



**Rules of
Department of Health
and Senior Services**

**Division 25—Missouri State Public Health Laboratory
Chapter 36—Testing for Metabolic Diseases**

| Title | Page |
|---|-------------|
| 19 CSR 25-36.010 Testing for Metabolic and Genetic Disorders | 3 |



**Title 19—DEPARTMENT OF
HEALTH AND SENIOR SERVICES
Division 25—Missouri State Public Health
Laboratory
Chapter 36—Testing for Metabolic
Diseases**

**19 CSR 25-36.010 Testing for Metabolic
and Genetic Disorders**

PURPOSE: State law requires that all infants be tested for metabolic and genetic disorders as prescribed by the Department of Health and Senior Services. This rule establishes the collection and submission procedures to be used by health care providers in sending newborn screening specimens to the Missouri State Public Health Laboratory and establishes the fee for newborn screening.

(1) As used in this rule—

(A) Newborn screening means the testing of infants for metabolic and genetic disorders pursuant to sections 191.331, 191.332, and 191.333, RSMo;

(B) Parent information sheet means the top sheet of the newborn screening specimen form that is to be detached and handed to the infant's parent or guardian at the time of specimen collection which explains the parent's or guardian's options and process for opting out of the specimen storage and/or release for anonymous research pursuant to section 191.317, RSMo;

(C) Specimen storage means the five- (5-) year storage of the leftover newborn screening specimens at the Missouri State Public Health Laboratory after testing has been conducted pursuant to section 191.317, RSMo; and

(D) Submitter(s) means a person or persons responsible for collecting specimens under section 191.331, RSMo, for newborn screening tests.

(2) Submitters shall collect specimens on the newborn screening collection forms purchased from the Department of Health and Senior Services. The submitter of the specimen shall provide all information requested on the specimen collection form.

(3) Specimens shall be collected in accordance with instructions on the specimen collection form. At the time of specimen collection, the submitter shall detach the parent information sheet from the newborn screening collection form and give it to the infant's parent or guardian. The timing of specimen collection shall be determined by the conditions specified in subsections (3)(A) through (C) below. All specimens shall be sent within twenty-four (24) hours of collection to the Missouri State

Public Health Laboratory in Jefferson City.

(A) A specimen shall be taken from all infants before being discharged from the hospital or birthing facility regardless of age. A specimen collected between twenty-four (24) and forty-eight (48) hours of age is considered optimum for newborn screening. A second, or repeat, specimen shall be required within fourteen (14) days of age if the initial specimen was collected before twenty-four (24) hours of age.

(B) Initial specimens from ill or premature infants shall be collected before a blood transfusion or between twenty-four (24) to forty-eight (48) hours of age. All ill or premature infants shall have a repeat screen collected between seven (7) to fourteen (14) days of age. All infants who are less than thirty-four (34) weeks gestational age or are less than two thousand (2000) grams at birth are recommended to have a third screen collected at twenty-eight (28) days of age.

(C) If an infant has been transferred from one hospital to another, the records shall clearly indicate if a specimen for newborn screening was collected and submitted. If no specimen was collected, the hospital the infant is transferred to shall collect a specimen and submit it within forty-eight (48) hours of the transfer.

(D) If it is discovered or highly suspected that a child has never received a newborn screen, a newborn screen is recommended regardless of the child's age.

(4) Parents who object to testing on religious grounds shall state those objections in writing. The written objection shall be filed with the attending physician, certified nurse midwife, public health facility, ambulatory surgical center, or hospital. Upon receipt, the attending physician, certified nurse midwife, public health facility, ambulatory surgical center, or hospital shall send a copy of the written objection to the Department of Health and Senior Services, Bureau of Genetics and Healthy Childhood, PO Box 570, Jefferson City, MO 65102-0570.

(5) Parents or guardians who object to the storage or release of their child's leftover newborn screening specimen for anonymous research shall state those objections in writing by submitting a letter to the Missouri State Public Health Laboratory Director requesting the remaining specimen to be destroyed, returned to the parents or guardians, or stored for five (5) years but not released for anonymous research. This letter shall be sent to the Missouri State Public Health Laboratory, Newborn Screening Laboratory, PO Box 570, Jefferson City, MO 65102-0570. The parents

or guardians may submit this request at any point during the five- (5-) year storage process.

(6) The health care provider caring for an infant with an abnormal high-risk test result from newborn screening shall report a definitive diagnosis within thirty (30) days of the date of the diagnosis for that infant to the appropriate newborn screening contracted follow-up center as contracted by the Department of Health and Senior Services. The department shall prescribe and furnish all necessary reporting forms for this purpose.

(7) The health care provider responsible for the medical care of the infant shall provide newborn screening education to the parents or guardians. Educational materials regarding the newborn screening conducted by the state, including the disorders screened for and the management and treatment of these disorders, are made available by the Department of Health and Senior Services. The educational materials may be ordered at www.health.mo.gov/warehouse/eliterature.html or by contacting the Department of Health and Senior Services' Newborn Screening Program at 800-877-6246.

(8) Effective July, 1, 2019, a fee of up to one hundred thirty-five dollars (\$135) shall be charged for each specimen collection form used to obtain a newborn screening blood specimen. If the Missouri State Public Health Laboratory determines a submitted blood specimen to be unsatisfactory for testing due to laboratory or transportation issues, then a replacement specimen collection form will be made available without the fee being imposed. The Department of Health and Senior Services may collect the fee from any entity or individual described in section 191.331.1, RSMo.

*AUTHORITY: sections 191.331 and 192.006, RSMo 2016, and section 191.332, RSMo Supp. 2017. * This rule was previously filed as 13 CSR 50-143.010 and 19 CSR 20-36.010. Original rule filed Sept. 29, 1965, effective Oct. 13, 1965. Amended: Filed April 6, 1967, effective April 16, 1967. Rescinded and readopted: Filed Sept. 30, 1980, effective April 11, 1981. Rescinded: Filed Aug. 1, 1986, effective Oct. 27, 1986. Readopted: Filed Aug. 4, 1986, effective Oct. 27, 1986. Amended: Filed March 16, 1987, effective May 28, 1987. Amended: Filed Jan. 15, 1993, effective Sept. 9, 1993. Changed to 19 CSR 25-36.010 Jan. 1, 1995. Emergency amendment filed Aug. 4, 1997, effective Aug. 28, 1997, expired Feb. 26, 1998. Amended:*



*Filed Aug. 4, 1997, effective Jan. 30, 1998.
Amended: Filed April 9, 2002, effective Oct.
30, 2002. Amended: Filed Feb. 1, 2005,
effective July 30, 2005. Amended: Filed June
12, 2007, effective Jan. 30, 2008. Amended:
Filed Jan. 29, 2015, effective July 30, 2015.
Amended: Filed Jan. 25, 2019, effective July
30, 2019.*

**Original authority: 191.331, RSMo 1965, amended 1985,
1992, 1993, 1995, 1997, 2007; 191.332, RSMo 2001,
amended 2005, 2016, 2017; and 192.006, RSMo 1993,
amended 1995.*