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**IDAPA 16
TITLE 02
CHAPTER 12**

**16.02.12 - RULES GOVERNING PROCEDURES AND TESTING
TO BE PERFORMED ON NEWBORN INFANTS**

000. LEGAL AUTHORITY.

The Idaho Legislature has given the Board of Health and Welfare legislative power to promulgate rules governing the testing of newborn infants for phenylketonuria and other preventable diseases and governing the instillation of an ophthalmic preparation in the eyes of the newborn to prevent Ophthalmia Neonatorum, pursuant to Sections 39-906, 39-909, 39-910 and 39-911, Idaho Code. (5-3-03)

001. TITLE AND SCOPE.

01. Title. These rules are to be cited in full as Idaho Department of Health and Welfare Rules, IDAPA 16.02.12, "Rules Governing Procedures and Testing to Be Performed on Newborn Infants." (5-3-03)

02. Scope. These rules specify the tests and procedures that must be performed on newborn infants for early detection of mental retardation, developmental disabilities, blood amino acid levels, and prevention of infant blindness. (5-3-03)

002. WRITTEN INTERPRETATIONS.

There are no written interpretations that apply to these rules. (5-3-03)

003. ADMINISTRATIVE APPEALS.

All contested cases shall be governed by the provision of IDAPA 16.05.03, "Rules Governing Contested Case Proceedings and Declaratory Rulings." (5-3-03)

004. INCORPORATION BY REFERENCE.

Pursuant to Section 67-5229, Idaho Code, this chapter incorporates by reference the following document. (5-3-03)

01. Document. "Blood Collection on Filter Paper for Neonatal Screening Programs; Approved Standard." Third Edition. National Committee for Clinical Laboratory Standards, 1997. ISBN 1-56238-334-5. (5-3-03)

02. Availability. This document is available through the National Committee for Clinical Laboratory Standards, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898, telephone 610-688-0100. (5-3-03)

005. OFFICE -- OFFICE HOURS -- MAILING ADDRESS AND STREET ADDRESS.

The state office of the Department of Health and Welfare is located at 450 W. State St., Boise, ID 83720-0036, telephone number 208-334-5930. The office hours are 8 a.m. to 5 p.m. Monday through Friday. (5-3-03)

006. PUBLIC RECORDS ACT COMPLIANCE.

These rules have been promulgated according to the provisions of Title 67, Chapter 52, Idaho Code, and are public records. Any disclosure of information obtained by the Department is subject to the restrictions contained in Idaho Department of Health and Welfare Rules, IDAPA 16.05.01, "Use and Disclosure of Department Records," and Section 9-338 et seq., Idaho Code. (5-3-03)

007. -- 009. (RESERVED).

010. DEFINITIONS.

The following definitions will apply in the interpretation and enforcement of this chapter: (5-3-03)

01. Department. The Idaho Department of Health and Welfare. (5-3-03)

02. Dried Blood Specimen. A blood specimen obtained from an infant by means of skin puncture, not by means of venipuncture or any other method that is placed on special filter paper kits and allowed to dry. (5-3-03)

03. Laboratory. A medical or diagnostic laboratory certified according to the provisions of the Clinical Laboratory Improvement Amendments of 1988 by the United States Department of Health and Human Services. (5-3-03)

04. Newborn Screening. Newborn screening means a laboratory procedure performed on dried blood specimens from newborns to detect those at risk for the diseases specified in Subsection 100.01 of these rules. (5-3-03)

05. Person Responsible for Registering Birth of Child. The person responsible for preparing and filing the certificate of birth is defined in Section 39-255, Idaho Code. (5-3-03)

06. Test Kit. The materials provided by the laboratory for the purposes of dried blood specimen collection and submission of specimens for newborn screening laboratory procedures. (5-3-03)

011. -- 099. (RESERVED).

100. DUTIES OF THE ADMINISTRATOR OF THE RESPONSIBLE INSTITUTION AND THE PERSON REQUIRED TO REGISTER THE BIRTH OF A CHILD.

01. Conditions for Which Infants Will Be Tested. All infants born in Idaho shall be tested for at least the following conditions: (5-3-03)

- a.** Biotinidase deficiency; (5-3-03)
- b.** Congenital hypothyroidism; (5-3-03)
- c.** Galactosemia; (5-3-03)
- d.** Maple syrup urine disease; and (5-3-03)
- e.** Phenylketonuria. (5-3-03)

02. Blood Specimen Collection. (5-3-03)

a. The dried blood specimen collection procedures shall follow the National Committee for Clinical Laboratory Standards, "Blood Collection on Filter Paper for Neonatal Screening Programs; Approved Standard-Third Edition," 1997. (5-3-03)

b. For premature infants, in-hospital, the dried blood specimen for newborn screening shall be obtained between forty-eight (48) hours of age and ten (10) days of age. (5-3-03)

c. For non-premature infants, in-hospital, the dried blood specimen for newborn screening shall be obtained between forty-eight (48) hours of age and five (5) days of age. (5-3-03)

d. For newborns transferred from one hospital to another, the originating hospital shall assure that the dried blood specimen is drawn. If the newborn is too premature or too sick to have a dried blood specimen drawn for screening prior to transfer and a dried blood specimen is not obtained, the originating hospital shall be responsible for clearly documenting this, and notifying the hospital to which the newborn is being transferred that a dried blood specimen for newborn screening has not been obtained. (5-3-03)

e. Prior to the discharge of an infant from the institution where initial newborn care or specialized medical care was rendered, the Administrator shall assure that an adequate dried blood specimen has been collected regardless of the time the infant is discharged from the institution. (5-3-03)

f. For births occurring outside of a hospital, the birth attendant shall be responsible for assuring that an acceptable dried blood specimen is properly collected for newborn screening as stipulated in Section 100 of these

rules. (5-3-03)

g. Newborns who require a blood transfusion or dialysis shall have a dried blood specimen collected for screening prior to transfusion or dialysis. (5-3-03)

h. If a dried blood specimen cannot be obtained for newborn screening before transfusion or dialysis, the physician shall ensure that a repeat dried blood specimen is obtained at the appropriate time when the specimen will reflect the infant's own metabolic processes and phenotype. (5-3-03)

i. Infants from whom the dried blood specimen has been collected for newborn screening less than forty-eight (48) hours after birth shall be retested. A test kit shall be given to the parents or responsible party at the time of discharge from the institution where initial newborn care was rendered, with instructions to have a second dried blood specimen collected. In such cases the preferred time for sample collection is after five (5) but before fifteen (15) days of age. (5-3-03)

03. Specimen Mailing. Within twenty-four (24) hours after collection, the dried blood specimen shall be mailed to the laboratory by first class mail or its equivalent, except when mailing service is not available. When mailing service is not available on weekends and holidays, dried blood specimens shall be mailed to the laboratory on the first available mail pick-up day. (5-3-03)

04. Record Keeping. Maintain a record of all dried blood specimens collected for newborn screening. This record shall indicate the name of the infant, name of the attending physician or other attendant, date specimen was collected, and name of person collecting specimen. (5-3-03)

05. Collection Protocol. Ensure that a protocol for collection and submission for newborn screening of adequate dried blood specimens has been developed, documented, and implemented. Individual responsibilities shall be clearly defined and documented. The attending physician shall request that the test be done. The hospital may make an appropriate charge for this service. (5-3-03)

06. Responsibility for Recording Specimen Collection. (5-3-03)

a. The administrator of the responsible institution, or his designee, shall be responsible for recording on the birth certificate whether the dried blood specimen for newborn screening has been collected. (5-3-03)

b. When a birth occurs outside a hospital, the person responsible for registering the birth of the child shall also be responsible for recording on the birth certificate whether the dried blood specimen for newborn screening has been collected and submitted within twenty-four (24) hours following collection. (5-3-03)

07. Fees. The Department shall provide access to newborn screening laboratory services. If the administration of the responsible institution or the person required to register the birth of a child chooses to utilize this service, the Department shall collect a fee equal to the cost of the test kit, analytical, and diagnostic services provided by the laboratory. The fees shall be remitted to the Department before the laboratory provides the test kit to those responsible for ensuring the infant is tested according to these rules. (5-3-03)

101. -- 199. (RESERVED).

200. LABORATORY DUTIES.

01. Participation in Centers for Disease Control and Prevention (CDC) Newborn Screening Quality Assurance Program. All laboratories receiving dried blood specimens for newborn screening on infants born in Idaho shall participate in the Newborn Screening Quality Assurance Program operated by the CDC. (5-3-03)

02. Specimen Processing. Dried blood specimens for newborn screening must be processed within twenty-four (24) hours of receipt by the laboratory or before the close of the next business day. (5-3-03)

03. Result Notification. Normal test results may be reported by mail to the submitter. Other results must be reported in accordance with Section 300 of these rules. (5-3-03)

201. -- 299. (RESERVED).

300. FOLLOW-UP FOR UNSATISFACTORY SPECIMENS, PRESUMPTIVE POSITIVE RESULTS AND POSITIVE CASES.

01. Follow-Up for Unsatisfactory Specimens. (5-3-03)

a. The laboratory will immediately report any unsatisfactory dried blood specimens to the submitting institution which originated the dried blood specimen with an explanation of the results. The laboratory will request a repeat dried blood specimen for newborn screening from the institution or individual submitting the original sample. (5-3-03)

b. Upon notification from the laboratory, the health care provider responsible for the newborn's care at the time of the report will cause another dried blood specimen to be appropriately forwarded to the laboratory for screening. (5-3-03)

02. Follow-Up of Presumptive Positive Results. The laboratory will report positive or suspicious results on an infant's dried blood specimen to the attending physician or midwife, or, if there is none or the physician or midwife is unknown, to the person who registered the infant's birth, and make recommendations on the necessity of follow-up testing. (5-3-03)

03. Positive Case Notification. Confirmed positive cases of biotinidase deficiency, congenital hypothyroidism, galactosemia, maple syrup urine disease, and phenylketonuria must be reported as described in IDAPA 16.02.10, "Idaho Reportable Diseases." (5-3-03)

301. -- 399. (RESERVED).

400. SUBSTANCES WHICH FULFILL REQUIREMENTS FOR OPHTHALMIC PREPARATION.

Only those germicides proven to be effective in preventing ophthalmia neonatorum and recommended for use in its prevention by the U.S. Department of Health and Human Services (including the U.S. Public Health Service, the Center for Disease Control and Prevention, and the U.S. Food and Drug Administration) will satisfy the requirements established herein, pursuant to Section 39-903, Idaho Code. (5-3-03)

401. -- 999. (RESERVED).

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