South Carolina Department of Public Health (SC DPH)
Official Departmental Instructions

Specimen Collection Process

Since 1962, newborn screening has been mandated by *South Carolina Code of Laws, Care of the Newly Born, Sections 44-37-30 and 44-37-35:* https://www.scstatehouse.gov/code/t44c037.php

And *South Carolina Code of Regulations 61-80, Neonatal Screening for Inborn Metabolic Errors and Hemoglobinopathies*: https://www.scstatehouse.gov/coderegs/Chapter61.php

Therefore, all **children born in this state have neonatal testing performed at birth**. Hospital and birthing center personnel are responsible for collecting blood spot specimens from all newborns in their care. Licensed midwives must also ensure that specimens are collected. To obtain the best specimen, follow the collection and handling of blood spot specimens process below:

1. **Collect a specimen from each infant between 24 and 48 hours of age.**

2. **Provide all required information on the newborn screening collection form** (DPH 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 blood collection procedures established by the Clinical and Laboratory Standards Institute (CLSI) NBS01-A6. See the *Neonatal Screening Blood Specimen Collection and Handling Procedure* photos on pages 3-4 for details.

4. **Allow specimens to air dry** in a horizontal position for at least 4 hours before sending them to the SC Department of Public Health (DPH) Public Health Laboratory (PHL).

5. Carefully **inspect the quality and quantity of each specimen prior to submission**. Use the *Simple Spot Check* chart on page 5 as a guide for suitability of testing. Recollect the specimen if necessary.

6. **Send all satisfactory specimens to the PHL within 24 hours of collection.** Unless there are extenuating circumstances that prohibit compliance, such as no mail or courier pick up. **Do not hold specimens.**

7. **Do not** place specimens in plastic bags prior to submission. Also **ensure 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.

8. **Specimens shipped to the lab 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 when the infant's specimen is collected between 24 and 48 hours of age.**

1. If the infant is transferred to another hospital before screening has occurred, the hospital or birthing center must inform the receiving hospital that a 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 notify the infant's parents so that prompt specimen collection can be arranged.

3. Complete demographic information on the collection form. Write at the top "**Specimen Not Collected**" and send it to the PHL.

4. If the infant is discharged prior to **24 hours of age**, collect a specimen as close to discharge as possible. Inform the parents that retesting is necessary **within 1 week** of age.

5. Give the parent/guardian a copy of the *Newborn Screening for Your Baby's Health* brochure. It is available from DPH in English and Spanish. Obtain a copy online here:

   English: https://dph.sc.gov/sites/scdph/files/Library/ML-000032.pdf and
   Spanish: https://dph.sc.gov/sites/scdph/files/Library/ML-025096.pdf

6. Encourage the parent/guardian to ask the infant's primary care provider about the test results at baby's first visit after discharge.

7. Review, evaluate, and record the newborn screening test results in the infant's health record upon completion. **Review each infant's lab report no later than 7 days after delivery to ensure that a specimen was submitted and that a report was retrieved.**

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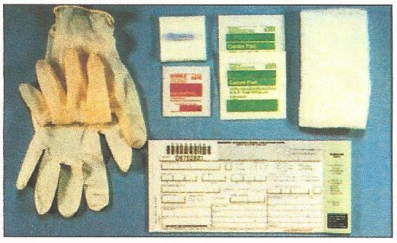
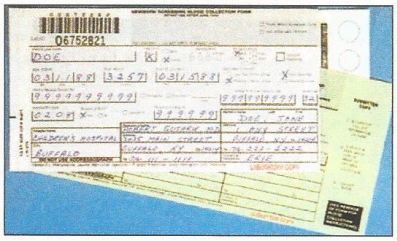
Neonatal Screening

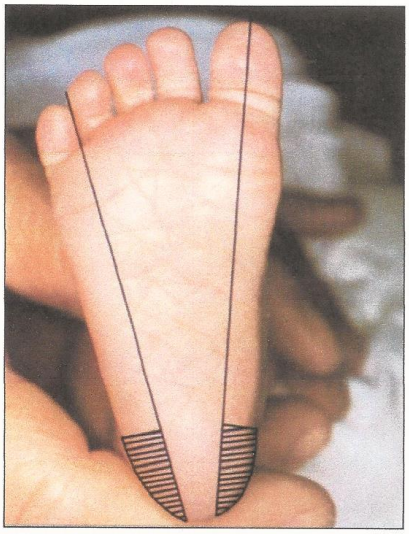
Blood Specimen Collection and Handling Procedure



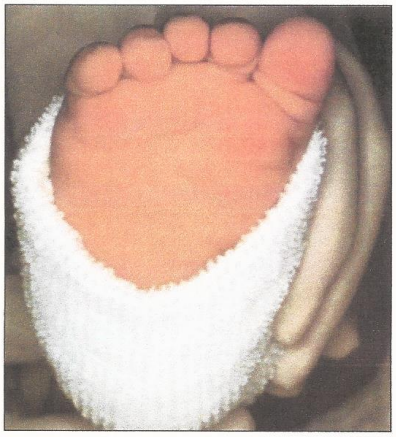
1 Equipment: sterile lancet with tip approximately 2.0 mm – sterile alcohol prep, sterile gauze pads, soft cloth, blood collection form, gloves.



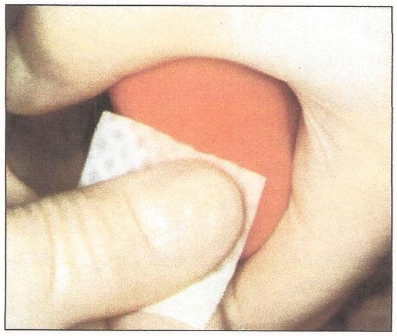
2 Complete ALL information. Do not contaminate filter paper circles by allowing the circles to come into contact with spillage or by touching before or after blood collection. Keep "SUBMITTER COPY" if applicable.



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

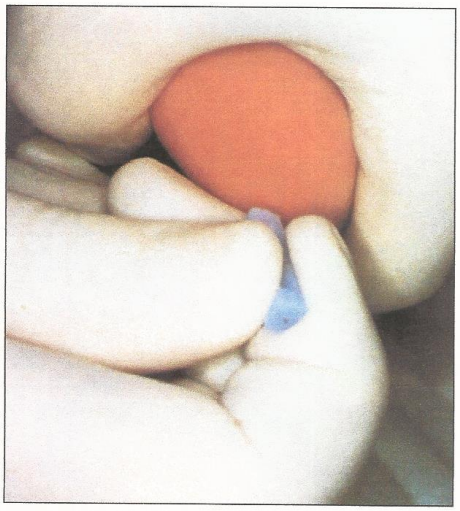


4 Warm site with soft cloth, moistened with warmwater up to 41°C, for three to five minutes.

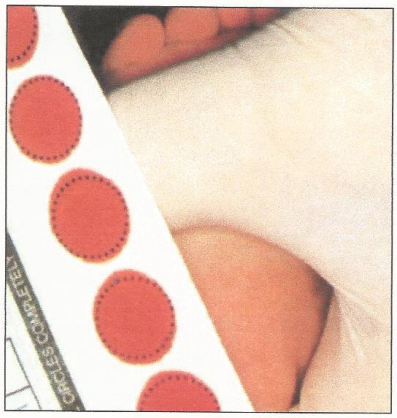


5 Cleanse site with alcohol prep. Wipe DRY with sterile gauze pad.

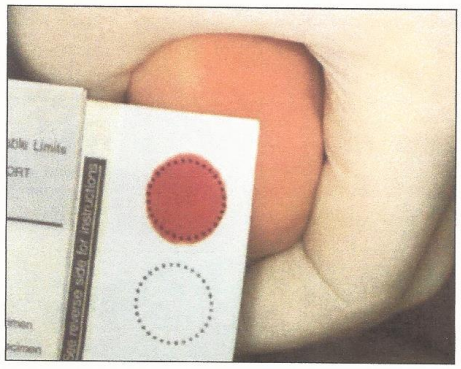
Over



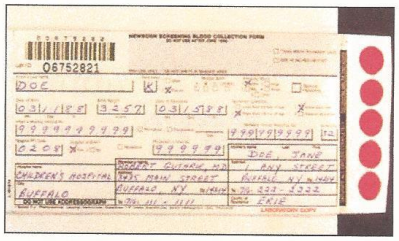
6 Puncture heel. Wipe away first blood drop with sterile gauze pad. Allow another LARGE blood drop to form.



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

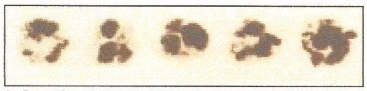
Whatman®

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:

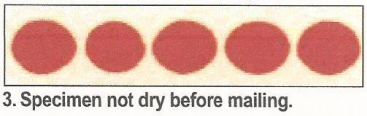


1. Specimen quantity insufficient for testing.

- 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.

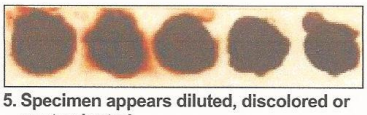


3. Specimen not dry before mailing.

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

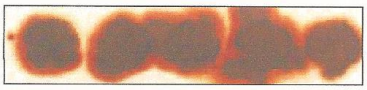
4. Specimen appears supersaturated.

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



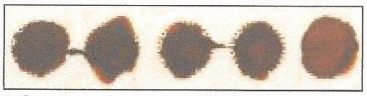
5. Specimen appears diluted, discolored or contaminated.

- 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 a specimen from the infant as previously instructed. The patient's name fields on the newborn screening filter paper form **should reflect the infant's legal name at the time of birth or adopted name (when known)**. If the infant's name is unknown at the time of collection, enter the infant's last name as the birth mother's last name, first name "**Adoption**". Example "Smith, Adoption".

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

When known, always enter the physician's demographics and infant's medical record number in its 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 3rd day of life, the person in attendance at the birth should contact DPH Newborn Screening Follow-up program 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 a fetus is affected, arrangements should be made for delivery at the appropriate level hospital. Treatment should be coordinated with an appropriate medical specialist and initiated as soon as possible.

A specimen for newborn screening shall still be collected to test 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 all other disorders on the panel.

Testing Older Infants, Children, and Adults

Lab reference ranges for newborn screening are based on expected results for *newborns* tested within the first few weeks of life. **For that reason, the PHL will perform a modified newborn screening panel on infants between 6 to 12 months of age.** Contact PHL staff for assistance in locating another laboratory for this service on babies greater than 12 months of age.

The modified newborn screening lab panel for infants aged 6 to 12 months includes:

- An amino acid profile (for amino acid disorders),
- Succinyl acetone (SUAC) for Tyrosinemia,
- Hemoglobin disorders and traits,
- Galactose-1-P-uridyl transferase enzyme (GALT) and total galactose (GAO) levels for Galactosemia,
- Cystic Fibrosis mutation analysis (CFTR),
- Biotinidase (BIO) enzyme level for Biotinidase deficiency,
- Spinal Muscular Atrophy (SMA) screening, and
- T-cell receptor excision circles (TRECs) for Severe Combined Immunodeficiency (SCID).

The PHL can also test specimens from older babies, children, and adults, for the monitoring of select amino acids (such as phenylalanine and tyrosine levels for known PKU patients) and hemoglobin disorders and traits (such as Sickle Cell Disease).

Unsatisfactory Specimens

The PHL receives some specimens that are considered unsatisfactory for officially reporting test results. The PHL does test unsatisfactory specimens for extreme values, when possible. However, improper collection and handling may compromise the accuracy of test results. This delays the screening and diagnosis of potentially affected infants 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 a phone, fax, and/or mail notification from MCH.

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

Transfusion

Whenever possible, obtain all newborn screening specimens **prior** to transfusion of any blood products (even if the infant is less than 24 hours old). These specimens will be acceptable for the

detection of biotinidase activity, galactosemia, and any hemoglobin disorders. Another specimen will still be needed between **24-48 hours** of age. Or prior to discharge for all other tests.

If this is not possible, collect the initial specimen and indicate the date of the most recent transfusion. Infants who receive transfusions after collecting the initial newborn screen should have a repeat hemoglobin, 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, NICU, and/or Sick Infants

In premature, low birth weight, NICU, and/or sick infants, screening results can be falsely increased or decreased 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, NICU, and/or 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

Numeric 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 when 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 hemoglobin disorders is **120 days** after the last transfusion date.

Infants who Exhibit Clinical Signs of a Newborn Screening or other Disorder

If signs and symptoms of a newborn screening or other disorder are clinically evident, the provider should proceed to diagnostic testing, pending results of the screening and despite the results of screening.

⏭ **If results of the newborn screen are "pending":**

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

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

⏭ **If results of the newborn screen are "within acceptable limits":**

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

Parental Refusal

Newborn screening is mandated by *South Carolina Code of Laws, Care of the Newly Born, Sections 44-37-30 and 44-37-35:* https://www.scstatehouse.gov/code/t44c037.php

Unless the parents object on religious grounds (only) and indicate this objection before testing, in writing. A **Parental Statement of Religious Objection form (DPH 1804)** shall be completed if parents refuse newborn screening. The Religious Objection form is available in English, Spanish, Russian, and Ukrainian, and located here:

English: https://dph.sc.gov/sites/scdph/files/Library/D-1804.pdf
Spanish: https://dph.sc.gov/sites/scdph/files/Library/D-1804s.pdf
Russian: https://dph.sc.gov/sites/scdph/files/Library/D-1804r.pdf
Ukrainian: https://dph.sc.gov/sites/scdph/files/Library/D-1804u.pdf

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 the Bureau of Maternal and Child Health (MCH), Newborn Screening section, along with the name and mailing address of the parents. The third copy can be given to the parents.

Upon receipt of the signed Parental Statement of Religious Objection, MCH will send the parents a notification letter as a final attempt to offer newborn screening services free of charge at a local health department.

Lab Reports

As of 4/12/2021, the PHL no longer mails copies of newborn screening lab reports. Licensed healthcare providers can retreive completed newborn screening lab reports online anytime via Specimen Gate® eReports. Specimen Gate® eReports is a secure web portal that gives the end user the ability to view, download, and/or print electronic copies of patient lab reports for infants under their care 24/7 for a period of 6 months.

For access, go to https://apps.dhec.sc.gov/Health/eReportsGateway and request an account.

A User Agreement and manual will be emailed to qualified providers in response to requests. The user agreement (DPH 3268) is also available at www.scdhec.gov/LIMSFORM.

Email the signed agreement to NBSLab@dph.sc.gov or fax it to (803) 896-3862.

If a response is not received by the time of the infant's first visit, call LIMS (Lab Information Management Systems) staff at 803-896-4777 or 803-896-0945 for support.

Physicians and other healthcare providers should also request a sender number from the PHL to ensure timely access to newborn screening reports. Requests should be made to the PHL LIMS Section, Attention: LIMS Admin, 803-896-0945 (via phone) or 803-896-3862 (via fax).

Practices may choose to retrieve laboratory reports by individual physicians. Or they may obtain a group sender number for an entire practice. However, only one address can be associated with each sender number. If a practice has multiple locations and/or physicians, then multiple sender numbers will be needed to route reports correctly.

If there is no sender number associated with the name of a provider as documented on the collection form, 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 practice/facility names, addresses, phone and fax number changes must be sent in writing to the PHL. It is acceptable to fax this information to the LIMS department at 803-896-3862. Or email this information to the LIMS Admin at NBSLab@dph.sc.gov.

Hospital Specimen Collection Reports

In addition to routine lab reports, the PHL provides monthly newborn screening quality reports to hospitals. Hospital reports are related to quality improvement measures such as timeliness of specimen collection, submission to the lab, and percentage of unsatisfactory specimens. These reports are distributed to all birthing hospitals via the South Carolina Hospital Association (SCHA) as a collaborative endeavor with DPH.

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

The attending physician, health care provider attending the child's birth, or their designee, is responsible for the collection of newborn screening specimens for all infants under his or her care.

Other physicians, nurse practitioners, and/or physician assistants may also be involved in the care of infants after birth. Collection of a specimen may be done under a standing order. Refusal of testing is only allowed for religious reasons documented in writing. See the *Parental Refusal* section listed within this document for details.

Per South Carolina Code of Regulations 61-80, Neonatal Screening for Inborn Metabolic Errors and Hemoglobinopathies, Section E, Assurance of Diagnosis and Follow-up:

https://www.scstatehouse.gov/coderegs/Chapter61.php

Information obtained from tests conducted for screening of inborn metabolic errors and hemoglobinopathies is confidential. It may be released only to the infant's physician, other staff acting under the direction of the physician, the child's parent or legal guardian, and the child when he/she is 18 years of age or older, when requested on a form promulgated in regulation by the department.

- The attending physician (healthcare provider of record) is responsible for informing the parents or legal guardian of normal and abnormal newborn screening lab results.

- Upon notification that a specimen was unsatisfactory, or that it is necessary for a test to be repeated, the attending physician will submit a second specimen to the laboratory.

    - This responsibility includes ensuring that any repeat specimen is collected as soon as possible. Either because the initial specimen was unsatisfactory for testing, or the specimen showed an abnormality.

- The attending physician will initiate appropriate medical follow-up and diagnosis when abnormal test results occur.

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

    - This may include referrals to pediatric medical specialists. If prompt treatment or referral is not possible, the provider shall notify MCH.

- The attending physician shall notify MCH of all children born in South Carolina who are diagnosed as having inborn metabolic errors or hemoglobinopathies.

    - In addition, it is the responsibility of the provider to notify MCH 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 (or false negative) result based upon further diagnostic work up.

- Appropriate genetic education and counseling should be offered to all families of children with abnormal test results. Thus, the attending physician should refer families for genetic counseling when appropriate.

- If the attending physician (healthcare provider of record) will not be providing follow-up care for an infant, he or she will notify the Bureau of Maternal and Child Health (MCH) with the name of the provider who will be providing follow-up care.

    - MCH will then notify the new healthcare provider, parents, or legal guardian, of the test results.

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

Also, every facility providing health care to infants should have procedures in place to ensure that newborns scheduled for an initial visit have a completed newborn screen on file. Office records should be checked prior to patient arrival for the newborn screening results.

If screening results are not found in the record, or via e-Reports online, the office should contact the department to ascertain the screening status of the infant.

DPH Responsibilities

Lab Analysis and Reporting

The PHL receives, analyzes, and reports results of lab specimens for newborn screening on all infants tested in South Carolina. Completed screening results are available electronically via eReports to the submitter and the physician of record indicated on the newborn screening collection form.

Lab reports for infants with test results indicative of hemoglobin traits are also sent by the PHL to designated regional sickle cell community-based organizations to facilitate genetic education and counseling.

Abnormal Test Result Notifications

If results of testing are **abnormal**, the department may recommend additional testing and, in addition to the notification requirements established in Section 44-37-30(B)(1), notify one or more of the following to ensure timely provision of follow-up services:

(a) the physician or health care provider attending the child's birth or his designee;

(b) the physician or health care provider responsible for newborn care in the hospital; or

(c) the physician or health care provider identified for follow-up care after the newborn's discharge from the hospital.

Depending upon the severity of abnormal screening results, the physician will receive either phone, fax, and/or mail notification from the department, soon after laboratory results are known.

Time Sensitive or Time Critical Test Result Notifications

If results of testing are **abnormal**, **time-sensitive, and/or time-critical**, the department may, in addition to notification requirements established in Section 44-37-30(B)(1) and (2), notify and provide information about the abnormal, time-sensitive, or time-critical screening results to a qualified pediatric specialist.

Care Coordination for Diagnosed Infants

Parent/provider contact and demographic information for infants diagnosed with test results indicative of Sickle Cell Anemia, S/β + Thalassemia, Hemoglobin S/C Disease, Pompe disease, Mucopolysaccharidosis Type 1 (MPS I), and Spinal Muscular Atrophy (SMA), are also sent to MCH Newborn Screening and Children and Youth with Special Healthcare Needs (CYSHCN) staff for infant care coordination.

MCH Newborn Screening staff establish notification protocols, ensure infants' linkage to care, provide recommendations to physicians, collaborate with birthing hospitals and pediatric specialists, maintain a short-term follow-up tracking system, order metabolic formulas, and monitor infant cases up to diagnostic closure.

MCH CYSHCN staff offer care coordination, long-term follow-up, additional services, and financial support for medical needs, when certain criteria are met. Depending upon the infant's

final diagnosis, the physician and infant's family will receive either phone, fax, and/or certified mail correspondence from the department, within 1 month of receiving diagnostic information.

Nutrition Services and Metabolic Formula

Community Nutrition Services (WIC) and MCH Registered Dietitians/Nutritionists (RD/RDNs) assist in the management of clients with metabolic disorders, such as PKU and other inborn errors of metabolism. They ensure that medically necessary metabolic formulas are ordered and distributed for treatment as needed, when certain residency and/or financial criteria are met.

Select metabolic formulas are available to legal residents of South Carolina with PKU and other metabolic disorders through WIC and MCH, currently at no charge. Procurement is based upon set criteria, which are subject to change based on the availability of funds.

Additional Services

Each public health region has additional MCH and Epidemiology staff designated to facilitate follow-up services in emergency situations. Department staff will make all reasonable efforts to locate any infant at high risk of morbidity/mortality for further services.

These services may include newborn screening specimen collection, parent education, internal referrals, and/or external specialty care referrals identified during requested MCH Postpartum Newborn Home Visits (PPNBHV).

Missing Infants

When an attending physician is unable to locate an infant who needs further testing or treatment, the physician shall notify MCH. If the infant is at high risk of morbidity/mortality, MCH will contact the appropriate region staff, law enforcement, or emergency personnel, to make a home visit. In low-risk instances, MCH contacts the parents by phone or mail to inform them of the need for additional testing.

Saturday/Holiday Newborn Screening Services

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