

FREQUENTLY ASKED QUESTIONS AND PARTICIPANT SUPPORT

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Enrollment and Program Addition Questions

| INQUIRY | ACTION |
|--|--|
| What are criteria for participation in the Newborn Screening Quality Assurance Program (NSQAP)? | The laboratory must use the dried blood spot (DBS) matrix, and the laboratory's analyte reference ranges must represent the newborn period of life. |
| How do I enroll in the Newborn Screening Quality Assurance Program? | NEW PARTICIPANTS must complete the Participation Request Form at this link https://nbs.dynamics365portals.us/pr/ <i>NOTE: When completing the request form, you must provide a business street address. We cannot ship to a residential address or a Post Office Box. Tax ID and broker information may be required for laboratories located outside the United States.</i> |
| We are a manufacturer of newborn screening analysis kits. Can we enroll in NSQAP? | A manufacturer must have at least three NSQAP participants using your product to enroll in our program. We will verify this criterion when we receive your registration request. |
| Is there a cost for materials or shipping? | There is no cost for DBS materials or shipping for regularly scheduled shipments. You are responsible for any documents, import permits, fees, taxes, or other costs required by your country for release of your package from customs. |
| I am already a participant, but I want to add a program. | Log into the NSQAP Participant Portal https://nbs.dynamics365portals.us/ <ul style="list-style-type: none"> • Click on HELP on black bar • Click on HELP on the drop-down • Click "OPEN NEW REQUEST" • On next screen, click on "Modify (Add/Delete) Program under the Help Category • Type the program(s) to add or delete. (refer to the list of programs at the end of these FAQs) |
| When will I begin receiving PT and/or QC DBS materials? | All participation requests must be received by October 31 to begin receiving materials in January of the upcoming year. Refer to the shipping schedule in the calendar section on the home page of the NSQAP Participant Portal. https://nbs.dynamics365portals.us/ <i>Example: Enroll by October 31, 2023 for participation starting in January of 2024. Participation requests received after October 31 are processed for the following year.</i> |
| I am a participant in NSQAP. Why am I not receiving materials or correspondence from the Program? | Make sure your account information is up to date: <ul style="list-style-type: none"> • Log into the NSQAP Participant Portal https://nbs.dynamics365portals.us/ • Click on Lab Information on the black bar • Click on Lab Information on the drop-down |

General Questions

| INQUIRY | ACTION |
|---|--|
| How do I update the Primary Contact for our laboratory? | <p>Contact NSQAP at NSQAPDMT@cdc.gov Include your laboratory code number in all correspondence.</p> |
| How do I update our laboratory's demographic information such as address, phone number, etc? | <p>Log into the NSQAP Participant Portal https://nbs.dynamics365portals.us/</p> <ul style="list-style-type: none"> • Click on HELP from the black bar • Click HELP in the pulldown menu • Click "OPEN NEW REQUEST" in blue box • Choose "Contact/Address Update" under Help Category • Type your updates in the box and click submit |
| How can I request additional users for the NSQAP Participant Portal? | <p>Log into the NSQAP Participant Portal https://nbs.dynamics365portals.us/</p> <ul style="list-style-type: none"> • Click on HELP from the black bar • Click on Add/Remove Users |
| Do we need to re-enroll each year? | <p>No. Your laboratory must report data at least once per year for each program in your account to remain enrolled.</p> |
| Where can I see the programs in which my lab is enrolled? | <p>Log into the NSQAP Participant Portal https://nbs.dynamics365portals.us/</p> <ul style="list-style-type: none"> • Click on Lab Information on black bar • Click on Lab Information in the pull-down • Scroll to Details-Laboratory Profile |
| Can you extend the data reporting deadlines? | <p>We cannot extend data deadlines. We encourage you to conduct a self-evaluation using the summary report.</p> |
| Can we email our results instead of reporting in the NSQAP Participant Portal? | <p>All data must be reported using the NSQAP Participant Portal. No results will be accepted by email. https://nbs.dynamics365portals.us/</p> |
| I have not received my current shipment. | <p>Group Shipment: If you are part of a group shipment, you will need to contact the distributor for shipment questions.</p> <p>Direct Lab Shipment: Check the status of your shipment with FedEx using the tracking number provided to you and contact FedEx with any questions.</p> |
| Will we receive a certificate of participation? | <p>The Newborn Screening Quality Assurance Program (NSQAP) does not issue certificates of participation for reporting proficiency testing or quality control results.</p> <p>The CDC Newborn Screening and Molecular Biology Branch is accredited to ISO/IEC 17043:2010 as a Proficiency Testing (PT) provider. This accreditation does not require PT providers to issue program participants "Certificates of Participation" which do not assure <u>successful</u> performance in any program. CDC is not an accreditation entity, and therefore does not have the authority to deem any participant technically competent. Your laboratory must decide how to provide your customers with proof of assured quality for your operations.</p> |

SAMS/NSQAP Participant Portal Access Questions

NOTE: USE MICROSOFT EDGE TO AVOID BROWSER COMPATIBILITY ISSUES

| INQUIRY | ACTION |
|--|---|
| I forgot my password and cannot log in. | Enter your UserID then click “Forgot My Password” and follow the instructions to recover your password. |
| I don’t remember the answers to the questions to recover my password. | Contact the SAMS helpdesk at samshelp@cdc.gov or 877-681-2901 and ask them to delete your account. After your account is deleted, you must contact NSQAPDMT@cdc.gov to ask for a new registration invitation. |
| Can we have one login that everyone uses? | NO. SAMS prohibits shared accounts. See the SAMS User Guide for more information. https://auth.cdc.gov/sams/SAMSUserGuide.pdf?disp=true |
| How can I see who has access to our NSQAP Participant Portal account? | Log into the NSQAP Participant Portal https://nbs.dynamics365portals.us/ <ul style="list-style-type: none">• Click on Lab Information on black bar• Click on Lab Information in the pull-down• See CONTACTS list Note: YES next to name indicates portal access NO next to name indicates no portal access |
| How can I request additional users for the NSQAP Participant Portal? | Log into the NSQAP Participant Portal https://nbs.dynamics365portals.us/ <ul style="list-style-type: none">• Click on HELP from the black bar• Click on Add/Remove Users |
| What is the difference between SAMS and the NSQAP Participant Portal? | SAMS is an authentication authority that provides central access to applications operated by the CDC. The NSQAP Participant Portal is one of those applications. |

Proficiency Testing Questions

| INQUIRY | ACTION |
|---|---|
| <p>When are PT materials shipped?</p> | <p>The NSQAP event schedule is located on the NSQAP Participant Portal CALENDAR: KEY DATES AND EVENTS. https://nbs.dynamics365portals.us/</p> |
| <p>When is the PT data reporting deadline?</p> | <p>The NSQAP event schedule is located on the NSQAP Participant Portal CALENDAR: KEY DATES AND EVENTS. https://nbs.dynamics365portals.us/</p> |
| <p>How do I enter PT data into the portal?</p> | <p>PT Data reporting instructions are located under the help section:</p> <ul style="list-style-type: none"> • Click on HELP • Click on NSQAP Portal User Guides |
| <p>Can I email my PT data to NSQAP?</p> | <p>We do not accept data by email. All data must be reported in the NSQAP Participant Portal https://nbs.dynamics365portals.us/</p> |
| <p>Where is my PT evaluation?</p> | <p>PT Evaluation Location:</p> <ul style="list-style-type: none"> • Log into the NSQAP Data Reporting Portal https://nbs.dynamics365portals.us/ • Click on Lab Information in the black bar • Click on Reports from the pull-down menu • Click on RESULTS-LAB-#### under Portal Reports and Document <p>To find the most current PT Evaluation, sort by date:</p> <ul style="list-style-type: none"> • Click on Modified at the top of the date column <ul style="list-style-type: none"> ○ One click will sort the reports oldest to newest ○ Two clicks will sort the reports newest to oldest |
| <p>Where can I find the PT Summary Report?</p> | <p>PT summary report location:</p> <ul style="list-style-type: none"> • Log into the NSQAP Data Reporting Portal https://nbs.dynamics365portals.us/ • Click on Lab Information in the black bar • Click on Reports from the pull-down menu |
| <p>Can NSQAP extend the data reporting deadline?</p> | <p>We cannot extend data deadlines. We encourage you to conduct a self-evaluation using the quarterly summary report.</p> |
| <p>How do I enter a cutoff with a <?</p> | <p>The cutoff section can only accept numeric values. Cutoff values are not required so it is acceptable to leave those sections blank.</p> |

Quality Control Testing Questions

| INQUIRY | ACTION |
|---|--|
| When are QC materials shipped? | The NSQAP event schedule is located on the NSQAP Participant Portal CALENDAR: KEY DATES AND EVENTS. https://nbs.dynamics365portals.us/ |
| When is the QC data reporting deadline? | The NSQAP event schedule is located on the NSQAP Participant Portal CALENDAR: KEY DATES AND EVENTS. https://nbs.dynamics365portals.us/ <i>Note: NSQAP does not accept QC data after the QC data reporting deadline under ANY circumstances.</i> |
| How do I enter QC data into the portal? | QC Data reporting instructions are located under the QC section: https://nbs.dynamics365portals.us/ <ul style="list-style-type: none"> • Click on QC • Click on QC Information to find the QC Portal Data Entry Instructions |
| Can I email my QC data to NSQAP? | We do not accept data by email. All data must be reported in the NSQAP Participant Portal https://nbs.dynamics365portals.us/ |
| How do I use the template to upload my QC data? | QC Data reporting instructions are located under the QC section: https://nbs.dynamics365portals.us/ <ul style="list-style-type: none"> • Click on QC • Click on QC Information to find the QC Portal Data Entry Instructions • See section 3.1 |
| How do I use a < or > to report results? | QC Portal Data Entry Instructions are located under “QC” in the main menu: https://nbs.dynamics365portals.us/ <ul style="list-style-type: none"> • Click on QC • Click on QC Information • Click in QC Portal Data Entry Instructions |
| Where are QC certification pages? | QC Certification pages are located under “QC” in the main menu: https://nbs.dynamics365portals.us/ <ul style="list-style-type: none"> • Click on QC • Click on QC Information • Click in QC Certification Information |
| How do I know if my QC data submission was successful? | Do not email NSQAP to confirm submission of QC Data. QC Portal Data Entry Instructions are located under “QC” in the main menu: https://nbs.dynamics365portals.us/ Instructions for confirmation of data submission can be found on page 29. |
| Where can I find the QC summary reports? | QC summary report location: <ul style="list-style-type: none"> • Log into the NSQAP Data Reporting Portal https://nbs.dynamics365portals.us/ • Click on Lab Information in the black bar • Click on Reports from the pull-down menu <i>NOTE: NSQAP posts all completed QC reports. If the latest report is not available, it is still in publication phase.</i> |

PROFICIENCY TESTING PROGRAMS

(Enrollment in these programs is not guaranteed and is subject to review)

| PROFICIENCY TESTING PROGRAMS Three events per year | ANALYTE(S) INCLUDED |
|---|---|
| Acylcarnitines (ACPT) | C0(L), C2(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 |
| Adrenoleukodystrophy (ALDPT) | 24:0-Lysophosphatidylcholine, 26:0-Lysophosphatidylcholine |
| Amino Acids and SUAC (AAPT) | Arginine, Citrulline, Creatine, Guanidinoacetic Acid, GAMT Ratio, Leucine, Methionine, Phenylalanine, Succinylacetone, Tyrosine, Valine |
| Biotinidase Deficiency (BIOTPT) | Biotinidase |
| Cystic Fibrosis DNA Variant Detection (CFDNA) | Cystic Fibrosis DNA Variants |
| Galactose-1-phosphate Uridyltransferase Deficiency (GALTPT) | Galactose-1-phosphate Uridyltransferase |
| Glucose-6-phosphate Dehydrogenase Deficiency (G6PDPT) | Glucose-6-phosphate Dehydrogenase |
| anti-HIV-1 Antibodies (HIVPT) | anti-HIV-1 Antibodies |
| Hormone + Total Galactose (HORMPT) | Thyroxine, Thyroid Stimulating Hormone, 17 α -Hydroxyprogesterone, and Total Galactose |
| Immunoreactive Trypsinogen (IRTPT) | Immunoreactive Trypsinogen |
| Lysosomal Storage Disorders (LSDPT) | Galactoceramidase, Acid α -Glucosidase, α -L-Iduronidase |
| Second-tier Congenital Adrenal Hyperplasia (CAHPT) by LC-MS/MS | 17 α -hydroxyprogesterone, 4-androstenedione, cortisol, 11-deoxycortisol, 21-deoxycortisol |
| Sickle Cell Disease and Other Hemoglobinopathies (HbPT) | Enrollment currently closed. Sickle Cell Disease and Other Hemoglobinopathies |
| Spinal Muscular Atrophy (SMAPT) | Survival Motor Neuron 1 (SMN1) Exon 7 |
| T-cell Receptor Excision Circle (TRECPT) | T-cell Receptor Excision Circle |
| anti-Toxoplasma Antibodies (TOXOPT) | <i>Toxoplasma gondii</i> IgM Antibodies |

QUALITY CONTROL PROGRAMS

(Enrollment in these programs is not guaranteed and is subject to review)

| QUALITY CONTROL PROGRAMS Two events per year | ANALYTE(S) INCLUDED |
|--|---|
| 17 α-Hydroxyprogesterone + Total Galactose (17OHPQC and TGalQC) | 17 α -Hydroxyprogesterone, and Total Galactose |
| Galactose-1-phosphate Uridyltransferase (GALTQC) | Galactose-1-phosphate Uridyltransferase |
| anti-HIV-1 Antibodies (HIVQC) | anti-HIV-1 Antibodies |
| Immunoreactive Trypsinogen (IRTQC) | Immunoreactive Trypsinogen |
| Lysosomal Storage Disorders (LSDQC) | Galactoceramidase, Acid α -Glucosidase, α -L-Iduronidase α -Galactosidase, β -Glucocerebrosidase, Acid Sphingomyelinase |
| Tandem MS 1 (MSMS1QC) | Arginine, Alanine, Citrulline, Creatine, Creatinine, Guanidinoacetic Acid, Glycine, Leucine, Methionine, Ornithine, Phenylalanine, Succinylacetone, Tyrosine, Valine, C0, C2, C3, C3DC, C3DC+C4OH, C4, C4OH, C5, C5:1, C5DC, C5OH, C6, C8, C10, C12, C14, C14:1, C16, C16OH, C18, C18OH, C20-LPC, C22-LPC, C24-LPC, C26-LPC |
| Thyroxine (T4QC) | Thyroxine |
| Thyroid-Stimulating Hormone (TSHQC) | Thyroid Stimulating Hormone |

| SECOND-TIER QUALITY CONTROL PROGRAMS Two events per year | ANALYTE(S) INCLUDED |
|--|--|
| Second-tier Congenital Adrenal Hyperplasia by LC-MS/MS (CAHQC) | 17 α -Hydroxyprogesterone, 4-Androstenedione, Cortisol, 11-Deoxycortisol, 21- Deoxycortisol |
| Second-tier Maple Syrup Urine Disease and Phenylketonuria by LC-MS/MS (MSUD-PKUQC) | Alloisoleucine, Isoleucine, Leucine, Phenylalanine, Tyrosine, Valine |
| Second-tier Methylmalonic/Propionic Acidemia and Homocystinuria by LC-MS/MS (MMA-HCYQC) | Malonic Acid, Methylmalonic Acid, Ethylmalonic Acid, 2-Methylcitric Acid, Total Homocysteine |