



ALABAMA DEPARTMENT OF PUBLIC HEALTH BUREAU OF CLINICAL LABORATORIES

Newborn Screening Collection Guidelines

Revised 3/18/2016



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Bureau of Clinical Laboratories
Newborn Screening Division
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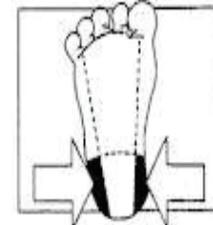


Alabama Department of Public Health Bureau of Clinical Laboratories Newborn Screening Collection Guidelines

Section 22-20-3 (as amended in 1987) of the Code of Alabama states that all infants must be administered a reliable test for PKU, Cystic Fibrosis, Hypothyroidism, CAH, Galactosemia, Abnormal Hemoglobins, Biotinidase Deficiency, Amino Acid Disorders, Fatty Acid Disorders, and Organic Acid Disorders and that the testing be performed by the Public Health Laboratory.

Timing of Screening: See page 8 for NBS Blood Collection Algorithm	
FIRST TEST ("A" FORM) – This specimen is tested for Hypothyroidism, CAH, Cystic Fibrosis, Galactosemia, Hemoglobinopathies, Biotinidase Deficiency, Amino Acid Disorders, Fatty Acid Disorders, and Organic Acid Disorders.	
Full Term Infants	A newborn screening test should be collected when the infant is 24-48 hours of age. If the infant is discharged prior to 24 hours of age, a specimen MUST be obtained before discharge, and the parent or guardian must be informed of the importance of obtaining a repeat test before one week of age.
Home Births	The Newborn Screening Statute applies to all infants born in Alabama. The birthing attendant is responsible for collecting the newborn screening test. It is recommended that the test be collected at 24-48 hours of age.
Extended Hospital Stay <small>(low birth weight/sick infants)</small>	It is recommended that a first specimen be collected upon admission (0-2 hours of age) to the NICU if the infant is expected to receive TPN or transfusions unless the infant is so unstable that it cannot be done safely. A second specimen is recommended at 48-72 hours of age, and a third specimen is recommended at 28 days of age or discharge, whichever comes first. See page 8 for Sick Infant Blood Collection Algorithm.
Transitioning Infants	Infants admitted to NICU for short term observation but are not receiving TPN or transfusions should have a specimen collected according to the Full Term Infant Protocol.
Dying Infants	If an infant is likely to die, it is appropriate to collect a newborn screening specimen. While dying infants may have abnormal results as a response to organ failure, the specimen may also provide a diagnosis of an early onset screening disorder.
Older Infants	The American Academy of Pediatrics recommends that physicians know the screening status of all children in their care. While older infants may enter the practice without evidence of a newborn screen, the Alabama Department of Public Health's Newborn Screening Program has established standards and cutoffs for newborns and infants and therefore cannot accept specimens on children older than 12 months of age.
Special Considerations:	
Transfused Infants	A specimen should be collected prior to transfusion regardless of age or treatments unless the infant is so unstable it cannot be done safely. If the specimen is not collected prior to transfusion, collect a specimen greater than 72 hours post transfusion. Another specimen should be collected at 3-4 months post transfusion for Hemoglobinopathies, Biotinidase Deficiency, and Galactosemia if a satisfactory screen for these conditions has not been reported. If a Galactosemia condition is suspected and the specimen was not collected prior to transfusion, place the infant on a galactose-free diet until a definitive diagnosis can be made.
Transferred Infants	The transferring hospital must collect a specimen prior to transfer on Form A regardless of age or treatments unless the baby is so unstable that it cannot be done safely. If the specimen cannot be obtained prior to transfer, the transferring facility must ensure that the receiving hospital is aware of the need for collection of the newborn screening specimen. The receiving hospital, on admission, should collect a specimen on a second test form (Form B) and mark the "First Test" box.

Parent Refusal	Parents may refuse newborn screening only for religious reasons. Parents who refuse under this condition should sign a statement that is placed in the infant's medical record. A newborn screening collection form should be filled out completely with a statement as to the refusal and mailed to the State Laboratory.
<p>SECOND TEST ("B" FORM) – <i>This specimen is tested for Hypothyroidism, CAH, Cystic Fibrosis, Galactosemia, Biotinidase Deficiency, Amino Acid Disorders, Fatty Acid Disorders, and Organic Acid Disorders.</i></p> <p>Note: This specimen is not routinely tested for Hemoglobinopathies. If no valid test has been done for this disorder, please see instructions below for collection of requested repeat specimens, "Requested Repeat."</p> <ol style="list-style-type: none"> 1. A second newborn screening specimen should be collected at 2-6 weeks of age (4 weeks optimal) on all full term infants with a normal first test screen. 2. If the first test specimen was collected when the infant was greater than one week of age but less than two weeks of age, the second test specimen should be collected at 4-6 weeks of age. 3. If the first test specimen was collected after two weeks of age, a second ("B") specimen need NOT be collected. 	
<p>Requested Repeat ("B" form)</p> <ol style="list-style-type: none"> 1. A repeat specimen may be requested by the State Laboratory when the results are abnormal or questionable. The specimen should be collected in the time frame indicated by the report. The "Retest-Prior Abnormal" box must be marked on the collection form. 2. If the first test is unsatisfactory for testing, a repeat test should be collected as soon as possible. The "Retest-Prior Unsat" box must be marked on the collection form. 	
<p>Collection of Filter Paper Bloodspot Specimen</p>	
<p>Materials needed for Blood Collection:</p> <ol style="list-style-type: none"> 1. Gloves 2. 70% isopropyl alcohol pads 3. Dry sterile gauze pads 4. Sterile sticking device with a point not greater than 2.4 mm in depth (the most effective method is the use of scalpel bladed lancets) 5. Newborn Screening filter paper collection form (CL-89) with protective envelope 	
<p>Bleeding Procedure:</p> <ol style="list-style-type: none"> 1. The preferred puncture site is indicated by the shaded areas on the heel. The least hazardous sites for heel puncture are medial to a line drawn posterior from the middle of the big toe to the heel or lateral to a similar line drawn on the other side extending from between the 4th and 5th toe to the heel. 2. Warm the infant's foot if necessary using warm water, towel, or chemical pack. Heat sources should not exceed 42°C and should not be left in contact with the skin for a prolonged period. 3. Disinfect the skin with alcohol pads and allow to air dry. Vigorous rubbing during this step stimulates blood flow to the area. 4. Puncture the skin in one continuous motion using a sterile sticking device with a tip <2.4mm. THE USE OF LONGER TIPS MAY DAMAGE THE HEEL BONE. 5. Wipe away and discard the first drop of blood since it may be contaminated by alcohol or tissue fluid. 6. Allow the second drop of blood to form by the spontaneous free flow of blood. 	



Collecting the Blood Spots:

1. Before collecting the blood, fold back the protective flap to expose the filter paper. Do not touch or handle the filter paper before or after applying the blood.
2. Lightly touch the filter paper against a large drop of blood and allow a sufficient quantity of blood to soak through to completely fill the circle. Apply blood to one side of the filter paper only, allowing full saturation of each circle. Either side of the filter paper may be chosen. Fill all circles. Do not layer successive small drops of blood to the same circle. Avoid touching or smearing the blood spots.
3. If blood flow is diminished, repeat the bleeding procedure with sterile equipment.
4. Once all the circles have been filled, press a sterile gauze pad to the puncture site and hold the infant's foot above the level of the heart until bleeding has stopped.
5. Dry the blood spots on a level, non-absorptive surface away from direct sunlight and at room temperature for at least 4 hours.
6. After blood spots are completely dry, replace the protective flap over the specimen and place form in the protective envelope (do not use plastic) and mail to the State Laboratory within 24 hours.

Guidelines and Possible Sources of Error:

The following guidelines may help eliminate unsatisfactory specimens or erroneous test results.

1. Do not touch any part of the filter paper circles before, during, or after collection.
2. Collect the specimen on the proper Newborn Screening collection form.
3. Complete all demographic data. This information is vital for interpretation of newborn screening results and for identification and location of infants for follow-up of abnormal test results.
 - a) Always note any transfusion of red blood cells.
 - b) Mark TPN feeding if TPN is being administered at time of collection.
 - c) NPI # should be provided for the Ordering Physician (physician ordering the NBS screen).
4. Wipe away the first drop of blood to remove tissue fluids and alcohol. Do not "milk" the puncture site.
5. Do not expose the specimen to heat or humidity at any time. Do not dry on heater, in microwave, with a hair dryer, or in the sunlight. Do not place in plastic bags, leave in hot mailbox, or hot car; proteins and enzymes will be destroyed.
6. Ensure that the specimen is properly dried before replacing the protective flap and before placing in the protective envelope.
7. Dry specimens in a horizontal position. Hanging wet specimens will cause heavier red cells to migrate to the end of the circle causing an uneven saturation.
8. Do not superimpose blood drops on top of each other.
9. Apply blood to only one side of the filter paper.
10. Collecting blood samples after feeding promotes better blood flow.
11. Do not allow specimens to come in contact with water, feeding formulas, antiseptics, urine, etc.

Improperly prepared blood spots and failure to complete the information form accurately constitute a major problem for the testing laboratory. Good blood spot preparation will assure prompt and accurate testing.

Completing the Demographic Data - A & B FORMS

Always complete the specimen collection form using a black or blue ball point pen and print legibly to ensure that the patient is identified properly.

Expiration Date → 2017-05

SEE BACK OF FORM FOR SPECIMEN COLLECTION INSTRUCTIONS

ALABAMA NEWBORN SCREENING PROGRAM						Alabama Department of Public Health Bureau of Clinical Laboratories 8140 ALUM Drive, PO Box 244018 Montgomery, AL 36124-4018		STATE LAB (334) 260-3400
Infant's Last Name 1	Infant's First Name 1	Medical Record # 2				Infant's Medicaid # 3		
Date of Birth 4	Time of Birth (Military) 5	Birth Weight 6 (gms) <small>(Current WT. if > 1 mth.)</small>	Multiple Birth Order 7	Weeks Gestation 8				
Date of Collection 9	Time of Collection (Military) 10	<input type="checkbox"/> Male 11 <input type="checkbox"/> Female 12 <input type="checkbox"/> TPN	Last Transfusion 13					
<input type="checkbox"/> Home Birth 14	Infant's Age 15	<input type="checkbox"/> White <input type="checkbox"/> Black <input type="checkbox"/> Other	<input type="checkbox"/> First Test 17	<input type="checkbox"/> Routine Second Test				
		<input type="checkbox"/> Asian <input type="checkbox"/> Hispanic 16	<input type="checkbox"/> Retest - Prior Unsat		<input type="checkbox"/> Retest - Prior Abnormal <small>(Requested by State)</small>			
Mother's Last Name 18		Mother's First Name 18		Mother's Social Security Number 18				
Mailing Address 18		Mother's Phone Number 18		Mother's Medicaid Number 18				
City 18		County 18	State 18	Zip 18				
Ordering Physician (Last) 19 (First) (MI)		HEARING: Risk Factors: <input type="checkbox"/> Yes <input type="checkbox"/> No		Right Ear: <input type="checkbox"/> Pass <input type="checkbox"/> Refer				
NPI # 20		Date 22 Method: <input type="checkbox"/> AABR <input type="checkbox"/> OAE		Left Ear: <input type="checkbox"/> Pass <input type="checkbox"/> Refer				
Referral Physician 21		<input type="checkbox"/> Refused <input type="checkbox"/> Not Performed		Transferred:				
SUBMITTER ADDRESS 24		PULSE OXIMETRY SCREENING: Age at screening (hrs) 23		<input type="checkbox"/> Pass <input type="checkbox"/> Fail <input type="checkbox"/> Not Performed		<input type="checkbox"/> Refused <input type="checkbox"/> Expired <input type="checkbox"/> NICU <input type="checkbox"/> On O2		
		-Laboratory use only-		Do not write on or affix labels in this area 25				
		AL Zip		FORMS MUST BE FILLED OUT COMPLETELY IN BLUE OR BLACK INK - PRINT LEGIBLY SN 109252				

INSURANCE INFORMATION - Complete Form (Instructions on Back) - DO NOT REMOVE

2017-05

Expiration Date

26

Expiration Date → 2017-05

SEE BACK OF FORM FOR SPECIMEN COLLECTION INSTRUCTIONS

ALABAMA NEWBORN SCREENING PROGRAM						Alabama Department of Public Health Bureau of Clinical Laboratories 8140 ALUM Drive, PO Box 244018 Montgomery, AL 36124-4018		STATE LAB (334) 260-3400
Infant's Last Name 1	Infant's First Name 1	Medical Record # 2				Infant's Medicaid # 3		
Date of Birth 4	Time of Birth (Military) 5	Birth Weight 6 (gms) <small>(Current WT. if > 1 mth.)</small>	Multiple Birth Order 7	Weeks Gestation 8				
Date of Collection 9	Time of Collection (Military) 10	<input type="checkbox"/> Male 11 <input type="checkbox"/> Female 12 <input type="checkbox"/> TPN	Last Transfusion 13					
<input type="checkbox"/> Home Birth 14	Infant's Age 15	<input type="checkbox"/> White <input type="checkbox"/> Black <input type="checkbox"/> Other	<input type="checkbox"/> First Test 17	<input type="checkbox"/> Routine Second Test				
		<input type="checkbox"/> Asian <input type="checkbox"/> Hispanic 16	<input type="checkbox"/> Retest - Prior Unsat		<input type="checkbox"/> Retest - Prior Abnormal <small>(Requested by State)</small>			
Mother's Last Name 18		Mother's First Name 18		Mother's Social Security Number 18				
Mailing Address 18		Mother's Phone Number 18		Mother's Medicaid Number 18				
City 18		County 18	State 18	Zip 18				
Ordering Physician (Last) 19 (First) (MI)		NOTES:						
NPI # 20								
Referral Physician 21								
SUBMITTER ADDRESS 24		-Laboratory use only-		Do not write on or affix labels in this area 25				
		AL Zip		FORMS MUST BE FILLED OUT COMPLETELY IN BLUE OR BLACK INK - PRINT LEGIBLY SN 339167				

INSURANCE INFORMATION - Complete Form (Instructions on Back) - DO NOT REMOVE

2017-05

Expiration Date

26

These forms are examples and may not be current. **These forms will expire 5-2017.**



1	Name field – enter the patient’s last name and first name (if applicable).	2	Medical Record field – enter the patient’s medical record number. This number is for the submitting facility to identify the patient when the report is received.
3	Medicaid field – enter the infant’s Medicaid number if applicable.	4	Birth date field – enter the birth date in the format MM/DD/YY (required field).
5	Time of Birth field – enter in military format, failure to use military format may result in erroneous test results since many lab tests are based on the age of the infant at the time of collection.	6	Birth Weight field – enter the infant’s birth weight in grams . If the infant is more than one month of age, enter the current weight. The laboratory sets standards and cutoffs for some tests using weight. Indicating the weight helps to ensure accurate test results and eliminate the need for unnecessary repeat specimens.
7	Multiple Birth Order field – complete only if there is a multiple birth. Enter the birth order as A, B, C, etc.	8	Gestational Age field – enter the gestational age as number of completed weeks.
9	Date of Collection – enter the date of collection in the format MM/DD/YY (required field).	10	Time of Collection – enter the time of collection in military format (required field)
11	Sex field – check appropriate box	12	TPN field – If infant is receiving TPN feeding at time of collection, check the box
13	Last Transfusion field – Complete this box with the date and time of the infant’s last transfusion of red blood cells . Date should be entered as MM/DD/YY and time in military format. The date and time of transfusion are important for the laboratory to determine whether the the results are valid. Failure to indicate transfusions can result in an infant with a NBS disorder being missed due to the presence of donor cells in the specimen.	14	Home birth field – check the home birth box if the infant was born outside of the birthing facility with a birthing attendant present.
15	Infant’s Age field – enter the infant’s age at the time of specimen collection.	16	Race field – mark the appropriate box for the infant’s race.
17	Type of Tests field - mark the “First Test” box if the specimen is the first one collected on this infant. Mark the “Routine Second Test” box if the specimen is the routine second test specimen collected on this infant. If a prior test on this infant was reported as unsatisfactory, mark the “Retest-Prior Unsat” box. If a prior test on this infant was abnormal and the State Laboratory requested a repeat sample, mark the “Retest-Prior Abnormal” box.	18	Mother’s Information fields – enter the mother’s information in the appropriate fields. Mother’s social security number should be entered accurately. This will allow the submitting facility to access test results more readily and ensures that infants needing immediate follow-up can be located quickly.
19	Ordering Physician field – enter the full name of the physician who has ordered the NBS tests. <i>This information is required to be provided and complete.</i>	20	NPI field - enter the National Provider Identification 9 digit number for the ordering physician . <i>This information is required to be provided and complete.</i>
21	Referral Physician field – enter the full name of the physician who will be caring for the infant. This physician will be contacted if the infant has a potential NBS disorder and his/her name will be listed as the physician on the NBS laboratory report. (This physician may be the same as the ordering physician – but should be entered in this field as instructed)	22	Hearing field – On the “A” form enter the date that the hearing screen was performed in the format MM/DD/YY and check the appropriate boxes to indicate the results of the hearing screen and the testing method used.
23	Pulse Oximetry Screening field – On the “A” form enter the age, in hours, of the infant when the screening was performed. Check appropriate “Pass” or “Fail” box. Check appropriate “Not Performed”, “Refused”, “Expired”, “NICU”, and/or “On O2” as it applies	24	Submitter field – enter the name and address of the facility submitting the specimen. Do not use abbreviations as there are facilities with similar names. An address label may be attached in this area as long as it does not obscure other fields or hang off of the edge. <i>This information is required to be complete and accurate.</i>
25	Lab use field - Do not write or place labels in this area. This space is used by the laboratory to attach a unique identification number to the specimen for use in the laboratory.	26	INSURANCE FORM: - Insurance information MUST be entered completely and accurately. This sheet should not be removed from the NBS form.

Sick Infant and Well Baby Newborn Screening Blood Collection Algorithm

February 22, 2016

The following newborn screening algorithm has been developed by a task force of professional medical providers and consultants and has been approved by the Alabama Newborn Screening Advisory Committee. These recommendations are in keeping with the recommendations of the Clinical Laboratory Standards Institute (CLSI) as well as the standards required by the Alabama Department of Public Health Laboratory.

Birth of preterm, LBW or sick newborn

Serial screening, with the collection of three specimens, is proposed as the most expedient and efficient paradigm for this population (CLSI Preterm, LBW, and Sick Newborns, page 19)

Transfer/Arrival NICU NBS Specimen

Collect the "**arrival NICU**" NBS specimen on admission to the NICU (if not already collected) **regardless of age*** before any other treatments are begun (transfusions, TPN or antibiotics). If transferred, the **transfer hospital** should collect a specimen on Form A before transported unless infant is unstable. The **receiving hospital**, on admission, should collect a specimen on a second test form (Form B) and mark the "First Test" box.

***For most preterm and LBW newborns, admission to the NICU occurs immediately after birth, usually 1 to 2 hours of age, or up to 24 hours of age. If an infant is 24 hours of age or older on admission to the NICU, repeat screening should be done according to local program recommendations for normal infants unless there were abnormalities on the initial specimen (CLSI, page 20).**

Acute NICU NBS Specimen

Collect the "**acute NICU**" NBS specimen at **48-72 hours of life** on infants initially tested at <24 hours of age at first screen.

- **If receiving blood** – wait and collect 72 hours after the last transfusion.
- **If on TPN** – collect acute screen plus an additional screen when TPN is discontinued.

Final NICU NBS Specimen

Collect the "**final routine NICU**" NBS specimen at **28 days of age** or at discharge, whichever comes first, for any infant in the NICU > 2 weeks of age. All NICU infants discharged before 2 weeks of age should have the recommended routine NBS specimen collected by their pediatrician at 2-6 weeks of age.

Birth of full-term or well newborn**Initial NBS Specimen**

Collect an initial NBS specimen at **24-48 hours of age** (mail within 24 hours).

- Collect the first sample on a First Test Form (A Form) and any subsequent samples on a second test form (B Form).
- If the infant is discharged prior to 24 hours of age, a specimen **must** be obtained before discharge, and the parent or guardian must be informed of the importance of obtaining a second test before one week of age.

Routine Repeat NBS Specimen

Collect a recommended routine second NBS specimen at **2-6 weeks of age**.

- This specimen is not routinely tested for Hemoglobinopathies.
- Collect on a Second Test Form (B Form)

Note: If results from the first or second newborn screens place infant at high suspicion for a condition, appropriate confirmatory or diagnostic tests should be done, being alert to the effects that treatments and the infant's condition may have on the screening test results.

If a well infant has had 2 newborn screens collected or a sick infant has had 4 screens collected (check Secure Remote Viewer to determine), please contact the NBS Lab at 334-260-3476, or the NBS Follow-up Program at 334-206-5556 for follow-up issues.