

ARTICLE 44:19
NEWBORN SCREENING

Chapter

- 44:19:01 Definitions.
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CHAPTER 44:19:01

DEFINITIONS

Section

- 44:19:01:01 Definitions.
- 44:19:01:02 Transferred.
- 44:19:01:03 Repealed.
- 44:19:01:04 Required tests.

44:19:01:01. Definitions. Terms used in this article mean:

~~(1) "Abnormal specimen," a newborn's blood specimen that is defined as positive for reporting purposes;~~

~~(2) "Birth attendant," a person licensed or certified by the state under SDCL title 36 to provide maternity care and to deliver pregnant women;~~

(3 1) "Days of age," the measurement of the age of a newborn in 24-hour periods; i.e., a newborn is one day of age 24 hours following the hour of birth;

(4 2) "Department," the South Dakota Department of Health;

(5 3) "Designated laboratory," a laboratory or laboratories authorized by the department pursuant to § 44:19:02:03.01 to perform newborn screening services for infants born in South Dakota;

(6 4) "Filter paper specimen," a sample of blood collected from an infant by saturating marked areas of a filter paper card with blood obtained by skin puncture of the heel;

~~(7) "Discharge," the release of a newborn from the care of an institution or hospital to the parents or into the community;~~

(8 5) "Initial specimen," the first metabolic screening specimen collected subsequent to birth;

~~(9) "Initial test," the first valid metabolic screening test or combination of tests of a newborn for each disorder;~~

~~(10~~ 6) "Metabolic disorder," a malfunction in the processes that convert compounds to protoplasm, energy, and waste;

~~(11 7)~~ "Newborn," an infant 28 days of age or under;

~~(12 8)~~ "Newborn's physician," the physician responsible for the care of a newborn;

~~(13 9)~~ "Newborn screening," a ~~laboratory test~~ laboratory testing performed on newborn blood specimens to identify newborns with metabolic disorders;

~~(14)~~ "Repeat specimen," a ~~specimen collected from a newborn because a previously collected specimen was either unsatisfactory or the test results were inconclusive, abnormal, or positive;~~

~~(15)~~ "Repeat test," a test repeated because the previous specimen or test results were unsatisfactory, test results were not complete, or the test results were abnormal;

~~(16 10)~~ "Secretary," the secretary of the department of health; and

~~(17 11)~~ "Submitter," the ~~person~~ attending physician, other health professional, hospital, or public health facility who sends the newborn screening requisition form to the designated laboratory for initial, repeat, or confirmatory screening tests, ~~including the hospital, laboratory, or physician;~~

~~(18)~~ "Transfer," the release of a newborn from the care of one institution or hospital to the care of another institution or hospital;

~~(19) "TSH," thyroid stimulating hormone; and~~

~~(20) "Unacceptable or unsatisfactory specimen," a newborn's blood specimen that is not suitable in quality or quantity for performing newborn screening for one or more of the disorders covered by this article.~~

Source: 12 SDR 167, effective April 20, 1986; 15 SDR 59, effective October 19, 1988; 18 SDR 67, effective October 16, 1991; 23 SDR 91, effective December 9, 1996; 31 SDR 164, effective May 9, 2005.

General Authority: SDCL 34-24-25.

Law Implemented: SDCL 34-24-23.

44:19:01:04. Required tests. In addition to those metabolic disorders required in SDCL 34-24-18, any infant born in South Dakota shall be screened for the following metabolic disorders by a laboratory designated by the department to perform such testing:

- (1) Hemoglobinopathies;
- (2) Biotinidase deficiency;
- (3) Classical congenital adrenal hyperplasia;
- (4) Fatty acid oxidation disorders;
- (5) Amino acid disorders;
- (6) Organic acid disorders; and
- (7) Cystic fibrosis.

Source: 31 SDR 164, effective May 9, 2005; 33 SDR 180, effective May 7, 2007.

General Authority: SDCL 34-24-25.

Law Implemented: SDCL 34-24-22.

CHAPTER 44:19:02

NEWBORN SCREENING LABORATORY

Section

44:19:02:01 to 44:19:02:03	Repealed.
44:19:02:03.01	Designation of laboratories.
44:19:02:03.02	Criteria for designation of laboratories <u>Repealed.</u>
44:19:02:04	Public notice of designated laboratories.
44:19:02:04.01	Designated laboratory responsibilities <u>Repealed.</u>
44:19:02:05	Responsibilities of parents.
44:19:02:06	Responsibilities of hospitals, physicians, and other health professionals.
44:19:02:07	Responsibilities of Department of Health.

44:19:02:03.01. Designation of laboratories. ~~In accordance with criteria in~~
~~§ 44:19:02:03.02 the~~ The department shall designate the laboratories that are authorized to perform newborn screening services for infants born in of South Dakota. The number of laboratories to be designated at any one time is at the discretion of the secretary.

Source: 23 SDR 91, effective December 9, 1996; 31 SDR 164, effective May 9, 2005.

General Authority: SDCL 34-24-25.

Law Implemented: SDCL 34-24-25.

44:19:02:03.02. Criteria for designation of laboratories. ~~The department shall use the following criteria in designating laboratories to conduct newborn screening tests:~~

~~(1) Professional qualifications necessary for satisfactory performance of the required services;~~

~~(2) Demonstrated experience and technical expertise;~~

~~(3) Demonstrated capacity to accomplish work in the required time and maintain a continuity of services;~~

~~(4) Past performance on similar contracts with publicly or privately funded programs in terms of cost control, quality of work, and compliance with performance schedules;~~

~~(5) Proposed fee to be charged per specimen for newborn screening; and~~

~~(6) Any other criteria as deemed appropriate by the secretary Repealed.~~

Source: 23 SDR 91, effective December 9, 1996.

General Authority: SDCL 34-24-25.

Law Implemented: SDCL 34-24-25.

44:19:02:04.01. Designated laboratory responsibilities. ~~The designated laboratory shall provide the following notices regarding specimens received:~~

~~(1) Any unacceptable or unsatisfactory specimen and the need for a repeat specimen shall be reported to the submitter no later than 24 hours after the analysis or within four working days of specimen receipt, whichever is earlier; and~~

~~(2) Any abnormal and positive test results shall be reported to the submitter no later than 24 hours after the analysis or within four working days after specimen receipt, whichever is earlier~~ Repealed.

Source: 31 SDR 164, effective May 9, 2005

General Authority: SDCL 34-24-25.

Law Implemented: SDCL 34-24-17, 34-24-23, 34-24-24.

44:19:02:05. Responsibilities of parents. The parents, guardian, or custodian of each infant is responsible for having blood tests for metabolic disorders performed within the first 48 hours of an infant's life. If a parent, guardian, or custodian refuses to have a newborn tested for metabolic disorders pursuant to § 44:19:01:04, despite having been notified of the need for testing, the parent, guardian, or custodian shall sign a written statement regarding the refusal.

Source: 18 SDR 67, effective October 16, 1991; 23 SDR 91, effective December 9, 1996; 31 SDR 164, effective May 9, 2005.

General Authority: SDCL 34-24-25.

Law Implemented: SDCL 34-24-17, 34-24-23, 34-24-24.

44:19:02:06. Responsibilities of hospitals, physicians, and other health professionals.

The attending physician, other health professional, hospital, or public health facility shall notify the parents, guardian, or custodian of each infant of the responsibility and need to have the newborn screening tests performed. The attending physician or other health professional submitter shall place all newborn screening test results in the newborn patient's record. If a parent, guardian, or custodian refuses to have the newborn tested, the attending physician, other health professional, hospital, or public health facility shall obtain a written signed statement from the parent, guardian, or custodian of the infant regarding the refusal and place it in the newborn patient's record, notify the department within 24 hours of the refusal at 1-800-738-2301, and send a copy of the signed refusal to the department. If a parent, guardian, or custodian refuses to sign the statement, the attending physician, other health professional, hospital, or public health facility shall document such refusal, place it in the newborn patient's record, and send a copy of such documentation to the department.

~~Once the physician receives the results of the newborn screening test, the physician shall place the results in the newborn's medical record.~~

Source: 31 SDR 164, effective May 9, 2005.

General Authority: SDCL 34-24-25.

Law Implemented: SDCL 34-24-17, 34-24-23, 34-24-24.

CHAPTER 44:19:03

TIME SEQUENCE FOR TESTING

Section

44:19:03:01 Specimen submission to designated laboratory.

44:19:03:02 Collection of filter paper specimens.

44:19:03:03 Specimen disposition, retention, and disposal.

44:19:03:01. Specimen submission to designated laboratory. Specimens must be submitted to a the designated laboratory pursuant to the designated laboratory's protocol. ~~Only filter paper specimens may be submitted for newborn screening.~~

Source: 15 SDR 59, effective October 19, 1988; 18 SDR 67, effective October 16, 1991; 23 SDR 91, effective December 9, 1996.

General Authority: SDCL 34-24-25.

Law Implemented: SDCL 34-24-18.

44:19:03:02. Collection of filter paper specimens. Filter paper specimens for submission to the designated laboratories laboratory must be collected ~~as follows~~ pursuant to the designated laboratory's protocol:

~~(1) A filter paper specimen must be collected from each newborn infant as close as possible to the time of discharge and no later than seven days by the institution or hospital where initial or subsequent newborn care was provided regardless of prematurity, illness, feeding history, or antibiotics being given. The designated laboratory shall retain the specimen until the laboratory determines that the specimen can be destroyed;~~

~~(2) Filter paper specimens must be collected from newborns prior to a transfusion of whole blood, plasma, or packed red blood cells regardless of the infant's age. If the pre-transfusion specimen was collected before 24 hours of age, or if the initial specimen was collected after a transfusion, the repeat specimen shall be collected as determined by the designated laboratory's transfusion protocol for the testing of disorders;~~

~~(3) The receiving institution shall obtain filter paper specimens from newborns transferred within the first 48 hours of life;~~

~~(4) The institution initiating the transfer shall obtain blood specimens from newborns transferred after the first 48 hours of life;~~

~~(5) If a birth occurs that is not attended by a birth attendant, the local registrar shall inform the parent or guardian of the need for a blood test for metabolic disorders when inquiring about or filing a certificate of birth. The registrar shall inform the parent or guardian where the blood sample may be drawn or refer them to the local community health nurse; and~~

~~(6) For any specimen collected on a newborn less than 24 hours of age, a repeat specimen must be collected within two weeks.~~

Source: 15 SDR 59, effective October 19, 1988; 23 SDR 91, effective December 9, 1996; 31 SDR 164, effective May 9, 2005; 33 SDR 180, effective May 7, 2007.

General Authority: SDCL 34-24-25.

Law Implemented: SDCL 34-24-18.

44:19:03:03. Specimen disposition, retention, and disposal. The designated laboratory shall maintain each specimen in a manner that provides security, confidentiality, and stability of temperature and humidity. Upon completion of newborn screening testing, the designated laboratory is responsible for specimen destruction in a secure manner. No specimen may be used for any purpose other than the screening of newborn infants pursuant to SDCL 34-24-17.

Source:

General Authority: SDCL 34-24-25.

Law Implemented: SDCL 34-24-18.