وقاية

هيئة الصحة العامة
PUBLIC HEALTH AUTHORITY

NATIONAL

NEWBORN SCREENING

LABORATORY STANDARDS

NNLS. VERSION 1.0 / 2023

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DEFINITIONS AND ABBREVIATIONS

DEFINITIONS

Accreditation	"Accreditation is a procedure by which an authoritative body formally recognizes that a body or person is competent to carry out specific tasks."
Assessment	"The process of evaluation and judgment about something"
Appeal	"Applying a serious request for a decision to be reversed."
Corrective Action	"Corrective action is the process, known as a corrective action plan (CAP), of taking the appropriate steps to identify the root cause of a problem and implementing a solution that corrects the root cause to prevent its recurrence."
Policy	"a written operational statement that formalizes the task approach consistent with the organizational objectives."
Procedures	"A written set of instructions conveying the approved and recommended steps for act or series of acts"
Process	"a series of actions or steps to achieve a particular end."
Risk Management	"a systematic process of identifying, assessing and taking action to prevent or manage clinical, administrative, property and occupational health and safety risks in the organization"
Reference Interval	The range of test values expected for a designated population of individuals.
Validation	The process by which a laboratory checks or approve the validity or accuracy of the equipment or the methods used for testing.

DEFINITIONS AND ABBREVIATIONS

ABBREVIATIONS

DBS	Dry Blood Spot	**QC**	Quality Control
GLS	General Laboratory Standards	**QMS**	Quality Management System
HPLC	High-Performance Liquid Chromatography	**TAT**	Turn Around Time
KPI	Key Performance Indicator	**TIC**	Total Ion Chromatogram
L(C) L(R)	Crucial & Required	**TPN**	Total Parenteral Nutrition
LC	Liquid Chromatography	**MOH**	Ministry of Health
LIS	Laboratory Information System	**PHA**	Public Health Authority
NBS	Newborn Screening	**PHL**	Public Health Laboratory
NLS	Newborn Screening Laboratory Standard	**PHLA**	Public Health Laboratory Accreditation
NNLS	National Newborn Screening Laboratory Standards	**PHLA-D**	Public Health Laboratory Accreditation Department

INTRODUCTION

Newborn screening program is a national program in Saudi Arabia that mandates testing all newborns in the kingdom to detect serious and rare health conditions that can be treatable in early stages to prevent serious health issues. The test is performed in the early few days of the baby's birth on dry blood spots using a special card to test a variety of genetic and metabolic disorders.

Newborn screening laboratories are mandated to fulfil essential requirements and standards to be accredited to perform the tests ensuring accurate results to optimize the quality and newborn safety to ensure a healthy population.

This book is to provide the required Newborn Screening Laboratory Standards with the guidelines and policies for accreditation.

The standards are structured based on the Pre-Analytical, Analytical, and Post-Analytical laboratory's process covering all laboratory's quality management essentials.

It is divided into two main parts; General Laboratory Standards (GLS) that must be applied in all clinical laboratories and specific Newborn Screening Laboratory Standards (NLS). Standards are divided into two levels; Crucial (C), those have to be met from the during the assessment visit, and Required (R), which can be recommended during the visit, and the lab will be given one month to correct it.

SCOPE AND ELIGIBILITY

National Newborn Screening Laboratory Standards (NNLS) applied to all newborn screening laboratories in the kingdom in government and private sectors, either in hospitals or standalone laboratories, to be accredited by Public Health Authority (PHA) to be eligible to perform the tests.

POLICY STATEMENTS

- All neonates in the Kingdom of Saudi Arabia must be tested for all the disorders in the referral testing panel.
- The laboratory should not test for other diseases not included in the NBS panel approved by the regulatory bodies.
- All laboratories that perform newborn screening tests in the kingdom must be accredited by PHA against NNLS based on the Council of Ministers' decree No. (401) on the 2nd of March, 2021, that mandates PHA to provide standards and accredit all public health-related laboratories.
- The laboratories must meet all the NNLS to be accredited.
- All level (C) standards must be met during the assessment visit to be entitled to submit a corrective action for level (R) standards recommendations.
- Providing relevant evidence of implementation for each written standards' statement is a must to considered as met.
- ·Accredited laboratories must maintain and renew the accreditation within the accreditation time frame.
- ·Accredited laboratories must send the KPIs and Proficiency Testing (PT) reports to the PHA accreditation department quarterly.
- Revocation policy will be applied; if any laboratory fails to submit the reports on time with an acceptable corrective action, falsification of documents, and or alteration from applying the standards and the program requirements after accreditation.
- Laboratories with revoked accreditation for the second time will be allowed to request the accreditation after two years from the revocation date.
- Any newborn screening laboratory that fails to achieve the accreditation will be prohibited from performing the tests.
- Accrediting the newborn screening laboratory with NNLS will ensure accrediting the newborn screening laboratory only, not the entire institute. The institute must achieve accreditation from a recognized accredited body.
- Required data and statistics (analyzed samples, rejected samples, positive reports, and confirmed cases) must be sent monthly to the Public Health Authority and Newborn Screening Program Management.

ACCREDITATION PROCESS AND GUIDELINES

REQUESTING ACCREDITATION

- The newborn screening laboratory will submit a request to PHA through the online website, filing all the required fields in the electronic form.
- PHA Laboratory Accreditation Department (PHLA-D) will receive and review the filled request forms.
- The laboratory will receive an email with approval status with the standards, guidelines, and the required action to prepare for the assessment visit (if meeting the initial requirements on the page).
- The date of the visit will be coordinated between the lab and PHLA-D

ASSESSMENT'S VISITS

- PHLA-D will assign a team of at least two assessors to visit the lab on the selected date.
- An email with the visit's notification details will be sent to the laboratory beforehand.
- Assessors will use an assessment tool to score all the NNLS provided.
- Assessment report will be discussed immediately with the lab, and the assessors' leader will submit a copy to PHLA-D.
- The laboratories and assessors will fill out a feedback questionnaire about the visit and the standards and submit it directly to PHLA-D through email at PHLA@pha.gov.sa.

ASSESSMENT'S REPORT

- Based on the scoring policy, the assessment report will be reviewed for decision by a committee from external members.
- The standards are divided into two levels based on severity, (C) and (R). The lab will be denied accreditation immediately if any (C) standards are unmet during the visit. Findings with (R) standards will be corrected within one month from the visit date and be sent to PHLA-D for review and decision.

ACCREDITATION CERTIFICATION

- Once the lab meets all the standards, the lab will receive a notification with the accreditation results.
- The NNLS accreditation period will be one year from issuing the accreditation.
- Denied accreditation notification email will be sent when the lab fails to meet all the standards or fails to submit a corrective action successfully.
- The laboratory that was not accredited the first time can resubmit a new request one month after the result's date.
- If the lab is denied accreditation for the next time, the lab will be rescheduled after at minimum 6 months.

ACCREDITATION MAINTENANCE

- The lab will maintain meeting the standards during the accreditation lifetime.
- KPI & PT reports will be requested to be submitted every 3 months to PHLA-D.

  Required KPIs are:
  - TAT.
  - Identification Errors.
  - Lost Samples.
  - Reports Correction Rate.
- Failure to submit the reports on time will result in the accreditation's revocation.

ACCREDITATION REVOCATION

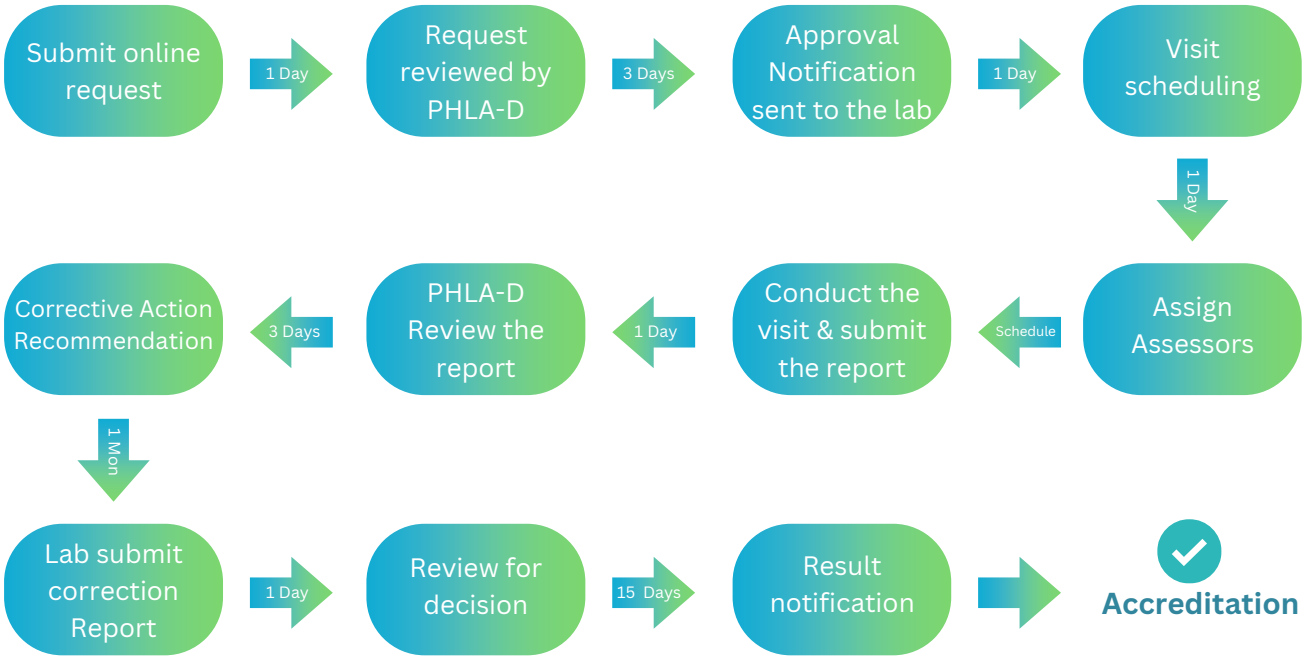
- The accreditation certificate will be revoked in case of the following:
  - Fails to submit the maintenance KPIs and PT reports on time with acceptable corrective action.
  - Falsification of documents.
  - Alteration from applying the standards and the program requirements after accreditation.
  - A complaint received from patients, health workers, hospitals, or other stakeholders that approves of misconduct.
- PHLA will make the required investigations.
- The laboratory will be notified of the decision and be requested to return the accreditation certificate to PHLA.

- The laboratory will stop testing newborns screening in their laboratories and inform the hospitals with contracts to redirect the specimens to another accredited laboratory.
- After correcting all the issues, the laboratory can resubmit a request for accreditation after 6 months from the revocation date.
- If the accreditation is revoked for the second time, the laboratory is allowed to resubmit a new accreditation request after two years.

APPEAL

- The laboratory will have the right to submit an appeal on the received decision in case of dissatisfaction.
- The laboratory will fill out a form, complete all the fields and submit it within 10 working dates from the decision date.
- Any appeals that did not follow previous instructions will be rejected.
- An external committee will review the form to resolve the dispute.
- A notification of the committee's decision will be sent to the laboratory through email.

Fig (1) NNLS Accreditation Process



STANDARDS

GENERAL LABORATORY STANDARDS

1- Organization, Leadership and Customer

PHLA-GLS-1000 (R)
The laboratory has a clear structure and governing body roles and responsibilities.

PHLA-GLS-1005 (C)
The laboratory director, head, supervisor, and technical staff possess requisite qualifications commensurate with the laboratory's services and are licensed by the Saudi Commission for Health Specialties.

PHLA-GLS-1010 (C)
The laboratory director delegates, in writing, responsibilities for a category to a person who qualifies for a relevant category when required.

PHLA-GLS-1015 (C)
Job discerptions explicitly indicate the responsibilities and duties of the lab consultant, supervisor, and testing personnel for this laboratory.

PHLA-GLS-1020 (C)
The laboratory has a rigorous system for overseeing the competency of personnel while also effectively identifying the necessary corrective training or continuing education measures related to the lab services.

PHLA-GLS-1025 (R)
The laboratory defines its customers and establishes an accessible, efficient, and user-friendly mechanism for collecting customer feedback.

PHLA-GLS-1030 (C)
The laboratory has a service agreement or contract with all requesting parties clarifying the requirements ensuring the specimen's integrity and results reporting.

PHLA-GLS-1035 (C)
The laboratory has a valid MOH license (for private laboratories).

2- Resource Management

PHLA-GLS-2000 (C)
The laboratory has systems to ensure all required supplies for generating test results are available.

PHLA-GLS-2005 (C)
The laboratory uses all physical resources according to manufacturer instructions and requirements.

PHLA-GLS-2010 (C)
The laboratory verifies and documents the suitability of consumable materials, including acceptance and rejection criteria, that affect the test result's quality and timeliness.

PHLA-GLS-2015 (R)
The laboratory maintains equipment and instruments' documentation of:

- The serial number or unique identifier and, if applicable, version number.
- Date(s) of:
- Initial calibration, certification, and performance verifications;
- Placement into service; and
- Required recertification or performance verifications, as applicable.

PHLA-GLS-2020 (C)
The laboratory has policies and procedures for maintenance and preventive maintenance of equipment and instruments readily available to laboratory staff.

PHLA-GLS-2025 (C)
The laboratory performs and document maintenance for all equipment and instruments used for specimen testing and reporting. Documentation includes:

- All scheduled maintenance and preventive maintenance records.
- Occurrences and outcomes of damage, malfunctions, modifications, and repairs.

PHLA-GLS-2030 (C)
The laboratory has a process for defective equipment and instruments, which includes:

- Clearly label the equipment or instrument as being out of service.
- Document and investigate the nonconformance according to the laboratory policy of nonconformance event
- Examine and document the effect on specimen test results
- Ensure that repaired or serviced equipment and instruments meet manufacturer or laboratory-defined performance specifications through calibration, and performance verification, as applicable, before being used for reporting test results.

PHLA-GLS-2035 (R)
The laboratory has policies and procedures defining the proper labeling of reagents, calibrators, controls, chemicals, and solutions as applicable and appropriate, with the following elements:

- Content and quantity, concentration, or titer
- Storage requirements
- Date prepared, filtered, or reconstituted by laboratory
- Expiration date
- Staff initial

PHLA-GLS-2040 (C)
The laboratory has policies and procedures for using all reagents and chemicals before expiration.

PHLA-GLS-2045 (R)
The laboratory has policies and procedures for evaluating reagents lacking the manufacturer's expiration date.

PHLA-GLS-2050 (C)
The laboratory has policies and procedures for each new reagent lot to verify the reagent's performance before use.

3- Quality Management

PPHLA-GLS-3000 (R)
There is a written Quality Management Program that continuously assesses and improves the quality of laboratory services and ensures compliance with regulatory requirements.

PHLA-GLS-3005 (C)
According to the manufacturer's instructions, the laboratory has policies and procedures for Instrument / Method validation or verification study. The studies include:

- Accuracy.
- Precision.
- Carryover.
- Analytical sensitivity (as applicable).
- Analytical specificity (as applicable).
- Analytical Measurement Range (AMR).
- Interferences (as applicable).
- Reference interval(s).
- Reportable range as applicable, including revalidation criteria.

PHLA-GLS-3010 (C)
There is a record for Instrument / Method validation or verification study approved by the lab director or designee confirming the acceptance of the method for newborn testing.

PHLA-GLS-3015 (C)
The laboratory has policies defining the below elements as appropriate for each instrument/test system:

- The method types
- Calibration type
- Calibration frequency
- Calibration verification acceptable criteria.
- Recalibration criteria.
- Calibration records are reviewed for acceptability. The limit of blank samples must be established and entered into the software for daily monitoring the carry over.
- The laboratory must obtain square shaped chromatogram for each and every sample before results review.

- Minimum acceptable limit of the internal standard intensity must be established during the method validation study.
- Flow profile must be established before the validation of method.
- Laboratory must verify the calculation factor for each analyte whenever possible and applicable.

PHLA-GLS-3020 (C)
For each lot of assayed control material, the laboratory verifies the:

- Assayed value before and/or concurrent with being placed into use.
- Assayed value corresponds to the method and instrument used.
- Ranges reflect accepted medical and analytical requirements for each analyte.

PHLA-GLS-3025 (C)
The laboratory use at least two levels assayed quality control material with batch regardless the number of samples. The same quality control must be injected at the beginning and end of the batch before finalizing the patient results. Both controls should be provided by the kit manufacturer.

PHLA-GLS-3030 (R)
All staff use the same control material and test it in the same manner as the specimens.

PHLA-GLS-3035 (C)
Records of actual results for each quality control are maintained by the laboratory, including:

- Quality control charts.
- Other records that identify the controls by date and lot.

PHLA-GLS-3040 (C)
The laboratory has a system for documented review of quality control records that identify shifts, trends, or other indicators of test instability.

PHLA-GLS-3045 (C)
There are records in which quality control data are reviewed and assessed monthly by the laboratory director or designee, including follow-up for outliers, trends, or omissions.

PHLA-GLS-3050 (R)
The laboratory has policies and procedures describing the process for monitoring the KPIs.

- Frequency for monitoring, which must be at least annually.
- Data collection method, analysis, and documentation.
- Acceptable performance and threshold(s) for each indicator.
- Actions to be taken for KPIs that did not meet defined performance expectations and threshold(s), including notifications to appropriate parties, if applicable.

PHLA-GLS-3055 (C)
The laboratory established Key Performance Indicators (KPIs) to assess laboratory services and identify processes for quality goals:

- Monitoring specimen submissions for compliance with test request requirements and submission instructions.
- Timeliness and completeness for personnel training and competency
- Performance on proficiency testing and alternative assessments of test accuracy and reliability.
- Corrected test reports
- Turnaround times for laboratory tests.
- Complaint studies/ investigations.

PHLA-GLS-3060 (R)
The laboratory has records of monitoring and reporting the newborn KPIs to the PHA and NBS program monthly as per the regulation requirements.

PHLA-GLS-3065 (C)
The laboratory has policies and procedures for proficiency testing (PT) to cover all newborn tests.

PHLA-GLS-3070 (C)
The laboratory maintains the following documentation of the processing and reporting of proficiency testing samples:

- Steps were taken in preparing, processing, examining, testing, and reporting all results in the proficiency test event.
- The proficiency testing provider's attestation form was completed per the provider's instructions and requirements.
- Copies of all testing records, including copies of the proficiency test report forms.

PHLA-GLS-3075 (C)
The laboratory implements and documents corrective action(s), if needed when an unsatisfactory or unacceptable proficiency testing (PT) or alternative assessment result is identified.

PHLA-GLS-3080 (R)
The laboratory has a continuous improvement program for newborn screening testing. This program should include a process for identifying and addressing areas for improvement.

PHLA-GLS-3085 (R)
The laboratory implants a risk management program to identify the source of potential failures and errors and evaluate the frequency, impact, and how to be managed.

4- Laboratory Design and Safety

PHLA-GLS-4000 (R)
The laboratory has a comprehensive safety program that includes the following:

- Occupational Injuries and Evaluation
- Occupational Exposure Response
- Chemical Hygiene Plan
- Biohazard Risk Assessment
- Biohazard Warning Signs and Labels
- Personal Protective Equipment for Biohazards
- Biological Safety Cabinets
- Decontamination Procedures
- Food Storage
- Packaging and Shipping Requirements
- Regulated Medical Waste Management
- Staff safety training and competency
- Safety auditing and corrective action

PHLA-GLS-4005 (C)
The laboratory has initial and annual safety training records for all personnel in applicable safety standard operating procedures and policies.

PHLA-GLS-4010 (R)
The laboratory design and environment must be suitable for the tasks performed, including but not limited to adequate:

- Equipment, instruments, reagents, kits, supplies, and any other materials required to provide clinical testing service.
- Space, such that the workload can be performed without compromising the quality of work or safety of personnel.
- Furnishings and technology infrastructure, including communication and data processing systems.
- Energy sources that mitigate fluctuations and interruptions, including applicable backup power.
- Lighting, ventilation, water, waste and refuse disposal, and environmental controls.
- Monitor, control, and record environmental conditions that may influence the quality of test results.
- Ensure documents that record environmental conditions are consistent with manufacturer requirements and laboratory standard operating procedures, if applicable.
- Ensure that the laboratory and work areas are clean and well-maintained.

PHLA-GLS-4015 (R)
The laboratory has records for documenting and reporting safety auditing, incidences, and corrective actions.

5- Laboratory Information System

PHLA-GLS-5000 (C)
The laboratory has a system that manages the information necessary to receive and track specimens and report results. The information must be accurate, complete, and readily accessible. The system(s) may be manual, electronic, or combined.

PHLA-GLS-5005 (R)
The laboratory has policies and procedures for laboratory information systems (LIS) that include:

- Quality goals and performance expectations for the LIS, as described in the laboratory's Quality Management System (QMS).
- Protection of personally identifiable information and protected health information.
- Facility design requirements for proper system function, such as power protection.
- Approval of procedures and LIS changes, as delegated in writing by the laboratory director.
- Authorization for staff access and protection from unauthorized access.
- Initial validation of system components and as required for changes.
- Documentation of verification.
- Requirements and documentation for maintenance.
- Mechanism to ensure that previous data is retrievable when the LIS is upgraded or replaced.
- Requirements for tracking and audit trails.
- Steps to be followed if the system is not functioning.

PHLA-GLS-5010 (R)
The laboratory has policies to ensure that:

- Electronic data are backed up at a frequency that minimizes the risk of data loss.
- Systems are in place to ensure data integrity and timely reporting of results if the laboratory information system (LIS) is out of service.
- Data are retrievable within twenty-four (24) hours.

PHLA-GLS-5015 (C)
The laboratory ensures that protected patient health information is kept confidential throughout all phases of the total testing process under the laboratory's control. In addition, the laboratory has a policy to educate staff on protected health information. Confidentiality training must be done during initial employee training and annually after that.

6- Document Control

PPHLA-GLS-6000 (R)
All standard operating procedures, policies, instructions, programs, plans, manuals, and any other documents are:

- Under document control.
- In a standardized format with a system of numbering and titling of each procedure.
- Current and accurate.
- Available and accessible at all times in applicable work areas.

PHLA-GLS-6005 (C)
Laboratory staff follow policies, procedures, and other laboratory documents under document control. The laboratory must have a system to ensure the following:

- Notify relevant staff of revisions.
- Provide and document training for staff on procedures and other applicable documents.

PHLA-GLS-6010 (R)
The laboratory has a system to:

- Maintain and archive a copy of each revised document under document control, with the dates of use and discontinuation
- Retain these records, if required, according to Document and Specimen Retention Standards of Practice.

PHLA-GLS-6015 (C)
The laboratory has written policies and procedures for all performed laboratory tests, including (if applicable):

- The implementation date for the current version of the test procedure.
- Test purpose and intended use.
- Analytic principle of the test.
- Biological, chemical, and radiological safety.
- Specimen type, acceptable container(s), and, if applicable, minimum specimen quantity or volume and required preservative.
- Requirements for newborn preparation, specimen collection, labeling, storage, preservation, transportation, processing, and sending to a reference or contract laboratory.

- Criteria for specimen acceptance and rejection that are consistent with requirements in the Specimen Processing Standard of Practice
- Storage of residual specimens and time limits for requesting additional testing.
- Required equipment, instruments, and reagents.
- Instrument and equipment function checks and preventive maintenance;
- Test performance specifications for accuracy, precision, reportable range, and analytical sensitivity and specificity;
- Environmental requirements, including as needed, the separation of incompatible activities and precautions to mitigate specimen contamination;
- Actions to be taken if the laboratory is unable to perform any part of the testing procedure;
- Steps required for testing, including, as appropriate:

- Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing;
- Microscopic examination, including the detection of inadequately prepared slides.
- Calibration and calibration verification procedures.
- Quality control procedures that specify acceptance and rejection criteria.
- Corrective action is to be taken when quality control or calibration verification fails to meet acceptability criteria.
- Calculations or evaluation criteria used to determine test results;
- Interpretation of test results.
- Confirmatory, supplemental, or additional testing, if required.
- Reporting results, including imminently life-threatening or panic or alert values, to the ordering centers.
- Notifications and recording life-threatening results, or panic or alert values maintaining records with readback.
- Reportable range for quantitative tests.
- Reference ranges, therapeutic or toxic concentrations, or other interpretive criteria appropriate to the test.
- Limitations of the test, including interfering substances when applicable.
- References to pertinent literature.
- Any laboratory policy, service, or additional requirements as indicated in the Clinical Laboratory Standards of Practice.

PHLA-GLS-6020 (R)
The laboratory director reviews and approves the content of policies, procedures, and laboratory forms every two years.

PHLA-GLS-6025 (C)
The laboratory has written policies and procedures based on national and international document and specimen retention guidelines.

NEWBORN SCREENING LABORATORY STANDARDS

1- Pre-Analytical

PHLA-NLS-1000 (C)
An assigned laboratory coordinator is responsible for receiving and checking newborn specimens, communicating results with the hospital, sending all DBS cards, and reporting the monthly performance indicators to PHA.

PHLA-NLS-1005 (C)
The laboratory tests all disorders included in the newborn screening panel approved by the regulatory authorities, as all Newborns in the kingdom have to be tested for a unified panel.

PHLA-NLS-1010 (R)
The laboratory does not test any other diseases not included in the approved NBS panel.

PHLA-NLS-1015 (C)
Newborn specimen collection manual distributed to all collecting centers includes instructions for the following elements:

- Specimen collection will be in the nursery department in the same hospital where the baby was born.
- Specimen collection is to be within 24-72 hours of birth.
- Dry Blood Spot (DBS) card requirements.
- Identification of the newborn.
- Site Preparation of Newborns.
- Specimen collection procedure (the proper application and drying of blood spots).
- All information is to be filled on the DBS card, including Specimen collection time (in case of premature, on total parenteral nutrition (TPN), low birth weight, having blood transfusion, and gestational age).
- DBS card information recording procedure (All information to be filled on the DBS card).
- Acceptable specimen criteria.
- Precautions regarding sample stacking, contamination, and exposure to heat and humidity (avoiding the use of EDTA or citrate tubes).
- Need for special Instructions for proper Specimen handling between the time of collection and the time received by the laboratory (e.g., refrigeration, immediate delivery).
- Proper specimen labeling- misidentification procedure.
- Need for appropriate Providing clinical data when indicated.

- Any requirements for newborn consent (e.g., consent to disclose clinical information and family history to relevant healthcare professionals where referral is needed).
- Available tests and their turnaround time (TAT)
- Specimen rejection criteria

PHLA-NLS-1020 (C)
All specimens received with a test request form or electronic equivalent form must elicit the following information:

- Name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results.
- Specimen collection center.
- newborn name and mother name
- Newborn and mother identification numbers.
- Sex and age or date of birth of the patient.
- Date and, if appropriate, time of specimen collection; and
- Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

PHLA-NLS-1025 (C)
The laboratory has policies and procedures for the acceptance and rejection of specimens. The laboratory must document the reason(s) for rejecting a specimen and notify the collection center. The procedure must describe the criteria for rejecting specimens, including:

- Evidence that the specimen is unsatisfactory for testing or that it is inappropriate for the test requested:

- Evidence of improper collection, labeling, preservation, handling, or other conditions that make the specimen unsatisfactory or unreliable for testing.
- Rejection of a specimen if the time between collection and receipt in the laboratory has exceeded requirements.
- The date and, when required, the time of collection are not recorded on the test request.
- The required temperature for specimen transportation.

PHLA-NLS-1030 (C)
The laboratory has policies and procedures to receive and document all specimens in an accession book, worksheet, electronic, or other comparable system. Documentation must include the following:

- Unique accession number or another unique identifier for the specimen.
- Name or another identifier for the patient
- Date and time the specimen was received in the laboratory.

PHLA-NLS-1035 (C)
There are records that all personnel collecting newborn specimens have been trained in collection techniques and the proper selection and use of equipment/supplies and are knowledgeable about the contents of the specimen collection procedures.

PHLA-NLS-1040 (C)
Specimen collection supplies such as blood collection filter paper and collection devices (e.g., heel lancets) are used within their expiration date and stored per the manufacturer's instructions.

PHLA-NLS-1045 (C)
The individual collecting the specimen positively identifies the newborn (newborn wristband) before collecting a specimen and labels the specimen in the presence of the newborn parents (if possible).

PHLA-NLS-1050 (C)
The DBS demographic information consists of the following:

- Adequate Newborn identification information (e.g., full name, registration number, location, or a unique confidential specimen code if an alternative audit trail exists).
- Mother's full name.
- Mother’s National identification number.
- Newborn sex.
- Gestational age.
- Newborn date and time of birth.
- Physician's (health care provider's) name and contact number.
- Name and address of the laboratory referring to the specimen
- Date and time of specimen collection.
- Birth weight.
- The expiration date of the specimen collection device (card).
- An appropriate number of preprinted circles, with preprinted broken- or dotted-line circles on one side of the filter paper section (with optional printing of circles on both sides).
- Clinical information, including a significant family history of relevant disorders.

PHLA-NLS-1055 (C)
There are written policies and procedures defining the proper procedure of drying the blood card, allowing the blood specimen to air-dry in a horizontal position for at least 3 hours at ambient temperature (18 to 25°c).

PHLA-NLS-1060 (C)
There are written policies and procedures defining specimen handling and transportation procedures that avoid direct light, heat, humidity, and stacking when handling dried blood cards.

PHLA-NLS-1065 (C)
There is a written policy and procedure for specimen submission (shipment). Specimens should be transported after being dried, at most 72 hours after collection. To maintain specimen integrity, All specimens must be kept cooled (2-8°c) during shipment. Shipment numbers and airway bills have to be recorded for tracking purposes.

PHLA-NLS-1070 (C)
In cases where an indication of consent is required on the newborn screening DBS cards for later use (research), there is a procedure for review and action to ensure the appropriate use of the specimen.

2- Analytical

PHLA-NLS-2000 (C)
Handling Mass Spectrometry

- The laboratory has the expertise and resources to handle mass spectrometry
- The laboratory has a reliable mass spectrometer with high sensitivity and accuracy for identifying and quantifying metabolites in the blood samples.
- There is training on the use of mass spectrometers
- Expertise in interpreting mass spectrometry data
- Manufacturer recommendation on the QC and blank position and frequency is followed.
- Two blank samples containing the standard material must be run before the patient sample (on each 96-well plate).

PHLA-NLS-2005 (C)
Handling Enzyme Activity Analysis

- The laboratory has the expertise and resources to handle enzyme activity analysis.
- The laboratory has a range of high-quality reagents and chemicals for performing enzymatic assays that measure enzyme activity in the blood samples.
- There is rain on the use of enzyme activity assay kits
- Expertise in interpreting enzyme activity assay data
- Manufacturer recommendation on the QC and blank position and frequency is followed.

PHLA-NLS-2010 (C)
Handling High-Performance Liquid Chromatography

- The laboratory has the expertise and resources on how to use (HPLC)
- There is training on the use of HPLC handling and running samples
- Expertise in interpreting HPLC assay data
- The system must be able to handle the small sample volumes that are typically used for newborn screening.
- Manufacturer recommendation on the QC and blank position and frequency is followed.
- To accept a run, the total area of quality control samples should be within the manufacturer recommended range.

PHLA-NLS-2015 (C)
For laboratories performing electrophoresis:

- Each electrophoretic cell or chamber must include at least one control sample containing fractions representative of those routinely reported in specimens.
- There is training on the use of electrophoresis handling and running samples.
- Expertise in interpreting electrophoresis assay data
- Manufacturer recommendation on the QC and blank position and frequency is followed.
- Assays, where the final product is assessed by product size, must, with every analysis:
- Include molecular weight markers of known size that span the range of sizes routinely encountered by the method
- Flanking size markers must be used with sufficient frequency to perform accurate sizing

PHLA-NLS-2020 (C)
The laboratory identifies the substances that can interfere with the measurement of analytes in newborn screening tests and must be removed from the samples before analysis.

PHLA-NLS-2025 (C)
The lab has a policy and procedure for review and approval of chromatographic characteristics of each run before results are released. The total ion chromatogram (TIC) must be checked for shape, proper retention time, and acceptable intensity before the run is accepted. Corrective action documented in case of unacceptable TIC.

3- Post-Analytical

PPHLA-NLS-3000 (C)
The newborn screening result report includes the following elements:

- Name and address of testing laboratory.
- Newborn name and unique identification number.
- Sample identification number.
- Mother's National identification number.
- Date of specimen collection and time of collection
- Date of release of the report.
- Newborn date of birth
- Time of release of the report.
- Test result(s) and units of measurement.
- Reference intervals or Cutoffs
- Conditions of the specimen that may limit the adequacy of testing
- Reports should provide adequate guidance on further testing to confirm and establish the diagnosis

PHLA-NLS-3005 (C)
There is a procedure for reviewing and reporting positive (clinically significant abnormal results) by qualified and expert consultants in biochemical genetics and hematopathology to the center's coordinator and other appropriate entities.

PHLA-NLS-3010 (R)
In cases where the testing laboratory is responsible for testing and follow-up (including neonatal follow-up), all follow-up procedures are "closed loop" and must comply with local laws and regulations. Therefore, the laboratory's written procedures should include:

- Cases requiring notification
- Roles and responsibilities of all individuals in the follow-up system, as appropriate (laboratory staff, physicians, and birthing centers)
- Method and timing of notifications (e.g., phone call, fax, or letter)
- Monitoring of follow-up to track the actions taken until resolution — specimen monitoring, follow-up calls/letters, nurse visits, etc.
- Case Resolution - follow-up actions, including the extent of actions required before closing a case without resolution, or loss to follow-up occurs when a notification cannot be made.
- ·Case definition: type of confirmatory testing required to rule in/rule out the suspected condition

PHLA-NLS-3015 (C)
The laboratory has defined turnaround times (i.e., the interval between specimen receipt by laboratory personnel and results reporting) for each of its tests to be at most 48 hours, and it has a policy for notifying the requester when testing is delayed.

PHLA-NLS-3020 (C)
Test results are available promptly to the authorized ordering source or client. Laboratories must be capable of producing a hard copy of a laboratory report. Test results, whether transmitted electronically or by hard copy, must include all required report information, including:

- Newborn name and identification number.
- Name and address under which the reporting laboratory has been issued a permit unless the laboratory has reported an alternative name.
- Date and time the specimen was collected.
- Test report date.
- Specimen type and source
- Test results, and if applicable, units of measure, reference ranges, or a similar method for identifying abnormal values.
- Signature of the qualified person who reviewed, approved, and diagnosed the case
- Any additional information required for the interpretation of the results

PHLA-NLS-3025 (C)
When errors or inaccuracies in test reports are detected, the laboratory:
- Promptly notify the center's coordinator or client of the reporting error(s).
- Promptly issue a report that identifies the corrected information and indicates the report as corrected.
- Maintain the ability to generate the information contained in the original report and the corrected report to include; the original report date and the corrected report date.
- Maintain documentation to demonstrate the basis for the change to the test report.
- Records of notifications are retained, including "read-back."

PHLA-NLS-3030 (C)
The laboratory has documents that all newborn DBS cards are sent to PHL weekly per the national guidelines.

PHLA-NLS-3035 (C)
The laboratory has documents that provide PHA monthly with all statistical findings, including the total number of successful and unsuccessful samples.

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PUBLIC HEALTH AUTHORITY

NATIONAL

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LABORATORY STANDARDS

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