Official Departmental Instructions

Collection and Handling of Blood Specimens

Specimen Collection Process

Hospital and birthing center personnel are responsible for collecting blood spot specimens from all newborn infants in their care. Licensed midwives must also ensure that specimens are collected. To collect the best specimen, follow the process below:

1. **Collect a specimen from each infant between 24 and 48 hours of age.**
2. Provide all information on the newborn screening collection form (DHEC 1327) accurately and completely. Confirm the legal name of the infant and the name of the primary care provider with the mother before recording it on the collection form.
3. Use the blood collection procedures established by the Clinical and Laboratory Standards Institute (CLSI) NBS01-A6. See the Neonatal Screening Blood Specimen Collection and Handling charts for details.
4. Allow the specimen to air dry in a horizontal position for at least 4 hours before sending to the DHEC Public Health Laboratory (PHL).
5. Carefully inspect each specimen prior to mailing. Use the Simple Spot Check chart as a guide to suitability for testing. **Recollect the specimen if necessary.**
6. **Send all specimens to the PHL within 24 hours of collection, unless there are extenuating circumstances that prohibit compliance, such as no mail/courier pick up. Do not hold specimens.**
7. **Do not** place specimens in plastic bags prior to mailing. **Ensure that commercial carriers do NOT place envelopes containing specimens in plastic/polymer mailing envelopes!** Plastic/polymer envelopes may create an atmosphere that exposes the specimens to heat and/or humidity. These conditions can invalidate test results. Thus, specimens shipped to the laboratory in plastic/polymer mailers **will be deemed unsatisfactory.**

Timing of Specimen Collection

Hospitals and birthing centers shall screen all newborn infants, regardless of their length of stay. However, **newborn screening test results are most accurate if the infant's specimen is collected between 24 and 48 hours of age.**

1. If the infant will be transferred to another hospital before screening has occurred, the hospital or birthing center must inform the receiving hospital that the specimen has not been collected.
2. If the specimen is not collected for any reason other than parental refusal, the hospital or birthing center must contact the infant's parent(s) so that prompt specimen collection can be arranged. Complete the collection form demographic information, write at the top "**Specimen Not Collected**" and send it to DHEC.

3. If the infant is to be discharged before 24 hours of age, collect the specimen as close to discharge as possible. Inform the parent(s) that retesting is necessary within one week of age.
4. Give the parent(s) a copy of the brochure *Newborn Screening for Your Baby's Health* that is provided by DHEC. Encourage the parent(s) to ask the infant's primary care provider about the test results at the first visit after discharge.
5. Record the test results in the infant's record upon receipt. **Review each infant's record no later than 10 days after delivery to ensure that a specimen was submitted and that a report was received.**

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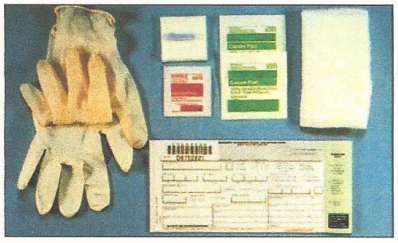
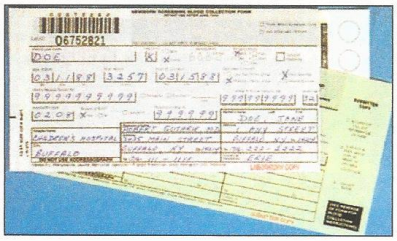
Neonatal Screening

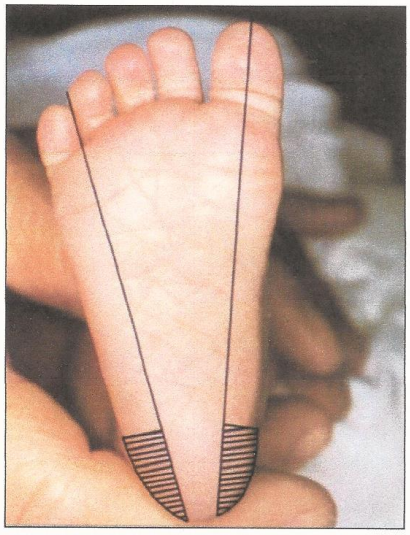
Blood Specimen Collection and Handling Procedure



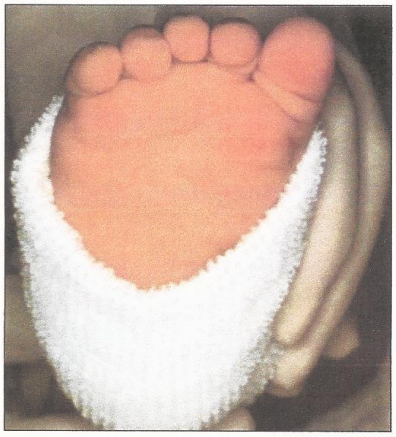
1 Equipment: sterile lancet with tip approximately 2.0 mm – sterile alcohol prep, sterile gauze pads, soft cloth, blood collection form, gloves.



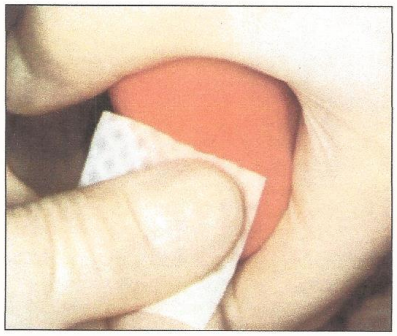
2 Complete ALL information. Do not contaminate filter paper circles by allowing the circles to come into contact with spillage or by touching before or after blood collection. Keep "SUBMITTER COPY" if applicable.



3 Hatched area (▨) indicates safe areas for puncture site.

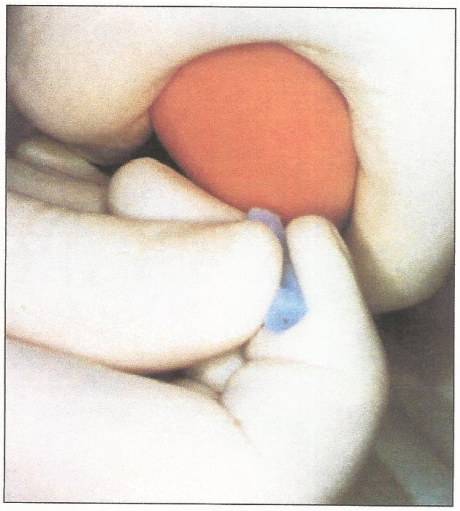


4 Warm site with soft cloth, moistened with warmwater up to 41°C, for three to five minutes.

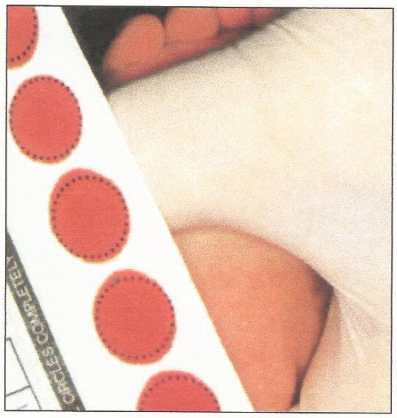


5 Cleanse site with alcohol prep. Wipe DRY with sterile gauze pad.

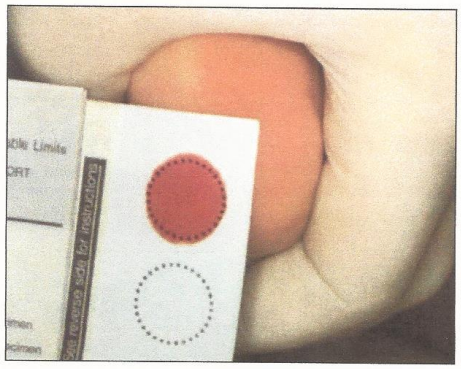
Over



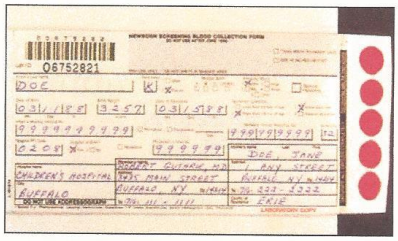
6 Puncture heel. Wipe away first blood drop with sterile gauze pad. Allow another LARGE blood drop to form.



8 Fill remaining circles in the same manner as step 7, with successive blood drops. If blood flow is diminished, repeat steps 5 through 7. Care of skin puncture site should be consistent with your institution's procedures.



7 Lightly touch filter paper to LARGE blood drop. Allow blood to soak through and completely fill circle with SINGLE application of LARGE blood drop. (To enhance blood flow, VERY GENTLE intermittent pressure may be applied to the area surrounding the puncture site). Apply blood to one side of filter paper only.



9 Dry blood spots on a dry, clean, flat, non-absorbent surface for a minimum of four hours.

10 Mail completed form to testing laboratory within 24 hours of collection.

Information provided by The New York State Department of Health.

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Simple Spot Check

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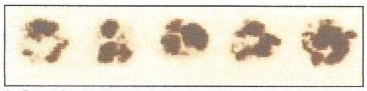
Valid specimen:

Allow a sufficient quantity of blood to soak through to completely fill the preprinted circle on the filter paper. Fill all required circles with blood. Do not layer successive drops of blood or apply blood more than once in the same collection circle. Avoid touching or smearing spots.

Invalid specimen:

Possible causes:

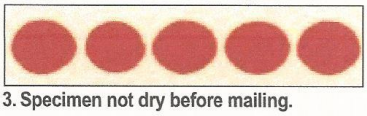


1. Specimen quantity insufficient for testing.

- Removing filter paper before blood has completely filled circle or before blood has soaked through to second side.
- Applying blood to filter paper with a capillary tube.
- Touching filter paper before or after blood specimen collection with gloved or ungloved hands, hand lotion, etc.
- Allowing filter paper to come in contact with gloved or ungloved hands or substances such as hand lotion or powder, either before or after blood specimen collection.

2. Specimen appears scratched or abraded.

- Applying blood with a capillary tube or other device.

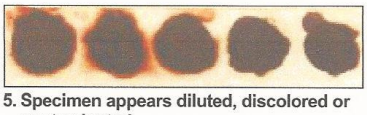


3. Specimen not dry before mailing.

- Mailing specimen before drying for a minimum of four hours.

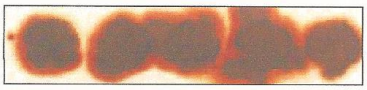
4. Specimen appears supersaturated.

- Applying excess blood to filter paper, usually with a device.
- Applying blood to both sides of filter paper.



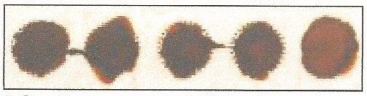
5. Specimen appears diluted, discolored or contaminated.

- Squeezing or "milking" of area surrounding the puncture site.
- Allowing filter paper to come in contact with gloved or ungloved hands or substances such as alcohol, formula, antiseptic solutions, water, hand lotion or powder, etc., either before or after blood specimen collection.
- Exposing blood spots to direct heat.



6. Specimen exhibits serum rings.

- Not wiping alcohol from puncture site before making skin puncture.
- Allowing filter paper to come in contact with alcohol, hand lotion, etc.
- Squeezing area surrounding puncture site excessively.
- Drying specimen improperly.
- Applying blood to filter paper with a capillary tube.



7. Specimen appears clotted or layered.

- Touching the same circle on filter paper to blood drop several times.
- Filling circle on both sides of filter paper.

8. No blood.

- Failure to obtain blood specimen.

Information provided by The New York State Department of Health.

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Special Circumstances

Infants Being Placed for Adoption

Collect the specimen from the infant as previously instructed. The patient's name field on the newborn screening filter paper form should reflect the infant's legal name at the time of birth or adopted name (if known). If the infant's name is unknown at the time of collection, enter the infant's last name as birth mother's last name, first name "Adoption"; example "Smith, Adoption".

If the birth mother is not to be contacted, please enter the lawyer's first and last name or adoption agency's name in the mother's name fields as the legal guardian. In the street address field, enter the lawyer or adoption agency's address as the legal guardian contact. Also, enter the phone number of the lawyer or adoption agency in lieu of the birth mother's phone number.

When known, always enter the physician's demographics and infant's medical record number in entirety. This will assist the Newborn Screening Program in locating an infant if there is a need to alert the lawyer/legal guardian or adoption agency of an abnormal or potentially life-threatening result and ensure the infant gets the medical attention s/he needs.

Infants Born Outside of a Hospital

It is the responsibility of the person in attendance at a birth outside of a hospital to obtain a specimen for newborn screening. **If the specimen has not been collected by the third day of life the person in attendance at the birth should contact DHEC Division of Children's Health (CH) for assistance.**

Infants with an Affected Close Relative

Most of the disorders on the newborn screening test panel are genetic disorders. Prenatal diagnosis is possible for many of these disorders. If prenatal testing determines that the fetus is affected, arrangements should be made for delivery at the appropriate level hospital and treatment should be initiated as soon as possible.

A specimen for newborn screening shall still be collected to test for all disorders on the panel. If prenatal testing predicts an unaffected fetus, a specimen shall still be collected to confirm the results of the prenatal testing and to provide screening for the other disorders on the panel.

Testing Older Infants and Children

Analyte ranges for newborn screening are based upon expected results for infants tested within the first several weeks of life. **For that reason, the PHL will not process specimens for the**

complete newborn screening test panel of infants and children older than six months of age. Contact staff in CH for assistance in locating another laboratory for this service.

The PHL can perform a modified newborn screening test panel for infants from six to twelve months of age. The modified panel includes an amino acid profile (AA), succinyl acetone (SUAC), galactose-1-P-uridyl transferase enzyme (GALT), total galactose (GAO), biotinidase enzyme (BIO), and hemoglobinopathies (HB).

The PHL will process specimens from older infants, children and adults for monitoring of certain metabolic disorders (such as PHE and TYR for PKU) and for hemoglobinopathies.

Unsatisfactory Specimens

The PHL receives some specimens that are considered unsatisfactory for officially reporting test results. While the PHL does test unsatisfactory specimens for extreme values when possible, improper collection and handling may compromise the accuracy of test results. This delays the screening and diagnosis of a potentially affected infant and requires that a repeat specimen be submitted as soon as possible.

If the testing of an unsatisfactory specimen yields an abnormal test result, the provider will be notified by the program. Depending upon the severity of the abnormal test result, the provider will receive either phone notification or mail notification.

The official laboratory report will still indicate that the specimen was unsatisfactory and that a repeat specimen collection is necessary.

Transfusion

Obtain a specimen **prior** to transfusion of any blood products (even if the infant is less than 24 hours old). This specimen will be acceptable for the detection of galactosemia, biotinidase and hemoglobinopathies. However, another specimen will be needed at **24-48 hours** of age and again at **28 days** of age or prior to discharge.

If this is not possible, collect the initial specimen and indicate the date of the most recent transfusion. Infants who receive transfusions, prior to collection of the newborn screen should have a repeat hemoglobinopathy, biotinidase deficiency and galactosemia screening **120 days** after the date of the last transfusion.

If the date of the last transfusion is unknown, put the date of hospital discharge as the date of the most recent transfusion.

Premature, Low Birth Weight and Sick Infants

In premature, low birth weight and sick infants, the results can be falsely abnormal due to system immaturity and/or the stress of prematurity/illness. To ensure the best specimen:

If the infant is receiving **only IV fluids or total parenteral nutrition/ hyperalimentation**, the specimen may be collected if the infant is at least **24 hours of age and the lab slip is clearly marked "TPN or NPO."**

All premature, low birth weight and sick infants shall receive their initial screening by 2 days of age, regardless of their health status.

See the chart on the following page for detailed instructions.

South Carolina Guidelines for Newborn Screening Specimens from Premature, Low Birth Weight (LBW), Sick or NICU Infants:

Infant Category	1st Specimen	2nd Specimen	3rd Specimen
Category A Applies to ill or premature infants who are ≥ 34 weeks gestational age and ≥ 2,000 grams at birth	24-48 hours of age **(1)**	N/A	N/A
Category B Applies to premature infants who are < 34 weeks gestational age or < 2,000 grams at birth	24-48 hours of age **(1)**	28 days of age or at discharge **(2)**	N/A
Category C Applies to Pre-Transfusion specimen collected < 24 hours of age*	Collect before transfusion **(3)**	24-48 hours of age **(4)**	28 days of age or at discharge **(2)**
Category D Applies if a specimen was **NOT** collected **PRIOR** to Transfusion	24-48 hours of age **(4)**	Collect another specimen after 120 days **(5)**	N/A

Key

Code Description

1. Specimen supports timely detection of newborn screening conditions.
2. A newborn screen collected at **28 days of age** is recommended for all infants who are less than 34 weeks gestational age or less than 2,000 grams at birth to improve the detection of delayed onset metabolic and endocrine conditions for which ill and premature infants are at higher risk.
3. Acceptable specimen for the detection of galactosemia, hemoglobinopathies, and biotinidase deficiency, **before** 24 hours of age.

*Collecting a specimen prior to transfusion or transfer is recommended, even if the infant is < 24 hours old. The receiving hospital should receive a report from the sending hospital.

4. Specimen is necessary for the timely detection of conditions **other than** galactosemia, hemoglobinopathies and biotinidase deficiency, **after** 24 hours of age.

5. Acceptable post transfusion specimen for the detection of galactosemia, biotinidase deficiency and hemoglobinopathies is **120 days** after the last transfusion date.

Infants who Exhibit Clinical Signs of a Newborn Screening Disorder

If signs and symptoms of one of the newborn screening disorders are evident clinically, the provider should proceed to diagnostic testing, pending the results of the screening and despite the results of the screening.

⏭ **If the results of the newborn screening are pending:**

For any of the disorders, but especially those in which a metabolite accumulation has immediate clinical repercussions, treat the infant as if he or she has the disorder. Consultation with the appropriate medical specialist is indicated.

For other disorders, contact the appropriate medical specialist for assistance with rapid diagnosis and institution of treatment until the results of the screening test are known.

⏭ **If the results of the newborn screening are "normal":**

If clinical symptoms suggest one of the newborn screening disorders, the provider should treat the infant as if he or she has the disorder. Another specimen for newborn screening should be collected and the appropriate medical specialist should be contacted for assistance with further evaluation of the infant.

Parental Refusal

Newborn screening is mandated by law, and parents may only decline testing for religious reasons. A **Parental Statement of Religious Objection form (DHEC 1804)** shall be completed if parents refuse newborn screening. A copy of this three-part form is included in the Appendix.

One copy should be maintained in the infant's medical record at the facility where the screening was declined. The second copy is sent to Child Health (CH) along with the mailing address of the parent. The third copy can be given to the parents.

Upon receipt of the signed Parental Statement of Religious Objection, CH will send the parents a certified letter as a final attempt to offer newborn screening services.

Report Related Issues

Lab reports are mailed to the provider who is documented on the collection form and to the facility where the specimen is collected. **If a report is not received by the time of the infant's first visit, call newborn screening staff at 803-896-0878 for a verbal or faxed report.**

Physicians and other providers should request a sender number from the PHL to ensure timely receipt of newborn screening reports. Requests should be made to the PHL LIMS (Lab Information Management Systems) Section, Attention: Linda Conway, 803-896-4777 (via phone) or 803-896-3862 (via fax).

Practices may choose to receive laboratory reports by individual physician. Or, they may obtain a group sender number for the entire practice. However, only one address can be associated with a sender number. If a practice has multiple locations and/or physicians, more than one sender number will be needed to route reports to the correct location.

If there is no sender number associated with the name of the provider as documented on the collection form, then the PHL will look up the physician's name in the on-line directory of the Department of Labor, Licensing and Regulation and create a sender number for the physician. This process cannot be done if there is more than one physician with the same name or if the first and last name of the physician is not clearly documented on the collection form.

To keep the newborn screening database as accurate as possible, all address changes must be sent in writing to the PHL. It is acceptable to fax this information to the PHL at 803-896-3862 or to email this information to Linda Conway at conwayll@dhec.sc.gov.

In coordination with the PHL, the Bureau of Maternal and Child Health (MCH) will provide reports to hospitals related to quality improvement measures such as timeliness of specimen submission and percentage of unsatisfactory specimens.

Physician, Certified Nurse Midwife, Licensed Midwife, Nurse Practitioner or Physician Assistant Responsibilities

The physician or certified nurse midwife is responsible for the collection of the newborn screening specimen for all infants under his or her care. Licensed midwives are likewise responsible for the collection of the specimen for infants under their care.

Nurse practitioners or physician assistants may also be involved in the care of infants after birth. Collection of the specimen may be done under standing orders. Refusal of testing is only allowed for religious reasons documented in writing.

The newborn healthcare provider of record assumes responsibility for providing any necessary follow-up based upon the results of the newborn screening tests.

This responsibility includes ensuring that any repeat specimen is collected as soon as possible either because the initial specimen was unacceptable or because the initial specimen showed an abnormality.

Additionally, appropriate medical management and/or diagnostic testing must be done to avoid potential morbidity in certain infants with abnormal newborn screening results.

If the newborn healthcare provider of record will not be providing follow-up care for an infant, he or she shall notify CH with the name of the provider who will be providing follow-up care. If the provider of record does not know the name of the provider who will be assuming follow-up care, DHEC staff will make reasonable efforts to locate the infant and obtain a repeat specimen.

It is vital that notifications regarding change in provider are made in a timely manner to ensure that no affected infants are missed.

Also, every office providing health care to infants should have procedures in place to ensure that newborns presenting for an initial visit, whether for routine preventive care or related to an illness, have the office records checked for the newborn screening results. If these results are not found in the record, the office should call CH to ascertain the screening status of the infant.

The primary care provider is responsible for initiating appropriate medical follow-up and diagnosis of infants with abnormal test results. This may include referral to medical specialists. The primary care provider should also refer parents for genetic counseling when appropriate.

If prompt treatment or referral is not possible, the provider shall notify CH. **In addition, it is the responsibility of the provider to notify DHEC of the final diagnosis of the infant and the date treatment was initiated. This includes notification that the initial screening test was a false positive result based upon further diagnostic work up.**

DHEC Responsibilities

The PHL analyzes dried blood specimens for newborn screening on all infants born in South Carolina. All test results are sent to the submitter and the physician indicated on the newborn screening collection form. Moreover, when abnormal test results are found, the PHL notifies CH staff, who in turn communicate with the primary healthcare provider, so that further testing and/or other diagnostic procedures can be arranged by the appropriate medical specialist. The names of infants with test results indicative of hemoglobinopathy traits are also sent to the designated regional sickle cell community based organizations by the PHL.

CH provides recommendations to physicians, maintains follow-up tracking documents, monitors screening processes, and establishes follow-up protocols. Depending upon the severity of the abnormal screening result, the physician will receive either phone notification, fax or mail notification from CH.

Each public health region has staff designated to provide follow-up services. When a physician is unable to locate an infant who needs further testing or treatment, the physician shall notify CH.

If the infant is at high risk of morbidity/mortality, CH contacts the appropriate region staff. In other instances, CH contacts the parents by mail to inform them of the need for additional testing.

The region staff makes reasonable efforts to locate the infant at high risk of morbidity/mortality for further services. These services may include specimen collection, parent education, and specialty care referrals.

Registered Dietitians/Nutritionists (RDNs) assist in the management of persons with metabolic disorders. They ensure that the prescribed metabolic formula for treatment of PKU and other select metabolic disorders is ordered and dispensed. Metabolic formulas are available to legal residents of South Carolina with PKU and other select metabolic disorders through DHEC, currently at no charge. Availability is based upon set criteria, which is subject to change based upon availability of funds.

Saturday/Holiday Newborn Screening Services

PHL and CH staff perform modified newborn screening services on Saturdays and certain state holidays. Please refer to the charts in the Appendix for information on how providers are notified regarding abnormal test results during non-standard office hours.