PURPOSE

The purpose of this policy is to establish for the Michigan Department of Health and Human Services (MDHHS) a maximum retention schedule and destruction guidelines for newborn screening (NBS) residual dried blood spot specimens. This policy does not cover residual dried blood spot specimens collected for non-NBS purposes such as HIV serology or lead.

DEFINITIONS

NBS: Newborn screening is a comprehensive program that tests for and provides long- and short-term follow up for children with disorders identified through the program and connects families with providers for the medical management of those disorders. (PA 368 of 1978, 333.5430, 333.5431)

DBS: Dried blood spots are the blood specimens collected from the heel of a newborn post-birth on a filter paper collection device for the purpose of newborn screening. After drying, the filter paper collection device containing patient identifying information is sent to the MDHHS Bureau of Laboratories (BOL) for testing.

POLICY

MDHHS may store residual DBS for up to 100 years from specimen receipt date, but presently stores DBS for 35 years consistent with the MDHHS BOL Retention Schedule. MDHHS retains qualified ownership of residual DBS while in storage

MDHHS NBS laboratory may use the residual DBS for NBS program improvement activities such as quality improvement, quality assurance, and new test development as may be necessary to the continued well-functioning of the NBS program. Other State NBS laboratories may request the MDHHS NBS laboratory send de-identified DBS for improvement activities such as quality improvement, quality assurance, or new test development.

De-identified residual DBS may be released for public health or medical research with the approval of MDHHS's scientific advisory panel and Institutional Review Board.

Requests to store but not use residual DBS for any research can be made on behalf of a minor by the parent or legal guardian by contacting the NBS program. The individual may make the request if they are an adult.

The department will release part or all of the residual DBS for research studies or other uses upon written request of the parent or legal guardian of a minor or the individual if they are an adult.

MDHHS will destroy an individual's residual DBS upon written request, receipt of the directive to destroy form, and proof of identity documentation from a parent or legal guardian of a minor or the individual if they are an adult. The requestor will receive a notification letter once the DBS has been destroyed.

PROCEDURE

The BOL NBS Section Manager:

- Oversees the processing and packaging of residual DBS for storage and maintains specimen identification.
- Oversees and confirms in writing the destruction of specimens when request for destruction has been received and confirmed as authentic.
- Oversees and confirms the destruction of specimens following completion of the retention period or assigns a designee to do so on their behalf.

The BOL Director:

- Identifies resources for an adequate and secure storage environment for the residual DBS.
- Ensures that the storage environment protects the integrity of the biological components of the specimen.

DESTROYING DRIED BLOOD SPOTS FOLLOWING COMPLETION OF RETENTION PERIOD

Upon reaching the end of the retention period set by the MDHHS Bureau of Laboratories, coordination of DBS destruction will be overseen by a NBS Laboratory Manager or a Bureau of Laboratories Director. Destruction can be performed by MDHHS or an approved contractor. When destruction is carried out by an approved contractor, the following must apply:

- MDHHS will supply the vendor with an inventory list of residual DBS that are to be destroyed.
- The transfer of residual DBS from MDHHS to the vendor will be witnessed by the NBS Laboratory Section Manager or designee.
- The vendor is to provide written confirmation following residual DBS destruction.
- The NBS Laboratory Section Manager will confirm that all residual DBS set for destruction are destroyed.

REFERENCES

Association of Public Laboratories(APHL)/Programs/Newborn Screening & Genetics.

Therrell, B.L, H.W. Hannon, et al. 1996. Guidelines for the retention, storage and use of residual dried blood spot samples after newborn screening analysis: Statement of the Council of Regional Networks for Genetic Services. Biochemical and Molecular Med. 57:116-124. in US National Library Of Medicine National Institutes of Health.

MDHHS/Adult & Children's Services/Children & Families/Hereditary Disorders/ Michigan Newborn Screening Program/ State of Michigan Links: Michigan Bio Trust for Health:

MDHHS-5683, Residual Newborn Screening Blood Spot Directive. http://michigan.gov/documents/mdhhs/MDHHS-5683_610453_7.dot

Michigan Public Health Code, Act 368 of 1978, 333.5431, 333.5430

CONTACT

For additional information concerning this policy, contact the Newborn Screening Laboratory by email at mdhhslab@Michigan.gov.