

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**

SMAPT PARTICIPANT GUIDE

August 2021

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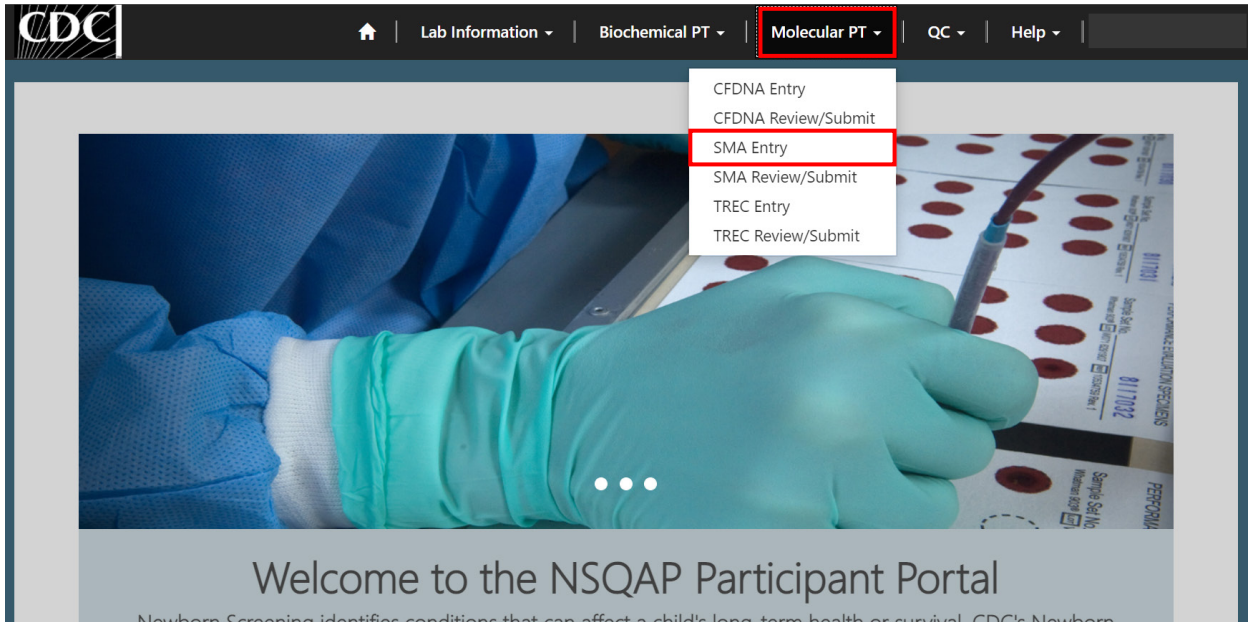
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1. SMAPT Program Entry Page

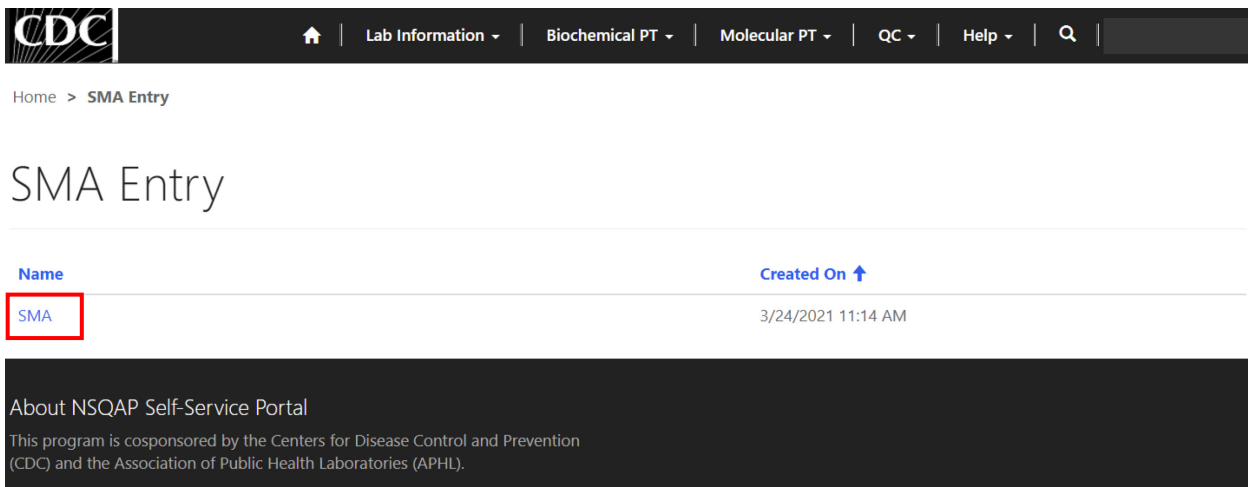
1.1 Navigation

To enter and save SMAPT data, navigate to the SMAPT program entry page. Access the page from the ‘SMA Entry’ option on the Molecular PT drop-down menu.

1. Click ‘Molecular PT’ then ‘SMA Entry’ from the drop-down menu.



2. Select ‘SMA’ to navigate to the entry page.



- You will be directed to the SMA entry page to enter method information and analyte data. Required fields are indicated with an asterisk(*).

CDC

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Home > Spinal Muscular Atrophy (SMAPT)

Spinal Muscular Atrophy (SMAPT)

Method Information

Select a method - LDT refers to Lab Developed Test RUO refers to Research Use Only *

Select a DNA extraction method *

SMN1 assay primer and probe information

Was a commercial kit used? *

No

SMN1 probe sequence including dye and quencher: *

SMN1 forward amplification primer sequence *

SMN1 reverse amplification primer sequence: *

Reference Gene assay primer and probe information

Select a reference gene: *

Was a commercial kit used? *

No

Reference gene probe sequence including dye and quencher: *

Reference gene forward amplification primer sequence: *

Reference gene reverse amplification primer sequence: *

SMN1 Exon 7

Specimen Number	Clinical Assessment Code *	Comments
20212017001	<input type="text"/>	<input type="text"/>
20212017002	<input type="text"/>	<input type="text"/>
20212017003	<input type="text"/>	<input type="text"/>
20212017004	<input type="text"/>	<input type="text"/>
20212017005	<input type="text"/>	<input type="text"/>

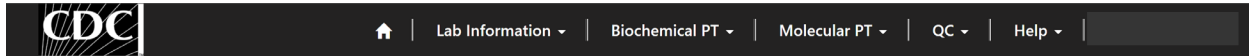
Participating laboratories must generate and submit their own results and must not share NSQAP PT test results or specimens with any other laboratory under ANY circumstance, even if the laboratory normally sends specimens to referral laboratories for routine or confirmatory testing. If participants are found to have falsified or shared results or specimens, the NSQAP committee will convene to discuss response actions for the participant which may include termination from the program.

Use of trade names is for identification only and does not imply endorsement by the Public Health Service, the U.S. Department of Health and Human Services, or the Association of Public Health Laboratories.

1.2 Method Information

Navigate to the page titled 'Spinal Muscular Atrophy (SMAPT)' to enter method information.

1. Enter method, DNA extraction method, SMN1 assay primer and probe information, and reference gene assay primer and probe information. Navigation details can be found in section 1.1.



Home > Spinal Muscular Atrophy (SMAPT)

Spinal Muscular Atrophy (SMAPT)

Method Information

Select a method - LDT refers to Lab Developed Test RUO refers to Research Use Only *

Select a DNA extraction method *

SMN1 assay primer and probe information

Was a commercial kit used? *

SMN1 probe sequence including dye and quencher: *

SMN1 forward amplification primer sequence *

SMN1 reverse amplification primer sequence: *

Reference Gene assay primer and probe information

Select a reference gene: *

Was a commercial kit used? *

Reference gene probe sequence including dye and quencher: *

Reference gene forward amplification primer sequence: *

Reference gene reverse amplification primer sequence: *

2. Click on the magnifying glass to look up methods and click 'Select'.

Home > Spinal Muscular Atrophy (SMAPT)

Spinal Muscular Atrophy (SMAPT)

Method Information

Select a method - LDT refers to Lab Developed Test RUO refers to Research Use Only *

Select a DNA extraction method *

Lookup records

✓	Name ↑
✓	LDT Real Time PCR - SMN1 AND Reference Gene run in a single tube
	LDT Real Time PCR - SMN1/TREC AND Reference Gene run in a single tube
	Other
	Perkin Elmer NeoMDx RUO

Select Cancel Remove value

Home > Spinal Muscular Atrophy (SMAPT)

Spinal Muscular Atrophy (SMAPT)

Method Information

Select a method - LDT refers to Lab Developed Test RUO refers to Research Use Only *

LDT Real Time PCR - SMN1 AND Reference Gene run in a single tube

Select a DNA extraction method *

- If 'Other' is selected, a text box will appear. You are **required** to list a commercial method or describe the lab developed test.

Lookup records ×

Q

✓	Name ↑
	LDT Real Time PCR - SMN1 AND Reference Gene run in a single tube
	LDT Real Time PCR - SMN1/TREC AND Reference Gene run in a single tube
✓	Other <small>Perkin Elmer NeoMDx RUO</small>

Select
Cancel
Remove value

Home > Spinal Muscular Atrophy (SMAPT)

Spinal Muscular Atrophy (SMAPT)

Method Information

Select a method - LDT refers to Lab Developed Test RUO refers to Research Use Only *

× Q
Other

YOU MUST list commercial method or describe lab developed test *

Select a DNA extraction method *

Q

- Click on the magnifying glass to select a DNA extraction method.

Spinal Muscular Atrophy (SMAPT)

Method Information

Select a method - LDT refers to Lab Developed Test RUO refers to Research Use Only *

× Q
LDT Real Time PCR - SMN1 AND Reference Gene run in a single tube

Select a DNA extraction method *

Q

5. Choose a DNA extraction method then click **'Select'**.

Lookup records ×

Search

✓	Name ↑
✓	Extracta™ DBS Generation™ DNA Elution Solution (S2 only)
	Generation™ DNA Purification and Elution Solutions (S1/S2)
	In situ/on card (DNA is NOT extracted)
	Other
	Perkin Elmer DNA Extraction Solution

Spinal Muscular Atrophy (SMAPT)

Method Information

Select a method - LDT refers to Lab Developed Test RUO refers to Research Use Only *

LDT Real Time PCR - SMN1 AND Reference Gene run in a single tube ✕ Q

Select a DNA extraction method *

Extracta™ DBS ✕ Q

6. If 'Other' is selected, a text box will appear. You are **required** to indicate if your DNA extraction reagent is lab developed or commercial.

Lookup records ×

✓	Name ↑
	Extracta™ DBS
	Generation™ DNA Elution Solution (S2 only)
	Generation™ DNA Purification and Elution Solutions (S1/S2)
	In situ/on card (DNA is NOT extracted)
✓	Other
	Perkin Elmer DNA Extraction Solution

Spinal Muscular Atrophy (SMAPT)

Method Information

Select a method - LDT refers to Lab Developed Test RUO refers to Research Use Only *

LDT Real Time PCR - SMN1 AND Reference Gene run in a single tube



Select a DNA extraction method *

Other



Indicate if this reagent is lab developed or commercial *

- SMN1 assay primer and probe information should be entered into the 'SMN1 assay primer and probe information' section.

Spinal Muscular Atrophy (SMAPT)

Method Information

Select a method - LDT refers to Lab Developed Test RUO refers to Research Use Only *

LDT Real Time PCR - SMN1 AND Reference Gene run in a single tube



Select a DNA extraction method *

Extracta™ DBS



SMN1 Assay Primer and Probe Information

Was a commercial kit used? *

Yes



- Indicate whether a commercial kit was used by clicking the drop-down arrow.

SMN1 assay primer and probe information

Was a commercial kit used? *

Yes

No

Yes



- If a commercial kit was used, select 'Yes', and no further information is required for the SMN1 assay primer and probe information section.

SMN1 assay primer and probe information

Was a commercial kit used? *

Yes



10. If a commercial kit was not used, select 'No', and additional probe and primer sequence information will be required.

SMN1 assay primer and probe information

Was a commercial kit used? *

No

SMN1 probe sequence including dye and quencher: *

SMN1 forward amplification primer sequence *

SMN1 reverse amplification primer sequence: *

11. Enter 'Reference gene assay primer and probe information'.

SMN1 assay primer and probe information

Was a commercial kit used? *

No

SMN1 probe sequence including dye and quencher: *

SMN1 forward amplification primer sequence *

SMN1 reverse amplification primer sequence: *

Reference Gene assay primer and probe information

Select a reference gene: *

Was a commercial kit used? *

No

Reference gene probe sequence including dye and quencher: *

12. Select a reference gene by clicking the magnifying glass.

Reference Gene assay primer and probe information

Select a reference gene: *

13. Choose a reference gene then click **'Select'**.

Lookup records ×

✓	Name ↑
✓	Beta-actin (ACTB)
	Other
	RNaseP subunit (RPP30)
	TaqMan™ RNase P Control Reagents Kit

Reference Gene assay primer and probe information

Select a reference gene: *

Beta-actin (ACTB)
✕ Q

14. If 'Other' is selected, you are required to specify a gene name and symbol.

Lookup records ×

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

Reference Gene Assay Primer and Probe Information

Select a reference gene: *

Other
✕ Q

YOU MUST specify gene name and symbol *

15. Indicate whether a commercial kit was used, by click the drop-down arrow.

Reference Gene assay primer and probe information

Select a reference gene: *

Beta-actin (ACTB) ✕ 🔍

Was a commercial kit used? *

No ▼

Reference gene probe sequence including dye and quencher: *

Reference gene forward amplification primer sequence: *

Reference gene reverse amplification primer sequence: *

16. If a commercial kit was used, select ‘Yes’, and no further information is required for reference gene assay primer and probe information section.

Reference Gene assay primer and probe information

Select a reference gene: *

Beta-actin (ACTB) ✕ 🔍

Was a commercial kit used? *

Yes ▼

17. If a commercial kit was not used, select ‘No’, and additional reference gene probe and primer sequence information will be required.

Reference Gene assay primer and probe information

Select a reference gene: *

Beta-actin (ACTB) ✕ 🔍

Was a commercial kit used? *

No ▼

Reference gene probe sequence including dye and quencher: *

Reference gene forward amplification primer sequence: *

Reference gene reverse amplification primer sequence: *

1.3 Results Entry

Navigate to the page titled ‘Spinal Muscular Atrophy (SMAPT)’ to enter SMAPT specimen clinical assessments and comments (optional). Navigation details can be found in section 1.1.

1. Select a clinical assessment for each of the five specimens by clicking the drop-down arrow.

SMN1 Exon 7

Specimen Number	Clinical Assessment *	Comments
20214017001	<input type="text" value="v"/>	<input type="text"/>
20214017002	<input type="text" value="v"/>	<input type="text"/>
20214017003	<input type="text" value="v"/>	<input type="text"/>
20214017004	<input type="text" value="v"/>	<input type="text"/>
20214017005	<input type="text" value="v"/>	<input type="text"/>

Participating laboratories must generate and submit their own results and must not share NSQAP PT test results or specimens with any other laboratory under ANY circumstance, even if the laboratory normally sends specimens to referral laboratories for routine or confirmatory testing. If participants are found to have falsified or shared results or specimens, the NSQAP committee will convene to discuss response actions for the participant which may include termination from the program.

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2. If necessary, enter optional comments into the appropriate comment box.

SMN1 Exon 7

Specimen Number	Clinical Assessment *	Comments
20214017001	<input type="text" value="v"/>	<input type="text"/>
20214017002	<input type="text" value="v"/>	<input type="text"/>
20214017003	<input type="text" value="v"/>	<input type="text"/>
20214017004	<input type="text" value="v"/>	<input type="text"/>
20214017005	<input type="text" value="v"/>	<input type="text"/>

Participating laboratories must generate and submit their own results and must not share NSQAP PT test results or specimens with any other laboratory under ANY circumstance, even if the laboratory normally sends specimens to referral laboratories for routine or confirmatory testing. If participants are found to have falsified or shared results or specimens, the NSQAP committee will convene to discuss response actions for the participant which may include termination from the program.

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1.4 Save

1. Save SMAPT specimen results by clicking the **'Save'** button located at the bottom of the page.

NOTE: All information & data must be saved at the same time. Data cannot be partially saved.

Participating laboratories must generate and submit their own results and must not share NSQAP PT test results or specimens with any other laboratory under ANY circumstance, even if the laboratory normally sends specimens to referral laboratories for routine or confirmatory testing. If participants are found to have falsified or shared results or specimens, the NSQAP committee will convene to discuss response actions for the participant which may include termination from the program.

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*-Required Field.

2. If you attempt to save the form without entering **all required fields**, you will receive an error message. Complete the missing fields and click 'Save' again.

Spinal Muscular Atrophy (SMAPT)

i The form could not be submitted for the following reasons:

Clinical Assessment is a required field.

Method Information

Select a method - LDT refers to Lab Developed Test RUO refers to Research Use Only *

LDT Real Time PCR - SMN1 AND Reference Gene run in a single tube



Select a DNA extraction method *

Extracta™ DBS



3. After you have successfully saved your data and information, you will be redirected to the SMAPT review and submit page.

NOTE: The data entry page can be saved and re-saved as many times as needed, but each new save will overwrite the previous save(s).



Home > SMAPT-Review/Submit

SMAPT-Review/Submit

Name ↑

Submitted By

Modified On

SMA

5/17/2021 1:3

About NSQAP Self-Service Portal

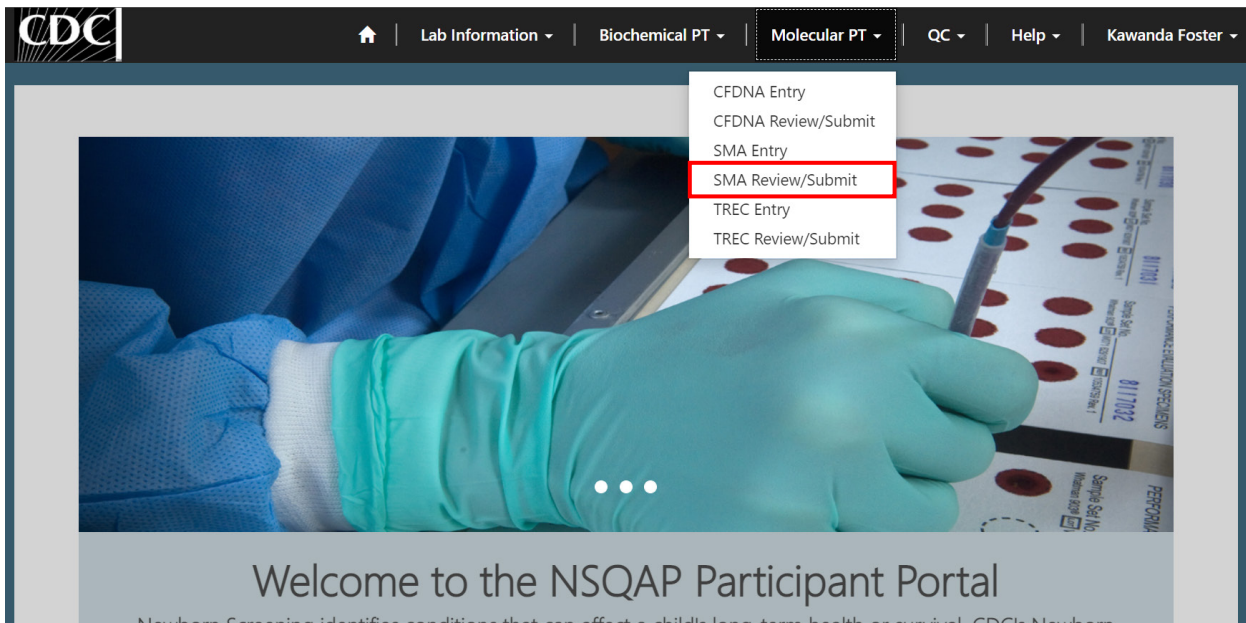
This program is cosponsored by the Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories (APHL).

2. SMAPT Review & Submit Page

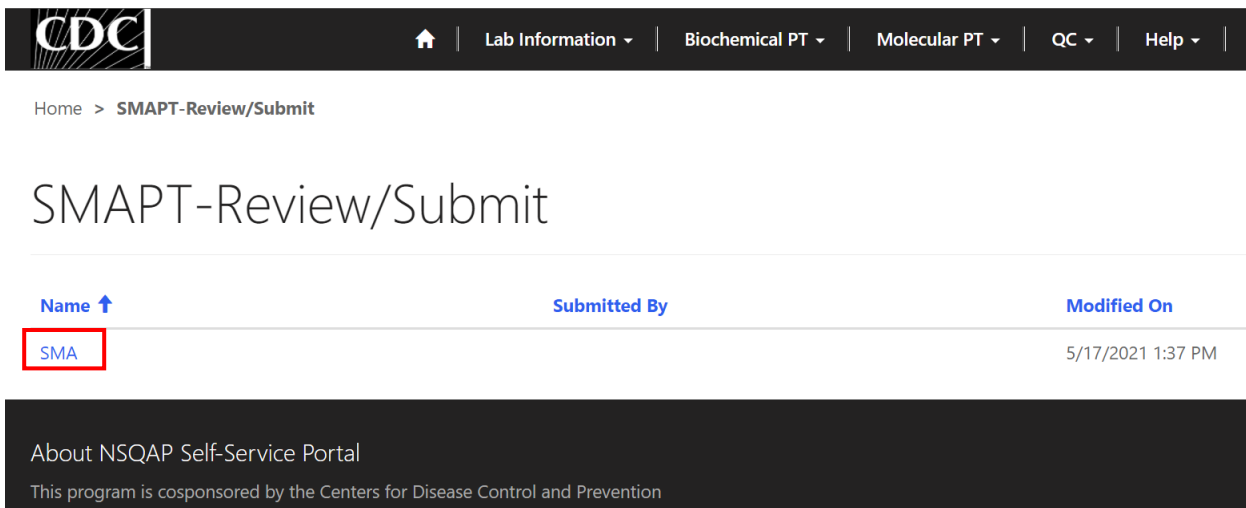
2.1 Navigation

Review and submit SMAPT specimen data after program information and results have been entered and saved (see section 1). Access the review/submit page via the ‘SMA Review/Submit’ option on the Molecular PT drop-down menu.

1. Location of the ‘SMA Review/Submit’ page on the main menu tool bar. Select ‘**Molecular PT**’ then ‘**SMA Review/Submit**’ from the drop-down menu.



2. The SMA Review/Submit landing page will appear. Select ‘**SMA**’ to navigate to the review and submit page.



2.2 Review

1. Navigate to the page titled 'SMAPT – Review/Submit' to review saved SMAPT program method information and results in a read-only format. Navigation details can be found in section 2.1.

☰

Home > SMAPT-Review/Submit

SMAPT-Review/Submit

Method Information

Select a method - LDT refers to Lab Developed Test RUO refers to Research Use Only *

LDT Real Time PCR - SMN1 AND Reference Gene run in a single tube

YOU MUST list commercial method or describe lab developed test

—

Select a DNA extraction method *

Extracta™ DBS

Indicate if this reagent is lab developed or commercial

—

SMN1 Assay Primer and Probe Information

Was a commercial kit used? *

No

SMN1 probe sequence including dye and quencher:

5'-FAM/CGG TGA TGC ATA GGC ACC TGC /BIABLFQ/-3'

SMN1 forward amplification primer sequence:

5'-TTT GTA AAG GTG CCC ACT CCT -3'

SMN1 reverse amplification primer sequence:

5'-TAT TGC AAC TCG TGA GAA CGG TGA AT -3'

Reference Gene Assay Primer and Probe Information

Select a reference gene: *

Beta-actin (ACTB)

YOU MUST specify gene name and symbol

—

Was a commercial kit used? *

No

Reference gene probe sequence including dye and quencher:

5'-HEX/ TTC TGA CCT GAA GGC TCT GCG CG /BIABLFQ/-3'

Reference gene forward amplification primer sequence:

5'-TTT GGA CCT GCG AGC G -3'

Reference gene reverse amplification primer sequence:

5'-GAG CGG CTG TCT CCA CAA GT -3'

SMN1 Exon 7

Specimen Number	Clinical Assessment *	Comments
20214017001	Screen Negative (no follow	—
20214017002	Screen Positive (SMN1 out	—
20214017003	Unsatisfactory sample (SMI	—
20214017004	Screen Positive (SMN1 out	—
20214017005	Screen Negative (no follow	—

NOTE:

After you click submit your submission will be locked and cannot be changed. [Navigate to the SMAPT Entry Page to Make Edits](#)

Submit

* Required Field.

[About NSQAP Self-Service Portal](#)

2. If edits are necessary, navigate back to the SMA entry page and make changes as described in section 1 or click the link **‘Navigate to the SMAPT Entry Page to Make Edits’**.

SMN1 Exon 7

Specimen Number	Clinical Assessment *	Comments
20214017001	Screen Negative (no follow up req)	—
20214017002	Screen Positive (SMN1 out of rang	—
20214017003	Unsatisfactory sample (SMN1 and	—
20214017004	Screen Positive (SMN1 out of rang	—
20214017005	Screen Negative (no follow up req)	—

NOTE:

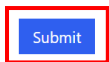
After you click submit your submission will be locked and cannot be changed. [Navigate to the SMAPT Entry Page to Make Edits](#)

3. After reviewing, submit your results by clicking the ‘Submit’ button. See section 2.3 for additional details.

20214017003	Unsatisfactory sample (SMN1 and	—
20214017004	Screen Positive (SMN1 out of rang	—
20214017005	Screen Negative (no follow up req)	—

NOTE:

After you click submit your submission will be locked and cannot be changed. [Navigate to the SMAPT Entry Page to Make Edits](#)



*-Required Field.

2.3 Submit

1. Navigate to the 'SMAPT Review/Submit' page to submit SMAPT method information and results.

Home > SMAPT-Review/Submit

SMAPT-Review/Submit

Method Information

Select a method - LDT refers to Lab Developed Test RUO refers to Research Use Only *
 LDT Real Time PCR - SMN1 AND Reference Gene run in a single tube

YOU MUST list commercial method or describe lab developed test
 —

Select a DNA extraction method *
 Extracta™ DBS

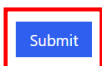
Indicate if this reagent is lab developed or commercial

2. After reviewing the SMA review and submit page, submit results by clicking the 'Submit' button located at the bottom of the page.

Specimen Number	Clinical Assessment *	Comments
20214017003	Unsatisfactory sample (SMN1 and I	—
20214017004	Screen Positive (SMN1 out of rang	—
20214017005	Screen Negative (no follow up req	—

NOTE:

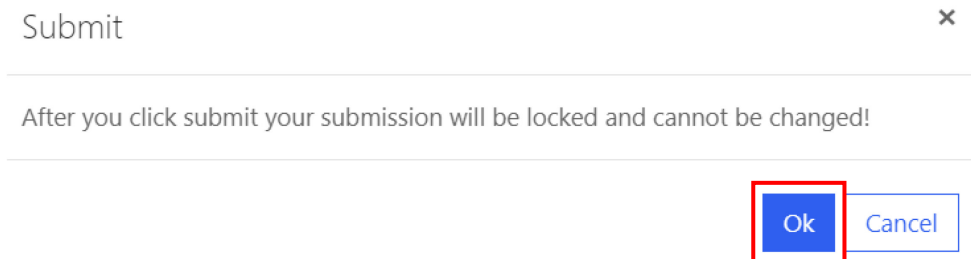
After you click submit your submission will be locked and cannot be changed. [Navigate to the SMAPT Entry Page to Make Edits](#)



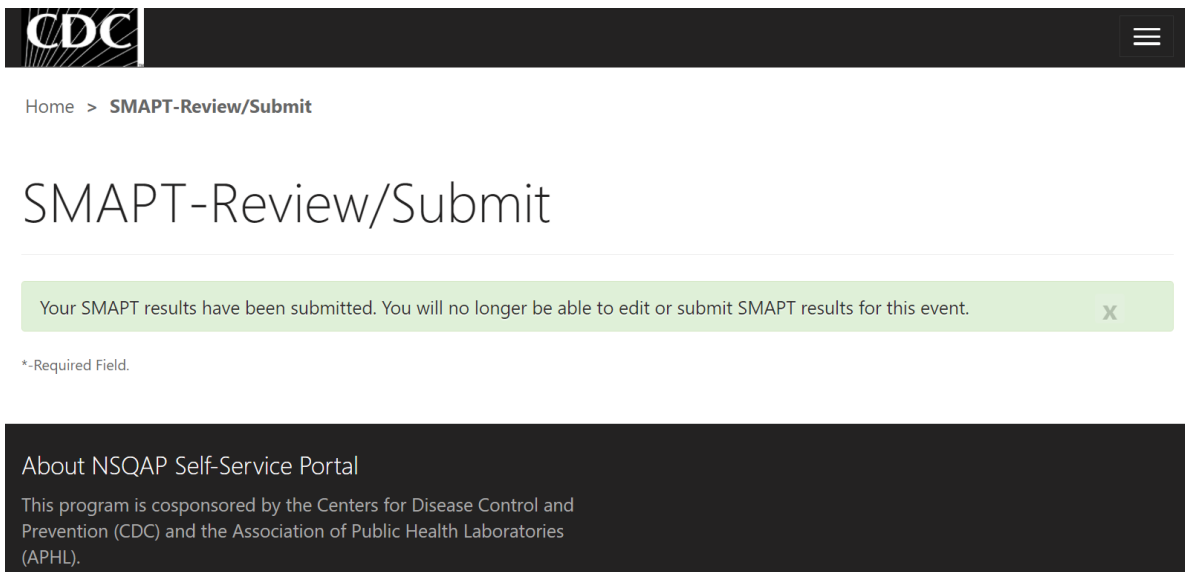
*-Required Field.

3. You will be prompted to confirm that you are ready to submit. Click **'Ok'** to confirm and submit your SMAPT program information and data.

NOTE: You are only allowed to submit your results **ONCE**. You must review and ensure your entered information and data is accurate **PRIOR** to submitting.



4. Once your data is successfully submitted you will be directed to a confirmation page.



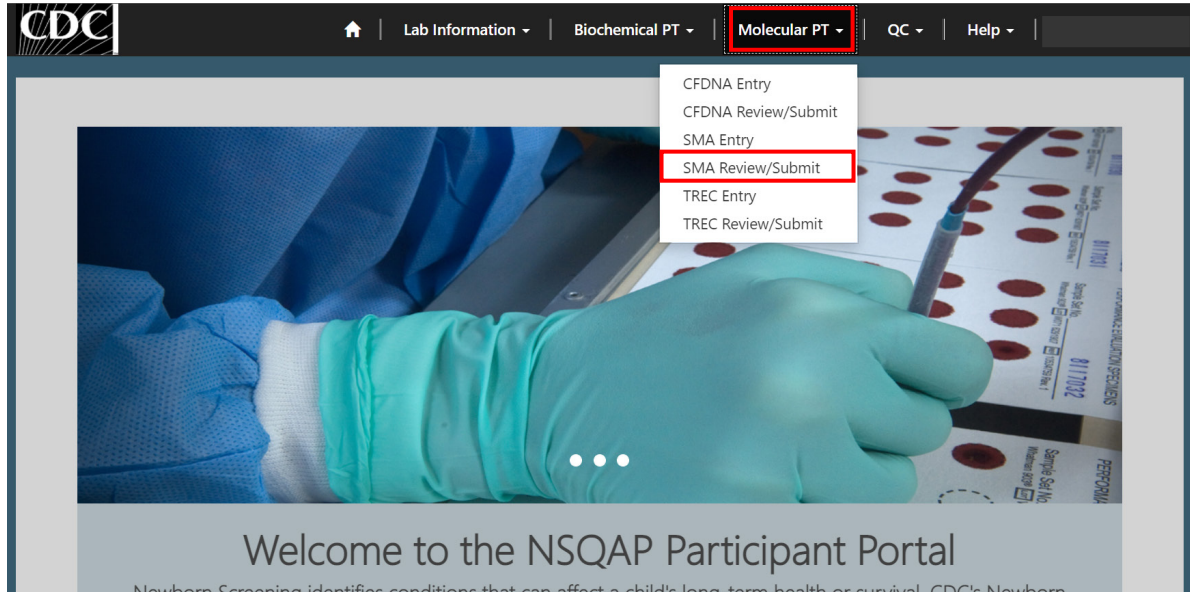
5. The SMAPT data entry page cannot be accessed after submission. You can view your submitted data in a read-only format by accessing the review and submit page (see sections 2.1 and 2.2).

2.4 Save Data – Pdf Format

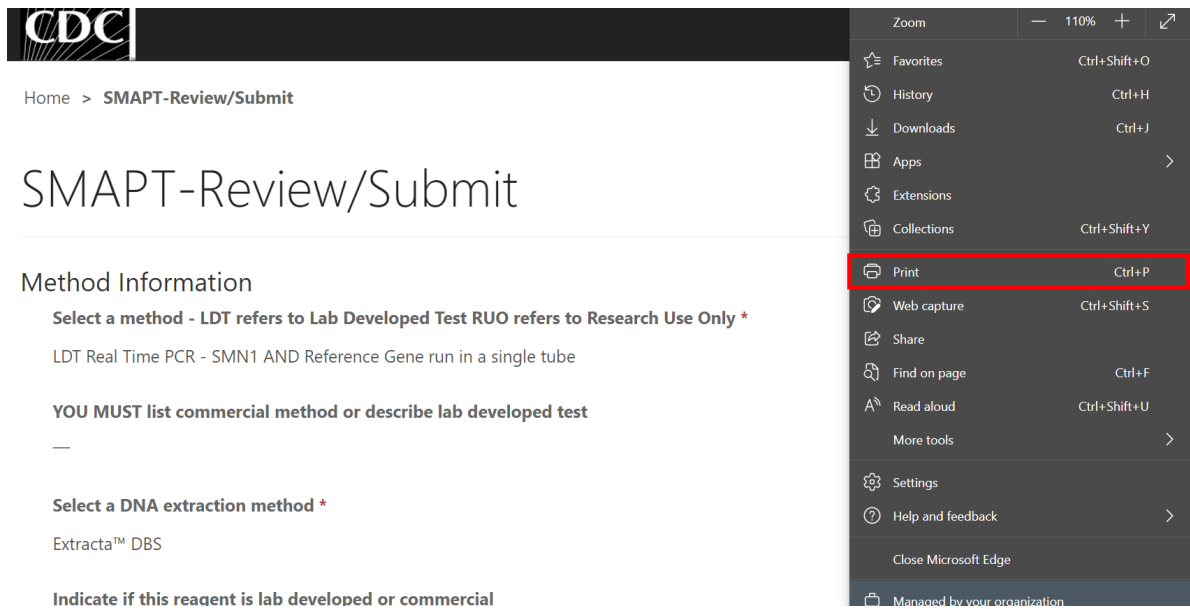
Submitted data can be saved in a pdf format by using the ‘Save a PDF’ function included in your web browser.

Note: The location and appearance of this functionality will vary depending on the web browser being used.

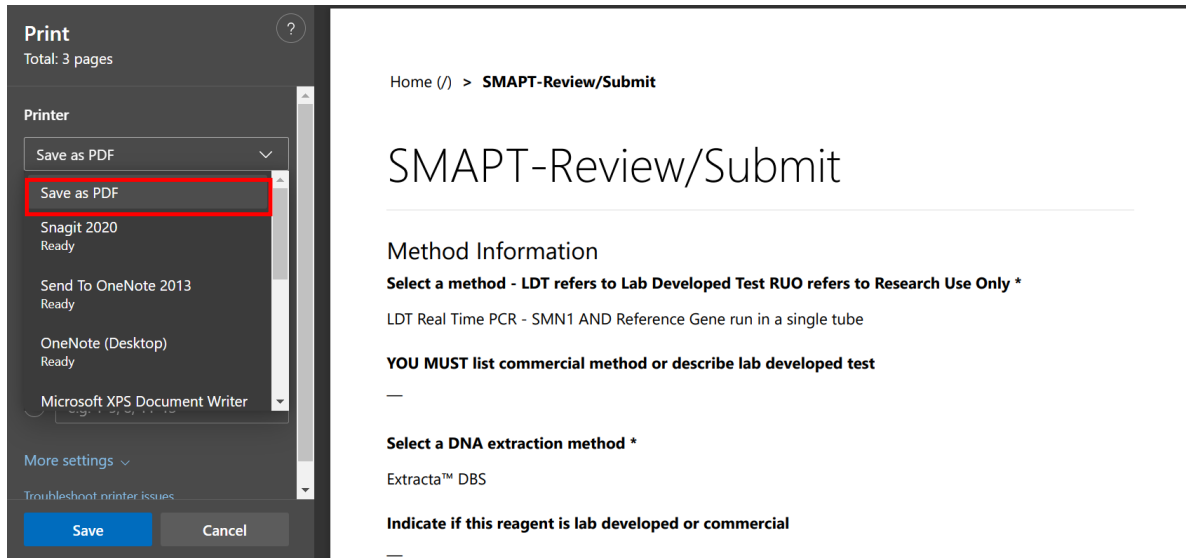
1. Navigate to the review and submit page as described in section 2.1.



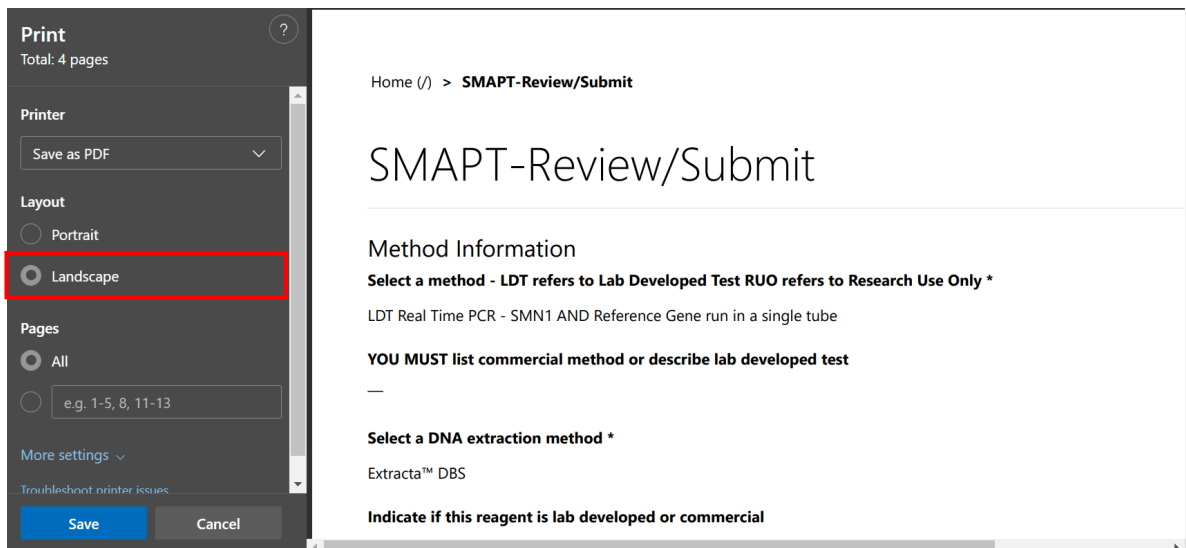
2. Locate the “Print’ function on your web browser.



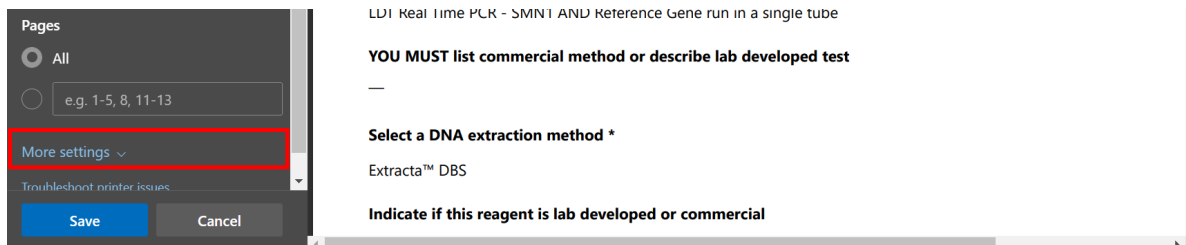
3. Select 'Save as PDF'.



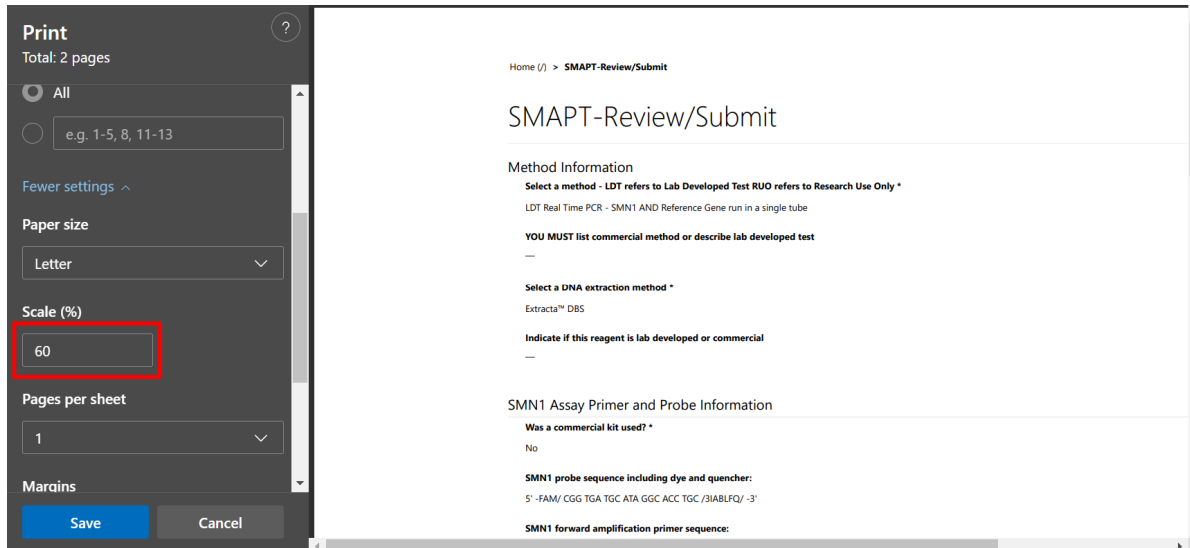
4. Select 'Landscape' as the layout choice.



5. Select 'More Settings'.



6. Adjust the scale percentage to 60%.



7. Select 'Save' to save the pdf file to your local drive's folder of choice.

