QC Submission Webpage - Manual

IMPORTANT: By clicking submit, you are submitting all of your QC data for the current event which will lock all records for editing. No changes can be made after this action.



3. A confirmation page will appear once the submission is complete.

QC Submission Complete

Your records are now locked, no further changes can be made. If you any issues, please email nsqapdmt@cdc.gov.

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3. QC Data Upload

Data for QC Programs can be uploaded to the NSQAP Portal by accessing the 'QC Data Upload' area.

Note: If you choose to upload data, you cannot manually enter data into the Portal.

1. Select the 'QC Data Upload' icon on the QC information page.

OC Information

Quality Control Testing

You can enter your data manually or upload it using a prepared template. Select QC Programs Manual Data Entry to enter data manually. Select QC Data Upload to access the template and upload your results.







Data Entry





OC Manual Review

Instructions



QC Manual Submit

QC Assay and Reporting



QC Programs Manual

QC Certification Information

2. The QC Data Upload Information homepage contains several icons to navigate to the various QC upload sections.

QC Data Upload Information

Quality Control Testing-Upload





OC Upload Instructions



Download Method List



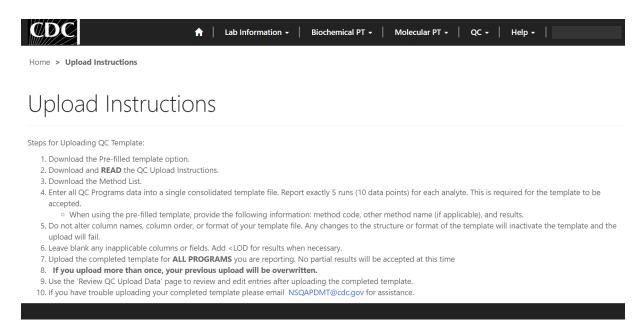
Download Template (pre-filled)







June 2021 17 1. **QC Upload Instructions** – Instructions for data upload process.



2. **Download Method List** – List of methods and their associated codes. (Method codes are needed for data upload.)

Home > Method List

Method List

- DOWNLOAD AND READ INSTRUCTIONS ON PROPER USAGE OF THE OC UPLOAD TEMPLATE.
- Use the method table below as a reference for entering method codes when using the pre-filled template.
- Method codes can be found by navigating through the pages of the table or searching by searching using the search bar.
- Note: Use an asterisk to search method names and codes using partial text (e.g. Enter *neobase to search for Non-derivatized MS/MS NeoBase™ PerkinElmer).



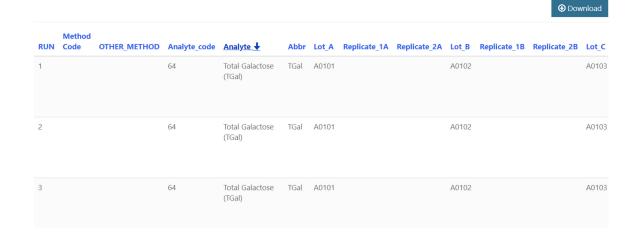
3. **Download Template (pre-filled)** – Downloadable template that is pre-filled with QC Lot Numbers, analytes, and analyte codes.

Download QC Template - (Pre-filled)

Note: You will see only the program(s) in which you are enrolled.

To obtain a pre-filled template click download (obtain a current template for each QC event). A completed template can be replaced up until the data is Submitted. The most recently uploaded file will be displayed. Data cannot be edited or replaced after the file is Submitted.

Do not change any of the column names as your data will not be uploaded correctly and the file will not be accepted. For more information please go to the resource area and review/download directions.



4. Upload QC Data - Page where completed templates are uploaded.

Home > QC Data Upload

QC Data Upload

Steps for Uploading QC Template:

- 1. Download the Pre-filled template option.
- 2. Download and **READ** the QC Upload Instructions.
- 3. Download the Method List.
- 4. Enter all QC Programs data into a single consolidated template file. Report exactly 5 runs (10 data points) for each analyte. This is required for the template to be accepted.
 - o When using the pre-filled template, provide the following information: method code, other method name (if applicable), and results.
- 5. Do not alter column names, column order, or format of your template file. Any changes to the structure or format of the template will inactivate the template and the upload will fail.
- 6. Leave blank any inapplicable columns or fields. Add <LOD for results when necessary.
- 7. Upload the completed template for ALL PROGRAMS you are reporting. No partial results will be accepted at this time
- $8.\ \mbox{If you upload more than once, your previous upload will be overwritten.}$
- 9. Use the 'Review QC Upload Data' page to review and edit entries after uploading the completed template.
- 10. If you have trouble uploading your completed template please email NSQAPDMT@cdc.gov for assistance.

Attach the Excel Template file *
Choose File No file chosen

UPLOAD DATA FILE

5. Review QC Upload Data – Review uploaded data before submission.

QC Review and Edit Upload Data

To filter the data by program, select the check box(es) next to the program and click the "Apply" button in the table below.





O Download

6. Submit QC Upload Data - Page to submit uploaded data.

Home > QC Submission Webpage - Upload

QC Submission Webpage - Upload

IMPORTANT: By clicking submit, you are submitting all of your *QC data* for the current event which will lock all records for editing. No changes can be made after this action.

Submit

3.1 Pre-filled Template

1. Select the 'Download Template (pre-filled)' icon from the QC Data Upload Information page.

QC Data Upload Information

Quality Control Testing-Upload











Review QC Upload Data

Submit QC Upload Data

Download Method List

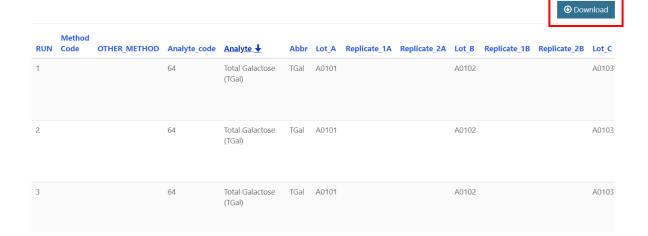
2. Select the **'Download'** button from the Pre-filled Template Page.

Download QC Template - (Pre-filled)

Note: You will see only the program(s) in which you are enrolled.

To obtain a pre-filled template click download (obtain a current template for each QC event). A completed template can be replaced up until the data is Submitted. The most recently uploaded file will be displayed. Data cannot be edited or replaced after the file is Submitted.

Do not change any of the column names as your data will not be uploaded correctly and the file will not be accepted. For more information please go to the resource area and review/download directions.



3. Select the 'Open' button on the downloaded Excel file at the bottom of the page.

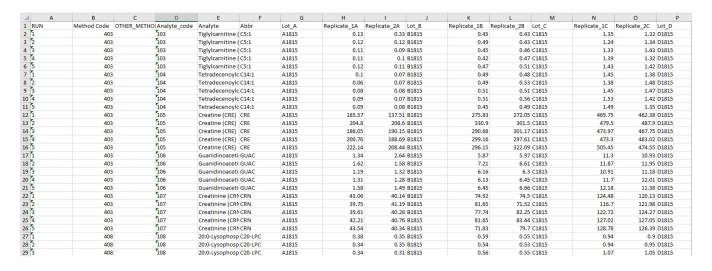


Note: The Excel download may look different depending on the browser used. This screenshot is from the Internet Explorer browser.

4. Complete the Excel template with data for submission and save the file.

To complete the Pre-filled template, you will need to include:

- Method Code
- 2. Replicate Values (Insert "<LOD" where necessary)



The table below explains each of the columns in the template.

Column name	Description	Values	Example Data
RUN	Shows the run number	Whole number (INTEGER) from 1-5	1
Method Code	Code for the method used	See Method list webpage	360
OTHER_METHOD	Name of method not in list	Type name of method	MYNewMethod
Analyte_code	Code for the analyte	Whole number	203
Lot_A	Lot number for Lot A	Name of lot provided for each event	A1811
		Decimal numbers with periods or	
Replicate_1A	Result for replicate 1 of Lot A	<lod< th=""><th>1.12</th></lod<>	1.12
		Decimal numbers with periods or	
Replicate_2A	Result for replicate 2 of Lot A	<lod< th=""><th>1.12</th></lod<>	1.12
Lot_B	Lot number for Lot B	Name of lot provided each event	B1811
		Decimal numbers with periods or	
Replicate_1B	Result for replicate 1 of Lot B	<lod< th=""><th>1.12</th></lod<>	1.12
		Decimal numbers with periods or	
Replicate_2B	Result for replicate 2 of Lot B	<lod< th=""><th>1.12</th></lod<>	1.12
Lot_C	Lot number for Lot C	Name of lot provided each event	C1811
		Decimal numbers with periods or	
Replicate_1C	Result for replicate 1 of Lot C	<lod< th=""><th>1.12</th></lod<>	1.12
		Decimal numbers with periods or	
Replicate_2C	Replicate 2 of Lot C	<lod< th=""><th>1.12</th></lod<>	1.12
Lot_D	Lot number for Lot D	Name of lot provided each event	D1811
		Decimal numbers with periods or	
Replicate_1D	Result for replicate 1 of Lot D	<lod< th=""><th>1.12</th></lod<>	1.12
		Decimal numbers with periods or	
Replicate_2D	Result for replicate 2 of Lot D	<lod< th=""><th>1.12</th></lod<>	1.12
Lot_E	Lot number for Lot E	Name of lot provided each event	E1811
		Decimal numbers with periods or	
Replicate_1E	Result for replicate 1 of Lot E	<lod< th=""><th>1.12</th></lod<>	1.12
		Decimal numbers with periods or	
Replicate_2E	Result for replicate 2 of Lot E	<lod< th=""><th>1.12</th></lod<>	1.12

Note: Method Codes are found on the 'Download Method List' pages.

Note: Do not change any of the column headers. Headers must be exact for information to be uploaded properly.

3.2 Upload Data

1. Navigate back to the 'QC Data Upload Information Page' and select the 'Upload QC Data' icon.

QC Data Upload Information

Quality Control Testing-Upload



QC Upload Instructions



Download Method List



Download Template (pre-filled)







2. Select the **'Choose File'** button on the 'QC Data Upload' page and select the completed template for upload.

Home > QC Data Upload

QC Data Upload

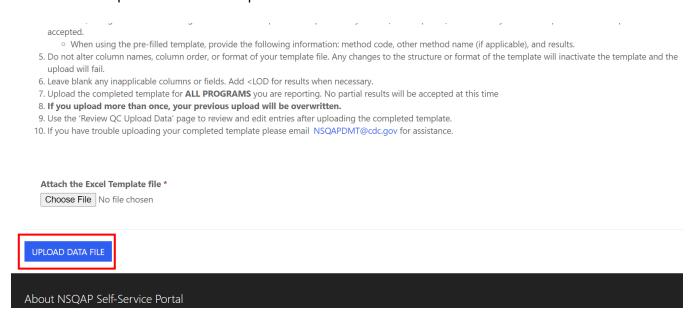
Steps for Uploading QC Template:

- 1. Download the Pre-filled template option
- 2. Download and **READ** the QC Upload Instructions.
- 3. Download the Method List.
- 4. Enter all QC Programs data into a single consolidated template file. Report exactly 5 runs (10 data points) for each analyte. This is required for the template to be accepted.
 - When using the pre-filled template, provide the following information: method code, other method name (if applicable), and results.
- 5. Do not alter column names, column order, or format of your template file. Any changes to the structure or format of the template will inactivate the template and the upload will fail.
- $^{\circ}$ 6. Leave blank any inapplicable columns or fields. Add <LOD for results when necessary.
- 7. Upload the completed template for **ALL PROGRAMS** you are reporting. No partial results will be accepted at this time
- 8. If you upload more than once, your previous upload will be overwritten.
- 9. Use the 'Review QC Upload Data' page to review and edit entries after uploading the completed template.
- $10.\ If you have trouble uploading your completed template please email \ \ NSQAPDMT@cdc.gov\ for\ assistance.$

Attach the Excel Template file *
Choose File
No file chosen

UPLOAD DATA FILE

3. Select the 'Upload Data File' to upload the document.

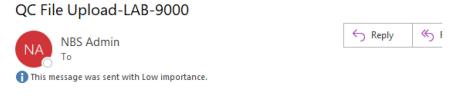


- 4. After the file has been uploaded two notification emails will be sent:
 - a. Notification the QC file was uploaded.



Here is a copy of the file you submitted.

b. Notification data is ready for review in the Portal.



Your QC upload data is now ready to be reviewed. Go to the upload review all page.

Note: It may take several minutes for this email to be sent. If your lab doesn't receive an email notifying the data is ready for review, an error with the upload may have occurred. Review Section 3.5 Troubleshooting and FAQs for more information.

3.3 Review Uploaded Data

1. Navigate back to the 'QC Data Upload Information' page and select the 'Review QC Upload Data' icon.

QC Data Upload Information

Quality Control Testing-Upload







(pre-filled)



Download Method List



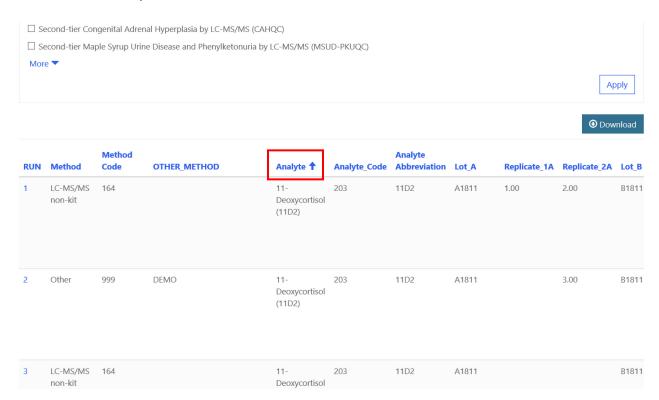
- 2. Review/edit the data that has been uploaded from the 'QC Review Upload Data' page.
 - a. Filter the data by program by selecting the check box next to the program(s) and selecting the 'Apply' button.

QC Review upload Data



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b. To sort data, click on the column header.



Note: The screenshot is sorted in ascending order by Analyte. The indicator is the arrow next to the header name.

c. To edit a record, select the number hyperlink in the 'Run' column.



d. Edit the information on the pop-up screen for the run and select the **'Save Run Data'** button.

Analyte: 11-Deoxycortisol (11D2)

RUN 2



Data cannot not be saved until all replicates have been completed

V	alues			
	A1811			
	Replicate 1A	✓ <lod< td=""><td>Replicate 2A *</td><td><pre><cod< pre=""></cod<></pre></td></lod<>	Replicate 2A *	<pre><cod< pre=""></cod<></pre>
	_		3.00	
	B1811			
	Replicate 1B *	<pre><cod< pre=""></cod<></pre>	Replicate 2B *	<pre><pre><cod< pre=""></cod<></pre></pre>

3.4 Submit Uploaded Data

1. After data has been reviewed, navigate back to the 'QC Data Upload Information' page and select the 'Submit QC Data Upload' icon.

QC Data Upload Information

Quality Control Testing-Upload



QC Upload Instructions



Download Method List



Download Template (pre-filled)



Upload QC [





2. Select the 'Submit' button to submit the uploaded data.

Home > QC Submission Webpage - Upload

QC Submission Webpage - Upload

IMPORTANT: By clicking submit, you are submitting all of your *QC data* for the current event which will lock all records for editing. No changes can be made after this action.



3. The submission confirmation message will appear upon successful upload.

QC Submission Complete

Your records are now locked, no further changes can be made. If you any issues, please email nsqapdmt@cdc.gov.

3.5 Troubleshooting and FAQs

If your uploaded data does not appear in the Portal after uploading

- 1. Confirm that you clicked the 'Review QC Upload Data' icon rather than the 'QC Manual Review' icon.
- 2. Confirm that you received a confirmation email stating that your data is ready. Note that it may take several minutes for this email to be sent.
- 3. If you received an email confirmation, refresh the web page.
- 4. If you clicked the 'Review QC Upload Data' icon, received an email confirmation, and refreshed the webpage and still do not see your data, confirm there are no issues with the file you uploaded. The following are common issues with the uploaded file:
 - a. The file should be in .xlsx or .xls format.
 - b. The data should appear on sheet 1 of the file.
 - c. Remove any table names in the spreadsheet. Table names are not encouraged unless you name the table 'Data'.
 - d. Check your headings. Make sure the headings are spelled correctly.
 - e. Check the values that have been entered for your data.
- 5. Confirm that your data was not already submitted.

If your method code does not appear

- 1. Confirm that the code exists in the method list that is provided on the Portal.
- 2. Check to see if any spaces or other characters are present before or after code. Remove as necessary.