

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**

CFDNAPT USER GUIDE

June 2021

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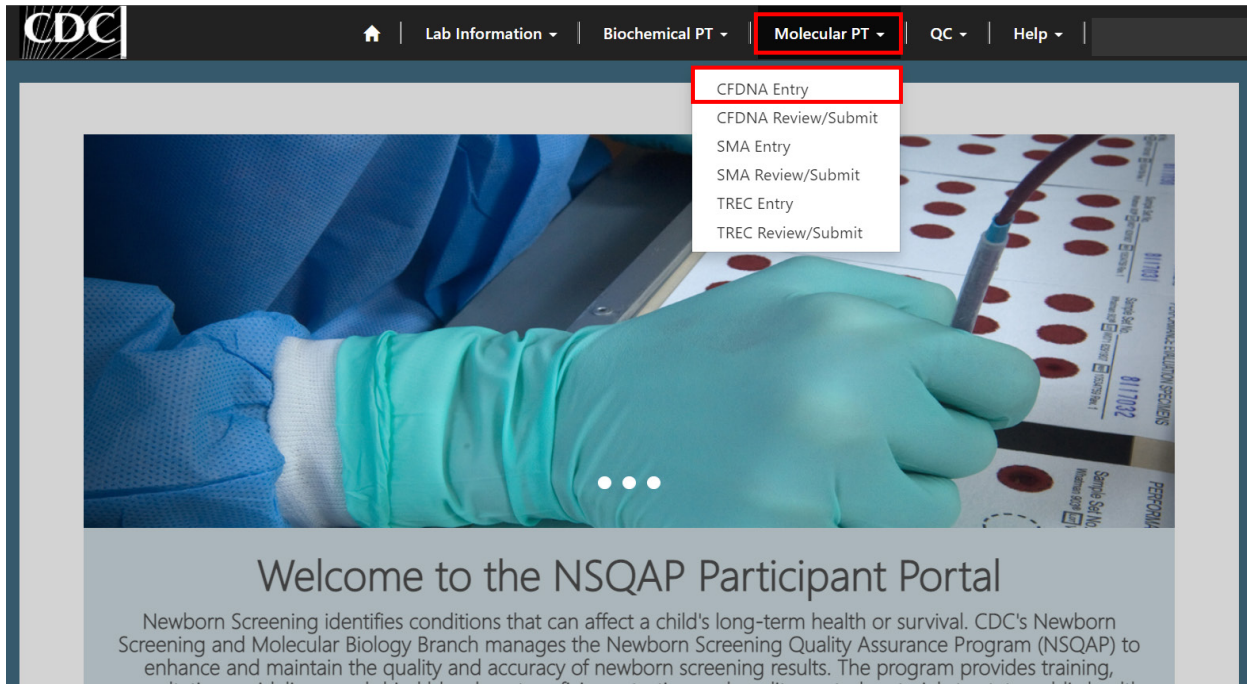
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1. CFDNAPT Program Entry Page

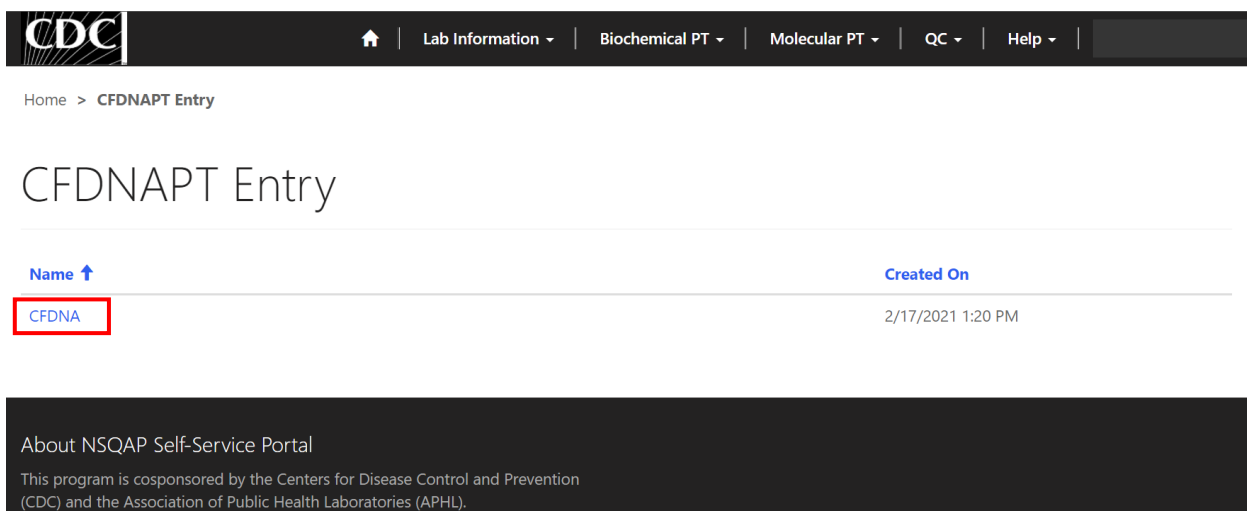
1.1 Navigation

To enter and save CFDNAPT data, navigate to the CFDNAPT program entry page. Access the page from the 'CFDNA Entry' option on the Molecular PT drop-down menu.

1. Click '**Molecular PT**' then '**CFDNA Entry**' from the drop-down menu.



2. Select '**CFDNA**' to navigate to the entry page.



3. You will be directed to the CFDNA entry page to enter method information and data.

1.2 Primary Method Information

Navigate to the page titled 'Cystic Fibrosis DNA Variant Detection Proficiency Testing (CFDNAPT)' to enter method information including primary method, secondary/confirmatory method, and extraction method. Navigation details can be found in section 1.1.

The screenshot shows the top of the CFDNAPT form. At the top left is the CDC logo. Below it is a breadcrumb trail: Home > Cystic Fibrosis DNA Variant Detection Proficiency Testing (CFDNAPT). The main heading is 'Cystic Fibrosis DNA Variant Detection Proficiency Testing (CFDNAPT)'. Below the heading is a definition: † Definition of commercial kit – A kit that has been designed by the manufacturer to sequence the CFTR gene. The section is titled 'Method Information' and 'Primary Method'. There are three input fields: 1. 'Select a primary method *' with a search icon. 2. 'Is your selected method a custom commercial assay OR a lab developed test OR does your lab place restrictions on a commercial assay? *' with a dropdown menu showing 'No'. 3. 'Was a gene sequencing method used? *' with a dropdown menu showing 'No'. Below this is the 'Secondary/Confirmatory Method' section with a search icon. At the bottom is the 'Extraction Method' section with a search icon.

1. Click on the magnifying glass to see the primary methods list.


Cystic Fibrosis DNA Variant Detection Proficiency Testing (CFDNAPT)

† Definition of commercial kit – A kit that has been designed by the manufacturer to sequence the CFTR gene

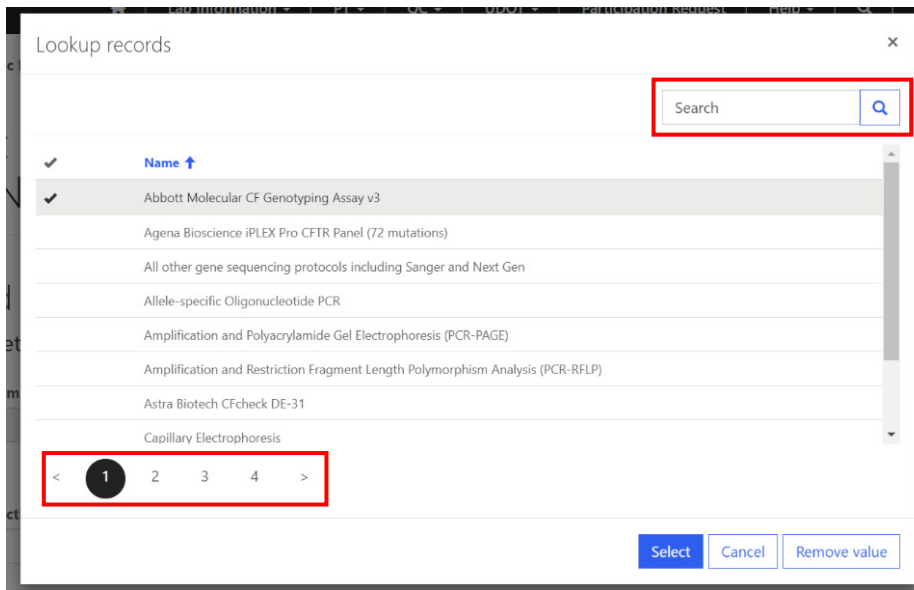
Method Information

Primary Method

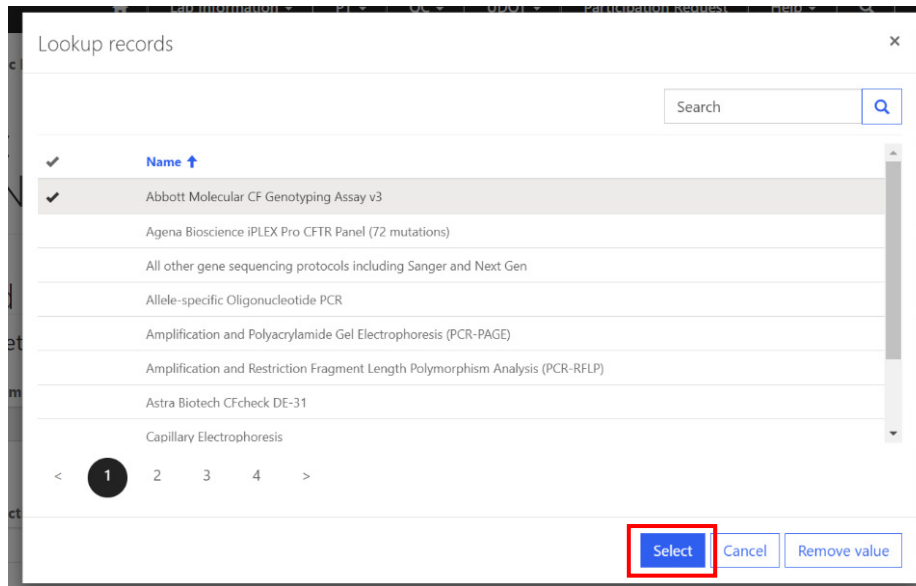
Select a primary method *



2. Search for methods using the search box or page numbers.



3. Choose a primary method then click 'Select'.



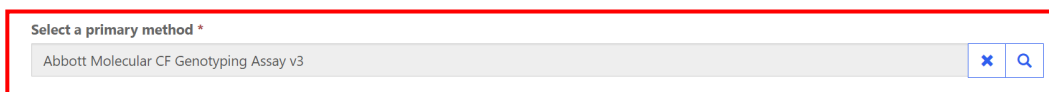
Home > Cystic Fibrosis DNA Variant Detection Proficiency Testing (CFDNAPT)

Cystic Fibrosis DNA Variant Detection Proficiency Testing (CFDNAPT)

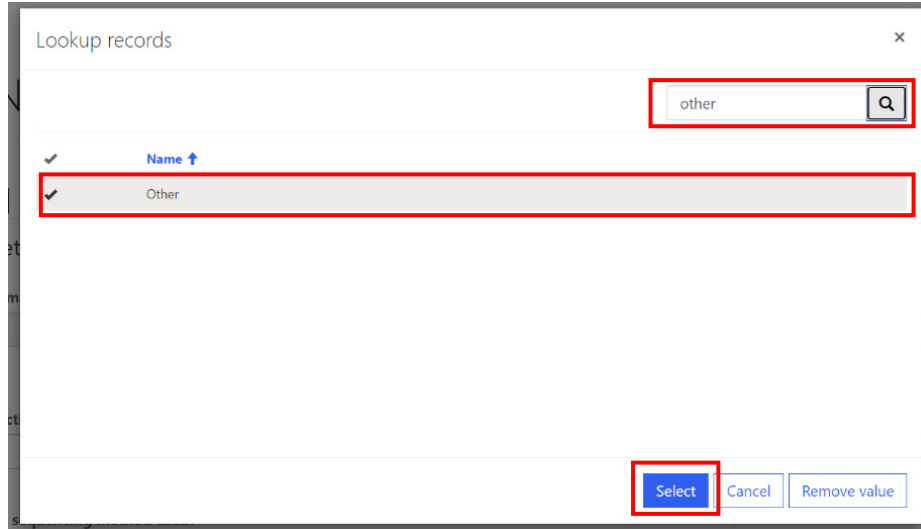
† Definition of commercial kit – A kit that has been designed by the manufacturer to sequence the CFTR gene

Method Information

Primary Method



- If 'Other' is selected, a text box will appear. You are **required** to specify your primary method details.



Cystic Fibrosis DNA Variant Detection Proficiency Testing (CFDNAPT)

† Definition of commercial kit – A kit that has been designed by the manufacturer to sequence the CFTR gene

Method Information

Primary Method

Select a primary method *

Other ✕ 🔍

Other-you must specify *

- Indicate whether your selected primary method is a custom commercial assay, laboratory developed test, or a commercial assay with restrictions set by your lab by clicking the drop-down arrow.

Cystic Fibrosis DNA Variant Detection Proficiency Testing (CFDNAPT)

† Definition of commercial kit – A kit that has been designed by the manufacturer to sequence the CFTR gene

Method Information

Primary Method

Select a primary method *

Abbott Molecular CF Genotyping Assay v3 ✕ 🔍

Is your selected method a custom commercial assay OR a lab developed test OR does your lab place restrictions on a commercial assay? *

No ▼

6. If no restrictions or laboratory specific customizations were made, no additional information is required.

Cystic Fibrosis DNA Variant Detection Proficiency Testing (CFDNAPT)

* Definition of commercial kit – A kit that has been designed by the manufacturer to sequence the CFTR gene

Method Information

Primary Method

Select a primary method *

Abbott Molecular CF Genotyping Assay v3 ✕ 🔍

Is your selected method a custom commercial assay OR a lab developed test OR does your lab place restrictions on a commercial assay? *

No ▾

Was a gene sequencing method used? *

No ▾

7. If restrictions were placed or laboratory specific customizations were made, you are required to specify the variants detected. See section 1.5 for additional information on a helpful tool for correctly formatting this information.

NOTE: List the variants detected by your lab, separate each variant by a semicolon ";". If the variants that your lab detect are on your program's website, you may instead reference your website.

Method Information

Primary Method

Select a primary method *

Abbott Molecular CF Genotyping Assay v3 ✕ 🔍

Is your selected method a custom commercial assay OR a lab developed test OR does your lab place restrictions on a commercial assay? *

Yes ▾

Specify variants detected: *

List the variants detected by your lab-separate each variant by a semicolon ";". If the variants that your lab detect are on your program's website, you may instead list your website.

Was a gene sequencing method used? *

No ▾

8. Indicate whether a gene sequencing method was used by clicking the drop-down arrow.

Select a primary method *

Abbott Molecular CF Genotyping Assay v3

Is your selected method a custom commercial assay OR a lab developed test OR does your lab place restrictions on a commercial assay? *

Yes

Specify variants detected: *

M1V | p.Met1Val / p.Met1? (c.1A>G);Q2X | p.Gln2* (c.4C>T);S4X | p.Ser4* (c.11C>A);S13F | p.Ser13Phe (c.38C>T);182delT | p.Phe17Serfs*8 (c.50delT);L15P | p.Leu15Pro (c.44T>C);185+1G->T | p.? (c.53+1G>T);W19X | p.Trp19* (c.57G>A);G27R | p.Gly27Arg (c.79G>A);G27X | p.Gly27* (c.79G>T);Q30X | p.Gln30* (c.88C>T);Q39X | p.Gln39* (c.115C>T);A46D | p.Ala46Asp (c.137C>A);296+1G->A | p.? (c.164+1G>A);296+1G->T | p.? (c.164+1G>T);296+2T->C | p.? (c.164+2T>C);296+3insT | p.? (c.164+4dupT);297-3C->T | p.? (c.165-3C>T);297-1G->A | p.? (c.165-1G>A);E56K | p.Glu56Lys (c.166G>A);W57G | p.Trp57Gly

List the variants detected by your lab-separate each variant by a semicolon ";". If the variants that your lab detect are on your program's website, you may instead list your website.

Was a gene sequencing method used? *

No

Secondary/Confirmatory Method

9. If a gene sequencing method was not used, no additional information is required.

Is your selected method a custom commercial assay OR a lab developed test OR does your lab place restrictions on a commercial assay? *

Yes

Specify variants detected: *

M1V | p.Met1Val / p.Met1? (c.1A>G);Q2X | p.Gln2* (c.4C>T);S4X | p.Ser4* (c.11C>A);S13F | p.Ser13Phe (c.38C>T);182delT | p.Phe17Serfs*8 (c.50delT);L15P | p.Leu15Pro (c.44T>C);185+1G->T | p.? (c.53+1G>T);W19X | p.Trp19* (c.57G>A);G27R | p.Gly27Arg (c.79G>A);G27X | p.Gly27* (c.79G>T);Q30X | p.Gln30* (c.88C>T);Q39X | p.Gln39* (c.115C>T);A46D | p.Ala46Asp (c.137C>A);296+1G->A | p.? (c.164+1G>A);296+1G->T | p.? (c.164+1G>T);296+2T->C | p.? (c.164+2T>C);296+3insT | p.? (c.164+4dupT);297-3C->T | p.? (c.165-3C>T);297-1G->A | p.? (c.165-1G>A);E56K | p.Glu56Lys (c.166G>A);W57G | p.Trp57Gly

List the variants detected by your lab-separate each variant by a semicolon ";". If the variants that your lab detect are on your program's website, you may instead list your website.

Was a gene sequencing method used? *

No

Secondary/Confirmatory Method

10. If a gene sequencing method was used, indicate whether a commercial kit was used.

Note: A commercial kit is defined as a kit that has been designed by the manufacturer to sequence the CFTR gene.

Is your selected method a custom commercial assay OR a lab developed test OR does your lab place restrictions on a commercial assay? *

Yes

Specify variants detected: *

M1V | p.Met1Val / p.Met1? (c.1A>G);Q2X | p.Gln2* (c.4C>T);S4X | p.Ser4* (c.11C>A);S13F | p.Ser13Phe (c.38C>T);182delT | p.Phe17Serfs*8 (c.50delT);L15P | p.Leu15Pro (c.44T>C);185+1G->T | p.? (c.53+1G>T);W19X | p.Trp19* (c.57G>A);G27R | p.Gly27Arg (c.79G>A);G27X | p.Gly27* (c.79G>T);Q30X | p.Gln30* (c.88C>T);Q39X | p.Gln39* (c.115C>T);A46D | p.Ala46Asp (c.137C>A);296+1G->A | p.? (c.164+1G>A);296+1G->T | p.? (c.164+1G>T);296+2T->C | p.? (c.164+2T>C);296+3insT | p.? (c.164+4dupT);297-3C->T | p.? (c.165-3C>T);297-1G->A | p.? (c.165-1G>A);E56K | p.Glu56Lys (c.166G>A);W57G | p.Trp57Gly

List the variants detected by your lab-separate each variant by a semicolon ";". If the variants that your lab detect are on your program's website, you may instead list your website.

Was a gene sequencing method used? *

Yes

‡ Was a commercial kit used? *

11. If a commercial kit was used, no further information is required.

Is your selected method a custom commercial assay OR a lab developed test OR does your lab place restrictions on a commercial assay? *

Yes

Specify variants detected: *

M1V | p.Met1Val / p.Met1? (c.1A>G);Q2X | p.Gln2* (c.4C>T);S4X | p.Ser4* (c.11C>A);S13F | p.Ser13Phe (c.38C>T);182delT | p.Phe17Serfs*8 (c.50delT);L15P | p.Leu15Pro (c.44T>C);185+1G->T | p.? (c.53+1G>T);W19X | p.Trp19* (c.57G>A);G27R | p.Gly27Arg (c.79G>A);G27X | p.Gly27* (c.79G>T);Q30X | p.Gln30* (c.88C>T);Q39X | p.Gln39* (c.115C>T);A46D | p.Ala46Asp (c.137C>A);296+1G->A | p.? (c.164+1G>A);296+1G->T | p.? (c.164+1G>T);296+2T->C | p.? (c.164+2T>C);296+3insT | p.? (c.164+4dupT);297-3C->T | p.? (c.165-3C>T);297-1G->A | p.? (c.165-1G>A);E56K | p.Glu56Lys (c.166G>A);W57G | p.Trp57Gly

List the variants detected by your lab-separate each variant by a semicolon ";". If the variants that your lab detect are on your program's website, you may instead list your website.

Was a gene sequencing method used? *

Yes

* Was a commercial kit used? *

Yes

12. If a commercial kit was not used, additional gene sequencing regions information is required.

Specify variants detected: *

M1V | p.Met1Val / p.Met1? (c.1A>G);Q2X | p.Gln2* (c.4C>T);S4X | p.Ser4* (c.11C>A);S13F | p.Ser13Phe (c.38C>T);182delT | p.Phe17Serfs*8 (c.50delT);L15P | p.Leu15Pro (c.44T>C);185+1G->T | p.? (c.53+1G>T);W19X | p.Trp19* (c.57G>A);G27R | p.Gly27Arg (c.79G>A);G27X | p.Gly27* (c.79G>T);Q30X | p.Gln30* (c.88C>T);Q39X | p.Gln39* (c.115C>T);A46D | p.Ala46Asp (c.137C>A);296+1G->A | p.? (c.164+1G>A);296+1G->T | p.? (c.164+1G>T);296+2T->C | p.? (c.164+2T>C);296+3insT | p.? (c.164+4dupT);297-3C->T | p.? (c.165-3C>T);297-1G->A | p.? (c.165-1G>A);E56K | p.Glu56Lys (c.166G>A);W57G | p.Trp57Gly

List the variants detected by your lab-separate each variant by a semicolon ";". If the variants that your lab detect are on your program's website, you may instead list your website.

Was a gene sequencing method used? *

Yes

* Was a commercial kit used? *

No

For non-commercial kits, provide regions of the gene that are sequenced *

Specify variants detected: *

M1V | p.Met1Val / p.Met1? (c.1A>G);Q2X | p.Gln2* (c.4C>T);S4X | p.Ser4* (c.11C>A);S13F | p.Ser13Phe (c.38C>T);182delT | p.Phe17Serfs*8 (c.50delT);L15P | p.Leu15Pro (c.44T>C);185+1G->T | p.? (c.53+1G>T);W19X | p.Trp19* (c.57G>A);G27R | p.Gly27Arg (c.79G>A);G27X | p.Gly27* (c.79G>T);Q30X | p.Gln30* (c.88C>T);Q39X | p.Gln39* (c.115C>T);A46D | p.Ala46Asp (c.137C>A);296+1G->A | p.? (c.164+1G>A);296+1G->T | p.? (c.164+1G>T);296+2T->C | p.? (c.164+2T>C);296+3insT | p.? (c.164+4dupT);297-3C->T | p.? (c.165-3C>T);297-1G->A | p.? (c.165-1G>A);E56K | p.Glu56Lys (c.166G>A);W57G | p.Trp57Gly

List the variants detected by your lab-separate each variant by a semicolon ";". If the variants that your lab detect are on your program's website, you may instead list your website.

Was a gene sequencing method used? *

Yes

* Was a commercial kit used? *

No

For non-commercial kits, provide regions of the gene that are sequenced *

exons 1 to 27 and at least 20 bases into the 5' and 3' ends of all introns, the CFTR poly T status and TG tract, intron 22

13. After entering primary method information, continue to the secondary/confirmatory method section (if necessary – section 1.3) or the extraction method section (section 1.4).

1.3 Secondary/Confirmatory Method Information

Navigate to the page titled ‘Cystic Fibrosis DNA Variant Detection Proficiency Testing (CFDNAPT)’ to enter method information including primary method, secondary/confirmatory method, and extraction method.

Reporting of secondary/confirmatory method information is only required by participants if a secondary/confirmatory method is utilized. If this method is not utilized, proceed to section 1.4 for guidance on reporting extraction method information. If a secondary/confirmatory method is utilized, continue to step 1 for reporting guidance.

1. Select a secondary/confirmatory method by clicking on the magnifying glass.

Was a gene sequencing method used? *

Yes

* Was a commercial kit used? *

No

For non-commercial kits, provide regions of the gene that are sequenced *

exons 1 to 27 and at least 20 bases into the 5' and 3' ends of all introns, the CFTR poly T status and TG tract, intron 22

Secondary/Confirmatory Method

Select a secondary/confirmatory method

Extraction Method

Select an extraction method *

2. Choose a method then click ‘Select’.

Lookup records

Search

Abbott Molecular CF Genotyping Assay v3

Agena Bioscience iPLEX Pro CFTR Panel (72 mutations)

All other gene sequencing protocols including Sanger and Next Gen

Allele-specific Oligonucleotide PCR

Amplification and Polyacrylamide Gel Electrophoresis (PCR-PAGE)

Amplification and Restriction Fragment Length Polymorphism Analysis (PCR-RFLP)

Astra Biotech CFcheck DE-31

Capillary Electrophoresis

1 2 3 4 >

Select Cancel Remove value

For non-commercial kits, provide regions of the gene that are sequenced *

exons 1 to 27 and at least 20 bases into the 5' and 3' ends of all introns, the CFTR poly T status and TG tract, intron 22

Secondary/Confirmatory Method

Select a secondary/confirmatory method

Agena Bioscience iPLEX Pro CFTR Panel (72 mutations) ✕ 🔍

Select an algorithm for utilization of the secondary/confirmatory method *

🔍

3. Select an algorithm for utilization of the secondary/confirmatory method by clicking on the magnifying glass.

For non-commercial kits, provide regions of the gene that are sequenced *

exons 1 to 27 and at least 20 bases into the 5' and 3' ends of all introns, the CFTR poly T status and TG tract, intron 22

Secondary/Confirmatory Method

Select a secondary/confirmatory method

Agena Bioscience iPLEX Pro CFTR Panel (72 mutations) ✕ 🔍

Select an algorithm for utilization of the secondary/confirmatory method *

🔍

4. Choose an algorithm then click 'Select'.

Lookup records

Search 🔍

- ✓ Utilization of Secondary Confirmatory ↑
- ✓ Both the primary and secondary methods are used to detect variants
- Other
- Secondary method run only when primary method is positive and may find additional variants
- Secondary method run only when primary method is positive and only for confirmation (NO new variants identified)

Select Cancel Remove value

Secondary/Confirmatory Method

Select a secondary/confirmatory method

Agena Bioscience iPLEX Pro CFTR Panel (72 mutations) ✕ 🔍

Select an algorithm for utilization of the secondary/confirmatory method *

Both the primary and secondary methods are used to detect variants ✕ 🔍

Is your selected method a custom commercial assay OR a lab developed test OR does your lab place restrictions on a commercial assay? *

5. Click the drop-down arrow to indicate whether your selected secondary/confirmatory method is a custom commercial assay, laboratory developed test, or a commercial assay with restrictions set by your lab.

Secondary/Confirmatory Method

Select a secondary/confirmatory method

Agena Bioscience iPLEX Pro CFTR Panel (72 mutations) ✕ 🔍

Select an algorithm for utilization of the secondary/confirmatory method *

Both the primary and secondary methods are used to detect variants ✕ 🔍

Is your selected method a custom commercial assay OR a lab developed test OR does your lab place restrictions on a commercial assay? *

✕ 🔍

6. If no restrictions or laboratory specific customizations were made, no additional information is required.

Secondary/Confirmatory Method

Select a secondary/confirmatory method

Agena Bioscience iPLEX Pro CFTR Panel (72 mutations) ✕ 🔍

Select an algorithm for utilization of the secondary/confirmatory method *

Both the primary and secondary methods are used to detect variants ✕ 🔍

Is your selected method a custom commercial assay OR a lab developed test OR does your lab place restrictions on a commercial assay? *

No

Was a gene sequencing method used? *

- If restrictions were placed or laboratory specific customizations were made, you are required to specify the variants detected. See section 1.5 for additional information on a helpful tool for correctly formatting this information.

NOTE: List the variants detected by your lab, separate each variant by a semicolon ";". If the variants that your lab detect are on your program's website, you may instead reference your website.

Secondary/Confirmatory Method

Select a secondary/confirmatory method

Agena Bioscience iPLEX Pro CFTR Panel (72 mutations)



Select an algorithm for utilization of the secondary/confirmatory method *

Both the primary and secondary methods are used to detect variants



Is your selected method a custom commercial assay OR a lab developed test OR does your lab place restrictions on a commercial assay? *

Yes

Specify Variants Detected *

List the variants detected by your lab-separate each variant by a semicolon ";". If the variants that your lab detect are on your program's website, you may instead list your website.

- Indicate whether a gene sequencing method was used by clicking the drop-down arrow.

Is your selected method a custom commercial assay OR a lab developed test OR does your lab place restrictions on a commercial assay? *

Yes

Specify Variants Detected *

(c.174_177delTAGA);Subinsa | p.Arg59Lys*10 (c.175dupA);E60K | p.Glu60Lys (c.178G>A);E60X | p.Glu60* (c.178G>T);P67L | p.Prob7Leu (c.200C>T);K75X | p.Arg75* (c.223C>T);365-366insT | p.Trp79Leufs*32(c.233dupT);G85E | p.Gly85Glu (c.254G>A);394delTT | p.Leu88Ilefs*22;(c.262_263delTT);L88X | p.Leu88* (c.263T>A);L88X | p.Leu88* (c.263T>G);G91R | p.Gly91Arg (c.271G>A);405+1G->A | p.? (c.273+1G>A);405+3A->C | p.? (c.273+3A>C);406-2A->G | p.? (c.274-2A>G);406-1G->A | p.? (c.274-1G>A);E92K | p.Glu92Lys (c.274G>A);E92X | p.Glu92* (c.274G>T);Q98X | p.Gln98* (c.292C>T);Q98R | p.Gln98Arg (c.293A>G);P99L | p.Pro99Leu (c.296C>T);L102R | p.Leu102Arg (c.305T>G);442delA | p.Arg104Glu*3 (c.310delA)

List the variants detected by your lab-separate each variant by a semicolon ";". If the variants that your lab detect are on your program's website, you may instead list your website.

Was a gene sequencing method used? *

v

Extraction Method

Select an extraction method *

Q

9. If a gene sequencing method was not used, no additional information is required.

Is your selected method a custom commercial assay OR a lab developed test OR does your lab place restrictions on a commercial assay? *

Yes

Specify Variants Detected *

(c.174_177delTAGA);306insA | p.Arg59Lys*10 (c.175dupA);E60K | p.Glu60Lys (c.178G>A);E60X | p.Glu60* (c.178G>T);P6/L | p.Pro67Leu (c.200C>T);K75X | p.Arg75* (c.223C>T);365-366insT | p.Trp79Leufs*32(c.233dupT);G85E | p.Gly85Glu (c.254G>A);394delTT | p.Leu88Ilefs*22;(c.262_263delTT);L88X | p.Leu88* (c.263T>A);L88X | p.Leu88* (c.263T>G);G91R | p.Gly91Arg (c.271G>A);405+1G->A | p.? (c.273+1G>A);405+3A->C | p.? (c.273+3A>C);406-2A->G | p.? (c.274-2A>G);406-1G->A | p.? (c.274-1G>A);E92K | p.Glu92Lys (c.274G>A);E92X | p.Glu92* (c.274G>T);Q98X | p.Gln98* (c.292C>T);Q98R | p.Gln98Arg (c.293A>G);P99L | p.Pro99Leu (c.296C>T);L102R | p.Leu102Arg (c.305T>G);442delA | p.Arg104Glu*3 (c.310delA)

List the variants detected by your lab-separate each variant by a semicolon ";". If the variants that your lab detect are on your program's website, you may instead list your website.

Was a gene sequencing method used? *

No

Extraction Method

Select an extraction method *

10. If a gene sequencing method was used, indicate whether a commercial kit was used.

Note: A commercial kit is defined as a kit that has been designed by the manufacturer to sequence the CFTR gene.

Is your selected method a custom commercial assay OR a lab developed test OR does your lab place restrictions on a commercial assay? *

Yes

Specify Variants Detected *

(c.174_177delTAGA);306insA | p.Arg59Lys*10 (c.175dupA);E60K | p.Glu60Lys (c.178G>A);E60X | p.Glu60* (c.178G>T);P6/L | p.Pro67Leu (c.200C>T);K75X | p.Arg75* (c.223C>T);365-366insT | p.Trp79Leufs*32(c.233dupT);G85E | p.Gly85Glu (c.254G>A);394delTT | p.Leu88Ilefs*22;(c.262_263delTT);L88X | p.Leu88* (c.263T>A);L88X | p.Leu88* (c.263T>G);G91R | p.Gly91Arg (c.271G>A);405+1G->A | p.? (c.273+1G>A);405+3A->C | p.? (c.273+3A>C);406-2A->G | p.? (c.274-2A>G);406-1G->A | p.? (c.274-1G>A);E92K | p.Glu92Lys (c.274G>A);E92X | p.Glu92* (c.274G>T);Q98X | p.Gln98* (c.292C>T);Q98R | p.Gln98Arg (c.293A>G);P99L | p.Pro99Leu (c.296C>T);L102R | p.Leu102Arg (c.305T>G);442delA | p.Arg104Glu*3 (c.310delA)

List the variants detected by your lab-separate each variant by a semicolon ";". If the variants that your lab detect are on your program's website, you may instead list your website.

Was a gene sequencing method used? *

Yes

Was a commercial kit used? *

11. If a commercial kit was used, no further information is required.

Is your selected method a custom commercial assay OR a lab developed test OR does your lab place restrictions on a commercial assay? *

Yes

Specify Variants Detected *

(c.174_177del1AGA);306insA | p.Arg59Lysfs*10 (c.175dupA);E60K | p.Glu60Lys (c.178G>A);E60X | p.Glu60* (c.178G>T);P67L | p.Prob7Leu (c.200C>T);R75X | p.Arg75* (c.223C>T);365-366insT | p.Trp79Leufs*32 (c.233dupT);G85E | p.Gly85Glu (c.254G>A);394delTT | p.Leu88Ilefs*22 (c.262_263delTT);L88X | p.Leu88* (c.263T>A);L88X | p.Leu88* (c.263T>G);G91R | p.Gly91Arg (c.271G>A);405+1G->A | p.? (c.273+1G>A);405+3A->C | p.? (c.273+3A>C);406-2A->G | p.? (c.274-2A>G);406-1G->A | p.? (c.274-1G>A);E92K | p.Glu92Lys (c.274G>A);E92X | p.Glu92* (c.274G>T);Q98X | p.Gln98* (c.292C>T);Q98R | p.Gln98Arg (c.293A>G);P99L | p.Pro99Leu (c.296C>T);L102R | p.Leu102Arg (c.305T>G);442delA | p.Arg104Glu fs*3 (c.310delA)

List the variants detected by your lab-separate each variant by a semicolon ";". If the variants that your lab detect are on your program's website, you may instead list your website.

Was a gene sequencing method used? *

Yes

Was a commercial kit used? *

Yes

12. If a commercial kit was not used, gene sequencing regions information is required.

Is your selected method a custom commercial assay OR a lab developed test OR does your lab place restrictions on a commercial assay? *

Yes

Specify Variants Detected *

(c.174_177del1AGA);306insA | p.Arg59Lysfs*10 (c.175dupA);E60K | p.Glu60Lys (c.178G>A);E60X | p.Glu60* (c.178G>T);P67L | p.Prob7Leu (c.200C>T);R75X | p.Arg75* (c.223C>T);365-366insT | p.Trp79Leufs*32 (c.233dupT);G85E | p.Gly85Glu (c.254G>A);394delTT | p.Leu88Ilefs*22 (c.262_263delTT);L88X | p.Leu88* (c.263T>A);L88X | p.Leu88* (c.263T>G);G91R | p.Gly91Arg (c.271G>A);405+1G->A | p.? (c.273+1G>A);405+3A->C | p.? (c.273+3A>C);406-2A->G | p.? (c.274-2A>G);406-1G->A | p.? (c.274-1G>A);E92K | p.Glu92Lys (c.274G>A);E92X | p.Glu92* (c.274G>T);Q98X | p.Gln98* (c.292C>T);Q98R | p.Gln98Arg (c.293A>G);P99L | p.Pro99Leu (c.296C>T);L102R | p.Leu102Arg (c.305T>G);442delA | p.Arg104Glu fs*3 (c.310delA)

List the variants detected by your lab-separate each variant by a semicolon ";". If the variants that your lab detect are on your program's website, you may instead list your website.

Was a gene sequencing method used? *

Yes

Was a commercial kit used? *

No

For non-commercial kits, provide regions of the gene that are sequenced *

Specify Variants Detected *

(c.174_177del1AGA);306insA | p.Arg59Lysfs*10 (c.175dupA);E60K | p.Glu60Lys (c.178G>A);E60X | p.Glu60* (c.178G>T);P67L | p.Prob7Leu (c.200C>T);R75X | p.Arg75* (c.223C>T);365-366insT | p.Trp79Leufs*32 (c.233dupT);G85E | p.Gly85Glu (c.254G>A);394delTT | p.Leu88Ilefs*22 (c.262_263delTT);L88X | p.Leu88* (c.263T>A);L88X | p.Leu88* (c.263T>G);G91R | p.Gly91Arg (c.271G>A);405+1G->A | p.? (c.273+1G>A);405+3A->C | p.? (c.273+3A>C);406-2A->G | p.? (c.274-2A>G);406-1G->A | p.? (c.274-1G>A);E92K | p.Glu92Lys (c.274G>A);E92X | p.Glu92* (c.274G>T);Q98X | p.Gln98* (c.292C>T);Q98R | p.Gln98Arg (c.293A>G);P99L | p.Pro99Leu (c.296C>T);L102R | p.Leu102Arg (c.305T>G);442delA | p.Arg104Glu fs*3 (c.310delA)

List the variants detected by your lab-separate each variant by a semicolon ";". If the variants that your lab detect are on your program's website, you may instead list your website.

Was a gene sequencing method used? *

Yes

Was a commercial kit used? *

No

For non-commercial kits, provide regions of the gene that are sequenced *

exons 1 to 27 and at least 20 bases into the 5' and 3' ends of all introns, the CFTR poly T status and TG tract, intron 22

Extraction Method

Select an extraction method *

Q


1.4 Extraction Method Information

Navigate to the page titled ‘Cystic Fibrosis DNA Variant Detection Proficiency Testing (CFDNAPT)’ to enter method information including primary method, secondary/confirmatory method, and extraction method.

1. To select an extraction method, click on the magnifying glass and select a method from the search box.


Extraction Method

Select an extraction method *



2. Choose a method then click ‘Select’.

Lookup records x



Name ↑
✓ In-house alkaline lysis prep
In-house boiling prep
In-house Chelex method
In-house lysis boil prep
Other
Perkin Elmer/Chemagen Chemagic kit
Qiagen Generation DNA Purification & DNA Elution Solutions (also sold as 5 Prime Easy PCR Solutions 1 & 2)
Qiagen magnetic bead kit (EZ1 or BioSprint 96)

< 1 2 >

Select

Cancel

Remove value

For non-commercial kits, provide regions of the gene that are sequenced *

Extraction Method

Select an extraction method *

x
Q

Pathogenic Variant Data

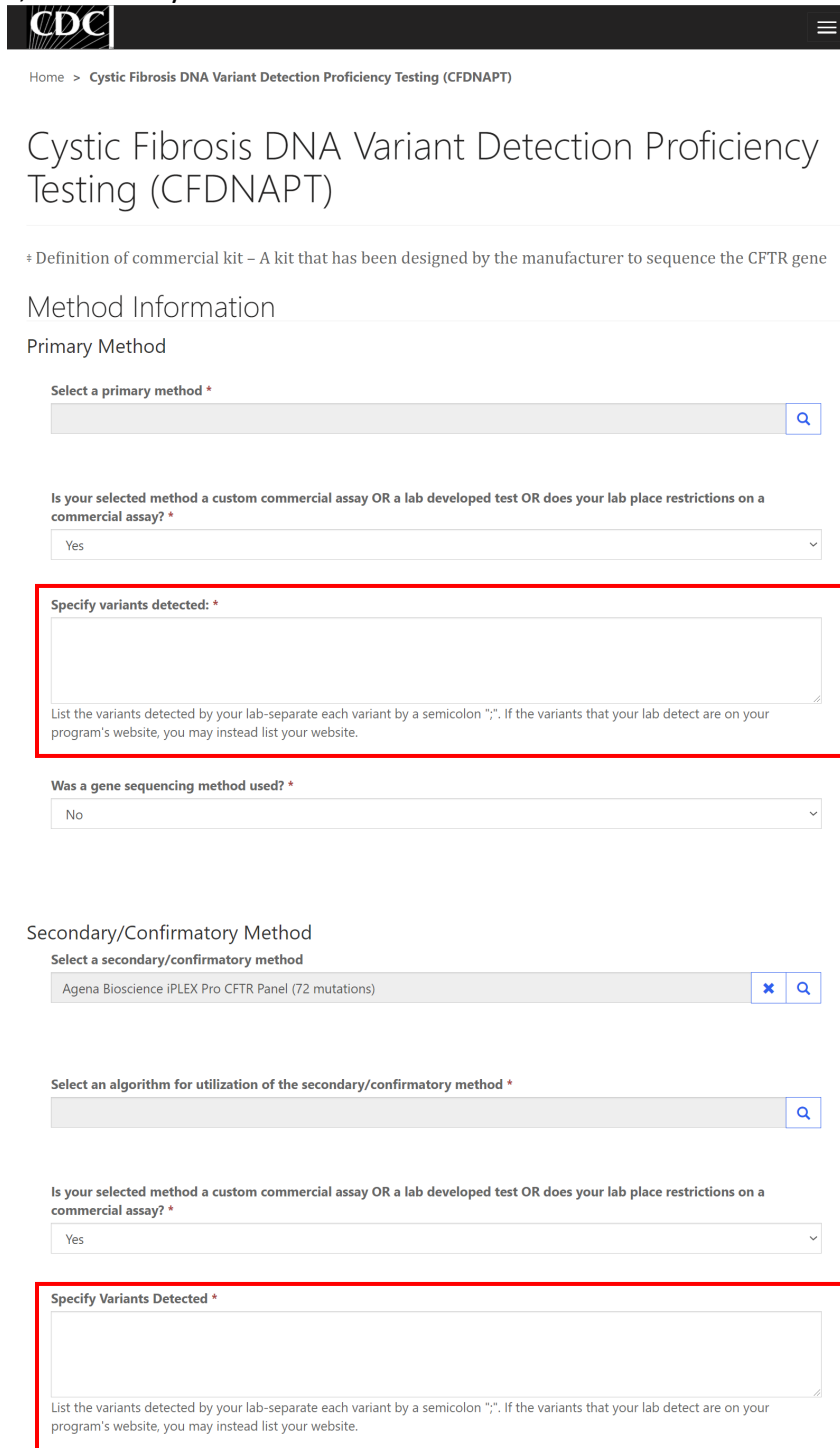
If the variant you wish to enter is not found within the searchable listing, select "other" and then enter the variant in the field that will appear when "other" is selected.

3. Continue to section 1.6 for guidance on reporting pathogenic variant data.

1.5 Specifying Variants Detected

If restrictions were placed or laboratory specific customizations were made on variants that are detectable using a primary or secondary/confirmatory method, the detected variants must be specified for each method.

The variants detected by your lab should be listed in the indicated text boxes. **Format each variant by separating each with a semicolon ";"**. Alternatively, if the variants that your lab detect are on your program's website, reference your website.



Home > Cystic Fibrosis DNA Variant Detection Proficiency Testing (CFDNAPT)

Cystic Fibrosis DNA Variant Detection Proficiency Testing (CFDNAPT)

+ Definition of commercial kit – A kit that has been designed by the manufacturer to sequence the CFTR gene

Method Information

Primary Method

Select a primary method *

Is your selected method a custom commercial assay OR a lab developed test OR does your lab place restrictions on a commercial assay? *

Yes

Specify variants detected: *

List the variants detected by your lab-separate each variant by a semicolon ";". If the variants that your lab detect are on your program's website, you may instead list your website.

Was a gene sequencing method used? *

No

Secondary/Confirmatory Method

Select a secondary/confirmatory method

Agena Bioscience iPLEX Pro CFTR Panel (72 mutations)

Select an algorithm for utilization of the secondary/confirmatory method *

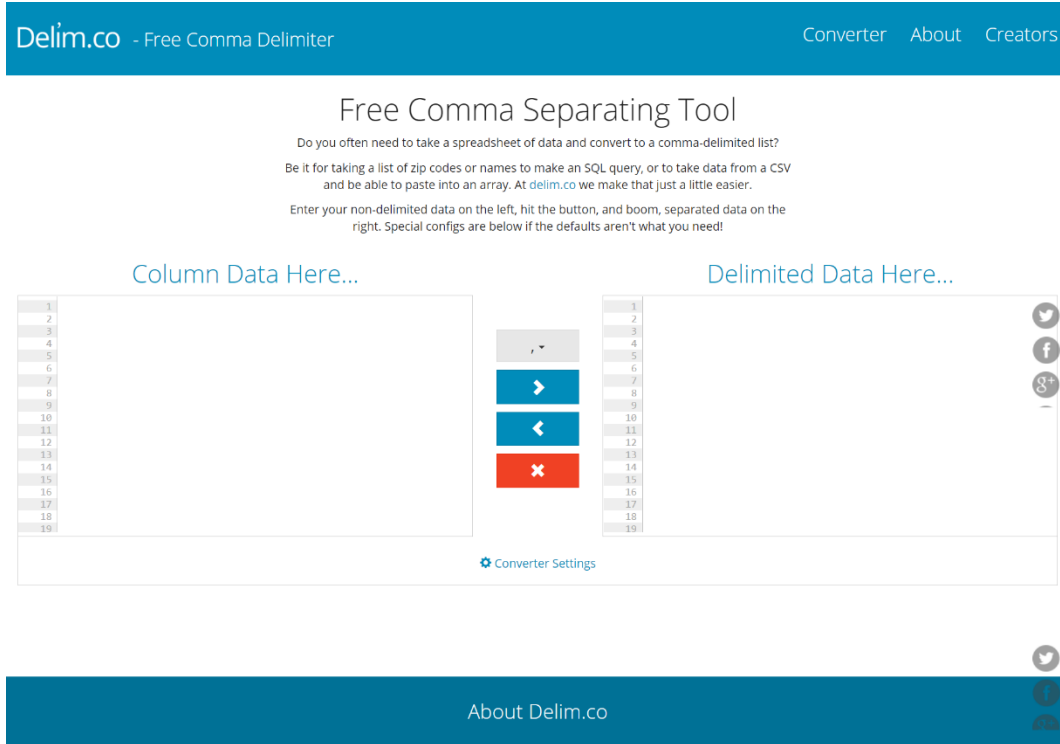
Is your selected method a custom commercial assay OR a lab developed test OR does your lab place restrictions on a commercial assay? *

Yes

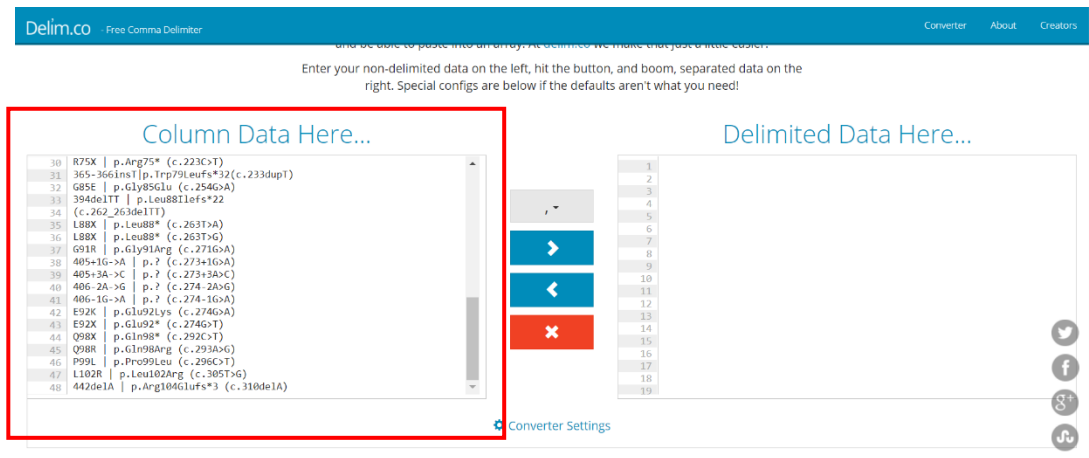
Specify Variants Detected *

List the variants detected by your lab-separate each variant by a semicolon ";". If the variants that your lab detect are on your program's website, you may instead list your website.

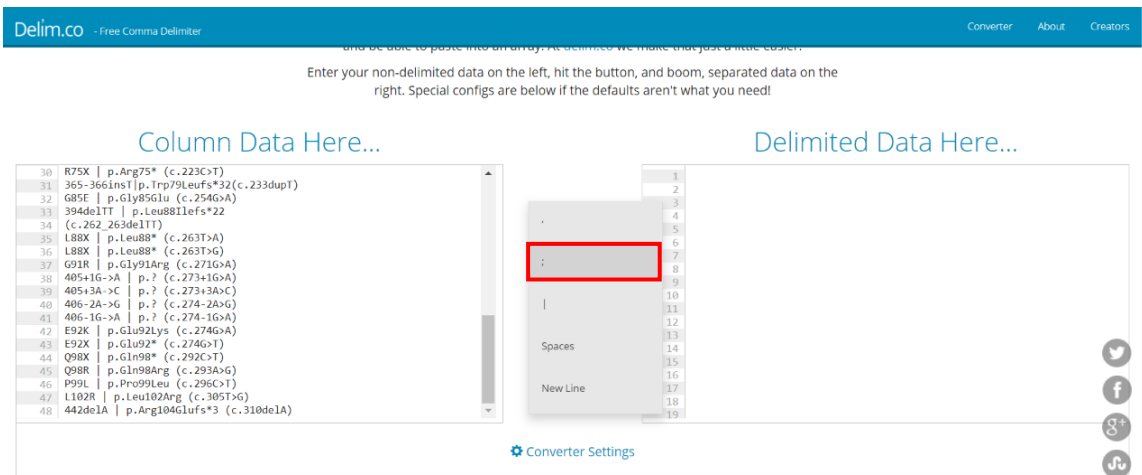
To assist with formatting the variant list, the delim.co website can be used as a tool to generate the formatted list. The tool can be found [here](http://delim.co).



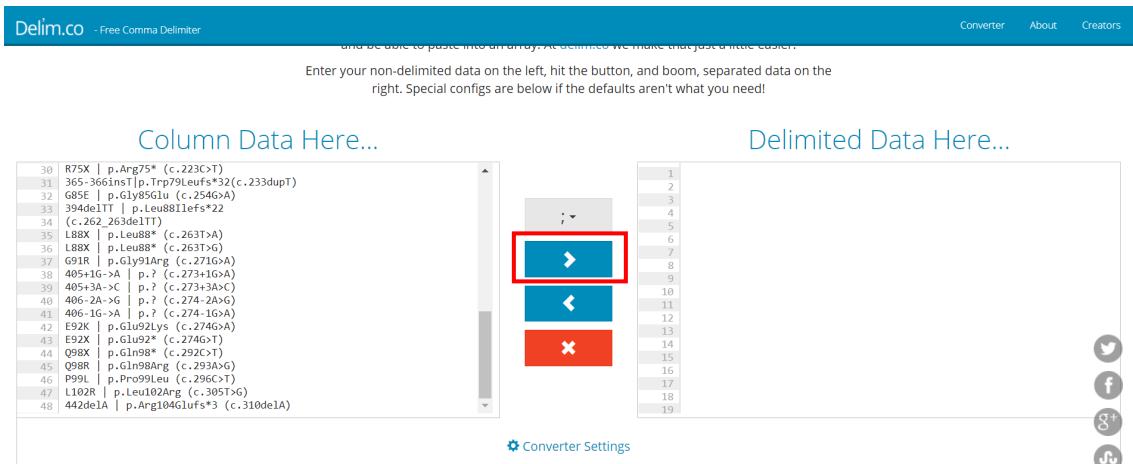
1. Paste the unformatted variant list in the box labeled 'Column Data Here'.



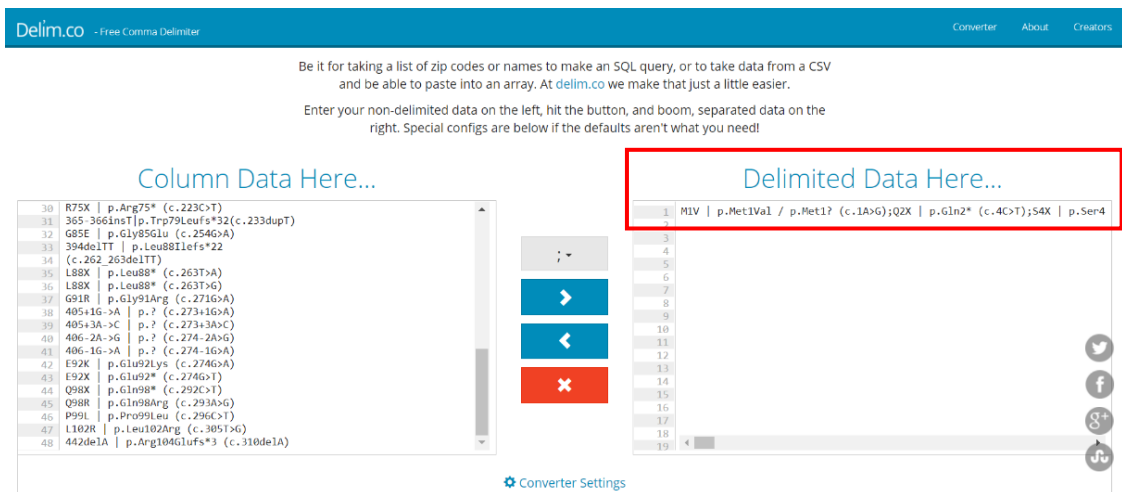
2. Select the semicolon option for the drop-down menu.



3. Select the blue right pointing arrow.



4. Copy formatted data and paste into the NSQAP CFDNAPT Portal page.



1.6 Specimen Results - Pathogenic Variant Data Entry

Navigate to the page titled ‘Cystic Fibrosis DNA Variant Detection Proficiency Testing (CFDNAPT)’ to enter CFDNAPT pathogenic variant results including allele 1, allele 2, and clinical assessment for each specimen. Navigation details can be found in section 1.1.



Home > Cystic Fibrosis DNA Variant Detection Proficiency Testing (CFDNAPT)

Cystic Fibrosis DNA Variant Detection Proficiency Testing (CFDNAPT)

Pathogenic Variant Data

If the variant you wish to enter is not found within the searchable listing, select "other" and then enter the variant in the field that will appear when "other" is selected.

Specimen Number

20211011001

Allele 1 *	Allele 2 *	Clinical Assessment *	Comments
<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>

Specimen Number

20211011002

Allele 1 *	Allele 2 *	Clinical Assessment *	Comments
<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>

Specimen Number

20211011003

Allele 1 *	Allele 2 *	Clinical Assessment *	Comments
<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>

Specimen Number

20211011004

Allele 1 *	Allele 2 *	Clinical Assessment *	Comments
<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>

Specimen Number

20211011005

Allele 1 *	Allele 2 *	Clinical Assessment *	Comments
<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>

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.

Save

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).

1. Click the magnifying glass to select a variant value for 'Allele 1' and 'Allele 2' for each specimen.

Pathogenic Variant Data

If the variant you wish to enter is not found within the searchable listing, select "other" and then enter the variant in the field that will appear when "other" is selected.

Specimen Number
20211011001

Allele 1 *

Allele 2 *

Clinical Assessment *

Comments

2. Search for variants using the search box. Click 'Select'.

Lookup records x

Search

✓ Display Name	Variant cDNA name ↓	Variant protein name	Variant legacy name
✓ No variants detected	No variants detected	No variants detected	No variants detected
G330X (p.Gly330X)	c.988G>T	p.Gly330X	G330X
1119delA (p.Gly330GlufsX39)	c.987delA	p.Gly330GlufsX39	1119delA
L320V (p.Leu320Val)	c.958T>G	p.Leu320Val	L320V
1078delT (p.Phe316LeufsX12)	c.948delT	p.Phe316LeufsX12	1078delT
G314E (p.Gly314Glu)	c.941G>A	p.Gly314Glu	G314E
F311L (p.Phe311Leu)	c.933C>G	p.Phe311Leu	F311L
F311del (p.Phe312del)	c.933_935delCTT	p.Phe312del	F311del

< 1 2 3 4 5 6 7 8 ... 43 >

Pathogenic Variant Data

If the variant you wish to enter is not found within the searchable listing, select "other" and then enter the variant in the field that will appear when "other" is selected.

Specimen Number
20211011001

Allele 1 *

Allele 2 *

Clinical Assessment *

Comments

Specimen Number
20211011002

Allele 1 *

Allele 2 *

Clinical Assessment *

Comments

3. Variants can be quickly located by typing the variant name in the provided search box.

Lookup records x

1898

✓ Display Name	Variant cDNA name ↓	Variant protein name	Variant legacy name
1898+5G>T (c.1766+5G>T)	c.1766+5G>T	None	1898+5G>T
1898+3A>G (c.1766+3A>G)	c.1766+3A>G	None	1898+3A>G
1898+1G>T (c.1766+1G>T)	c.1766+1G>T	None	1898+1G>T
1898+1G>C (c.1766+1G>C)	c.1766+1G>C	None	1898+1G>C
1898+1G>A (c.1766+1G>A)	c.1766+1G>A	None	1898+1G>A

- Choose a clinical assessment code for each specimen by clicking the drop-down arrow.

Pathogenic Variant Data

If the variant you wish to enter is not found within the searchable listing, select "other" and then enter the variant in the field that will appear when "other" is selected.

Specimen Number
20211011001

Allele 1 * No variants detect [x] [q] **Allele 2 *** No variants detect [x] [q] **Clinical Assessment** [dropdown] [v] **Comments** [text box]

Specimen Number
20211011002

Allele 1 * [text box] [q] **Allele 2 *** [text box] [q] **Clinical Assessment *** [dropdown] [v] **Comments** [text box]

Note: A red box highlights the Clinical Assessment dropdown menu in the first specimen entry, which is open to show options: Screen Negative-Normal, Screen Positive-1 or 2 variants, and Assay Failure.

- If 'Assay Failure' is chosen as the clinical assessment, choose it for both Allele 1 and Allele 2.

Lookup records

assay [q]

✓ Display Name	Variant cDNA name ↓	Variant protein name	Variant legacy name
✓ Assay Failure	Assay Failure	Assay Failure	Assay Failure

[Select] [Cancel] [Remove value]

Pathogenic Variant Data

If the variant you wish to enter is not found within the searchable listing, select "other" and then enter the variant in the field that will appear when "other" is selected.

Specimen Number
20211011001

Allele 1 * Assay Failure [x] [q] **Allele 2 *** Assay Failure [x] [q] **Clinical Assessment *** Assay Failure [dropdown] [v] **Comments** [text box]

Note: A red box highlights the Allele 1, Allele 2, and Clinical Assessment fields for the first specimen entry.

- If necessary, enter any comments into the appropriate comment box.

Pathogenic Variant Data

If the variant you wish to enter is not found within the searchable listing, select "other" and then enter the variant in the field that will appear when "other" is selected.

Specimen Number
20211011001

Allele 1 * Assay Failure [x] [q] **Allele 2 *** Assay Failure [x] [q] **Clinical Assessment *** Assay Failure [dropdown] [v] **Comments** [text box]

Specimen Number
20211011002

Allele 1 * [text box] [q] **Allele 2 *** [text box] [q] **Clinical Assessment *** [dropdown] [v] **Comments** [text box]

Note: A red box highlights the Comments text box for the first specimen entry.

1.7 Save

1. Save all information and data by clicking the **'Save'** button located at the bottom of the page.

NOTE: All information and results must be saved at the same time. Data cannot be partially saved.

Specimen Number
20211011004

Allele 1 * CFTRdup6b-10 (c. [x] [Q])	Allele 2 * 4259del5 (p.Leu13 [x] [Q])	Clinical Assessment * Screen Positive-1 or 2 varia [v]	Comments <input type="text"/>
---	--	---	----------------------------------

Specimen Number
20211011005

Allele 1 * R31L (p.Arg31Leu) [x] [Q]	Allele 2 * Q30X (p.Gln30X) [x] [Q]	Clinical Assessment * Screen Negative-Normal [v]	Comments <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.



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.

Home > Cystic Fibrosis DNA Variant Detection Proficiency Testing (CFDNAPT)

Cystic Fibrosis DNA Variant Detection Proficiency Testing (CFDNAPT)

* Definition of commercial kit – A kit that has been designed by the manufacturer to sequence the CFTR gene

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

- Select an extraction method is a required field.
- Allele 1 is a required field.
- Allele 2 is a required field.

Method Information

Primary Method

Select a primary method *

Abbott Molecular CF Genotyping Assay v3 [x] [Q]

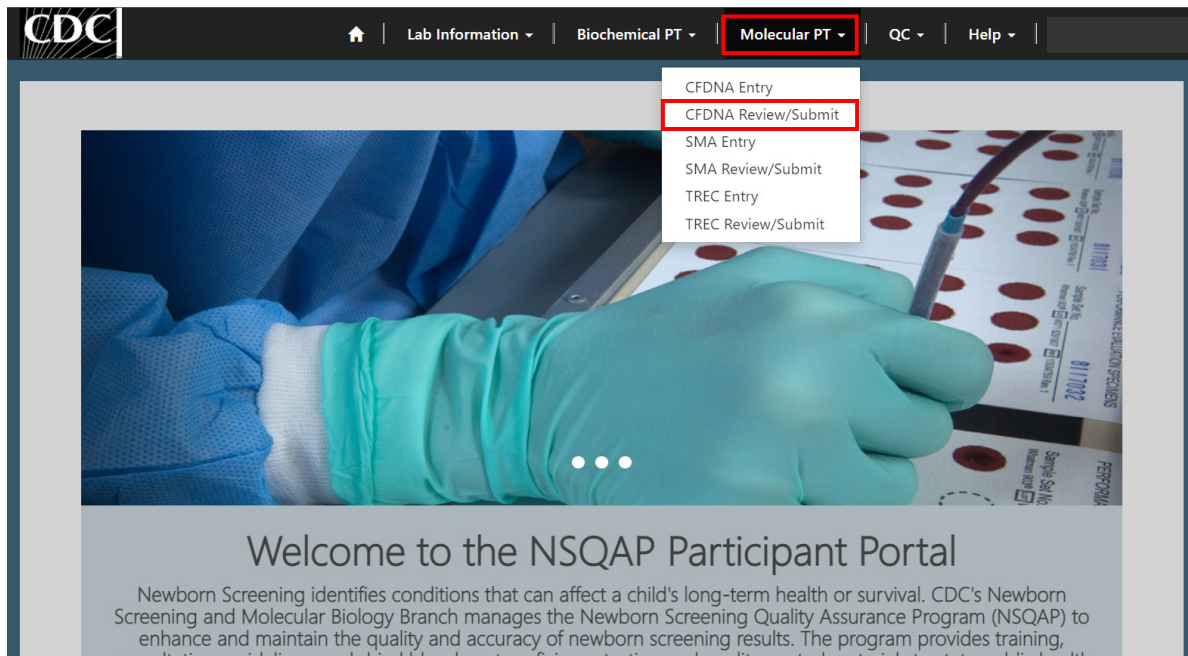
3. After you have successfully saved your results, you will be redirected to the 'CFDNA Review/Submit Page'. See section 2 for more guidance on this page.

2. CFDNAPT Review & Submit Page

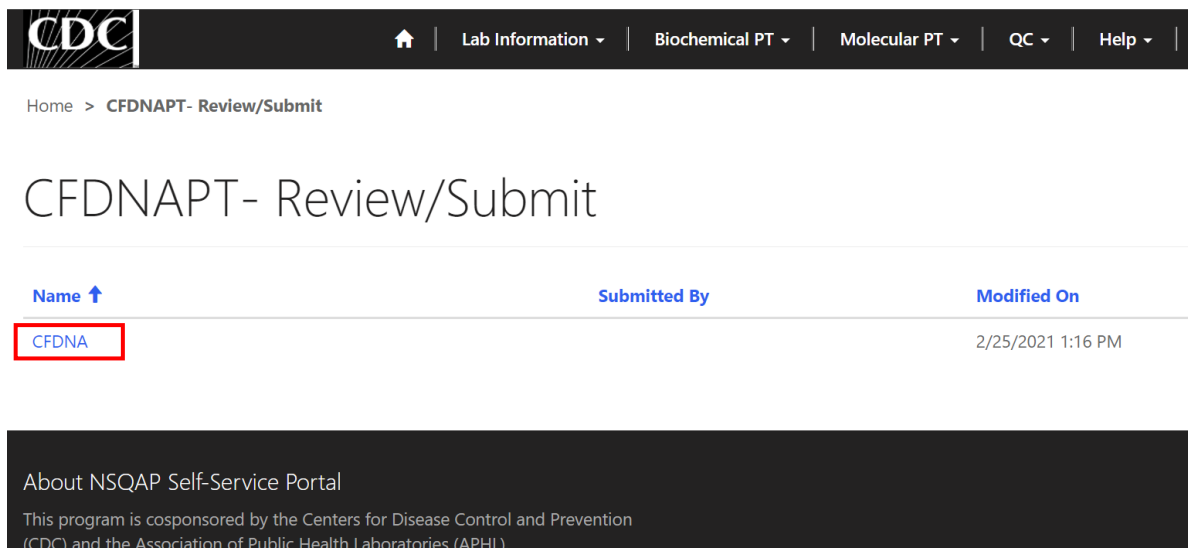
2.1 Navigation

CFDNAPT program participants should review and submit data in the NSQAP Portal after program information and results have been entered and saved. (see section 1).

1. Select **'Molecular PT'** then **'CFDNA Review/Submit'** from the drop-down menu.




2. The CFDNA Review/Submit landing page will appear. Select **'CFDNA'** to navigate to the review and submit page.



2.2 Review

Navigate to the 'CFDNA Review/Submit Page' to review CFDNAPT program method information and specimen results in a read-only format. Navigation details can be found in section 2.1.


☰

Home > CFDNAPT-Review/Submit

CFDNAPT-Review/Submit

Method Information

Primary Method

Select a primary method *

Abbott Molecular CF Genotyping Assay v3

Other-you must specify

—

Is your selected method a custom commercial assay OR a lab developed test OR does your lab place restrictions on a commercial assay? *

Yes

Specify variants detected: *

M1V | p.Met1Val / p.Met1? (c.1A>G);Q2X | p.Gln2* (c.4C>T);S4X | p.Ser4* (c.11C>A);S13F | p.Ser13Phe (c.38C>T);182delT | p.Phe17Serfs*8 (c.50delT);L15P | p.Leu15Pro (c.44T>C);185+1G->T | p.? (c.53+1G>T);W19X | p.Trp19* (c.57G>A);G27R | p.Gly27Arg (c.79G>A);G27X | p.Gly27* (c.79G>T);Q30X | p.Gln30* (c.88C>T);Q39X | p.Gln39* (c.115C>T);A46D | p.Ala46Asp (c.137C>A);296+1G->A | p.? (c.164+1G>A);296+1G->T | p.? (c.164+1G>T);296+2T->C | p.? (c.164+2T>C);296+3insT | p.? (c.164+4dupT);297-3C->T | p.?

Was a gene sequencing method used? *

Yes

Was a commercial kit used? *

No

For non-commercial kits, provide regions of the gene that are sequenced *

exons 1 to 27 and at least 20 bases into the 5' and 3' ends of all introns, the CFTR poly T status and TG tract, intron 22

Secondary/Confirmatory Method

Select a secondary/confirmatory method

Agena Bioscience iPLEX Pro CFTR Panel (72 mutations)

Other-you must specify

—

Select an algorithm for utilization of the secondary/confirmatory method *

Both the primary and secondary methods are used to detect variants

Other-you must describe

—

Is your selected method a custom commercial assay OR a lab developed test OR does your lab place restrictions on a commercial assay? *

Yes

Specify Variants Detected

M1V | p.Met1Val / p.Met1? (c.1A>G);Q2X | p.Gln2* (c.4C>T);S4X | p.Ser4* (c.11C>A);S13F | p.Ser13Phe (c.38C>T);182delT | p.Phe17Serfs*8 (c.50delT);L15P | p.Leu15Pro (c.44T>C);185+1G->T | p.? (c.53+1G>T);W19X | p.Trp19* (c.57G>A);G27R | p.Gly27Arg (c.79G>A);G27X | p.Gly27* (c.79G>T);Q30X | p.Gln30* (c.88C>T);Q39X | p.Gln39* (c.115C>T);A46D | p.Ala46Asp (c.137C>A);296+1G->A | p.? (c.164+1G>A);296+1G->T | p.? (c.164+1G>T);296+2T->C | p.? (c.164+2T>C);296+3insT | p.? (c.164+4dupT);297-3C->T | p.?

Was a gene sequencing method used? *

Yes

Was a commercial kit used? *

No

For non-commercial kits, provide regions of the gene that are sequenced *

exons 1 to 27 and at least 20 bases into the 5' and 3' ends of all introns, the CFTR poly T status and TG tract, intron 22

Extraction Method

Select an extraction method *

In-house alkaline lysis prep

Other-you must specify

—

Pathogenic Variant Data

Specimen Number 20211011001	
Allele 1 * Q1412X (p.Gln1412X)	Other Variant Detected —
Allele 2 * C276X (p.Cys276X)	Other Variant Detected —
Clinical Assessment * Screen Negative-Normal	Comments —
Specimen Number 20211011002	
Allele 1 * 849delG (p.Leu240X)	Other Variant Detected —
Allele 2 * D1152H (p.Asp1152His)	Other Variant Detected —
Clinical Assessment * Screen Negative-Normal	Comments —
Specimen Number 20211011003	
Allele 1 * 4374+1G>T (c.4242+1G>T)	Other Variant Detected —
Allele 2 * L1254X (p.Leu1254X)	Other Variant Detected —
Clinical Assessment * Screen Positive-1 or 2 variants	Comments —
Specimen Number 20211011004	
Allele 1 * CFTRdup6b-10 (c.(743+1_744-1)_(1584+1_1585-1)dup)	Other Variant Detected —
Allele 2 * 4259del5 (p.Leu1376SerfsX8)	Other Variant Detected —
Clinical Assessment * Screen Positive-1 or 2 variants	Comments —
Specimen Number 20211011005	
Allele 1 * R31L (p.Arg31Leu)	Other Variant Detected —
Allele 2 * Q30X (p.Gln30X)	Other Variant Detected —
Clinical Assessment * Screen Negative-Normal	Comments —

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

Submit

About NSQAP Self-Service Portal
This program is cosponsored by the Centers for Disease Control and

1. If edits are necessary, navigate back to the CFDNA entry page and make or click the link located at the bottom of the review and submit page labeled **‘Navigate to the CFDNAPT Entry Page to Make Edits’**.

Specimen Number	
20211011005	
Allele 1 *	Other Variant Detected
R31L (p.Arg31Leu)	—
Allele 2 *	Other Variant Detected
Q30X (p.Gln30X)	—
Clinical Assessment *	Comments
Screen Negative-Normal	—

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

Submit

2. If no further edits are needed, results can be submitted by clicking the ‘Submit’ button. See section 2.3 for additional details.

Allele 1 *	Other Variant Detected
R31L (p.Arg31Leu)	—
Allele 2 *	Other Variant Detected
Q30X (p.Gln30X)	—
Clinical Assessment *	Comments
Screen Negative-Normal	—

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

Submit

About NSQAP Self-Service Portal
 This program is cosponsored by the Centers for Disease Control and Prevention

2.3 Submit

1. Navigate to the 'CFDNA Review/Submit Page' to submit CFDNAPT method information and data.

2. After reviewing the CFDNA review and submit page, click on the 'Submit' button located at the bottom of the page.

Allele 1 * R31L (p.Arg31Leu)	Other Variant Detected —
Allele 2 * Q30X (p.Gln30X)	Other Variant Detected —
Clinical Assessment * Screen Negative-Normal	Comments —

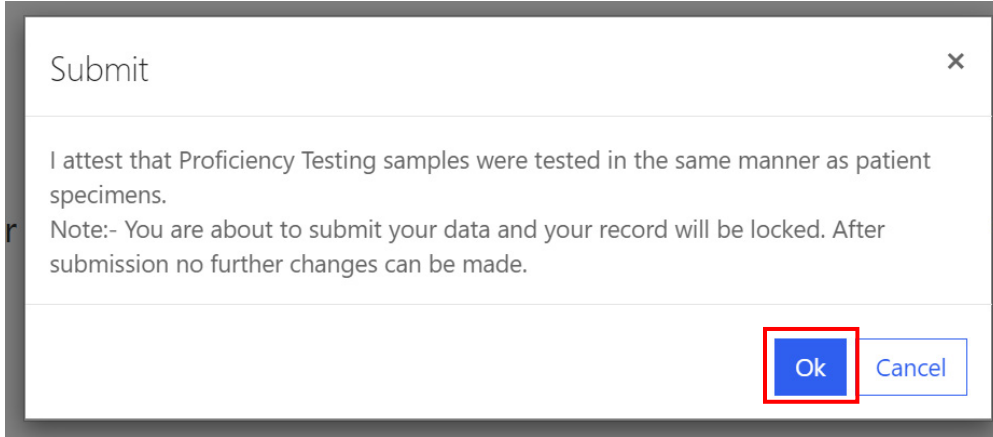
After you click submit your submission will be locked and cannot be changed. [Navigate to the CFDNA Entry Page to Make Edits](#)



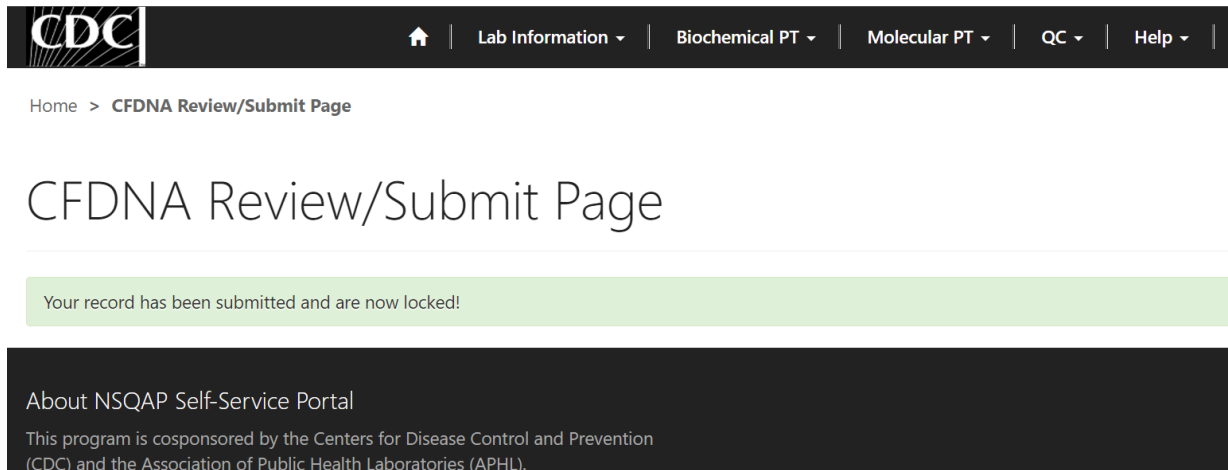
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- You will be prompted to confirm that you are ready to submit. Click **'Ok'** to confirm and submit your CFDNAPT results.

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



- After submitting you will be directed to a confirmation page.



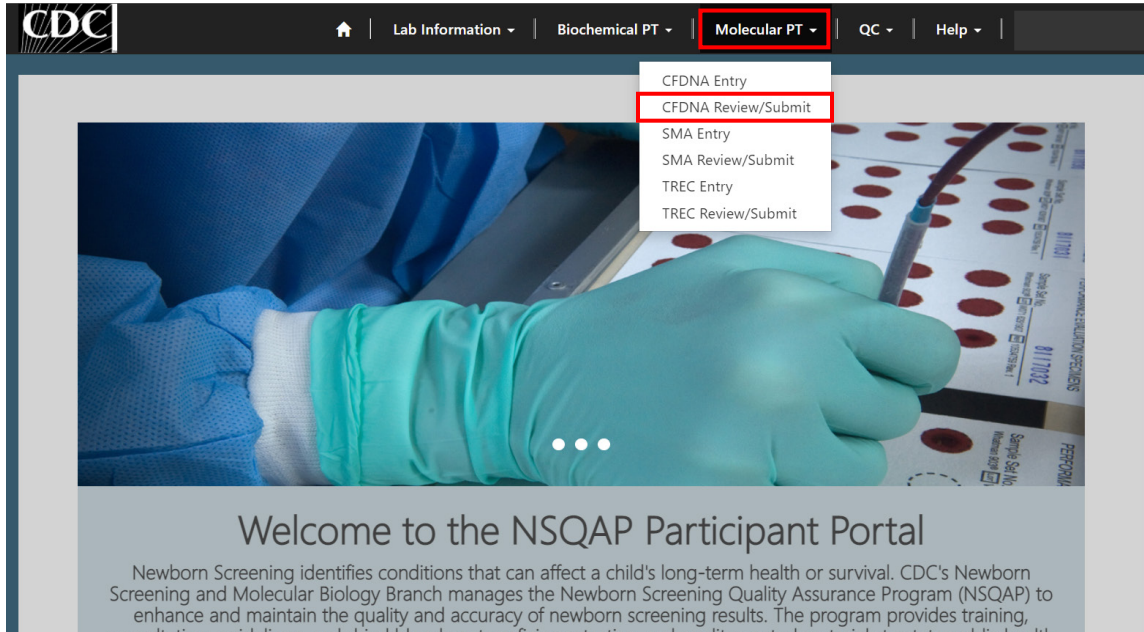
- Once your CFDNAPT results are submitted you will no longer be able to access the 'CFDNA Entry' page. You can view your submitted data in a read-only format by accessing the review and submit page (see sections 2.1 and 2.2).

2.4 Save Data – Pdf Format

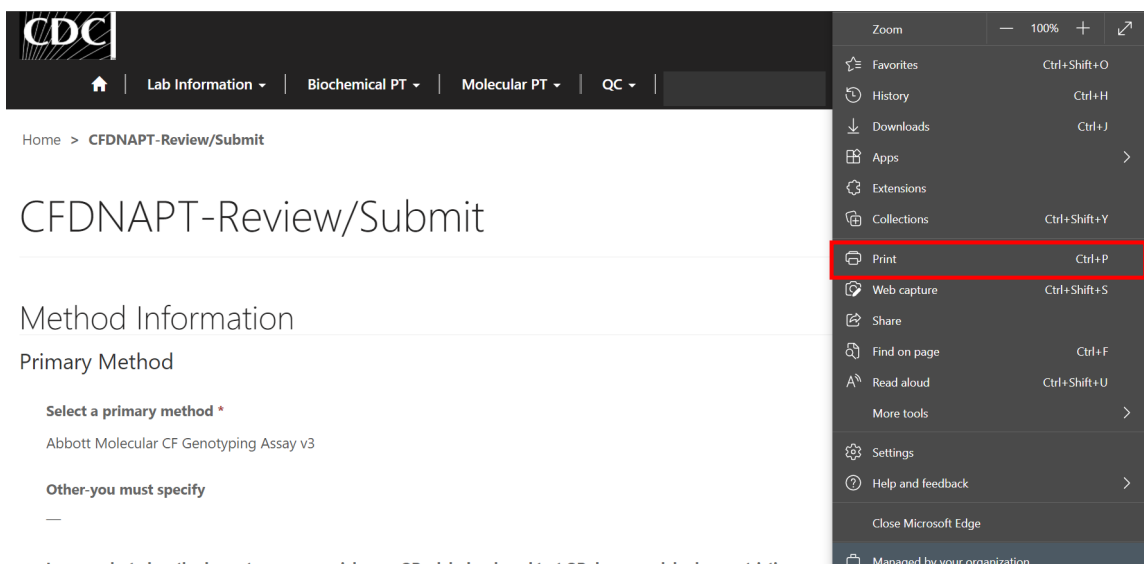
Submitted data can be saved in a pdf format by using the ‘Save a PDF’ function included in your web browser.

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

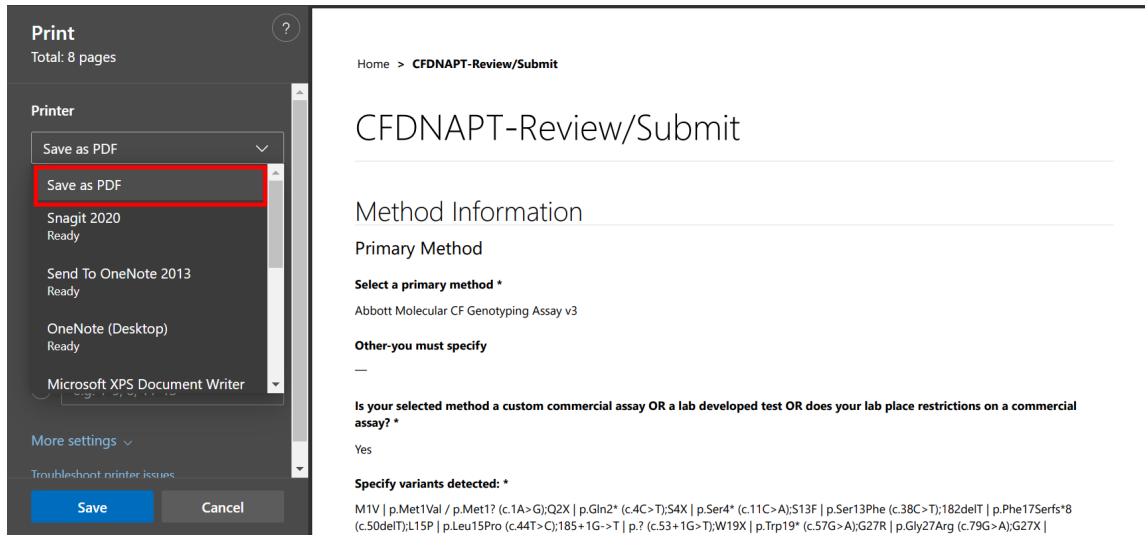
1. Navigate to the review and submit page as described in section 2.1.



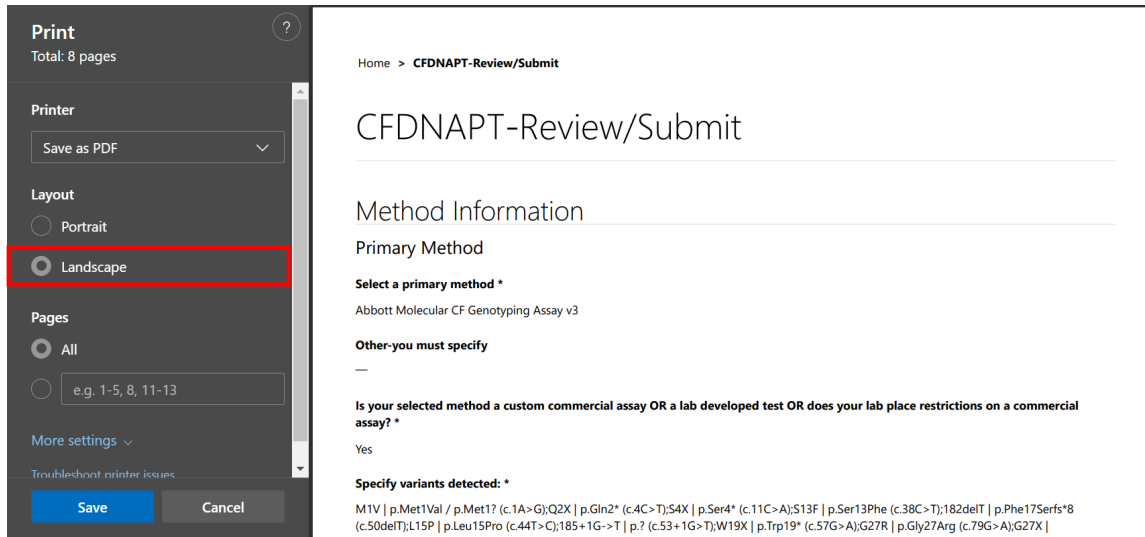
2. Locate the “Print’ function on your web browser.



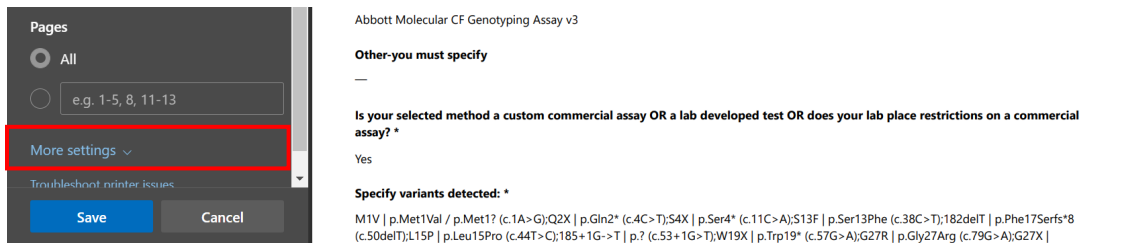
3. Select 'Save as PDF'.



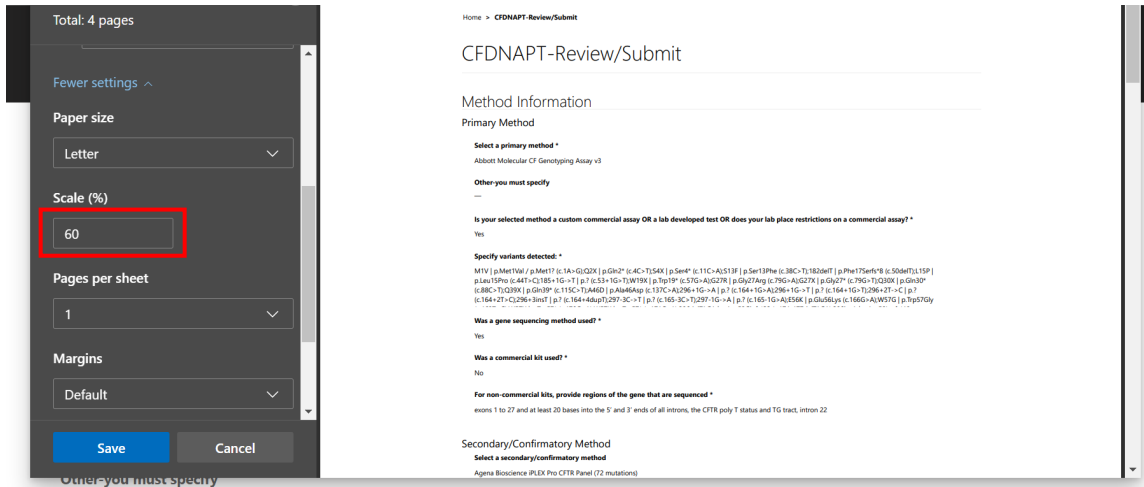
4. Select 'Landscape' as the layout choice.



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.

