

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**

**SMA AND TREC QUALITY
CONTROL USER GUIDE**

May 2024

Table of Contents

1. Introduction	2
2. QC Manual Data Entry	3
2.1 Manual Data Entry	3
2.2 Review Manually Entered Data.....	17
2.3 Submit Manually Entered Data.....	21

1. Introduction

The NSMBB Newborn Screening Quality Assurance Program (NSQAP) Portal SMA/TREC QC Program has been designed to accept participant Quality Control (QC) data using the manual data entry option. Participants are advised to consider the following before entering data:

1. Participants are permitted to only use manual upload data entry option for this program.
2. The review feature enables participants to review and edit manually entered data in the Portal directly from the review page.

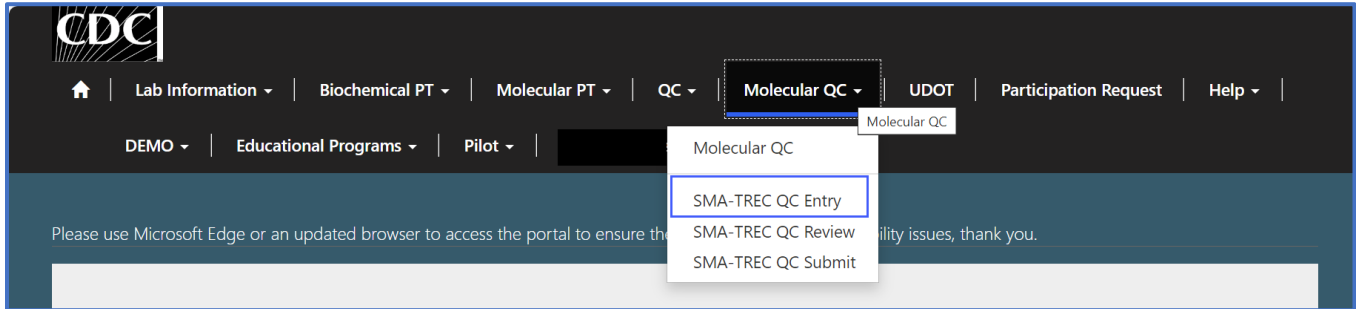
The following pages describe how to enter data into the NSQAP Portal.

2. QC Manual Data Entry

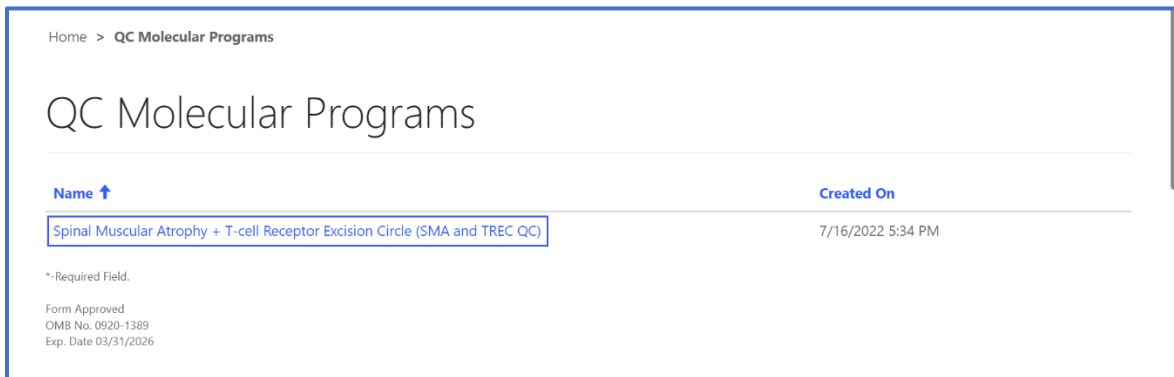
QC Programs data can be manually entered into the NSQAP Portal from the QC Information section of the Portal.

2.1 Manual Data Entry

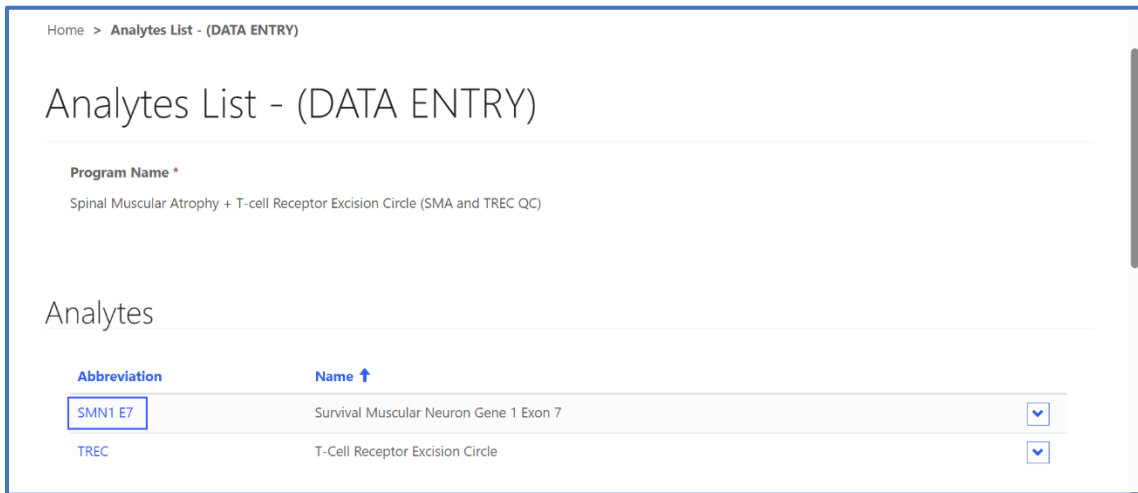
1. Navigate to the 'SMA-TREC QC Entry' under the 'Molecular QC' dropdown menu.



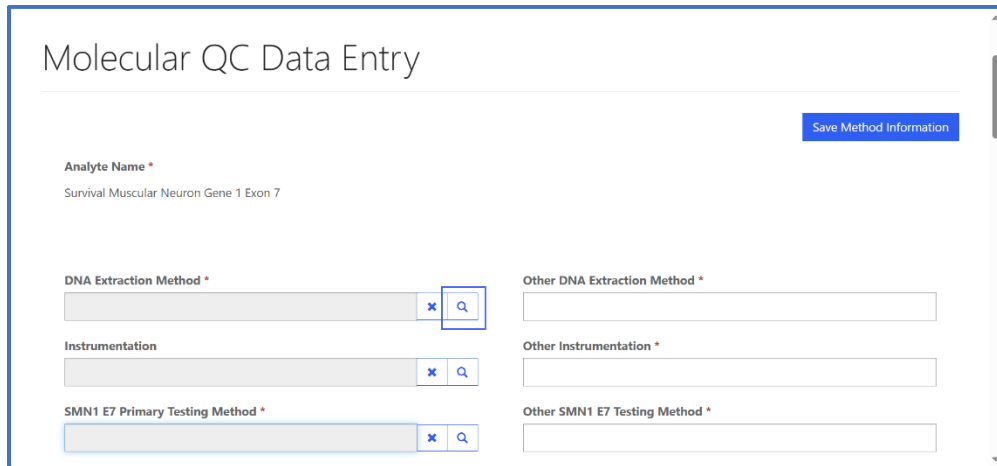
2. Select the 'Spinal Muscular Atrophy + T-cell Receptor Excision Circle (SMA and TREC QC)' by clicking on the program hyperlink.



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



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



- 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 and close the window.

The screenshot shows a window titled "Lookup records" with a search bar at the top right. Below the search bar, it says "Choose one record and click Select to continue". A list of methods is shown, each with a checkbox on the left and a "Name" header with an upward arrow. The methods listed are:

- Extracta™ DBS
- Extracta™ DBS with one wash
- Generation™ DNA Elution Solution (S2 only)
- Generation™ DNA Purification and Elution Solutions (S1/S2)
- ImmunoIVD SPOT-it™ TREC & SMN1 Screening Kit reagents
- In situ/on card (DNA is NOT extracted)
- Other

At the bottom right of the window, there are three buttons: "Select" (highlighted with a blue border), "Cancel", and "Remove value".

- If **'Other'** was chosen, enter the other method in the **'Other DNA Extraction Method'** field that appears.

The screenshot shows the "Molecular QC Data Entry" form. At the top right, there is a "Save Method Information" button. The form contains the following fields:

- Analyte Name ***: Survival Muscular Neuron Gene 1 Exon 7
- DNA Extraction Method ***: A dropdown menu with a search icon and a close icon.
- Other DNA Extraction Method ***: A text input field.
- Instrumentation**: A dropdown menu with a search icon and a close icon.
- Other Instrumentation ***: A text input field.
- SMN1 E7 Primary Testing Method ***: A dropdown menu with a search icon and a close icon.
- Other SMN1 E7 Testing Method ***: A text input field.

7. Select the **'Magnifying Glass'** icon on the 'Instrumentation' field.

Molecular QC Data Entry

Save Method Information

Analyte Name *
Survival Muscular Neuron Gene 1 Exon 7

DNA Extraction Method *
[Dropdown menu]

Instrumentation
[Dropdown menu]

SMN1 E7 Primary Testing Method *
[Dropdown menu]

Other DNA Extraction Method *
[Text field]

Other Instrumentation *
[Text field]

Other SMN1 E7 Testing Method *
[Text field]

8. A new window will appear listing instrumentation for the analyte. Click on the instrumentation, 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 instrumentation and close the window.

Lookup records

Search [Text field]

Choose one record and click Select to continue

✓ Name	Created On
<input type="checkbox"/> Viaa7	1/23/2024 7:49 AM
<input type="checkbox"/> QS5	1/23/2024 7:49 AM
<input type="checkbox"/> QS5-DX	1/23/2024 7:49 AM
<input type="checkbox"/> QS6	1/23/2024 7:49 AM
<input type="checkbox"/> QS7	1/23/2024 7:50 AM
<input type="checkbox"/> QS12	1/23/2024 7:50 AM
<input type="checkbox"/> QS7-Dx	1/23/2024 7:50 AM

Select Cancel Remove value

- If **'Other'** was chosen, enter the name of the other instrumentation in the **'Other Instrumentation'** field that appears.

Molecular QC Data Entry

[Save Method Information](#)

Analyte Name *
Survival Muscular Neuron Gene 1 Exon 7

DNA Extraction Method * x Q

Instrumentation x Q

SMN1 E7 Primary Testing Method * x Q

Other DNA Extraction Method *

Other Instrumentation *

Other SMN1 E7 Testing Method *

- Select the **'Magnifying Glass'** icon on the **'SMN1 E7 Primary Testing Method'** field.

Molecular QC Data Entry

[Save Method Information](#)

Analyte Name *
Survival Muscular Neuron Gene 1 Exon 7

DNA Extraction Method * x Q

Instrumentation x Q

SMN1 E7 Primary Testing Method * x Q

Other DNA Extraction Method *

Other Instrumentation *

Other SMN1 E7 Testing Method *

11. A new window will appear listing SMN1 E7 Primary Testing Methods for the analyte. Click on the record, 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 SMN1 E7 Primary Testing Method and close the window.

Lookup records

Search

Choose one record and click Select to continue

<input checked="" type="checkbox"/>	Name ↑
<input type="checkbox"/>	ImmunoIVD SPOT-it™ TREC & SMN1 Screening Kit
<input type="checkbox"/>	LDT Real Time PCR - SMN1 AND Reference Gene run in a single tube
<input type="checkbox"/>	LDT Real Time PCR - SMN1/TREC AND Reference Gene run in a single tube
<input type="checkbox"/>	MRC Holland SALSA MC002 SMA Newborn Screen
<input type="checkbox"/>	Other
<input type="checkbox"/>	Perkin Elmer Eonis™ SCID-SMA kit
<input type="checkbox"/>	Perkin Elmer NeoMDx RUO

Select Cancel Remove value

12. If **'Other'** was chosen, enter the other primary testing method into the **'Other SMN1 E7 Testing Method'** field that appears.

Molecular QC Data Entry

Save Method Information

Analyte Name *
Survival Muscular Neuron Gene 1 Exon 7

DNA Extraction Method * [Searchable Input Field]

Other DNA Extraction Method * [Input Field]

Instrumentation [Searchable Input Field]

Other Instrumentation * [Input Field]

SMN1 E7 Primary Testing Method * [Searchable Input Field]

Other SMN1 E7 Testing Method * [Input Field]

13. Select the **'Magnifying Glass'** icon on the 'SMN1 E7 Unit' field.

14. A new window will appear with other SMN1 E7 units for the analyte. Click on the record, 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 SMN1 E7 Unit and close the window.

Name	Created On
<input checked="" type="checkbox"/> Other	1/12/2024 10:32 AM
<input type="checkbox"/> Cq	1/12/2024 10:33 AM
<input type="checkbox"/> Copies/ul	1/12/2024 10:33 AM
<input type="checkbox"/> MoM Cq	1/12/2024 10:34 AM
<input type="checkbox"/> MoM Copy	1/12/2024 10:34 AM
<input type="checkbox"/> Copies/mL	4/19/2024 10:07 AM

15. If **'Other'** is selected, type in the other SMN1 E7 Unit.

The screenshot shows a form with two columns of input fields. The left column contains: 'SMN1 E7 Unit *' (with a search icon), 'SMN1 E7 Population Median *', 'SMN1 E7 Cutoffs by Cq/Multiple of the Median/copies for initial screen - use final cutoff value for screen positive reporting *', 'Reference gene *' (with a search icon), and 'Reference gene Unit *' (with a search icon). The right column contains: 'Other SMN1 E7 Unit *', 'SMN1 E7 Maximum qPCR cycle *', 'Other Reference Gene *', and 'Other Reference gene Unit *'. The 'Other SMN1 E7 Unit *' field is highlighted with a blue border.

16. Enter values for the **'SMN1 E7 Population Median,' 'SMN1 E7 Cutoffs'** and **'SMN1 E7 Maximum qPCR cycle'** fields.

This screenshot is identical to the previous one, but the 'SMN1 E7 Population Median *', 'SMN1 E7 Cutoffs by Cq/Multiple of the Median/copies for initial screen - use final cutoff value for screen positive reporting *', and 'SMN1 E7 Maximum qPCR cycle *' fields are highlighted with blue borders.

17. Select the **'Magnifying Glass'** icon on the 'Reference gene' field.

The screenshot shows a form with two columns of input fields. The left column contains: 'SMN1 E7 Unit *', 'SMN1 E7 Population Median *', 'SMN1 E7 Cutoffs by Cq/Multiple of the Median/copies for initial screen - use final cutoff value for screen positive reporting *', 'Reference gene *', and 'Reference gene Unit *'. The right column contains: 'Other SMN1 E7 Unit *', 'SMN1 E7 Maximum qPCR cycle *', 'Other Reference Gene *', and 'Other Reference gene Unit *'. Each field has a search icon (magnifying glass) and a clear icon (x). The 'Reference gene *' field's search icon is highlighted with a red box.

18. A new window will appear with other reference gene values for the analyte. Click on the record, 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 Reference gene and close the window.

The screenshot shows a 'Lookup records' window with a search bar at the top right. Below the search bar, it says 'Choose one record and click Select to continue'. There is a table with a header 'Name ↑' and four rows of reference genes, each with a checkbox on the left. The first row, 'Beta-actin (ACTB)', has a checkmark in the checkbox. At the bottom right of the window, there are three buttons: 'Select', 'Cancel', and 'Remove value'. The 'Select' button is highlighted with a red box.

	Name ↑
<input checked="" type="checkbox"/>	Beta-actin (ACTB)
<input type="checkbox"/>	Other
<input type="checkbox"/>	RNaseP subunit (RPP30)
<input type="checkbox"/>	TaqMan™ RNase P Control Reagents Kit

19. If **'Other'** is selected, type in the other SMN1 E7 Unit.

The screenshot shows a form with two columns of input fields. The left column contains: 'SMN1 E7 Unit *', 'SMN1 E7 Population Median *', 'SMN1 E7 Cutoffs by Cq/Multiple of the Median/copies for initial screen - use final cutoff value for screen positive reporting *', 'Reference gene *', and 'Reference gene Unit *'. The right column contains: 'Other SMN1 E7 Unit *', 'SMN1 E7 Maximum qPCR cycle *', 'Other Reference Gene *', and 'Other Reference gene Unit *'. The 'Other Reference Gene *' field is highlighted with a blue rectangular box.

20. Select the **'Magnifying Glass'** icon on the 'Reference gene Unit' field.

This screenshot is identical to the one above, showing the same form layout. However, the 'Magnifying Glass' icon (represented by a 'Q' in a circle) on the 'Reference gene Unit *' field is now highlighted with a blue rectangular box.

21. A new window will appear with other reference gene unit values for the analyte. Click on the record, 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 Reference gene unit and close the window.

The screenshot shows a window titled "Lookup records" with a search bar at the top right. Below the search bar, it says "Choose one record and click Select to continue". There is a table with two columns: "Name" and "Created On". The "Name" column has a checkmark icon to its left. The table contains the following rows:

Name	Created On
<input type="checkbox"/> Other	1/12/2024 10:32 AM
<input type="checkbox"/> Cq	1/12/2024 10:33 AM
<input type="checkbox"/> Copies/ul	1/12/2024 10:33 AM
<input type="checkbox"/> MoM Cq	1/12/2024 10:34 AM
<input type="checkbox"/> MoM Copy	1/12/2024 10:34 AM
<input type="checkbox"/> Copies/mL	4/19/2024 10:07 AM

At the bottom of the window, there are three buttons: "Select", "Cancel", and "Remove value".

22. If **'Other'** is selected, type in the Other Reference gene Unit.

The screenshot shows a form with several input fields. On the left side, there are five fields:

- SMN1 E7 Unit *
- SMN1 E7 Population Median *
- SMN1 E7 Cutoffs by Cq/Multiple of the Median/copies for initial screen - use final cutoff value for screen positive reporting *
- Reference gene *
- Reference gene Unit *

On the right side, there are three fields:

- Other SMN1 E7 Unit *
- SMN1 E7 Maximum qPCR cycle *
- Other Reference Gene *
- Other Reference gene Unit *

The "Other Reference gene Unit *" field is highlighted with a blue border.

23. Enter a value for the Reference Gene Population Median.

Reference Gene *

Reference Gene Unit *

Reference Gene Population Median *

Reference Gene Cutoff by Cq/Multiple of the Median/copies for initial screen - use final cutoff value for screen positive reporting *

Other Reference Gene *

Other Reference Gene Unit *

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

Molecular QC Data Entry

Analyte Name *
Survival Muscular Neuron Gene 1 Exon 7

DNA Extraction Method *

Instrumentation

SMN1 E7 Primary Testing Method *

Other DNA Extraction Method *

Other Instrumentation *

Other SMN1 E7 Testing Method *

Save Method Information

25. Enter a value for the Reference Gene Cutoff.

Reference Gene *

Reference Gene Unit *

Reference Gene Population Median *

Reference Gene Cutoff by Cq/Multiple of the Median/copies for initial screen - use final cutoff value for screen positive reporting *

Other Reference Gene *

Other Reference Gene Unit *

26. To add Molecular QC data, select the Run hyperlink in the **'Runs'** summary table.

Runs

[Download](#)

RUNS	Analyte	Method	DNA Extraction Method	Units	Lot_A	Replicate_1A	Replicate_2A	Reference Gene_1A	Reference Gene_2A	Lot_B	Replicate_1B	Replicate_2B	Re Ge
1	SMN1 E7	LDT Real Time PCR - SMN1 AND Reference Gene run in a single tube	Extracta™ DBS with one wash	Cq	LOT#1	23.500	24.212	1.000	1.000	LOT#2	23.548	23.548	1.0
2	SMN1 E7	LDT Real Time PCR - SMN1 AND Reference Gene run	Extracta™ DBS with one wash	Cq	LOT#1	24.500	23.200			LOT#2	21.300		

27. A data entry window will appear. Enter a quantitative value or select **'No signal detected'** for both replicates per lot, enter a reference gene value for both replicates per lot, then select the **'SAVE RUN DATA'** button.

View details

Analyte: Survival Muscular Neuron Gene 1 Exon 7

Run: 1

[SAVE RUN DATA](#)

NSQAP will interpret the data reported based on the method which is selected.

Values

LOT#1

Replicate_1A * No signal detected

Replicate_2A * No signal detected

Reference Gene_1A *

Reference Gene_2A *

LOT#2

Replicate_1B * No signal detected

Replicate_2B * No signal detected

Reference Gene_1B *

Reference Gene_2B *

LOT#3

NOTE: To save run data, each value must have quantitative data or ‘No signal detected’ selected.

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

RUNS	Analyte	Method	DNA Extraction Method	Units	Lot_A	Replicate_1A	Replicate_2A	Reference Gene_1A	Reference Gene_2A	Lot_B	Replicate_1B	Replicate_2B	Re Ge
1	SMN1 E7	LDT Real Time PCR - SMN1 AND Reference Gene run in a single tube	Extracta™ DBS with one wash	Cq	LOT#1	23.500	24.212	1.000	1.000	LOT#2	23.548	23.548	1.0
2	SMN1 E7	LDT Real Time PCR - SMN1 AND Reference Gene run	Extracta™ DBS with one wash	Cq	LOT#1	24.500	23.200			LOT#2	21.300		

29. 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)

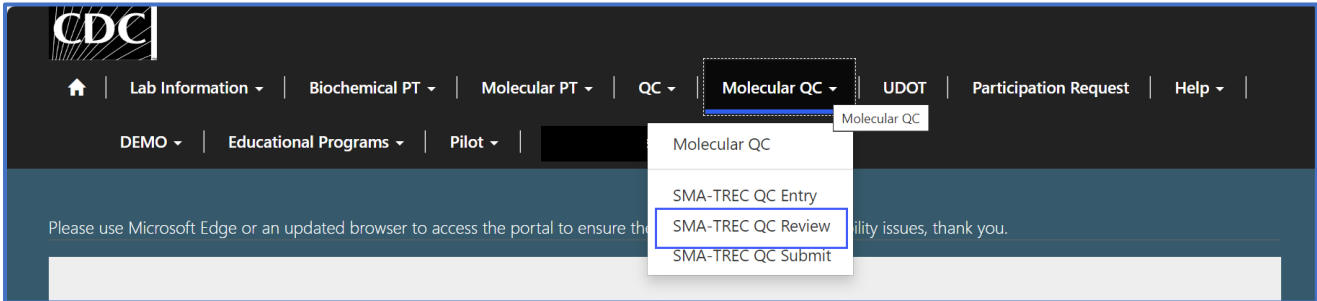
RUNS	Analyte	Method	DNA Extraction Method	Units	Lot_A	Replicate_1A	Replicate_2A	Reference Gene_1A	Reference Gene_2A	Lot_B	Replicate_1B	Replicate_2B	Re Ge
1	SMN1 E7	LDT Real Time PCR - SMN1 AND Reference Gene run in a single tube	Extracta™ DBS with one wash	Cq	LOT#1	23.500	24.212	1.000	1.000	LOT#2	23.548	23.548	1.0
2	SMN1 E7	LDT Real Time PCR - SMN1 AND Reference Gene run	Extracta™ DBS with one wash	Cq	LOT#1	24.500	23.200			LOT#2	21.300		

30. Repeat this process for each analyte.

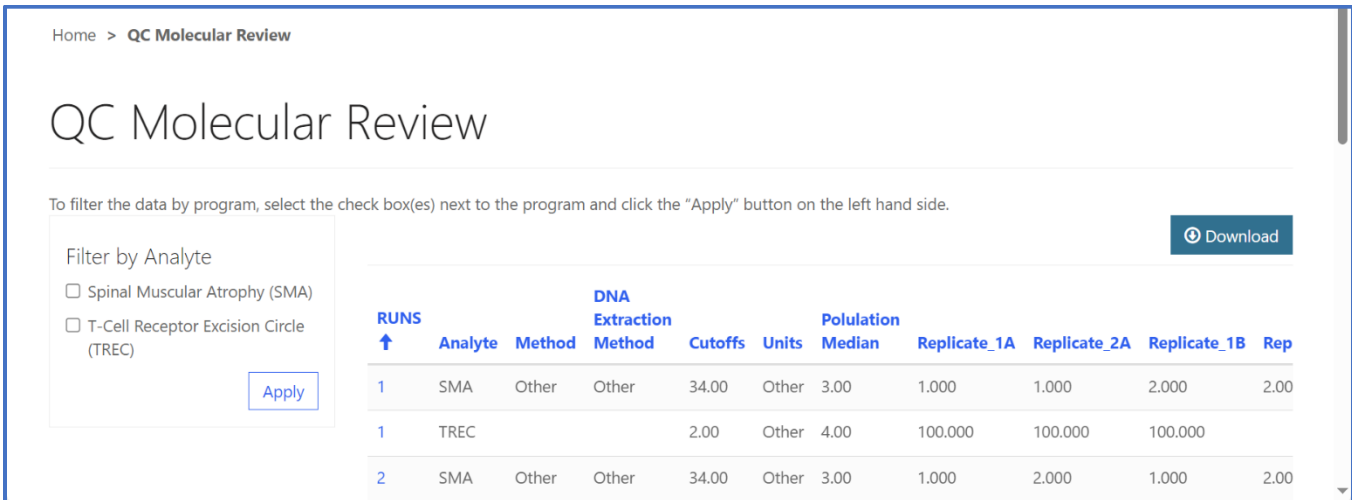
2.2 Review Manually Entered Data

All manually entered SMA & TREC QC data can be reviewed by accessing the ‘SMA & TREC QC Review’ option page on ‘Molecular QC’ at the top of the page on the toolbar.

1. Select the ‘Molecular QC’ button at the top of the page on the toolbar and select the ‘SMA-TREC QC Review’ option.



2. On the ‘SMA-TREC QC Review’ page, results can be reviewed, edited, and filtered by Analyte.



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

Filter by Analyte

Spinal Muscular Atrophy (SMA)

T-Cell Receptor Excision Circle (TREC)

[Apply](#)

RUNS	Analyte	Method	DNA Extraction Method	Cutoffs	Units	Polulation Median	Replicate_1A	Replicate_2A	Replicate_1B	Rep
1	SMA	Other	Other	34.00	Other	3.00	1.000	1.000	2.000	2.00
1	TREC			2.00	Other	4.00	100.000	100.000	100.000	
2	SMA	Other	Other	34.00	Other	3.00	1.000	2.000	1.000	2.00
2	TREC			2.00	Other	4.00				
3	SMA	Other	Other	34.00	Other	3.00	111.000	1,111.000	222.000	222.
3	TREC			2.00	Other	4.00				
4	SMA	Other	Other	34.00	Other	3.00	1.000	1.000	2.000	2.00
4	TREC			2.00	Other	4.00				
5	SMA	Other	Other	34.00	Other	3.00	2.000	2.000	3.000	2.00
5	TREC			2.00	Other	4.00				

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

Filter by Analyte

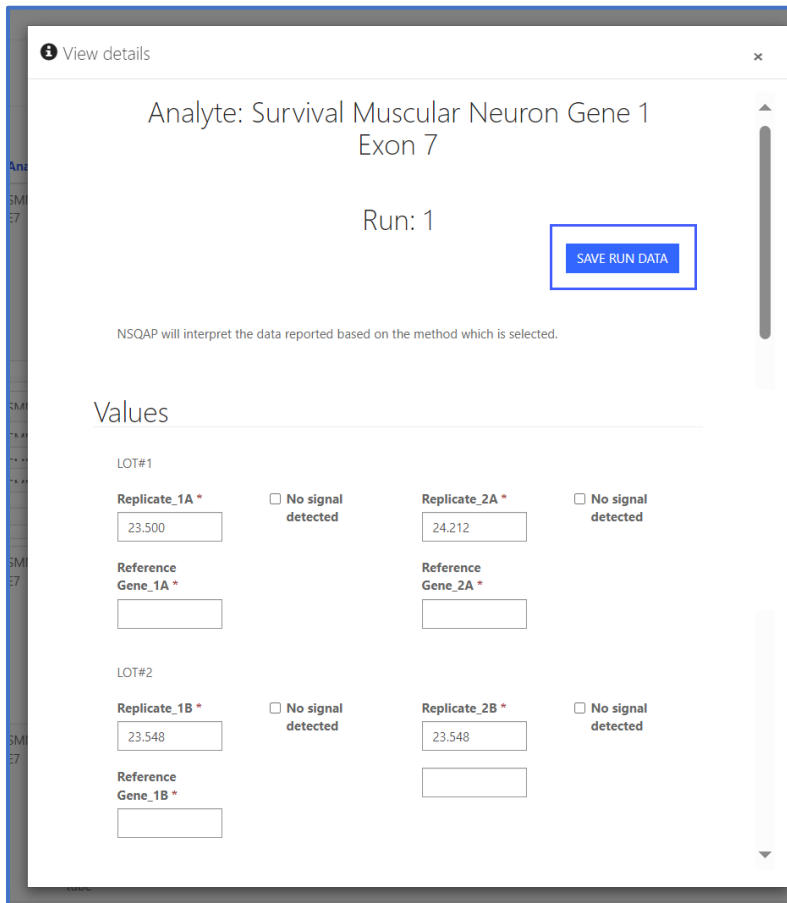
Spinal Muscular Atrophy (SMA)

T-Cell Receptor Excision Circle (TREC)

[Apply](#)

RUNS	Analyte	Method	DNA Extraction Method	Cutoffs	Units	Polulation Median	Replicate_1A	Replicate_2A	Replicate_1B	Rep
1	SMA	Other	Other	34.00	Other	3.00	1.000	1.000	2.000	2.00
1	TREC			2.00	Other	4.00	100.000	100.000	100.000	
2	SMA	Other	Other	34.00	Other	3.00	1.000	2.000	1.000	2.00
2	TREC			2.00	Other	4.00				
3	SMA	Other	Other	34.00	Other	3.00	111.000	1,111.000	222.000	222.
3	TREC			2.00	Other	4.00				
4	SMA	Other	Other	34.00	Other	3.00	1.000	1.000	2.000	2.00
4	TREC			2.00	Other	4.00				
5	SMA	Other	Other	34.00	Other	3.00	2.000	2.000	3.000	2.00
5	TREC			2.00	Other	4.00				

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



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

Filter by Analyte

Spinal Muscular Atrophy (SMA)

T-Cell Receptor Excision Circle (TREC)

Apply

RUNS	Analyte	Method	DNA Extraction Method	Cutoffs	Units	Polulation Median	Replicate_1A	Replicate_2A	Replicate_1B	Rep
1	SMA	Other	Other	34.00	Other	3.00	1.000	1.000	2.000	2.00
1	TREC			2.00	Other	4.00	100.000	100.000	100.000	
2	SMA	Other	Other	34.00	Other	3.00	1.000	2.000	1.000	2.00
2	TREC			2.00	Other	4.00				
3	SMA	Other	Other	34.00	Other	3.00	111.000	1,111.000	222.000	222.
3	TREC			2.00	Other	4.00				
4	SMA	Other	Other	34.00	Other	3.00	1.000	1.000	2.000	2.00
4	TREC			2.00	Other	4.00				
5	SMA	Other	Other	34.00	Other	3.00	2.000	2.000	3.000	2.00
5	TREC			2.00	Other	4.00				

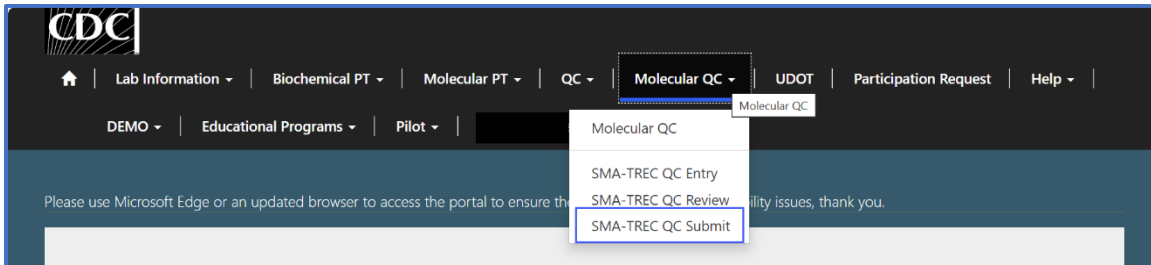
- Review QC data offline by selecting **'Download'** to generate an Excel spreadsheet of the data entered.

The screenshot shows the 'QC Molecular Review' page. At the top, there is a breadcrumb 'Home > QC Molecular Review'. Below this is the title 'QC Molecular Review'. A instruction reads: 'To filter the data by program, select the check box(es) next to the program and click the "Apply" button on the left hand side.' On the left, there is a 'Filter by Analyte' section with two checkboxes: 'Spinal Muscular Atrophy (SMA)' and 'T-Cell Receptor Excision Circle (TREC)'. An 'Apply' button is located below these checkboxes. On the right, there is a 'Download' button with a download icon. Below the instructions is a table with the following data:

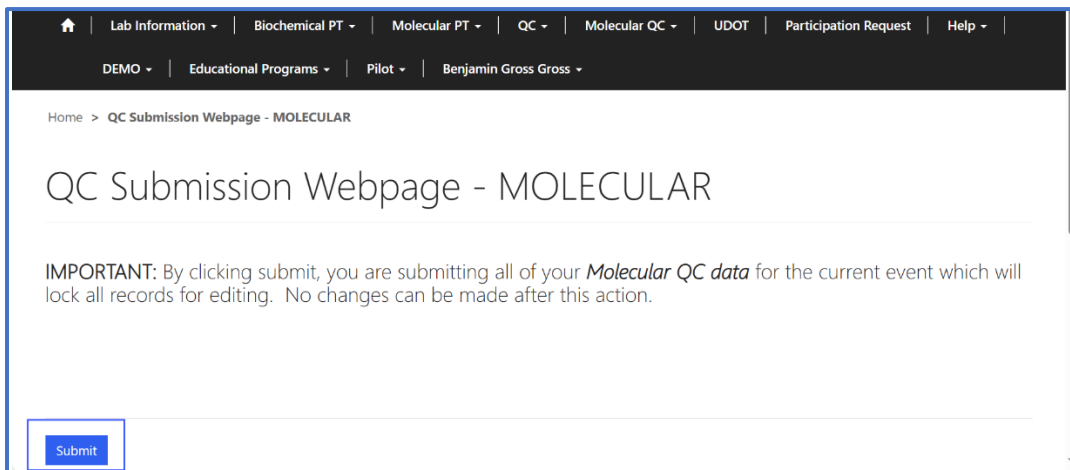
RUNS	Analyte	Method	DNA Extraction Method	Cutoffs	Units	Polulation Median	Replicate_1A	Replicate_2A	Replicate_1B	Rep
1	SMA	Other	Other	34.00	Other	3.00	1.000	1.000	2.000	2.00
1	TREC			2.00	Other	4.00	100.000	100.000	100.000	
2	SMA	Other	Other	34.00	Other	3.00	1.000	2.000	1.000	2.00

2.3 Submit Manually Entered Data

1. After reviewing data, navigate to the **'SMA & TREC QC Submit'** page by selecting the **'Molecular QC'** dropdown at the top of the page on the toolbar and select the **'SMA & TREC QC Submit'** option. This will take the User to the **'SMA & TREC QC Submit'** page to submit all data at once.



2. Select **'Submit'**.



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

