

Newborn Screening Program

Practitioner's Manual



Utah Department of

Health & Human Services

Utah Public Health Laboratory

STATE OF UTAH UTAH PUBLIC HEALTH LABORATORY NEWBORN SCREENING PROGRAM

Revised May 2024

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<p>The Utah Department of Health is legally required to collect three distinct data sets for each birth that occurs in Utah: 1) Newborn Screening data, 2) Newborn Hearing data, and 3) Birth Certificate data. The Department of Health is looking for ways to simplify and unify this effort through the following methods..... 29</p>	
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NEWBORN SCREENING KIT ORDERING

FEE
(effective July 1, 2023)

\$140

The two-part kit contains the first and second newborn screening cards, a parent brochure, and a return envelope for the second newborn screening specimen. Each two-part kit has a unique **kit number** and CANNOT BE SHARED with other newborns.

TWO-PART KIT
(first and second screening cards)

*For example, UT123A001F represents the first newborn screening card, and UT123A001S represents the second newborn screening card. The underlined portion (UT123A001) is the newborn's unique kit number. The ending letters 'F' and 'S' indicate whether it is the first or second newborn screening card, respectively. These letters, combined with the kit number, form the **card number**.*

MISCELLANEOUS CARD

Miscellaneous kits are replacement cards for inadequate specimens, recall specimens, or for use when the original kit has been lost.

KIT ORDERS

Order online
newbornscreening.utah.gov

INTRODUCTION

The Utah Newborn Screening handbook is designed to educate local hospital personnel such as nursery and laboratory staff, physicians, midwives, and other health care providers about the requirements for newborn screening in Utah. This handbook includes background information on the importance of newborn screening with specific instructions on completing the forms and submitting blood spot specimens.

The purpose of this handbook is to promote a better understanding of the newborn screening forms and the information entered on them. The quality of the newborn screening data and the ability to identify and locate families and medical providers quickly depends heavily on the correct completion of the forms. Forms sent in with missing or incorrect data or un-testable specimens cannot be processed, thus putting infants in jeopardy. The institution of birth or the midwife/practitioner providing assistance to the mother at the birth is responsible for initiating the newborn screening process.

The Newborn Screening Program uses the information on the form to efficiently locate and identify newborns with abnormal test results, as well as to notify health care providers when blood spot specimens are not adequate for testing.

IMPORTANCE

Utah State Law UCA 26B-4-319 [Appendix A] requires all infants born in Utah to be tested.

The scientific, political and social advancements in the United States came together to foster the development of the newborn screening practices. In the 1960's, parent advocacy groups were instrumental in getting legislation passed for prevention of mental retardation. In 1965, Utah State legislators adopted mandatory testing of all newborns for phenylketonuria (PKU) and other metabolic diseases that might result in brain damage or death.

HISTORY

The Utah Department of Health began managing the newborn screening process in 1979. At that time phenylketonuria (PKU), congenital hypothyroidism, and galactosemia were the diseases identified through screening. As of July 2023 Newborn Screening has expanded to include screening babies for biotinidase, congenital hypothyroidism, congenital adrenal hyperplasia, hemoglobinopathies, galactosemia, disorders of amino acid, organic acid and fatty acid metabolism, guanidinoacetate methyltransferase deficiency, cystic fibrosis, severe combined immunodeficiency syndrome, spinal muscular atrophy, X-linked adrenoleukodystrophy, mucopolysaccharidosis and Pompe.

The Newborn Screening Program is administered under the laws [Statute 26B-4-319] and rules [R438-15, Appendix B] of the State of Utah. The Newborn Screening Program, as part of the Department of Health and Human Services, is in charge of screening. This includes sample laboratory testing, follow-up on abnormal specimens, education to the public and health care providers.

CONFIDENTIALITY

Newborn Screening personnel protect the information on the newborn screening forms and in the database from unwarranted or indiscriminate disclosure. Records are available only to persons who are authorized access by State Law and supporting rules. Legal safeguards for the confidentiality of records have been strengthened in recent years. Physicians, hospitals, and families are assured that extensive legal and administrative measures are used to protect individuals from unauthorized disclosure of personal information.

MEDICAL HOME

The Newborn Screening Program supports and encourages the “Medical Home” concept for all infants. The health care provider for a baby must be identified at birth. These providers will be contacted for any follow up needs.

What is a Medical Home?

A medical home is not a building, house or hospital, but rather a family-centered approach to providing health care in a high quality and cost effective manner. Primary care providers, families, and allied health care professionals act as *partners* to identify and access all medical and non-medical services needed by children and families to help them achieve their maximum potential. A medical home includes care that is accessible, family-centered, continuous, comprehensive, coordinated, compassionate, and culturally competent.

The ideal source of a child’s medical home is a primary care pediatrician or family doctor working in partnership with the parents. All children deserve a medical home to provide consistent and personalized care and this relationship may be even more important for children who may have special health care needs. Benefits of a medical home include: increased patient and family satisfaction, establishment of a forum for problem solving, improved coordination of care, efficient use of available resources, increased professional satisfaction, and increased child wellness due to comprehensive care.

For more information contact the Medical Home Project Coordinator visit
<http://www.medicalhomeportal.org/>



RESPONSIBILITIES REGARDING SPECIMEN COLLECTION

FIRST SPECIMEN

Hospital personnel, midwives, and birth attendants must complete the personal data required on the form and collect and submit a testable blood specimen (see Simple Spot Check on page 23). Necessary procedures may cut across departmental lines, involving many different people. These procedures, when combined with the current emphasis on reducing the length of stay in hospitals, make it extremely important for one hospital staff member to be given the overall responsibility and authority to request and obtain the cooperation needed.

Responsibilities regarding the first screening specimen:

- Develop efficient procedures for prompt assignment of a Newborn Screening Kit, preparation of data, and collection of filter paper blood spot specimen on every newborn. [R438-15]
- Collect and record all information requested on the data portion of the first screen form: infant name, sex, feeding, adoption, transfusion, date of birth, mother's name, address and phone number, mother's date of birth, and medical home/health care provider information. If the baby is being adopted, an identifying name and a contact person must be included. [R438-15-9 (e)]
- Prepare a legible form; make certain every item is complete and correct. Print in block, capital letters using blue or black ink. Forms with missing information cannot be processed. *Completion of the second screen form at this time is discouraged as many items change between collection of the first and second specimens.*
- Collect an appropriate blood spot specimen using the heel-stick method. [R438-15-9] *The person drawing the specimen must complete the 'Specimen Collection Date' on the screening form, without which the specimen CANNOT be processed. Results are validated only for specimens collected using the heelstick method.* Do not use capillary tubes to transfer blood to the filter paper. This will result in abraded filter paper and cause over absorption.

- Timing of collection: **First specimen should be drawn between 24 - 48 hours** life, however there may be exceptions. [R438-15-6] *Results are based on the age of the infant at the time the specimen was drawn.*
- If the original first screen card is unusable (e.g., contaminated, destroyed, blood specimen is inadequate, etc.), it is not necessary to use a new 2-part kit and number. Use a Miscellaneous Form. Remove bar code labels from the back of the original first and place them over the miscellaneous numbers, or cross out the miscellaneous numbers and write the original number in each place.
- If possible, collect the specimen prior to a transfusion. [R438-15-7 (2)] This may necessitate drawing the specimen prior to 24-48 hours of age.
- Allow the specimen to dry horizontally at room temperature for 3 hours.
- Transport specimen **within 24 hours of collection** to the Newborn Screening Lab. Use of a courier is highly recommended to decrease delay in receipt and testing of the specimen. [R438-15-9 (2)]
- Fold the cardboard flap over the dried blood spots before sending the specimen.
- Educate the family regarding the required screening, which disorders are screened, and how to obtain the second screen collection. [R438-15-7]
- Develop efficient procedures for prompt collection of the screening specimen on the newborn whose first specimen was determined to be abnormal [R438-15-10] or unsatisfactory for testing (could not test). [R438-15-11]

SECOND SCREENING SPECIMEN

Utah law requires that all newborns have a second specimen drawn between 7 and 16 days of age. These specimens are usually collected during the first visit to the medical home/health care provider. Office personnel, clinic personnel and midwives must assemble and record the personal data to be entered onto the forms and must collect and submit a testable blood specimen (see Simple Spot Check on page 23).

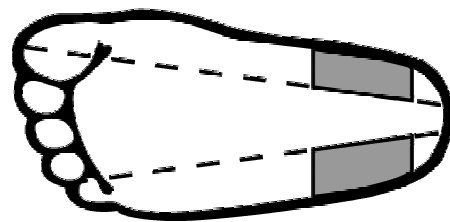
Responsibilities regarding the second screening specimen:

- Develop efficient procedures for preparation of data and collection of the second screening specimen on every newborn. [R438-15]
- Collect and record all information requested on the data portion of the second screen form: Infant name, gender, feeding, adoption, transfusion (if applicable), date of birth, mother's name, address, and phone number, mother's date of birth, and medical home/health care provider information. If the baby was adopted, identifying information needs to be included to link the first and second specimens. [R438-15-9 (e)]
- Prepare a legible form; making certain that every item is completed and correct. Print in block, capital letters using black ink. Forms with missing information cannot be processed.
- Collect an appropriate blood spot specimen using the heel-stick method.

The person who is drawing the specimen must complete the 'Specimen Collection Date' on the form; without a collection date, the specimen CANNOT be processed.

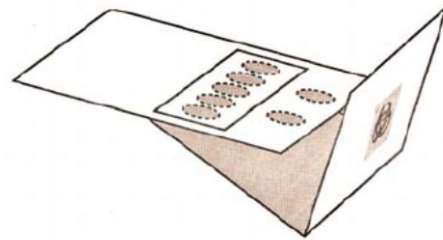
Results are validated only for specimens collected using the heelstick method. Do not use capillary tubes to transfer blood to the filter paper.

This will result in abraded filter paper and cause over absorption.



Draw specimen from shaded area using heel-stick method.

- Timing of collection: **Specimen should be collected between 7 and 16 days of age**, however there may be exceptions. [R438-15-8] *Results are based on the age of the infant at the time the specimen was drawn.*
- If possible, collect the specimen prior to a transfusion. [R438-15-6 (2)]
- Allow specimen to dry horizontally at room temperature for 3-4 hours, using designated drying rack.
- Transport specimen *within 24 hours of collection* to the Newborn Screening Lab. Using a courier is highly recommended to decrease delay in receipt and testing of specimen. [R438-15-9 (2)]
- To meet postal requirements, fold the cardboard flap over the dried blood spots before mailing the specimen.



- Develop efficient procedures for prompt collection of screening specimens for newborns whose specimen was determined to be abnormal [R438-15-10] or unsatisfactory for testing (could not test). [R438-15-11]

SUBMITTING THE NEWBORN SCREENING FORM

The testing for the Newborn Screen is considered to be “moderate or high complexity testing, or both” by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The Newborn Screening Laboratory must comply with the CLIA regulations, which includes CLIA’s minimum required data that must be collected to be in compliance.

The requested data is required in order to identify an infant, family, and health care provider, in compliance with federal regulations. Although the screened disorders are rare, their impact on an individual and family can be tremendous.

Correct identification of the infant and rapid notification the health care provider is critical when there are abnormal results.

Time is vital in getting the initial evaluation done and treatment started.

- Follow the instructions on the form that come with the newborn screening kit.
- Print legibly, in block letters, using blue or black ink.
- Avoid abbreviations, except the standard abbreviations used in addresses (use those acceptable from the US Postal Service).
- Verify ALL information with the mother (or informant) the spelling of names, especially those that have different spellings for the same sounding name (e.g., Peterson or Petersen).
- Collect only on the current form designated by the State of Utah. The filter paper is a Food and Drug Administration (FDA) regulated device and cannot be used after the expiration date.
- Avoid touching the filter paper at all times. Moisture, body oil, hand lotion, powder from gloves, and even compression of the filter paper fibers can interfere with the absorption of the blood and test results.
- Complete *all* requested data fields. Incomplete forms cannot be processed and the delay may result in poor infant outcomes
- Remove instruction part of the form prior to collecting the specimen. It may be kept for your records.
- Collect a blood specimen by the heel-stick method. Use of capillary tubes to transfer blood to the filter paper is not recommended. Capillary tubes tend to roughen the filter paper and cause over absorption, invalidating results.

- Dry specimen thoroughly, 3-4 hours at room temperature, before mailing. Specimen should be dried in a horizontal position. A rack designed for this purpose is available, free of charge, through the Newborn Screening program.
- Submit/send the specimen to the Newborn Screening Laboratory within 24 hours of the specimen collection. Use of a courier is recommended to reduce delay in transportation and testing times. If using the US Postal system, the regulations/standards for mailing clinical specimens apply.
- Use the envelope supplied for sending the second screen specimen to the lab.

Specific instructions for completing the demographic information on the newborn screening form

FOR UDOH LAB ONLY-DO NOT MARK: Leave this box blank. The Newborn Screening Lab uses it for the accession number and bar code.

Sample Collection Date (Month, Day, Year): Enter the sample collection date as eight digits: The first two digits for month, the next two for day, and the last four for year. For example: 04-01-2023 for April 1, 2023.

Medical Record Number (not required): Alpha or numeric digits may be entered. *This space is supplied at the request of the providers to assist in filing the results in the chart. This information may be the hospital medical record number or the health care provider medical record number (2nd screen specimens).*

Baby's Last Name: Enter the baby's last name(s). The baby's last name does not need to be the same as the mother's last name. Hyphens and apostrophes are acceptable.

Baby's First Name: Enter the baby's first name. If a first name has not been selected, leave this field blank. Do not enter 'baby girl,' 'girl,' 'bg,' 'baby boy,' 'boy,' 'bb,' or sex and mother's first name. **Enter 'A' or 'B' for multiple births.**

Gender: Check M (male) or F (female) box. If the gender is ambiguous, do not mark F or M and write in "ambiguous".

Birthplace/Hospital: Enter hospital name where baby was born. If born at home, enter 'home birth,' or birth center'. If born outside of Utah, enter 'out of state'.

This information is used to determine where the first screening results are to be sent. This information helps identify a baby from another born on the same day with the same last name and gender. The place of birth is a reference source for information. It is used in statistical reports to determine the number and/or percent of Utah babies screened.

Baby's Birth Date: Enter the baby's birth date as eight digits: The first two digits for month, the next two for day, and the last four for year. For example: 03-01-2023 for March 1, 2023. *This information is used for identification, quality assurance issues, and diagnostic purposes.*

Birth Weight (grams): Enter the baby's birth weight in grams. Birth weight is necessary to determine testing cutoff values. *This field will accept up to 4 characters.* Leading zeros are required.

Individual Items: Check all boxes that apply to the newborn

Feeding: Breast, Bottle (formula), TPN

Adopted: Adoption issues may cause some confusion.

- The Newborn Screening Program maintains patient and record confidentiality.
- The first screening form must be completed with information to identify the baby and health care provider.
- If there is concern about entering the birth mother's information, the adoptive agency or adoptive mother's information may be entered. A contact person must be entered. [R438-15-9 (e)]
- The second screening form and educational information should be given to the adoptive parent or adoptive agent with instructions for collection and submission of the second screen specimen. Do not fill out the information on the second screen card. The card should be completed at the health care provider's office with the adoptive names entered.

Premature/Sick: Mark if appropriate.

Meconium Ileus: Bowel obstruction requiring surgical intervention.

Steroids: Mark if infant or mother received steroids

Antibiotics: Mark if infant or mother received antibiotics

Transfusion: Enter date of transfusion.

- If transfusion occurred *prior to birth please indicate "in utero."*
- Transfusions prior to first screening specimens invalidate results for galactosemia and hemoglobinopathies.
- Transfusions given 7-10 days prior to second screen specimens could interfere with the results for phenylketonuria and congenital hypothyroidism. *This information is used for interpretation of the screening results, as well as diagnosis and treatment. Babies who have received*

transfusions may have results that are not valid and will need another specimen drawn at a later date.

Mother's Last Name: Enter the mother's legal last name(s). If the mother is unmarried, the last name and maiden name can be the same.

Mother's First Name: Enter the mother's first name.

Mother's Maiden Name (optional): Enter mother's maiden name for additional identification purposes.

Mother's Mailing Address: Enter the mother's mailing address including apartment number, PO Box number as applicable.

City: Enter the mother's city.

State: Enter mother's state, using the 2-digit abbreviation.

Zip: Enter mother's zip code.

Mother's Birth Date: Enter mother's birth date as 8 digits: the first two digits for the month, the next two digits for the day, and four digits for the year. For example: 04-01-1993 for April 1, 1993.

Mother's Area Code & Phone: Enter the mother's phone number, including the area code.

- *Do not use the father's phone number or insurance guarantor's number.*

Medical Home/PCP/Clinic Name: Enter the clinic or provider name (last, first) that will provide health care to the newborn. The information distinguishes providers with the same name (Jones, David or Jones, Sue).

Medical Home Doctor/Clinic Address: Enter the address of the health care provider or clinic that will provide health care to the newborn. This information identifies health care providers that have the same last name by identifying the clinic where the physician is located (some providers work at two or more clinics).

City: Enter the city of the health care provider or clinic that will provide health care to the newborn.

State: Enter the state of the health care provider or clinic that will provide health care to the newborn. Use the 2-digit abbreviation.

Zip: Enter the zip of the health care provider or clinic that will provide health care to the newborn.

Medical Home Doctor/Clinic Area Code & Phone: Enter the phone number of the health care provider or clinic that will provide health care to the newborn, including the area code.

Recall Screen Mark Only If Instructed: Mark this area only when instructed by the Newborn Screening program personnel, or in a recall notification letter sent to you from the Newborn Screening program. When this area is marked, the lab staff members are able to distinguish the recall specimen from a routine specimen.

SPECIAL INSTRUCTIONS - Abnormal Results

Program personnel will call the doctor/clinic noted on the demographic form for all abnormal results. Instructions will be given for follow-up. You may be asked for the collection of the routine second specimen, a third specimen or for additional confirmation testing at any time. If there are any questions, call the program for clarification (801) 584-8256. Below is an example of a normal and abnormal Newborn Screening Result.

NORMAL RESULT



Department of Health – Utah Public Health Laboratory
 4431 S 2700 W, Taylorsville, UT 84129
 Telephone: (801) 584-8256 FAX: (801) 538-0966
 Website: newbornscreening.health.utah.gov

Name:	Test Baby	Submitter:	Utah Hospital
Sex:	M	Sample #:	F2750001202012 (I)
DOB:	32-Sep-2020	Date Collected:	32-Sep-2020
UT (kit) #:	UT000B00	Date Received:	1-Oct-2020 09:41
Hospital MR #:	111222333	Date Reported:	3-Oct-2020
Mothers Name:	Test, Mother		


Disorder	Determination	Result (Reference Range)		
Overall Determination	Normal			
Amino Acid Profile	Normal			
Acylcarnitine Profile	Normal			
Biotinidase Deficiency	Normal			
Galactosemia	Normal	4.66	U/gHb	(3 - 20)
	<i>Enzyme Activity</i>			
Congenital Adrenal Hyperplasia	Normal	7.7	ng/mL	
	<i>17-OHP</i>			
<u>Comments:</u>				
Reference range: <25 ng/mL				
Congenital Hypothyroidism	Normal	16.8	uIU/mL	(0 - 40)
	<i>TSH</i>			
Cystic Fibrosis	Normal	18.0	ng/mL	(<51)
	<i>IRT</i>			
Hemoglobinopathies	Normal - FA			
SCID	Normal			
Spinal Muscular Atrophy	Normal			
X-Linked Adrenoleukodystrophy	Normal	0.000	umol/L	(<0.16)
	<i>C26:0 Init</i>			

FINAL REPORT - Please FILE and discard previous reports.

Page 1 of 1

Results are validated only for dried blood spot specimens collected using the heelstick method. A newborn screening result should not be considered diagnostic, and cannot replace the individualized evaluation and diagnosis of an infant by a well-trained, knowledgeable health care provider. *If glucocorticoids administered to infant or mother, use caution when interpreting the CAH result.
 Second tier testing for acylcarnitines, amino acids, and CAH is performed by ARUP Laboratories, 500 Chipeta Way, Salt Lake City, UT 84108-1211.

ABNORMAL RESULT

		Department of Health – Utah Public Health Laboratory 4431 S 2700 W, Taylorsville, UT 84129 Telephone: (801) 584-8256 FAX: (801) 538-0966 Website: newbornscreening.health.utah.gov	
Name:	EXAMPLE,	Birth Hospital:	VALLEY HOSPITAL
Sex:	F	Provider:	JOHNSON, J
DOB:	2021-09-15	Sample #:	F2600441202142
UT (kit) #:	UT000B000	Date Collected:	0/16/2021
Hospital MR #	123123123	Date Received:	0/17/2021
Mothers Name:	Exampe,	Date Reported:	0/20/2021
Overall Determination	ABNORMAL	*	
Amino Acid Profile	Normal		
Acylcarnitine Profile	ABNORMAL	*	
Comments: In this sample the concentrations of XX were elevated. This is suggestive of X. Additional testing is recommended and a referral to the XX Clinic at Primary Children's Hospital has been made. CRITICAL ACTION: PLASMA, URINE			
Biotinidase Deficiency	Normal		
Galactosemia	Normal	Enzyme Activity	14.63 U/gHb (>3.0)
Congenital Adrenal Hyperplasia	Normal	17-OH	10.9 ng/mL
Comments: Reference range: <25 ng/mL			
Congenital Hypothyroidism	Normal	TSH	10.3 uIU/mL (0 - 40)
Cystic Fibrosis	Normal	IRT	ng/mL (<51)
Hemoglobinopathies (IEF)	Normal - FA		
SCID	Normal		
Spinal Muscular Atrophy	Normal		
X-Linked Adrenoleukodystrophy	Normal	C26:0 Init	0.066

This is where any specifics about results, actions needed and notes from the lab will be entered; not all disorders will have

FINAL REPORT - Please FILE and discard previous reports.

Results are validated only for dried blood spot specimens collected using the heelstick method. A newborn screening result should not be considered diagnostic, and cannot replace the individualized evaluation and diagnosis of an infant by a well-trained, knowledgeable health care provider. *If glucocorticoids administered to infant or mother, use caution when interpreting the CAH result.

Second tier testing for acylcarnitines, amino acids, and CAH is performed by ARUP Laboratories, 500 Chipeta Way, Salt Lake City, UT 84108-1211.

MISCELLANEOUS FORMS

Miscellaneous forms are supplied without cost as replacement forms for inadequate specimens, recall specimens, or for use when the original kit form has been lost. The original kit was issued to the parent at the hospital/birthplace.

- **Write the original Kit ID Number** in each place on the miscellaneous form. This original kit number was issued by the hospital of birth and can usually be obtained from the Kit ID log kept in the hospital nursery. You can also contact the Newborn Screening program to obtain the original kit number.
- Mark the 'Test Requested' box for the appropriate screen needed (first or second screen).
- The 'Recall Screen' box is to be marked only if you have been instructed to do so by the Newborn Screening program. It is used to notify the laboratory of the need for the recall specimen procedure and testing.

Instructions For Filling Out A Miscellaneous Newborn Screening Form

1 Read all instructions on cover sheet before proceeding. Remove cover sheet.

2 Check expiration date. Do not use if expired.

3 Fill out form completely. Specimen will not be processed until information is complete.

4 Replace miscellaneous number with a stick-on label from the original kit if available (or draw a single line through it and write the number). To obtain the original number call the nursery at the hospital of birth.

The cover sheet includes the following text:

Utah Newborn Screening Miscellaneous Screen
SEE BACK FOR BLOOD SPOT COVER

MISCELLANEOUS:
First screen specimens should be collected on ALL newborns between 48 hours and 5 days of age. If newborn is discharged before 48 hours obtain specimen within 4 hours of discharge. A second screen is required between 7 days and 28 days of age.

COLLECTION INSTRUCTIONS

1. Legibly print ALL information in spaces provided using block capital letters.
2. Mark "test requested" box to indicate which screen (first or second) needs to be run.
3. If using this form to replace a lost or unusable kit form, cross out the miscellaneous number and write in original kit number.
4. Collect specimen with heel stick. See newborn screening handbook for detailed instructions.
5. Fill all 7 circles.
6. Dry 3-4 hours before mailing.

Mailing Instructions:

1. When blood is dry, fold stock card (from back of form) over blood spots. The flap should enclose the blood spots and reveal a biohazard symbol.
2. If using the postal service, place form with blood spots covered into envelope.

Mail to: Newborn Screening Laboratory
Utah Department of Health
46 N Medical Dr
Salt Lake City UT 84113-9903
Phone: (801) 584-8256

For more information, call, refer to your handbook or visit our website:
http://www.health.utah.gov/newbornscreening/MCF_instructions.htm

Retain this sheet for your records.

055M057

The miscellaneous newborn screening form includes the following fields:

MISCELLANEOUS NEWBORN SCREENING FORM
(BLOCK PRINT ALL CAPITALS - COMPLETE ENTIRE FORM)
FORM EXPIRES December 2008

Medical Record Number: _____ Sample collection date: MMDDYYYY
Baby's last name: _____ Baby's first name: _____
Sex: M F

Birthdate: MMDDYYYY

Phenothiazines: Yes No

Mother's maiden name: _____ Mother's legal first name: _____
Mailing address: _____
City: _____ State: _____ Zip: _____

Mother's birthdate: MMDDYYYY Mother's Area Code & Phone: _____
Baby's Medical Home: Doctor's Name: _____ Clinic Name: _____
Baby's Medical Home: Doctor's Address: _____
City: _____ State: _____ Zip: _____
Baby's Medical Home: Doctor's Clinic's Area Code & Phone: _____

TEST REQUESTED - Mark One
 First Screen Second Screen

RECALL SCREEN MARK ONLY IF INSTRUCTED
 Unacceptable Positive POST-TRANSFUSION

BELOW FOR UDOH LAB ONLY - DO NOT MARK
Sample Unacceptable

TRANSFUSIONS

Transfused blood adds foreign red blood cells (adult hemoglobin) to the infant's circulation thereby altering the level of fetal hemoglobin and enzymes found in the blood. Infants who have received transfusions containing red blood cells may not have an accurate screen. In addition, dialysis and plasma exchange transfusions may temporarily reduce the concentration of circulating metabolites and hormones for phenylketonuria (PKU) or hypothyroidism. This change may result in a false negative screen for PKU or a false positive screen for hypothyroidism.

- When possible, collect the first screening specimen prior to a transfusion.
- If the first screening specimen is collected after a transfusion, another specimen will be needed when the foreign red blood cells are no longer in circulation (approximately 120 days after the last transfusion given).
- Collect the second screening specimen 7-10 days after a transfusion is given.
- Newborn Screening Program personnel will follow up on all specimens with the 'Transfusion' box marked and/or if the hemoglobinopathy results are indicative of a transfusion (newborn's results will show a predominance of 'A' [adult] hemoglobin).

The Newborn Screening Program will need to review medical records and transfusion history. If a transfusion(s) is documented, instructions will be given for further action.

01 02 2007

SMITH

TWIN 1 X

YOUR HOSP



000A111x

01 01 2007
FOR UDOH LAB ONLY - DO NOT MARK
01/01/2007 1 2 3 6

UTAH DEPARTMENT OF HEALTH
FIRST NEWBORN SCREENING FORM

BLOCK PRINT ALL CAPITALS - COMPLETE ENTIRE FORM

FORM EXPIRES December 2007

Medical Record Number

Sample collection date MM/DD/YYYY

Baby's last name

Baby's first name
 M
 F

Birthplace/Hospital

Birthdate MM/DD/YYYY

- Breast
- Bottle
- Adopted
- Premature/sick
- Transfusion date:

BIRTHWEIGHT (gms)

SICK, PREMATURE, NICU INFANTS

The ideal timing to collect the first newborn screen is at 24 hours of life. If the baby is sick or preterm, certain interventions affect the newborn screen results. therefore we recommend the following:

1. Collect the **first** screen before treatment is started or transfusion is given.

- Certain treatments (TPN, synthetic blood products - darbepoetin, steroids, antibiotics*) and whole blood transfusion (packed red blood cells, whole blood, in-utero transfusions) can interfere with interpretation of the screening results.
- Otherwise, collect at 24-48 hours of age.
*If the infant will only be receiving antibiotics it is best to collect at 24-48 hours (i.e. chorioamnionitis prophylaxis).

2. Collect the **second** screen at 8 days of age

- Newborns discharged prior to 8 days of age should follow the routine collection requirement of collecting specimen between 7 and 28 days of age.

3. Mark all applicable fields on the newborn screen collection form (i.e. check or fill in the 'sick/preterm' box, TPN feeding, etc. as applicable). When marking the transfusion box include the date of the first transfusion or if prior to birth write "in-utero".

- This information allows for better result interpretation (differentiation between a possible disorder or a reflection of the medical state of the sick or preterm newborn).

Feeding:	Mark All That Apply:	Transfusion Date:
<input type="radio"/> Breast	<input type="radio"/> Preterm/sick	<input type="radio"/>
<input type="radio"/> Bottle	<input type="radio"/> Steroids	<input type="radio"/> Meconium Ileus
<input type="radio"/> TPN	<input type="radio"/> Adoption	<input type="radio"/> Antibiotics

UNSATISFACTORY SPECIMENS

The Utah State Lab frequently receives blood spot specimens in conditions that are unsatisfactory for testing. Unsatisfactory specimens are known to give invalid results. Submitting unsatisfactory specimens can result in delays and place the newborn at risk. A delay in processing could possibly result in death if the baby has a life-threatening disorder that would have otherwise been diagnosed if a satisfactory specimen was received and processed in a timely fashion.

Trained staff members review each specimen to determine if it is acceptable for testing or not.

If the specimen is determined to be unsatisfactory, the Newborn Screening tests are not done. The newborn's status - normal or abnormal - is unknown.

- Develop efficient procedures for recalling newborns, preparing data, and collecting filter paper blood spot specimens to replace the unsatisfactory specimens.
- Notification letter and screening result mailer (including the reason the sample was unsatisfactory) are sent to the hospital/birth institution for unsatisfactory **first** screening specimens [R438-15-4], and to the medical home on unsatisfactory **second** screening specimens [R438-15-7]. Recollect the screening on a miscellaneous card. Replacement miscellaneous cards can be ordered online. The hospital/birth institution is responsible for the collection of a repeat first screen in the event of an unsatisfactory specimen, even if the baby is no longer in the facility.
- Collect the repeat specimen for an unsatisfactory first screen and the specimen for the routine second screen on different days, at least five days apart. The Newborn Screening Program sometimes gets a repeat first specimen *after* having received the routine second specimen from the medical home. If the laboratory has not received the repeat first specimen, *do not draw the second specimen*. Call the facility at which the first specimen was collected and find out when the repeat first specimen was drawn. Make sure one full week has passed prior to collecting the second specimen.

When sending in a recall specimen, you will be instructed to mark the recall screen box.

Neonatal Screening

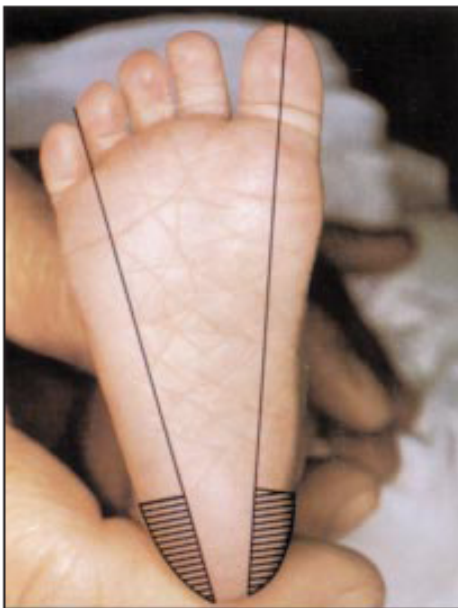
Blood Specimen Collection and Handling Procedure




- 1 Equipment: Sterile lancet with tip approximately 2.0 mm, sterile alcohol prep, sterile gauze pads, soft cloth (or disposable heat pack), blood collection form, gloves.



- 2 Complete ALL information. Do not contaminate filter paper circles by allowing the circles to come in contact with spillage or by touching before or after blood collection. Keep front sheet; sheet



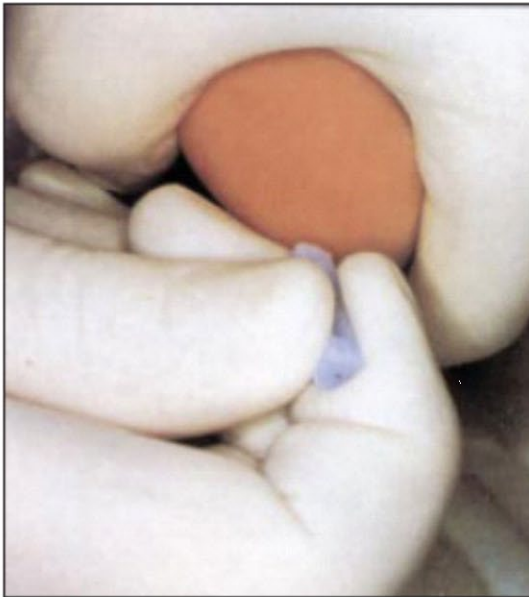
- 3 Hatched area () indicates safe areas for puncture site.



- 4 Warm site with a soft cloth moistened with warm water (up to 41° C), or a disposable heat pack, for three to five minutes.



- 5 Cleanse site with alcohol prep. Allow area to dry.



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



7 Lightly touch filter paper to LARGE blood drop. Allow blood to soak through and completely fill circle with a SINGLE application to LARGE blood drop. To enhance blood flow, VERY GENTLE



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.



9 Dry blood spots horizontally on drying rack provided by the Newborn Screening Program for at least 3 hours



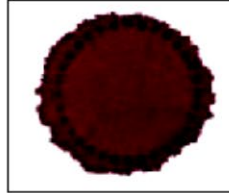
10 Send completed form to testing laboratory within 24 hours of collection. Use of a courier is recommended. To meet postal requirements, fold cardboard flap over blood specimen before mailing.

Information provided by The New York State Department of Health.

Schleicher & Schuell Inc. • 10 Optical Avenue • Keene N.H. 03431 USA • Tel. (603) 352-3810 • Fax (603) 355-6524 • Internet: <http://www.s-and-s.com> • e-mail: solutions@s-and-s.com
Schleicher & Schuell GmbH • P.O. Box 4, D-37582 Dassel • Germany • Tel. 49-5561-791-0 • Fax 49-5561-791536 • Internet: <http://www.s-und-s.de> • e-mail: salesdiagcomp@s-und-s.de

Simple Spot Check

Valid Specimen

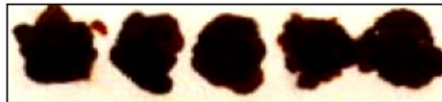


Allow a sufficient quantity of blood to soak through to completely fill the pre-printed circle on the filter paper. Fill all required circles with blood. Do not layer successive drops of blood or apply blood more than once in the same collection circle. Avoid touching or smearing spots.

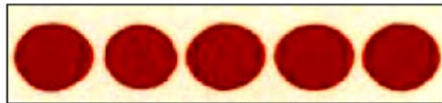
Invalid Specimens:



1. Specimen quantity insufficient for testing



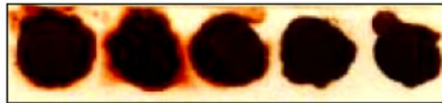
2. Specimen appears scratched or abraded.



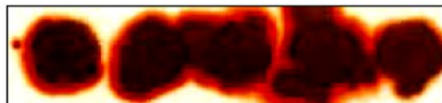
3. Specimen not dry before mailing.



4. Specimen appears supersaturated.



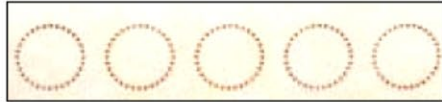
5. Specimen appears diluted, discolored or contaminated.



6. Specimen exhibits serum rings.



7. Specimen appears clotted or layered.



8. No blood.

Possible Causes:

- 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.
- Applying blood with a capillary tube or other device.
- Mailing specimen before drying for a minimum of four hours.
- Applying excess blood to filter paper, usually with a device.
- Applying blood to both sides of filter paper.
- 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.
- 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.
- Touching the same circle on filter paper to blood drop several times.
- Filling circle on both sides of filter paper.
- Failure to obtain blood specimen.

Information provided by The
New York State Department of Health.

BIRTH RECORD NUMBER – Kit Number

The Utah Department of Health and Human Services (DHHS) is legally required to collect four distinct data sets for each birth that occurs in Utah:

- 1) Newborn Screening data
- 2) Newborn Hearing data
- 3) Newborn pulse oximetry data and
- 4) Birth Certificate data.

The Newborn Screening Kit ID number, which is assigned to each Utah newborn, has been chosen as the 'Birth Record Number'. DHHS uses the newborn screening kit number to:

- Link the four data sets together with a single unique number
- Increase the accuracy of the data being collected
- Improve health status of newborns through enhanced follow-up activities
- Locate newborns missed in screening
- Identify newborns lost to follow-up
- Decrease/eliminate unnecessary contact of families of newborns that have expired.

The number is seven digits in length and includes both alpha and numeric characters (e.g. UT100A200). There are no spaces or hyphens in the number. The Newborn Screening kit will include a set of stick-on labels on the first screening form, which bear the Newborn Screening ID number. These labels can be placed in the field created for them on each of the other records. This unique number, called the "Birth Record Number" in the Hearing Screening and Birth Certificate databases, is used to identify each child.

Instructions:

- Assign the Birth Record Number for the newborn. This is the Newborn Screening kit number.
- Place a Birth Record Number label on the Birth Certificate worksheet, the Hearing Screening log, and the Newborn Screening log.

For Hearing Screening:



Hi*Track database use the 'Alternate record #' field

Hi*Screen database use the 'Medical ID' field

For Birth Certificate database:

Use the 'Newborn Screening Number' field

- If the first newborn screening form becomes contaminated or unusable for any reason, use a miscellaneous form. Enter the *original* kit number (one of the Birth Record Number labels may be applied over the miscellaneous number in each place) and mark the 'Test Requested' box as 'First Screen'. Collect the blood specimen.
- If the newborn expires prior to obtaining the newborn screen it is not necessary to assign a Birth Record Number. Enter "deceased" into the 'Newborn Screening number' field on the Birth Certificate, and into the 'inpatient screening results' field of the Hi*Track Hearing Screening database.
- Transfer of newborn to another institution:
 - 1) If transferred *prior* to assigning the Birth Record Number:
 - a) Enter "transferred" in to the 'Newborn Screening number' field on the Birth Certificate.
 - b) The receiving hospital is responsible for assigning the Birth Record Number, collecting the newborn screen first specimen, and entering the given Birth Record Number into the Hearing Screening database.
 - 2) If transferred *after* assigning the Birth Record Number and collecting the newborn screening first specimen, but before the hearing screen is done:
 - a) Notify the receiving nursery that the first newborn screening has been done and give the assigned Birth Record Number.
 - b) The receiving nursery is responsible for entering the Birth Record Number into the Hearing Screening database.
- Keep a detailed record of the assigned Birth Record Number for each infant, including the date each of the newborn screening specimens were drawn, and newborn's medical home.

Date of Birth	Name	Birth Weight	Birth Record/ Kit ID #	1 st done	Initials	2 nd done	Initials	Medical Home
1/1/2015	Smith	3216	000A100 	1/3/15	SB	1/15/15	SB	Bob Jones
1/2/2015	Jones	3159	000A000 	1/4/15	FK	D/C	FK	Family Peds.

Example: Birth Record Number Log -- Include the baby's date of birth, name, and assigned Birth Record Number. A stick-on label from the back of the first newborn screen form may be used. Make sure there is a place for the specimen collection date for both the first and the second screen, as some babies are still in the hospital at that time. If the baby has left the hospital before the second screen was drawn, "discharged" may be entered. The name of the baby's doctor or medical home should also be included in case the information is needed at a later date (i.e. the baby had an abnormal Newborn Screen and the doctor must be notified but no doctor was listed on the card). You may use our log (located on the following page), or create your own.

Appendix A

NEWBORN SCREENING STATUTE

26B-4-319 Testing of newborn infants.

(1) Except in the case where parents object on the grounds that they are members of a specified, well-recognized religious organization whose teachings are contrary to the tests required by this section, a newborn infant shall be tested for:

- (a) phenylketonuria (PKU);
- (b) other heritable disorders which may result in an intellectual or physical disability or death and for which:
 - (i) a preventive measure or treatment is available; and
 - (ii) there exists a reliable laboratory diagnostic test method;
- (c)
 - (i) an infant born in a hospital with 100 or more live births annually, hearing loss; and
 - (ii) an infant born in a setting other than a hospital with 100 or more live births annually, hearing loss; and
- (d) critical congenital heart defects using pulse oximetry.

(2) In accordance with Section 26-1-6, the department may charge fees for:

- (a) materials supplied by the department to conduct tests required under Subsection (1);
- (b) tests required under Subsection (1) conducted by the department;
- (c) laboratory analyses by the department of tests conducted under Subsection (1); and
- (d) the administrative cost of follow-up contacts with the parents or guardians of tested infants.

(3) Tests for hearing loss described in Subsection (1) shall be based on one or more methods approved by the Newborn Hearing Screening Committee, including:

- (a) auditory brainstem response;
- (b) automated auditory brainstem response; and
- (c) evoked otoacoustic emissions.

(4) Results of tests for hearing loss described in Subsection (1) shall be reported to:

- (a) the department; and
- (b) when results of tests for hearing loss under Subsection (1) suggest that additional diagnostic procedures or medical interventions are necessary:
 - (i) a parent or guardian of the infant;
 - (ii) an early intervention program administered by the department in accordance with Part C of the Individuals with Disabilities Education Act, 20 U.S.C. Sec. 1431 et seq.; and
 - (iii) the Utah Schools for the Deaf and the Blind, created in Section 53E-8-201.

(5)

- (a) There is established the Newborn Hearing Screening Committee.
- (b) The committee shall advise the department on:
 - (i) the validity and cost of newborn infant hearing loss testing procedures; and
 - (ii) rules promulgated by the department to implement this section.

- (c) The committee shall be composed of at least 11 members appointed by the executive director, including:
- (i) one representative of the health insurance industry;
 - (ii) one pediatrician;
 - (iii) one family practitioner;
 - (iv) one ear, nose, and throat specialist nominated by the Utah Medical Association;
 - (v) two audiologists nominated by the Utah Speech-Language-Hearing Association;
 - (vi) one representative of hospital neonatal nurseries;
 - (vii) one representative of the Early Intervention Baby Watch Program administered by the department;
 - (viii) one public health nurse;
 - (ix) one consumer; and
 - (x) the executive director or the executive director's designee.
- (d) Of the initial members of the committee, the executive director shall appoint as nearly as possible half to two-year terms and half to four-year terms. Thereafter, appointments shall be for four-year terms except:
- (i) for those members who have been appointed to complete an unexpired term; and
 - (ii) as necessary to ensure that as nearly as possible the terms of half the appointments expire every two years.
- (e) A majority of the members constitute a quorum, and a vote of the majority of the members present constitutes an action of the committee.
- (f) The committee shall appoint a chairman from the committee's membership.
- (g) The committee shall meet at least quarterly.
- (h) A member may not receive compensation or benefits for the member's service, but may receive per diem and travel expenses in accordance with:
- (i) Section 63A-3-106;
 - (ii) Section 63A-3-107; and
 - (iii) rules made by the Division of Finance pursuant to Sections 63A-3-106 and 63A-3-107.
- (i) The department shall provide staff for the committee.
- (6) Before implementing the test required by Subsection (1)(d), the department shall conduct a pilot program for testing newborns for critical congenital heart defects using pulse oximetry. The pilot program shall include the development of:
- (a) appropriate oxygen saturation levels that would indicate a need for further medical follow-up; and
 - (b) the best methods for implementing the pulse oximetry screening in newborn care units.

Appendix B

<https://adminrules.utah.gov/public/search/R438-15/Current%20Rules>

R438. Disease Control and Prevention, Laboratory Services.

R438-15. Newborn Screening.

R438-15-1. Purpose and Authority.

(1) The purpose of this rule is to facilitate early detection, prompt referral, early treatment, and prevention of disability and mental retardation in infants with certain genetic and endocrine disorders.

(2) Authority for the Newborn Screening program and promulgation of rules to implement the program are found in Sections 26-1-6, 26-1-30 and 26-10-6. 26B-4-319

R438-15-2. Definitions.

(1) "Abnormal test result" means a result that is outside of the normal range for a given test.

(2) "Appropriate specimen" means a blood specimen submitted on the Utah Newborn Screening form that conforms with the criteria in R438-15-9.

(3) "Blood spot" means a clinical specimen(s) submitted on the filter paper (specially manufactured absorbent specimen collection paper) of the Newborn Screening form using the heel stick method.

(4) "Department" means the Utah Department of Health.

(5) "Follow up" means the tracking of all newborns with an abnormal result, inadequate or unsatisfactory specimen or a quantity not sufficient specimen through to a normal result or confirmed diagnosis and referral.

(6) "Inadequate specimen" means a specimen determined by the Newborn Screening Laboratory to be unacceptable for testing.

(7) "Indeterminate result" means a result that requires another specimen to determine normal or abnormal status.

(8) "Institution" means a hospital, alternate birthing facility, or midwife service in Utah that provides maternity or nursery services or both.

(9) "Medical home/practitioner" means a person licensed by the Department of Commerce, Division of Occupational and Professional Licensing to practice medicine, naturopathy, or chiropractic or to be a nurse practitioner, as well as the licensed or unlicensed midwife who takes responsibility for delivery or the on-going health care of a newborn.

(10) "Metabolic diseases" means those diseases screened by the Department which are caused by an inborn error of metabolism.

(11) "Newborn Screening form" means the Department's demographic form with attached Food and Drug Administration (FDA)-approved filter paper medical collection device.

(12) "Quantity not sufficient specimen" or "QNS specimen" means a specimen that has been partially tested but does not have enough blood available to complete the full testing.

(13) "Unsatisfactory specimen" means an inadequate specimen.

R438-15-3. Newborn Screening Advisory Committee.

(1) Newborn Screening Advisory Committee shall be composed of at least 9 members as

follows:

- (a) an individual with an advanced degree (MS/PhD/MD) in genetics or other relevant field, who will serve as Chair;
 - (b) a representative from the Utah Hospital Association;
 - (c) a community pediatrician;
 - (d) the Director of the Division of Disease Control and Prevention;
 - (e) an advocate or a consumer of a newborn screening services;
 - (f) clinical consultants for the Newborn Screening program;
 - (g) a representative from the Utah Public Health Laboratory
 - (h) a representative from the Newborn Screening Follow-up Program;
 - (i) a representative from the research community with knowledge about disorders considered for future addition to the newborn screening panel.
- (2) The Department Executive Director shall approve committee membership with counsel from the advisory committee.
- (3) The term of committee members shall be four years;
- (a) members may serve up to three additional terms as requested;
 - (b) if a vacancy occurs in the committee membership for any reason, a replacement shall be appointed for the unexpired term in the same manner as the original appointment;
 - (c) a majority of the committee constitutes a quorum at any meeting. If a quorum is present, the action of the majority of members shall be the action of the advisory committee.
- (4) The committee shall:
- (a) advise the Department on policy issues related to newborn screening services;
 - (b) provide guidance to programs and functions within the Department having to do with newborn screening services and
 - (c) evaluate potential tests that could be added to newborn or population screening and make recommendations to the Department.

R438-15-4. Implementation.

(1) Each newborn in the state of Utah shall submit to the Newborn Screening testing, except as provided in Section R438-15-12.

(2) The Department of Health, after consulting with the Newborn Screening Advisory Committee, will determine the disorders on the Newborn Screening Panel, based on demonstrated effectiveness and available funding. Disorders for which the infant blood is screened are:

- (a) Biotinidase Deficiency;
- (b) Congenital Adrenal Hyperplasia;
- (c) Congenital Hypothyroidism;
- (d) Galactosemia;
- (e) Hemoglobinopathy;
- (f) Amino Acid Metabolism Disorders:
 - (i) Phenylketonuria (phenylalanine hydroxylase deficiency and variants);
 - (ii) Tyrosinemia type 1 (fumarylacetoacetate hydrolase deficiency);

- (iii) Tyrosinemia type 2 (tyrosine amino transferase deficiency);
- (iv) Tyrosinemia type 3 (4-OH-phenylpyruvate dioxygenase deficiency);
- (v) Maple Syrup Urine Disease (branched chain ketoacid dehydrogenase deficiency);
- (vi) Homocystinuria (cystathionine beta synthase deficiency);
- (vii) Citrullinemia (arginino succinic acid synthase deficiency);
- (viii) Argininosuccinic aciduria (argininosuccinic acid lyase deficiency);
- (ix) Argininemia (arginase deficiency);
- (x) Hyperprolinemia type 2 (pyroline-5-carboxylate dehydrogenase deficiency);
- (g) Fatty Acid Oxidation Disorders:
 - (i) Medium Chain Acyl CoA Dehydrogenase Deficiency;
 - (ii) Very Long Chain Acyl CoA Dehydrogenase Deficiency;
 - (iii) Short Chain Acyl CoA Dehydrogenase Deficiency;
 - (iv) Long Chain 3-OH Acyl CoA Dehydrogenase Deficiency;
 - (v) Short Chain 3-OH Acyl CoA Dehydrogenase Deficiency;
 - (vi) Primary carnitine deficiency (OCTN2 carnitine transporter defect);
 - (vii) Carnitine Palmitoyl Transferase I Deficiency;
 - (viii) Carnitine Palmitoyl Transferase 2 Deficiency;
 - (ix) Carnitine Acylcarnitine Translocase Deficiency;
 - (x) Multiple Acyl CoA Dehydrogenase Deficiency;
- (h) Organic Acids Disorders:
 - (i) Propionic Acidemia (propionyl CoA carboxylase deficiency);
 - (ii) Methylmalonic acidemia (multiple enzymes);
 - (iii) Malonic Aciduria;
 - (iv) Isovaleric acidemia (isovaleryl CoA dehydrogenase deficiency);
 - (v) 2-Methylbutyryl CoA dehydrogenase deficiency;
 - (vi) Isobutyryl CoA dehydrogenase deficiency;
 - (vii) 2-Methyl-3-OH-butyryl-CoA dehydrogenase deficiency;
 - (viii) Glutaric acidemia type 1 (glutaryl CoA dehydrogenase deficiency);
 - (ix) 3-Methylcrotonyl CoA carboxylase deficiency;
 - (x) 3-Ketothiolase deficiency;
 - (xi) 3-Hydroxy-3-methyl glutaryl CoA lyase deficiency;
 - (xii) Holocarboxylase synthase (multiple carboxylases) deficiency;
- (i) Cystic Fibrosis;
- (j) Severe Combined Immunodeficiency syndrome; and
- (k) Disorders of Creatine Metabolism
- (l) Spinal Muscular Atrophy and
- (m) X-Linked Adrenoleukodystrophy
- (n) Mucopolysaccharidosis type 1
- (o) Pompe disease

R438-15-5. Responsibility for Collection of the First Specimen.

(1) If the newborn is born in an institution, the institution must collect and submit an appropriate specimen, unless the newborn is transferred to another institution prior to 48 hours of age.

(2) If the newborn is born outside of an institution, the practitioner or other person primarily responsible for providing assistance to the mother at the birth must arrange for the collection and submission of an appropriate specimen.

(3) If there is no other person in attendance of the birth, the parent or legal guardian must arrange for the collection and submission of an appropriate specimen.

(4) If the newborn is transferred to another institution prior to 48 hours of age, the receiving health institution must collect and submit an appropriate specimen.

R438-15-6. Timing of Collection of First Specimen.

The first specimen shall be collected between 24 and 48 hours of the newborn's life. Except:

(1) If the newborn is discharged from an institution before 48 hours of age, an appropriate specimen must be collected within four hours of discharge.

(2) If the newborn is to receive a blood transfusion or dialysis, the appropriate specimen must be collected immediately before the procedure, except in emergency situations where time does not allow for collection of the specimen. If the newborn receives a blood transfusion or dialysis prior to collecting the appropriate specimen the following must be done:

(a) Repeat the collection and submission of an appropriate specimen 7-10 days after last transfusion or dialysis for a second screening specimen;

(b) Repeat the collection and submission of an appropriate specimen 120 days after last transfusion or dialysis for a first screening specimen.

R438-15-7. Parent Education.

The person who has responsibility under Section R438-15-5 shall inform the parent or legal guardian of the required collection and submission and the disorders screened. That person shall give the second half of the Newborn Screening form to the parent or legal guardian with instructions on how to arrange for collection and submission of the second specimen.

R438-15-8. Timing of Collection of the Second Specimen.

A second specimen shall be collected between 7 and 16 days of age.

(1) The parent or legal guardian shall arrange for the collection and submission of the appropriate second specimen through an institution, medical home/practitioner, or local health department.

(2) If the newborn's first specimen was obtained prior to 24 hours of age, the second specimen shall be collected by fourteen days of age.

(3) If the newborn is hospitalized beyond the seventh day of life, the institution shall arrange for the collection and submission of the appropriate second specimen.

R438-15-9. Criteria for Appropriate Specimen.

(1) The institution or medical home/practitioner collecting the appropriate specimen must:

(a) Use only a Newborn Screening form purchased from the Department. The fee for the Newborn Screening form is set by the Legislature in accordance with Section 26-1-6;

(b) Correctly store the Newborn Screening form;

(c) Not use the Newborn Screening form beyond the date of expiration;

- (d) Not alter the Newborn Screening form in any way;
 - (e) Complete all information on the Newborn Screening form. If the infant is being adopted, the following may be omitted: infant's last name, birth mother's name, address, and telephone number. Infant must have an identifying name, and a contact person must be listed;
 - (f) Apply sufficient blood to the filter paper;
 - (g) Not contaminate the filter paper with any foreign substance;
 - (h) Not tear, perforate, scratch, or wrinkle the filter paper;
 - (i) Apply blood evenly to one side of the filter paper and be sure it soaks through to the other side;
 - (j) Apply blood to the filter paper in a manner that does not cause caking;
 - (k) Collect the blood in such a way as to not cause serum or tissue fluids to separate from the blood;
 - (l) Dry the specimen properly;
 - (m) Not remove the filter paper from the Newborn Screening form.
- (2) Submit the completed Newborn Screening form to the Utah Department of Health, Newborn Screening Laboratory, 4431 South 2700 West, Taylorsville, Utah 84119.
- (a) The Newborn Screening form shall be placed in an envelope large enough to accommodate it without folding the form.
 - (b) If mailed, the Newborn Screening form shall be placed in the U.S. Postal system within 24 hours of the time the appropriate specimen was collected.
 - (c) If hand-delivered, the Newborn Screening form shall be delivered within 48 hours of the time the appropriate specimen was collected.

R438-15-10. Abnormal Result.

- (1)(a) If the Department finds an abnormal result consistent with a disease state, the Department shall send written notice to the medical home/practitioner noted on the Newborn Screening form.
 - (b) If the Department finds an indeterminate result on the first screening, the Department shall determine whether to send a notice to the medical home/practitioner based on the results on the second screening specimen.
- (2) The Department may require the medical home/practitioner to collect and submit additional specimens for screening or confirmatory testing. The Department shall pay for the initial confirmatory testing on the newborn requested by the Department. The Department may recommend additional diagnostic testing to the medical home/practitioner. The cost of additional testing recommended by the Department is not covered by the Department.
- (3) The medical home/practitioner shall collect and submit specimens within the time frame and in the manner instructed by the Department.
- (4) As instructed by the Department or the medical home/practitioner, the parent or legal guardian of a newborn identified with an abnormal test result shall promptly take the newborn to the Department or medical home/practitioner to have an appropriate specimen collected.
- (5) The medical home/practitioner who makes the final diagnosis shall complete a diagnostic form and return it to the Department within 30 days of the notification letter from the Department.

R438-15-11. Inadequate or Unsatisfactory Specimen, or QNS Specimen.

If the Department finds an inadequate or unsatisfactory specimen, or QNS specimen, the Department shall inform the institution or medical home/practitioner noted on the Newborn Screening form.

(1) The institution or medical home/practitioner that submitted the inadequate or unsatisfactory, or QNS specimen shall submit an appropriate specimen in accordance with Section R438-15-9. The responsible institution or medical home/practitioner shall collect and submit the new specimen within two days of notice, and the responsible institution or medical home/practitioner shall label the form for testing as directed by the Department.

(2) The parent or legal guardian of a newborn identified with an inadequate or unsatisfactory specimen or QNS specimen shall promptly take the newborn to the institution or medical home/practitioner to have an appropriate specimen collected.

R438-15-12. Testing Refusal.

A parent or legal guardian may refuse to allow the required testing for religious reasons only. The medical home/practitioner or institution shall file in the newborn's record documentation of refusal, reason, education of family about the disorders, and a signed waiver by both parents or legal guardian. The practitioner or institution shall submit a copy of the refusal to the Utah Department of Health, Newborn Screening Program, P.O. Box 144710, Salt Lake City, UT 84114-4710.

R438-15-13. Access to Medical Records.

(1) The Department shall have access to the medical records of a newborn in order to identify medical home/practitioner, reason appropriate specimen was not collected, or to collect missing demographic information.

(2) The institution shall enter the Newborn Screening form number, also known as the Birth Record Number, into the Vital Records database and the Newborn Hearing Screening database.

R438-15-14. Noncompliance by Parent or Legal Guardian.

If the medical home/practitioner or institution has information that leads it to believe that the parent or legal guardian is not complying with this rule, the medical home/practitioner or institution shall report such noncompliance as medical neglect to the Department.

R438-15-15. Confidentiality and Related Information.

(1) The Department initially releases test results to the institution of birth for first specimens and to the medical home/practitioner, as noted on the Newborn Screening form, for the second specimen.

(2) The Department notifies the medical home/practitioner noted on the Newborn Screening form as provided in Section R438-15-10(1) of any results that require follow up.

(3) The Department releases information to a medical home/practitioner or other health practitioner on a need to know basis. Release may be orally, by a hard copy of results or available electronically by authorized access.

(4) Upon request of the parent or guardian, the Department may release results as

directed in the release.

(5) All requests for test results or records are governed by Utah Code Title 26, Chapter 3.

(6) The Department may release information in summary, statistical, or other forms that do not identify particular individuals.

(7) A testing laboratory that analyzes newborn screening samples for the Department may not release information or samples without the Department's express written direction.

R438-15-16. Blood Spots.

(1) Blood spots become the property of the Department.

(2) The Department includes in parent education materials information about the Department's policy on the retention and use of residual newborn blood spots.

(3) The Department may use residual blood spots for newborn screening quality assessment activities.

(4) The Department may release blood spots for research upon the following:

(a) The person proposing to conduct the research applies in writing to the Department for approval to perform the research. The application shall include a written protocol for the proposed research, the person's professional qualifications to perform the proposed research, and other information if needed and requested by the Department. When appropriate, the proposal will then be submitted to the Department's Internal Review Board for approval.

(b) The Department shall de-identify blood spots it releases unless it obtains informed consent of a parent or guardian to release identifiable samples.

(c) All research must be first approved by the Department's Internal Review Board.

R438-15-17. Retention of Blood Spots.

(1) The Department retains blood spots for a minimum of 90 days.

(2) Prior to disposal, the Department shall de-identify and autoclave the blood spots.

R438-15-18. Reporting of Disorders.

If a diagnosis is made for one of the disorders screened by the Department that was not identified by the Department, the medical home/practitioner shall report it to the Department.

R438-15-19. Statutory Penalties.

As required by Subsection 63G-3-201(5): Any medical home/practitioner or institution responsible for submission of a newborn screen that violates any provision of this rule may be assessed a civil money penalty as provided in Section 26-23-6.

KEY: health care, newborn screening

Date of Enactment or Last Substantive Amendment: January 29, 2018

Authorizing, and Implemented or Interpreted Law: 26-1-6; 26-1-30; 26-10-6 26B-4-319



RELIGIOUS OBJECTION TO NEWBORN SCREENING

I/We, _____ and _____,
PRINT Parent or Guardian Full Name PRINT Parent or Guardian Full Name

am/are the parent(s)/legal guardian(s) of _____, who was born
PRINT Name of Infant

on ____/____/____ (date of birth).
Month Day Year

I/We understand that Utah law [§ 26B-4-319] requires that each newborn infant be tested for disorders which may result in an intellectual or physical disability or death. Disorders for which infants are screened are listed under Utah Rule 438-15.

I/we further understand that religious objection is the only reason which Utah rule allows for refusal to have newborn screening performed.

I/We understand that failure to detect and treat any of these conditions within the first few days or weeks of life can be life threatening or cause significant disabilities.

I/We have received a copy of the Newborn Screening informational brochure and have read it. Our health care provider _____ (print name) has informed us of the seriousness of these conditions.

With full knowledge of the possible consequences, I/we object to the newborn screening testing on the grounds that I/we am/are members of the _____ religion, which is a specified, well recognized, religious organization whose teachings are contrary to the testing required by Utah law for each newborn infant.

Parent/Guardian Signature Date

Parent/Guardian Signature Date

Witnessed by (Print Name): _____

Witness Signature Date

Fax or Mail completed and signed form to:

Utah Public Health Laboratory
Newborn Screening Program
PO Box 144710
Salt Lake City - Utah 84114
Fax: 801-536-0966

FREQUENTLY ASKED QUESTIONS

What do we do if the family brings their baby in for his/her second screen and they forgot/lost the second screen card?

- **Use a miscellaneous form.** Miscellaneous forms are supplied without cost as replacement forms for inadequate specimens, for recall specimens, or for use when the original kit form that was given to the parent/caregiver by the hospital or birthplace has been lost.
- Write the original Kit ID Number in place of the miscellaneous number in all three places on the form. This original kit number was issued by the hospital of birth and can usually be obtained from the Kit ID log kept in the hospital nursery.
- Mark the 'Test Requested' box for the appropriate screen needed. Please mark if you are requesting a first or a second screen.
- The 'Recall Screen' box is to be marked only if you have been instructed to do so by the program. It is used to notify the lab of the need for the recall specimen procedure and testing.

We have to use a miscellaneous form, how do we get the baby's original Kit ID number?

- **This original kit number was issued by the hospital of birth and can usually be obtained from the Kit ID log kept in the hospital nursery.** If you are having trouble obtaining the number from the hospital, please call the Newborn Screening Program for assistance.

We have a baby that was born at home and he/she never had a first screen, what do we do?

- **If the newborn is born outside of an institution, the practitioner or other person primarily responsible for providing assistance to the mother at the birth must arrange for the collection and submission of an appropriate specimen.** If there is no other person in attendance of the birth, the parent or legal guardian must arrange for the collection and submission of an appropriate specimen. The parents can purchase a Newborn Screening Kit by contacting the Newborn Screening Program prior to the birth of the baby.

We accidentally put the blood for the first screen on the second screen card or vice versa?

- **Sometimes there is an error and the blood is placed on the wrong card.** Rather than throw out the specimen, you may use that card and send it in. **Make sure to write on the card what screen it is.** If it is a first screen on a second card – write **FIRST SCREEN** on the card. If it is a second screen on a first card – write **SECOND SCREEN** on the card. Do not use whiteout.

What if the baby was not born in Utah?

- **Follow the protocol for the state the baby was born in.** Each state's newborn screening laws and rules are different.

The baby was adopted; what demographic information should we put on the newborn screening card?

- **Adoption issues may cause some confusion.** The Newborn Screening Program maintains patient and record confidentiality. The first screening form must be completed with information to identify the baby and health care provider. If there is concern about entering the birth mother's information, the adoptive agency or adoptive mother's information may be entered. A contact person **must** be entered. [R438-15-9 (e)] The second screening form and education should be given to the adoptive agent or adoptive parents with instructions for collection and submission of the second screen specimen. Do not fill out the information on the second screen card. The card should be completed at the health care provider's office with the adoptive names entered.
- **For surrogate births.** Complete the first screen with the birth mother's information (not biological mother). Mark adoption on the card and write in surrogate next to the adoption bubble.

We have a baby that needs a second screen but he/she has casts on both feet, what should we do?

- **If the baby has casts on both feet and the baby did not have any abnormal tests on his/her first screen, obtain second screen when/if casts are changed or when the casts are removed.** We can screen babies up to six months of age. If the baby had abnormal test results please contact the Newborn Screening Program to determine plan of care.

What if the parents refuse to have a newborn screen done?

- **A parent or legal guardian may refuse to allow the required testing for religious reasons only.** The medical home/practitioner or institution shall file in the newborn's record documentation of refusal, reason, education of family about the disorders, and signed waiver by both parents or legal guardian. The practitioner or institution shall submit a copy of the refusal to the Utah Public Health Laboratory, Newborn Screening Program, P.O. Box 144710, Salt Lake City, UT 84114-4710.