



STATE OF MICHIGAN  
DEPARTMENT OF COMMUNITY HEALTH  
**POLICY AND PROCEDURE MANUAL**  
*POLICY AND PROCEDURE*

<b>CHAPTER</b>
Laboratories
<b>NUMBER</b>
11.1
<b>EFFECTIVE DATE</b>
September 8, 2008

<b>SUBJECT</b>	Page 1 of 2
Newborn Screening Specimens	

**A. PURPOSE**

The purpose of this policy is to establish for the Michigan Department of Community Health (DCH) a retention schedule for newborn screening dried blood spot specimens.

**B. REVISION HISTORY**

Issued September 8, 2008.  
Revised January 5, 2009.  
Revised June 4, 2009

**C. DEFINITIONS**

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

**DBS:** Dried blood spot is the blood specimen collected from the heel of a newborn at 24-48 hours post-birth on a filter paper collection devise. After drying, the blood and patient identifying information contained on the same paper collection devise are sent to the DCH Bureau of Laboratories for testing.

**D. POLICY**

The DCH will maintain, or cause to be stored, newborn screening dried blood spots indefinitely. Parents, legal guardians of, and/or persons from whom the specimen was collected after reaching the age of majority, may request that their specimen not be used for any research, by contacting DCH by telephone or mail. Parents, legal guardians of, and/or persons from whom the specimen was collected after reaching the age of majority, may request that their specimen be destroyed by providing the name, date of birth and their relationship to the individual from whom the specimen was collected and must provide copies of the individual's birth certificate and a government-issued identification (e.g., drivers license or passport ) to confirm that they have authority to make such a request.

The DCH retains qualified ownership of DBS while in storage. The DCH may release part of the residual DBS upon written request of the individual for research studies or other uses. The DCH may release part, or all, of the de-identified specimen for NBS quality assurance and test development or public health or medical research with appropriate approval of the DCH scientific advisory panel and institutional review board. The DCH will reserve part of the specimen solely for the use of the individual or parent/guardian, unless requested otherwise by an authorized individual.

Retention schedules for DBS collected for other tests (e.g., HIV serology, lead) will be determined by Bureau of Laboratory policy.

**E. PROCEDURE**

<i>Responsibility</i>	<i>Action</i>
Bureau of Laboratories Newborn Screening Section Manager	Process and package dried blood spots for permanent storage maintaining specimen identification.
Bureau of Laboratories Newborn Screening Section	Oversee and confirm in writing the tagging of specimens as "not available for research" when request has been received from the



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Page 2 of 2

Manager	individual or parent or legal guardian of the individual.
Bureau of Laboratories Newborn Screening Section Manager	Oversee and confirm in writing the destruction of specimens when request for destruction has been received and confirmed authentic from the individual or parent or legal guardian of the individual.
Bureau of Laboratory Administrator	Assure an environment for the storage of the dried blood spot specimens that is secure and protects the integrity of the biological components of the specimen. Identify resources for an adequate storage environment for the specimens.

**F. REFERENCES**

Association of Public Laboratories Position/Policy statement on Residual Newborn Screening Specimens.

[http://www.aphl.org/policy/Documents/residual\\_newborn\\_screening\\_specimens.pdf](http://www.aphl.org/policy/Documents/residual_newborn_screening_specimens.pdf)

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.

Directive to Destroy Residual Newborn Screening Blood Specimen, DCH-1448

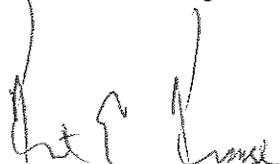
Directive to Remove Residual Newborn Screening Blood Specimen from Possible Research Uses, DCH-1465

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

**G. CONTACT**

For additional information concerning this policy, contact the DCH Bureau of Laboratories.

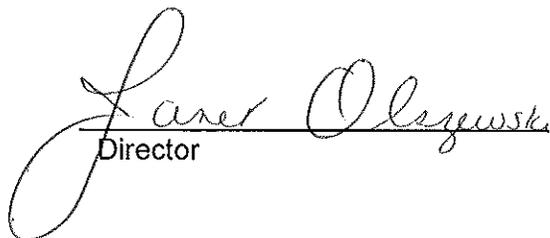
RECOMMENDED BY:

  
Deputy Director

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Director

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