

# NEWBORN SCREENING QUALITY ASSURANCE PROGRAM PARTICIPATION REQUEST FORM

INSTRUCTIONS: All sections (sections 1 – 4) of this form must be completed and emailed to [NSQAPDMT@cdc.gov](mailto:NSQAPDMT@cdc.gov). Missing information will delay your entry into the program. If you have any questions, please email [NSQAPDMT@cdc.gov](mailto:NSQAPDMT@cdc.gov) or call 770-488-4582.

## SECTION 1: GENERAL INFORMATION

Today's Date (mm/dd/yyyy) \_\_\_\_\_

Current or Previous Member of NSQAP? Yes \_\_\_ No \_\_\_ If yes, what is/was your laboratory code number? \_\_\_\_\_

Does your laboratory manufacture or distribute newborn screening testing products? Yes \_\_\_ No \_\_\_

If yes, what product(s)? \_\_\_\_\_

## SECTION 2: LABORATORY AND SHIPPING INFORMATION

**Provide physical street address. FedEx will not deliver to PO Boxes. There is no cost for dried blood spot (DBS) products and shipping. Any documents, import permits, fees, taxes, or other costs required by your country for release of your package from Customs are your responsibility.**

Contact First Name: \_\_\_\_\_ Last Name: \_\_\_\_\_

Laboratory Name: \_\_\_\_\_

Laboratory Address: \_\_\_\_\_

City: \_\_\_\_\_ State/Province/Region: \_\_\_\_\_

Country: \_\_\_\_\_ Postal Code: \_\_\_\_\_

Shipping Address: *(if different from laboratory address)* \_\_\_\_\_

City: \_\_\_\_\_ State/Province/Region: \_\_\_\_\_

Country: \_\_\_\_\_ Postal Code: \_\_\_\_\_

Telephone: \_\_\_\_\_

Email: \_\_\_\_\_

Laboratory Website address if available: \_\_\_\_\_

### **To be completed by laboratories outside the United States:**

Laboratory's Tax Identification Number \_\_\_\_\_

Import Broker Company Name: \_\_\_\_\_

Import Broker Identification Number: \_\_\_\_\_ Import Broker Account Number \_\_\_\_\_

Import Broker Company Address: \_\_\_\_\_

Import Broker City: \_\_\_\_\_ Import Broker State/Province/Region \_\_\_\_\_

Import Broker Country: \_\_\_\_\_ Import Broker Postal Code: \_\_\_\_\_

Import Broker Telephone: \_\_\_\_\_

***Any documents, import permits, fees, taxes, or other costs required by your country for release of your package from Customs are your responsibility.***

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## SECTION 3: PROGRAM SELECTION

All Proficiency Testing (PT) and Quality Control (QC) dried blood spot materials

**Registration Deadlines for PT Programs:**

1<sup>st</sup> quarter (January) – Enroll by November 1

2<sup>nd</sup> quarter (April) – Enroll by February 1

3<sup>rd</sup> quarter (July) – Enroll by May 1

4<sup>th</sup> quarter (October) – Enroll by August 1

✓ Proficiency Testing Materials
Amino Acids and SUAC (AAPT) (Analytes: Arginine, Citrulline, Leucine, Methionine, Phenylalanine, Succinylacetone, Tyrosine, Valine)
Acylcarnitines (ACPT) (Analytes: C0(L), C3, C3DC, C3DC+C4OH, C4, C4OH, C5, C5:1, C5DC, C5OH, C6, C8, C10, C10:1, C10:2, C14, C14:1, C16, C16OH, C18, C18:1, C18OH)
Biotinidase (BIOTPT)
Second-tier Congenital Adrenal Hyperplasia (CAHPT) (Analytes: 17 $\alpha$ -Hydroxyprogesterone, 4-Androstenedione, Cortisol, 11-Deoxycortisol, 21-Deoxycortisol)
Cystic Fibrosis DNA (CFDNAPT)
Galactose-1-phosphate Uridyltransferase (GALTPT)
Glucose-6-phosphate Dehydrogenase (G6PDPT)
Anti-HIV-1 Antibodies (HIVPT)
Hormone + Total Galactose (HORMPT) (Analytes: T4, TSH, 17OHP, TGal)
Immunoreactive Trypsinogen (IRTPT)
Lysosomal Storage Disorders (LSDPT) <i>Enrollment limited to United States participants only</i> (Analytes: Galactocerebrosidase, Acid $\alpha$ -Glucosidase, $\alpha$ -L-Iduronidase)
N/A Sickle Cell and Other Hemoglobinopathies (HbPT) <i>Program at capacity – Waitlist only</i>
anti-Toxoplasma (TOXOPT) – <i>Enrollment not guaranteed and subject to NSQAP Review</i>
T-cell Receptor Excision Circle (TRECPT)
X-linked Adrenoleukodystrophy (XALDPT) (Analytes: 24:0-Lysophosphatidylcholine, 26:0-Lysophosphatidylcholine)

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**Registration Deadlines for QC Programs:**

Set 1 Materials (January) – Enroll by November 1

Set 2 materials (July) – Enroll by May 1

✓ Quality Control Testing Materials
17 $\alpha$ -Hydroxyprogesterone + Total Galactose (17OHPQC and TGalQC)
Amino Acids (AAQC) (Analytes: Arginine, Alanine, Citrulline, Glycine, Leucine, Methionine, Ornithine, Phenylalanine, Succinylacetone, Tyrosine, Valine)
Acylcarnitines (ACQC) (Analytes: C0, C2, C3, C3DC, C3DC+C4OH, C4, C4OH, C5, C5DC, C5OH, C6, C8, C10, C12, C14, C16, C16OH, C18, C18OH)
Second-tier Congenital Adrenal Hyperplasia (CAHQC) (Analytes: 17 $\alpha$ -Hydroxyprogesterone, 4-Androstenedione, Cortisol, 11-Deoxycortisol, 21-Deoxycortisol)
Galactose-1-phosphate Uridyltransferase (GALTQC)
Guanidinoacetate Methyltransferase (GAMTQC) (Analytes: Guanidinoacetic Acid, Creatine)
Anti-HIV-1 Antibodies (HIVQC)
Immunoreactive Trypsinogen (IRTQC)
Lysosomal Storage Disorders (LSDQC) (Analytes: Galactocerebrosidase, Acid $\alpha$ -Glucosidase, $\alpha$ -L-Iduronidase $\alpha$ -Galactosidase, $\beta$ -Glucocerebrosidase, Acid Sphingomyelinase)
Second-tier Maple Syrup Urine Disease and Phenylketonuria by LC-MS/MS (MSUD-PKUQC) (Analyte: Alloisoleucine, Isoleucine, Leucine, Phenylalanine, Tyrosine, Valine)
Second-tier Methylmalonic/Propionic Acidemia and Homocystinuria by LC-MS/MS (MMA-HCYQC) (Analytes: Methylmalonic Acid, Ethylmalonic Acid, 2-Methylcitric Acid, Total Homocysteine)
Thyroxine (T <sub>4</sub> QC)
Thyroid-Stimulating Hormone (TSHQC)
X-linked Adrenoleukodystrophy (XALDQC) (Analytes: 24:0-Lysophosphatidylcholine, 26:0-Lysophosphatidylcholine)

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## SECTION 4: NSQAP POLICIES

### Review and initial each policy

\_\_\_ 1. **What is criteria for participation?**

The laboratory must use dried blood spot matrix, and the laboratory's analyte reference ranges must represent the newborn period of life.

\_\_\_ 2. **Is there a cost for materials or a cost for shipping?**

There is no cost for dried blood spot materials or shipping. However, any documents, import permits, fees, taxes, or other costs required by your country for release of your package from customs are your responsibility.

\_\_\_ 3. **What information do you need to ship my DBS materials?**

We need a physical street address. Our courier will not ship to a Post Office Box. If your laboratory is not located in the United States, we need your Tax Identification Number and import broker information.

\_\_\_ 4. **When will I start receiving PT and/or QC dried blood spot materials?**

To receive materials 1<sup>st</sup> quarter (January) – Enroll by November 1

To receive materials 2<sup>nd</sup> quarter (April) – Enroll by February 1

To receive materials 3<sup>rd</sup> quarter (July) – Enroll by May 1

To receive materials 4<sup>th</sup> quarter (October) – Enroll by August 1

\_\_\_ 5. **How do I remain active in the NSQAP?**

To remain active and continue receiving PT and QC newborn screening materials, your laboratory must report data for each product you receive at least once per year.

\_\_\_ 6. **Do I have to re-enroll each year?**

As long as your account is active, you do not need to re-enroll.

\_\_\_ 7. **How do I change the primary contact person, shipping address, email address, etc. for our laboratory?**

Send an email with your changes to [NSQAPDMT@cdc.gov](mailto:NSQAPDMT@cdc.gov). Include your lab code number, current information and new information.

\_\_\_ 8. **How do I report data?**

Use the NSQAP Data reporting website (<https://wwwn.cdc.gov/nsqap/public/default.aspx>) to report PT data for the following programs: Amino Acids, Acylcarnitines, Biotinidase, Immunoreactive Trypsinogen, Galactose-1-phosphate Uridyltransferase, Glucose-6-phosphate Dehydrogenase, and Hormone + Total Galactose.

All other PT programs and all QC programs are reporting using the proper Excel data report form located here:

[http://www.cdc.gov/labstandards/nsqap\\_resources.html#QCReportForms](http://www.cdc.gov/labstandards/nsqap_resources.html#QCReportForms)

\_\_\_ 9. **When are materials shipped? When are the data due?**

Our annual shipping and data reporting schedule is located here:

[http://www.cdc.gov/labstandards/nsqap\\_resources.html#QCReportForms](http://www.cdc.gov/labstandards/nsqap_resources.html#QCReportForms)

\_\_\_ 10. **What if I do not receive my materials?**

To avoid penalty for not reporting data, contact NSQAP at [NSQAPDMT@cdc.gov](mailto:NSQAPDMT@cdc.gov) if you have not received materials within seven days of scheduled shipment. The shipping schedule is located here:

[http://www.cdc.gov/labstandards/nsqap\\_resources.html#QCReportForms](http://www.cdc.gov/labstandards/nsqap_resources.html#QCReportForms)

\_\_\_ 11. **What if I cannot report my results by the data deadline? Can I ask for an extension?**

We cannot extend data reporting deadlines. If you miss the deadline, you can email your results to [NSQAPDMT@cdc.gov](mailto:NSQAPDMT@cdc.gov). Data-report forms are located on the Newborn Screening Quality Assurance Program (NSQAP) reporting website. Results received after the data-reporting deadline will not be evaluated; however, you will receive credit for participation. We encourage you to conduct a self-evaluation.