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

# **LSDPT PILOT PARTICIPANT GUIDE**

May 2024

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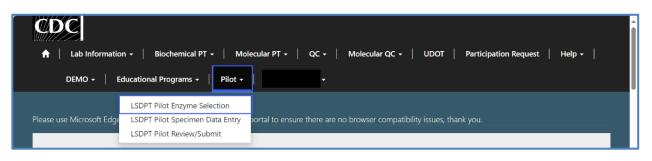
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# 1. LSDPT Pilot Program Enzyme, Method, and Cutoff Entry Page

## **1.1 Navigation**

To enter and save LSDPT data, navigate to the LSDPT program entry page. Access the page from the 'LSDPT Pilot Enzyme Selection' option on the Pilot drop-down menu.

1. Click 'Pilot' then 'LSDPT Pilot Enzyme Selection' from the drop-down menu.



2. Select 'PILOT - LSDPT' to navigate to the entry page.

Home > Enzymes Selection	
Enzymes Selection	
Program Name 🕇	Created On
PILOT - LSDPT	4/20/2024 4:54 PM
PILOT - LSDPT *-Required Field.	4/20/2024 4:54 PM

3. User will be directed to the LSDPT Pilot **Enzyme**, **Method**, and **Cutoff** entry page to select **Enzymes** and enter **Method** and **Cutoff** data. Required fields are indicated with an asterisk(\*).

Home > Setup - Enzyme(s), Method(s) and Cutoff(s)		
Setup - Enzyme(s), Method(s) and Cutoff(s)		
Select the enzyme(s) you w decimal places. e.g., (X.XX)	ant to report, method(s),	and give the cutoff for each enzyme. Report LSD data to two
LSD		
□ Acid beta-glucosidase (ABG)	Cutoff (µmol/hr/L)	Method
		Q
Acid sphingomyelinase (ASM)	Cutoff (µmol/hr/L)	Method
		Q
Acid alpha-glucosidase (GAA)	Cutoff (µmol/hr/L)	Method
		Q
Galactoceramidase (GALC)	Cutoff (umol/hr/L)	Method

## **1.2 Entering Enzyme, Method, and Cutoff Information**

From the 'Setup – Enzyme(s), Method(s) and Cutoff(s)' page, enter the Enzyme, Method, and Cutoff information. Navigation details can be found in Section 1.1.

1. For each enzyme a User wants to report, select the checkmark before that enzyme's name.

Setup - Enzym	ne(s), Method(s	s) and Cutoff(s)
Select the enzyme(s) you w decimal places. e.g., (X.XX) LSD	vant to report, method(s), a	and give the cutoff for each enzyme. Report LSD data to two
Acid beta-glucosidase (ABG)	Cutoff (µmol/hr/L)	Method
		Q
Acid sphingomyelinase (ASM)	Cutoff (µmol/hr/L)	Method
		Q
Acid alpha-glucosidase (GAA)	Cutoff (µmol/hr/L)	Method
		Q
Galactoceramidase (GALC)	Cutoff (µmol/hr/L)	Method Q
Alpha-galactosidase A (GLA)	Cutoff (µmol/hr/L)	Method
Alpha-L-iduronidase (IDUA)	Cutoff (µmol/hr/L)	Method
Iduronate-2-Sulfatase (I2S)	Cutoff (µmol/hr/L)	Method Q
I verify that I reviewed the values al	bove.	

# 2. For each selected enzyme, enter the cutoff for that enzyme. Values should be entered to two decimal places.

Setup - Enzym	e(s), Method(	s) and Cutoff(s)
Select the enzyme(s) you w decimal places. e.g., (X.XX)	ant to report, method(s),	and give the cutoff for each enzyme. Report LSD data to two
LSD		
Acid beta-glucosidase (ABG)	Cutoff (µmol/hr/L)	Method
		Q
Acid sphingomyelinase (ASM)	Cutoff (µmol/hr/L)	Method
		Q
Acid alpha-glucosidase (GAA)	Cutoff (µmol/hr/L)	Method
		Q
Galactoceramidase (GALC)	Cutoff (µmol/hr/L)	Method
		Q
Alpha-galactosidase A (GLA)	Cutoff (µmol/hr/L)	Method
		Q
Alpha-L-iduronidase (IDUA)	Cutoff (µmol/hr/L)	Method
Iduronate-2-Sulfatase (I2S)	Cutoff (µmol/hr/L)	Method
_ rearonate-z-sumatuse (res)		
□ I verify that I reviewed the values ab	pove.	

3. For each selected enzyme, select the method used by clicking the magnifying glass icon in the **Method** field to open the method selector.

Setup - Enzym	e(s), Method(	s) and Cutoff(s)
Select the enzyme(s) you w decimal places. e.g., (X.XX) LSD	vant to report, method(s),	and give the cutoff for each enzyme. Report LSD data to two
Acid beta-glucosidase (ABG)	Cutoff (µmol/hr/L)	Method
Acid sphingomyelinase (ASM)	Cutoff (µmol/hr/L)	Q       Method
Acid alpha-glucosidase (GAA)	Cutoff (µmol/hr/L)	Method
Galactoceramidase (GALC)	Cutoff (µmol/hr/L)	A Method
Alpha-galactosidase A (GLA)	Cutoff (µmol/hr/L)	Method
□ Alpha-L-iduronidase (IDUA)	Cutoff (µmol/hr/L)	Q       Method
□ Iduronate-2-Sulfatase (I2S)	Cutoff (µmol/hr/L)	Method Q
I verify that I reviewed the values a	bove.	

4. With the method selector open, click on a method name to choose a method, then click **Select**.

Lookup r	ecords	×
	Search	٩
Choose one re	ecord and click Select to continue	
~	Method Name 🕇	
	Digital Microfluidic Fluorescence	
	Flow Injection Analysis (FIA) - MS/MS non-derivitized non-kit	
	Flow Injection Analysis (FIA)-MS/MS multiplexed enzyme reaction	
	Flow Injection Analysis (FIA)-MS/MS non-kit individual enzyme reaction	
	Fluorometric manual LSD - non-kit	
	LC-MS/MS non-kit	
	LC-MS/MS positive ion mode	-
	Select Cancel Remo	ove value

5. For each selected Enzyme, if 'Other' is selected Users are **required** to enter the other method used in the **Other Method** text entry field.

LSD			
acid beta-glucosidase (ABG)	Cutoff (µmol/hr/L)	Method Other X Q	Other Method *

6. When all enzymes to be reported have been selected, and Cutoff and Method have been entered, verify the values are correct and then select the checkbox next to I verify that I reviewed the values above. Then click Save and Set Values.



7. After Saving and Setting values, a green message will appear letting the User know that their entries have been **Saved.** 

Home > Setup - Enzyme(s), Method(s) and Cutoff(s)	
Setup - Enzyme(s), Method(s) and	Cutoff(s)
Select the enzyme(s) you want to report, method(s), and give the decimal places. e.g., (X.XX)	e cutoff for each enzyme. Report LSD data to two
Saved	x
*-Required Field.	
Form Approved OMB No. 0920-1389 Exp. Date 03/31/2026	

<u>NOTE:</u> 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). Returning to re-enter enzyme(s), method(s) and cutoff(s) will reset any already entered data.

8. If the User attempts to save the form without entering **all required fields**, they will receive an error message. Complete the missing fields and click **'Save'** again.

Home > Setup - Enzyme(s), Method(s) and Cutoff(s)
Setup - Enzyme(s), Method(s) and Cutoff(s)
Select the enzyme(s) you want to report, method(s), and give the cutoff for each enzyme. Report LSD data to two decimal places. e.g., (X.XX) The form could not be submitted for the following reasons: Method is a required field.

## 2. LSDPT Pilot Specimen Data Entry Page

### **2.1 Navigation**

Review and save LSDPT Pilot specimen data after Enzymes, Methods and Cutoffs have been entered and saved (see Section 1). Access the review/save page via the **'LSDPT Pilot Specimen Data Entry'** option on the **Pilot** drop-down menu.

1. Select 'Pilot' then 'LSDPT Pilot Specimen Data Entry' from the drop-down menu.

CDC ↑   Lab Information DEMO -   Ec	n +   Biochemical PT +   Mol ducational Programs +   Pilot +	ecular PT +   QC +   Molecular QC +   UDOT   Participation Request   Help +   +	Î
Please use Microsoft Edge	LSDPT Pilot Enzyme Selection LSDPT Pilot Specimen Data Entry LSDPT Pilot Review/Submit	ortal to ensure there are no browser compatibility issues, thank you.	

2. The LSDPT Pilot Specimen Data Entry landing page will appear. Select **'PILOT – LSDPT'** to navigate to the data entry page.

Home > Specimen Data Entry	
Specimen Data Entry	
Program Name 🕇	Created On
PILOT - LSDPT	4/20/2024 4:54 PM
*-Required Field.	
Form Approved OMB No. 0920-1389 E.v. Date 03/71/2026	

#### 3. User will be directed to the LSDPT Pilot **Specimen List** page to input data.

ome > Specimen List			
pecimen List			
pecimen			
Specimen Number 🕇	Specimen Status	Created On	
20243013001	Saved	4/20/2024 4:55 PM	~
20243013002	Set	4/20/2024 4:56 PM	~
20243013003	Set	4/20/2024 4:56 PM	~
20243013004	Set	4/20/2024 4:57 PM	~
	Set	4/20/2024 4:57 PM	<b>~</b>

### 2.2 Data Entry

1. From the page titled 'Specimen List' the User can enter LSDPT pilot program results for each specimen. Navigation details can be found in Section 2.1.

ome > Specimen List			
Specimen List			
pecimen			
Specimen Number 🕇	Specimen Status	Created On	
20243013001	Saved	4/20/2024 4:55 PM	~
20243013002	Set	4/20/2024 4:56 PM	~
20243013003	Set	4/20/2024 4:56 PM	~
20243013004	Set	4/20/2024 4:57 PM	~

2. Select a specimen from the **Specimen List** to enter data for that specimen.

pecimen List			
pecimen			
Specimen Number 🕇	Specimen Status	Created On	
20243013001	Set	4/15/2024 9:16 PM	~
20243013002	Set	4/15/2024 9:16 PM	~
20243013003	Set	4/15/2024 9:16 PM	~
20243013004	Set	4/15/2024 9:17 PM	~
20243013005	Set	4/15/2024 9:17 PM	~

# NSQAP Portal LSDPT Pilot Participant Training 3. A **Data Entry** page will display with all the enzymes selected in the previous form.

Home > Data Entry				
Data Entry				
Acid beta-glucosidase (Al	BG)			
Method *			Cutoff (µmol/hr/L)	
LC-MS/MS non-kit			1.00	
Method Other —				
Specimen Number	Result (µmol/hr/L)	Clinical Assessment *		
20243013001				~

4. For each Enzyme, the information previously entered for **Method**, **Cutoff**, and **Method Other** (if provided) will be prefilled, and the selected **Specimen Number** will display.

Home > Data Entry			
Data Entry			
Acid beta-glucosidase (AB	G)		
Method * LC-MS/MS non-kit			Cutoff (µmol/hr/L) 1.00
Method Other —			
Specimen Number 20243013001	Result (µmol/hr/L)	Clinical Assessment *	~

5. For each enzyme, enter the value in the **Result** field, and select an answer from the **Clinical Assessment** dropdown menu.

			Home > Data Entry
			Data Entry
			Acid beta-glucosidase (ABG
toff (μmol/hr/L)	Cutoff (µmol/hr/L)		Method *
10	1.00		LC-MS/MS non-kit
			Method Other
			_
	Clinical Assessment *	Result (µmol/hr/L)	Specimen Number
~			20243013001
	Clinical Assessment *	Result (µmol/hr/L)	

<u>NOTE</u>: The Result data is recorded to 2 decimal places. Values with fewer than 2 decimals may be entered, but ending zeros will be appended to the saved data.

#### 6. When all the information is complete, select **Save Data** at the bottom of the page.

	Alpha-L-iduronidase (IDUA)			
	Method *			Cutoff (µmol/hr/L)
	LC-MS/MS non-kit			1.30
	ce maying non-kit			150
	Method Other			
	_			
	Specimen Number	Result (µmol/hr/L)	Clinical Assessment *	
	20243013001			~
	Iduronate-2-Sulfatase (I2S)			
	Method *			Cutoff (µmol/hr/L)
	LC-MS/MS non-kit			1.00
				100
	Method Other			
	_			
	Specimen Number	Result (µmol/hr/L)	Clinical Assessment *	
	20243013001			~
_				
	Save Data			
L				
	*-Required Field.			
	Form Approved OMB No. 0920-1389			
	Exp. Date 03/31/2026			

7. When the data has been successfully saved, a **Saved** banner will display.

Home > Data Entry	
Data Entry	
Saved	x
*-Required Field.	
Form Approved OMB No. 0920-1389 Exp. Date 03/31/2026	

8. Return to the **Specimen** page. Navigation details can be found in Section 2.1. The specimen for which data has been entered will show as **Saved**.

Specimen Number 🕇	Specimen Status	Created On	
20243013001	Saved	4/15/2024 9:16 PM	<b>~</b>
20243013002	Set	4/15/2024 9:16 PM	~
20243013003	Set	4/15/2024 9:16 PM	~
20243013004	Set	4/15/2024 9:17 PM	~
20243013005	Set	4/15/2024 9:17 PM	~

9. Repeat steps 2-8 until data has been saved for all specimens.

pecimen List			
pecimen			
Jecimen			
Specimen Number 🕇	Specimen Status	Created On	
20243013001	Saved	4/15/2024 9:16 PM	~
20243013002	Saved	4/15/2024 9:16 PM	~
20243013003	Saved	4/15/2024 9:16 PM	~
20243013004	Saved	4/15/2024 9:17 PM	~
	Saved	4/15/2024 9:17 PM	~

# **3. LSDPT Pilot Review/Submit Page**

### **3.1 Navigation**

Review and submit LSDPT specimen data after Enzymes, Methods and Cutoffs have been entered and saved (see Section 1) and Specimen data has been entered for each specimen (see Section 2). Access the review/submit page via the **'LSDPT Pilot Review/Submit'** option on the **Pilot** drop-down menu.

1. Select **'Pilot'** then **'LSDPT Pilot Review/Submit'** from the drop-down menu.

CDC ↑   Lab Information DEMO -   E	n +   Biochemical PT +   Mole ducational Programs +   Pilot +	cular PT +   QC +   Molecular QC +   UDOT   Participation Request   Help +   -
Please use Microsoft Edge	LSDPT Pilot Enzyme Selection LSDPT Pilot Specimen Data Entry LSDPT Pilot Review/Submit	ortal to ensure there are no browser compatibility issues, thank you.

2. The LSDPT Pilot Review/Submit landing page will appear. Select **'PILOT – LSDPT'** to navigate to the Review/Submit page.

Home > LSDPT Pilot Review/Submit	
LSDPT Pilot Review/Submit	
Program Name 🕇	Created On
PILOT - LSDPT	4/20/2024 4:54 PM
*-Required Field.	
Farm Approved OMB No. 3093-1180 Eqs. Date 33/21/2026	

# 3. User will be directed to the LSDPT Pilot Review/Submit page to review their data and submit it.

ne > LSDPT Pilot Review and Submit			
SDPT Pilot Review and	d Submit		
Program Name *			
PILOT - LSDPT			
SULTS			
		I	Ownload
Specimen Number 1 gba method alu gba method other al	Gaucher lu gba_cutoff Gba_Result Assessment a	sm method alu asm method other	alu asm_cutof
20243013001			
20243013002			
20243013003			
20243013004			
20243013004			
20243013005			
			•
pecimen			
Specimen Number 🕇	Specimen Status	Created On	
20243013001	Set	4/20/2024 4:55 PM	
20243013002	Set	4/20/2024 4:56 PM	
20243013003	Set	4/20/2024 4:56 PM	
20243013004	Set	4/20/2024 4:57 PM	
20243013005	Set	4/20/2024 4:57 PM	
uired Field.			
pined Field. Approved No. 0020-1889			

## 3.2 Review/Submit

1. From the page titled 'LSDPT Pilot Review/Submit', the User can review their entered LSDPT pilot program results and submit them. Navigation details can be found in Section 3.1.

	PT Pilot Review and Submit		
LSDP <sup>®</sup>	T Pilot Review and	d Submit	
Program N PILOT - LSD			
RESULT	ς		
	5		⊕ Downlaad
Specimen Number 1		Gauci gba_cutoff Gba_Result Asses	her sment asm_method_alu_asm_method_other_alu_asm_cutof
20243013	001		
20243013	002		
20243013	003		
20243013	004		
20243013	005		
			•
Coocina			
Specim			
	Number 1	Specimen Status	Created On
20243013		Set	4/20/2024 4:55 PM
20243013		Set	4/20/2024 4:56 PM
20243013		Set	4/20/2024 4:56 PM 4/20/2024 4:57 PM
20243013		Set	4/20/2024 4:57 PM
*-Required Field. Form Approved OMB No. 0920-138 Exp. Date 03/31/20			

#### 2. The RESULTS Section displays the User-entered data for each specimen.

							۲	) Download	
Specimen Number <b>↑</b>	gba_method_alu	gba_method_other_alu	gba_cutoff	Gba_Result	Gaucher Assessment	asm_method_alu	asm_method_other_alu	asm_cut	
20243013001	LC-MS/MS non- kit		1.00	5.00	Within Normal Limits	LC-MS/MS non- kit		1.00	
20243013002	LC-MS/MS non- kit		1.00	1.00	Outside Normal Limits	LC-MS/MS non- kit		1.00	
20243013003	LC-MS/MS non- kit		1.00		Outside Normal Limits	LC-MS/MS non- kit		1.00	
20243013004	LC-MS/MS non- kit		1.00		Outside Normal Limits	LC-MS/MS non- kit		1.00	
20243013005	LC-MS/MS non- kit		1.00		Within Normal Limits	LC-MS/MS non- kit		1.00	

3. Users can utilize the horizontal scroll bar to see all the data for a given specimen.

							۲	) Download	
Specimen Number <b>↑</b>	gba_method_alu	gba_method_other_alu	gba_cutoff	Gba_Result	Gaucher Assessment	asm_method_alu	asm_method_other_alu	asm_cut	
20243013001	LC-MS/MS non- kit		1.00	5.00	Within Normal Limits	LC-MS/MS non- kit		1.00	
20243013002	LC-MS/MS non- kit		1.00	1.00	Outside Normal Limits	LC-MS/MS non- kit		1.00	
20243013003	LC-MS/MS non- kit		1.00		Outside Normal Limits	LC-MS/MS non- kit		1.00	
20243013004	LC-MS/MS non- kit		1.00		Outside Normal Limits	LC-MS/MS non- kit		1.00	
20243013005	LC-MS/MS non- kit		1.00		Within Normal Limits	LC-MS/MS non- kit		1.00	

4. A copy of all entered data can be downloaded by clicking the **Download** button in the upper right corner of the Results Section.

							۲	Ownload	
Specimen Number <b>†</b>	gba_method_alu	gba_method_other_alu	gba_cutoff	Gba_Result	Gaucher Assessment	asm_method_alu	asm_method_other_alu	asm_cuto	
20243013001	LC-MS/MS non- kit		1.00	5.00	Within Normal Limits	LC-MS/MS non- kit		1.00	
20243013002	LC-MS/MS non- kit		1.00	1.00	Outside Normal Limits	LC-MS/MS non- kit		1.00	
20243013003	LC-MS/MS non- kit		1.00		Outside Normal Limits	LC-MS/MS non- kit		1.00	
20243013004	LC-MS/MS non- kit		1.00		Outside Normal Limits	LC-MS/MS non- kit		1.00	
20243013005	LC-MS/MS non- kit		1.00		Within Normal Limits	LC-MS/MS non- kit		1.00	

5. When User is satisfied with the entered data, clicking the **Submit** button at the bottom of the page will submit the data for the lab.



6. Data has been successfully submitted when a green **Submission completed successfully** message is displayed.

