



TITLE

**NEWBORN METABOLIC SCREENING PROGRAM**

**SCOPE**

Provincial

DOCUMENT #

HCS-32

APPROVAL AUTHORITY

Vice President & Chief Health Operations Officer Central & Southern Alberta

INITIAL EFFECTIVE DATE

October 2, 2013

SPONSOR

Senior Program Officer Population, Public & Indigenous Health

REVISION EFFECTIVE DATE

June 5, 2019

PARENT DOCUMENT TITLE, TYPE AND NUMBER

Not applicable

SCHEDULED REVIEW DATE

June 5, 2022

**NOTE:** The first appearance of terms in bold in the body of this document (except titles) are defined terms – please refer to the Definitions section.

If you have any questions or comments regarding the information in this document, please contact the Policy & Forms Department at [policy@ahs.ca](mailto:policy@ahs.ca). The Policy & Forms website is the official source of current approved policies, procedures, directives, standards, protocols and guidelines.

## OBJECTIVE

- To provide an integrated and coordinated approach to delivering **Newborn Metabolic Screening (NMS) Program** services to all infants born in Alberta.

## PRINCIPLES

Alberta Health Services (AHS) is committed to early identification and treatment of infants with a **screened condition** through the delivery of a comprehensive, resilient and organization-wide NMS Program.

All infants born in Alberta shall have timely access to the NMS Program with screen results reported on or before the 10<sup>th</sup> day of age (except for deoxyribonucleic acid [DNA] testing for cystic fibrosis which shall be reported by the 21<sup>st</sup> day of age).

**Parent(s)** or **guardian(s)** of infants shall be informed about the NMS Program.

## APPLICABILITY

Compliance with this document is required by all Alberta Health Services employees, members of the medical and midwifery staffs, Students, Volunteers, and other persons acting on behalf of Alberta Health Services (including contracted service providers as necessary).

## ELEMENTS

### 1. Registration

- All infants born in Alberta shall be registered in the **Person Directory** and assigned a **unique lifetime identifier (ULI)** using the 'add newborn' function

within 24 hours of age.

- 1.2 Infants born in Alberta shall be registered in accordance with the Alberta Health and AHS *Provincial Registration Standards and Practices Manual* and the AHS *Patient Identification - Registration Standard*.

## 2. Information and Informed Consent

- 2.1 Parent(s) or guardian(s) of infants and the public shall be informed by the **most responsible health practitioner (MRHP)** about the NMS Program and the associated health benefits of participating in newborn blood spot screening.
- 2.2 **Informed consent** shall be obtained and the discussion documented in accordance with the AHS *Consent to Treatment/Procedure(s)* Policy and the AHS *Newborn Blood Spot Screening Sample Collection Procedure*. The MRHP is responsible for ensuring informed consent for **sample collection** is obtained from the infant's parent(s) or guardian(s).

## 3. Sample Collection

- 3.1 All reasonable efforts shall be made to collect an initial **sample** between 24 hours and 72 hours of age and as close to 24 hours as possible.
- a) If the infant requires a blood transfusion, all attempts shall be made to collect an initial sample before an infant receives a blood transfusion, regardless if the collection is before 24 hours of age.
- 3.2 Samples shall be collected in accordance with the AHS *Newborn Blood Spot Screening Sample Collection Procedure*.
- 3.3 Infants born outside of Alberta who are obtaining health services within Alberta may have screening services as a part of the NMS Program at the discretion of the MRHP.

## 4. Sample Transportation

- 4.1 Samples shall be transported as soon as possible after sample collection and received at the **NMS Laboratory** within 72 hours of sample collection.
- 4.2 The sample shall be transported in accordance with the AHS *Newborn Blood Spot Screening Sample Collection Procedure*.

## 5. Sample Analysis

- 5.1 All initial and repeat samples shall be entered by the NMS Laboratory into the **laboratory information system** and analyzed by the NMS Laboratory within 48 hours of receipt of the sample and whenever possible on the day the sample is received.

- 5.2 All samples shall be analyzed by the NMS Laboratory in accordance with College of Physicians and Surgeons *Laboratory Accreditation Standards* and NMS Laboratory local service area resources (e.g., laboratory standard operating procedures, job aids, worksheets).
- 5.3 The NMS Laboratory shall be operational Monday to Saturday, except for statutory holidays and shall not be closed for more than two (2) consecutive days.

## 6. Reporting

- 6.1 All screen results shall be reported by the NMS Laboratory to the:
- birth facility;**
  - infant's Physician or Midwife; and
  - Alberta Health.
- 6.2 All screen results shall be reported within 96 hours of receipt of the sample by the NMS Laboratory except for cystic fibrosis results which shall be reported within 21 days of the receipt of sample.
- 6.3 Any delays in the reporting of screen results shall be monitored in accordance with College of Physicians and Surgeons of Alberta *Laboratory Accreditation Standards* and NMS Laboratory local service area resources (e.g., laboratory standard operating procedures, job aids, worksheets).

## 7. Follow-up

- 7.1 All reasonable efforts shall be made to ensure follow-up occurs in a timely manner when:
- an initial sample was not collected from an infant born in Alberta;
  - a repeat sample is required; or
  - a referral for clinical assessment and diagnostic testing is required for an infant with **abnormal results**.
- 7.2 Follow-up within the NMS Program shall occur in a timely manner in accordance with the AHS *Newborn Blood Spot Screening Follow-up Procedure*.

## 8. Privacy and Research

- 8.1 All AHS NMS Program records and samples shall be collected, used and disclosed in accordance with the *Health Information Act (Alberta)* and AHS privacy policies, including the *Privacy Protection and Information Access Policy*.
- 8.2 All research requests regarding access to AHS NMS Program records and

samples shall be made in accordance with the requirements of the *Health Information Act* (Alberta) and the *AHS Research Information Management Policy*.

## 9. Quality Management

- 9.1 The NMS Program shall be managed using a resilient, organization-wide quality management approach which includes:
- a) business continuity planning;
  - b) patient safety reporting;
  - c) performance management; and
  - d) quality improvement.
- 9.2 Patient safety reporting related to the NMS Program shall be conducted in accordance with the *AHS Recognizing and Responding to Hazards, Close Calls and Clinical Adverse Events Policy* and procedures.

## DEFINITIONS

**Abnormal result** means a screen result that is positive or has been reported as borderline twice for the same condition.

**Birth facility** means the Alberta Health Services hospital or health care setting where an infant is born.

**Guardian** means, where applicable:

For a Minor:

- a) A guardian as defined by the *Family Law Act*, a divorced parent with custody of the minor, or a person appointed pursuant to a will, personal directive, court order, agreement or by authorization of legislation (e.g. *Child, Youth and Family Enhancement Act*).

For an Adult:

- a) an individual appointed by the Court in accordance with the *Adult Guardianship and Trusteeship Act* to make to make decisions on behalf of the adult patient when the adult patient lacks capacity.

**Informed Consent** means the patient's agreement (or alternate decision-maker) to undergo a treatment/procedure after being provided, in a manner the patient can understand, with the relevant information about the nature of the treatment/procedure(s), its benefits, potential risks and alternatives, and the potential consequences of refusal.

**Laboratory information system** means a class of software that receives, processes and stores information generated by medical laboratory processes.

**Most responsible health practitioner** means the health practitioner who has responsibility and accountability for the specific treatment/procedure(s) provided to a patient and who is authorized by Alberta Health Services to perform the duties required to fulfill the delivery of such a treatment/procedure(s) within the scope of their practice.

**Newborn Metabolic Screening (NMS) Laboratory** means the Alberta Health Services designated laboratory for newborn blood spot screening located at the University of Alberta Hospital.

**Newborn Metabolic Screening (NMS) Program** means an organized population-based newborn blood spot screening program delivered by Alberta Health Services.

**Parent** means the guardian of a child with the legal authority to make decisions of behalf of the minor in accordance with the Alberta *Family Law Act*.

**Person Directory** means a secure, web-enabled application that delivers person-identifiable demographic and eligibility information to authorized health service providers.

**Sample** means the blood spots and health information collected on the requisition card for the purpose of newborn blood spot screening.

**Sample collection** means the process of completing the requisition card and poking the infant's heel to obtain the blood spots for the purpose of newborn blood spot screening.

**Screened condition** means one or more of the treatable conditions currently screened for within the Newborn Metabolic Screening Program.

**Unique lifetime identifier (ULI)** means a unique and permanent number assigned to all persons who receive health services in Alberta. Unique Lifetime Identifiers are assigned to all Alberta residents, residents of other provinces/territories or other countries.

## REFERENCES

- Alberta Health Services Governance Documents:
  - *Consent to Treatment/Procedure(s) Policy (#PRR-1)*
  - *Disclosure of Harm Procedure (#PS-95-01)*
  - *Immediate Management of Clinical Adverse Events Procedure (#PS-95-02)*
  - *Newborn Blood Spot Screening Sample Collection Procedure (#HCS-32-02)*
  - *Newborn Blood Spot Screening Follow-up Procedure (#HCS-32-01)*
  - *Ongoing Management of Clinical Adverse Events Procedure (#PS-95-03)*
  - *Patient Identification - Registration Standard (#PS-06-01)*
  - *Patient Safety Alerts and Safer Practices Notices Procedure (#PS-95-05)*
  - *Patient Safety Learning Summary Procedure (#PS-95-06)*
  - *Privacy Protection and Information Access Policy (#1177)*
  - *Recognizing and Responding to Hazards, Close Calls and Clinical Adverse Events Policy (#PS-95)*
  - *Research Information Management Policy (#1146)*

- Alberta Health Services Resources:
  - *Provincial Registration Standards and Practices Manual* (Alberta Health and Alberta Health Services)
- Non-Alberta Health Services Documents:
  - *Health Information Act* (Alberta)
  - *Laboratory Accreditation Standards* (College of Physicians & Surgeons of Alberta)
  - *Newborn Metabolic Screening Program Policy Document* (Alberta Health and Wellness)

**VERSION HISTORY**

<b>Date</b>	<b>Action Taken</b>
December 14, 2018	Revised
June 5, 2019	Revised