

Newborn Screening Program Practitioner's Manual



**Department of Health
& Human Services**

Utah Public
Health Laboratory

STATE OF UTAH UTAH PUBLIC HEALTH LABORATORY NEWBORN SCREENING PROGRAM

Revised September 2026

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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.	
• Link the three data sets together with a single unique number	29

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NEWBORN SCREENING KIT ORDERING

FEE
(effective July 1, 2025)

\$148

TWO-PART KIT
(first and second screening cards)

The two-part kit contains the first and second newborn screening cards, educational material, consent for retention, 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.

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 at 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.

This handbook helps in understanding the newborn screening forms and how to fill them out correctly. Getting the right details on these forms is very important. It allows health officials to find families and doctors quickly if a baby needs help. If a form has missing or incorrect information, or if the medical sample is bad, the lab cannot test it. This delays care and can put a baby's health at serious risk. The hospital where the baby is born, or midwife or doctor helping with the birth, is responsible for starting this 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 intellectual disability. 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. Currently, Newborn Screening has expanded to include screening babies for biotinidase, congenital adrenal hyperplasia, congenital hypothyroidism, galactosemia, hemoglobinopathies, 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 type I, mucopolysaccharidosis type II, and Pompe.

The Newborn Screening Program is administered under the laws [Statute 26B-4-319, Appendix A] 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, oversees screening. This includes 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 individuals who are authorized to access data 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.

RESPONSIBILITIES REGARDING SPECIMEN COLLECTION

FIRST SPECIMEN

Hospital personnel, midwives, and birth attendants are responsible for two critical steps:

- Fill out the required personal data completely on the form
- Collect and submit a valid, testable blood specimen (refer to the *Simple Spot Check* guide on page 26).

Newborn screening involves multiple departments and team members. Because patients are being discharged faster than ever, hospitals must assign one staff member the clear responsibility and authority to oversee this process. This coordinator ensures everyone works together so no baby misses their screening.

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 health care provider information. When a baby is being adopted, include a specific identifying name and a designated contact person in the documentation. [R438-15-8 (4)]
- 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, during the first screen collection, is discouraged as many items change between collection of the first and second specimens.***
- Collect an appropriate blood specimen using the heel-stick method. [R438-15-8] ***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 heel stick 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 of life, however, there may be exceptions. [R438-15-7] *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. [R438-15-5 (3b)] This may necessitate drawing the specimen prior to 24-48 hours of age.
- Allow the specimen to dry horizontally at room temperature for 3-4 hours.
- Transport the 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. [R438-15-8 (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. [R438-15-6]
- Develop efficient procedures for prompt collection of the screening specimen on the newborn whose first specimen was determined to be abnormal [R438-15-9] or unsatisfactory for testing (could not test). [R438-15-10]

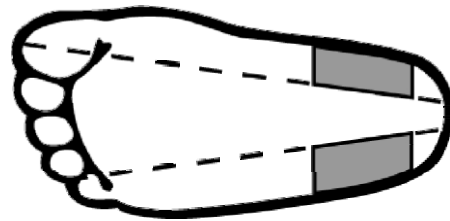
SECOND SCREENING SPECIMEN

Utah law requires that all newborns have a second specimen drawn between 7 and 16 days of age. 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 (refer to *Simple Spot Check* on page 26).

Responsibilities regarding the second screening specimen:

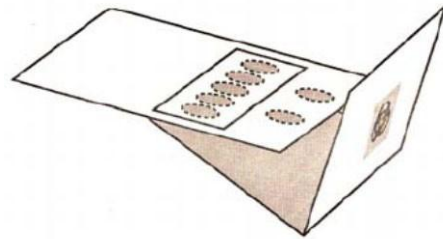
- Develop efficient procedures for preparation of data and collection of the second screening specimen on every newborn. [R438-15-7]
- Collect and record all information requested on the data portion of the second screen form: Infant name, gender, feeding, adoption, transfusion (if applicable), date 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. [R438-15-8 (4)]
- Make certain that every item is completed and correct. Print in block, capital letters using blue or 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 heel stick 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. [R438-15-7] *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. [R438-15-5 (b)]
- 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 delays in receipt and testing of specimen. [R438-15-8 (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 [R438-15-9] or unsatisfactory for testing (could not test). [R438-15-10]

SUBMITTING THE NEWBORN SCREENING FORM

The testing for the Newborn Screen is “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 include CLIA’s minimum required data that must be collected to comply.

The requested data is required 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 of 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 comes 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 the 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 delays 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 UPHL 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' for 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 can also identify a baby from another state born on the same day with the same last name and gender. 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), Total parenteral nutrition (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 so the Newborn Screening Program can notify them of critical results if needed. [R438-15-8 (5)]
- 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.*

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).

PCP/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.

PCP/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 can distinguish the recall specimen from a routine specimen.

SPECIAL INSTRUCTIONS - Abnormal Results

Newborn Screening 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 confirmatory 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
& Human Services**
Utah Public
Health Laboratory

Department of Health & Human Services- Utah Public Health Laboratory
4431 South 2700 West
Taylorsville, UT 84129
Phone: 801-584-8256 Fax: 801-536-0966
newbornscreening.utah.gov

Name:	EXAMPLE, BABY	Birth Hospital:	EXAMPLE HOSPITAL
Sex:	M	Provider:	EXAMPLE.DOCTOR
DOB:	8/7/2026	Sample #:	F2010924202677
UT (kit) #:	UT201A924	Date Collected:	8/9/2026
Hospital MR #	x-1234567	Date Received:	8/10/2026
Mothers Name:	EXAMPLE, GUARDIAN	Date Authorized:	8/10/2026
		Date Printed:	8/10/2026

Overall Determination	Normal			
Amino Acid Profile	Normal			
Acylcarnitine Profile	Normal			
Biotinidase Deficiency	Normal			
Galactosemia	Normal			
	Enzyme Activity	10.8	U/gHb	(>3.0)
Congenital Adrenal Hyperplasia	Normal			
	17-OHP	5.0	ng/mL	
<u>Comments:</u> 17-OHP Reference range: <25 ng/mL				
Congenital Hypothyroidism	Normal			
	TSH	10.0	uIU/mL	(0 - 40)
Cystic Fibrosis	Normal			
	IRT	18.8	ng/mL	(<51)
Hemoglobinopathies (IEF)	Normal - FA			
SCID	Normal			
Spinal Muscular Atrophy	Normal			
X-Linked Adrenoleukodystrophy	Normal			
	C26:0-LPC	0.05	umol/L	(<0.180)
Pompe Disease	Normal			
MPS1	Normal			
MPS2	Normal			

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 healthcare provider. If glucocorticoids are administered to an infant or mother, use caution when interpreting the CAH result.

SMA, SCID, amino acids, acylcarnitines, MPS1, MPS2, Pompe and X-Linked Adrenoleukodystrophy tests were developed and their performance characteristics determined by the Utah Public Health Laboratory. They have not been cleared or approved by the FDA.

Second tier testing for MPS1, MPS2, acylcarnitines, and amino acids are performed by Mayo Clinic Laboratories, 3050 Superior Dr NW, Rochester MN 55901. CAH second tier testing is performed by ARUP Laboratories, 500 Chipeta Way, Salt Lake City, UT 84108.



ABNORMAL RESULT



**Department of Health
& Human Services**
Utah Public
Health Laboratory

Department of Health & Human Services- Utah Public Health Laboratory
4431 South 2700 West
Taylorsville, UT 84129
Phone: 801-584-8256 Fax: 801-536-0966
newbornscreening.utah.gov

Name:	EXAMPLE, BABY	Birth Hospital:	EXAMPLE HOSPITAL
Sex:	F	Provider:	EXAMPLE, DOCTOR
DOB:	8/3/2026	Sample #:	F2010936202677
UT (kit) #:	UT201A936	Date Collected:	8/7/2026
Hospital MR #	x-123456	Date Received:	8/10/2026
Mothers Name:	EXAMPLE, GUARDIAN	Date Authorized:	8/10/2026
		Date Printed:	8/10/2026

Overall Determination	ABNORMAL	*
Amino Acid Profile	Normal	
Acylcarnitine Profile	Normal	
Biotinidase Deficiency	Normal	
Galactosemia	ABNORMAL	*
Enzyme Activity	1.2 L U/gHb	(>3.0)
<u>Comments:</u> Results indicate this newborn may have galactosemia. Additional testing and referral to the Metabolic Clinic at Primary Children's Hospital (801-213-3599) is recommended. ACTION: GALACTOSEMIA PANEL AND REFERRAL TO METABOLIC CLINIC		
Congenital Adrenal Hyperplasia	Normal	
17-OHP	5.0	ng/mL
<u>Comments:</u> 17-OHP Reference range: <25 ng/mL		
Congenital Hypothyroidism	Normal	
TSH	10.0	uIU/mL (0 - 40)
Cystic Fibrosis	Normal	
IRT	18.8	ng/mL (<51)
Hemoglobinopathies (IEF)	Normal - FA	
SCID	Normal	
Spinal Muscular Atrophy	Normal	
X-Linked Adrenoleukodystrophy	Normal	
C26:0-LPC	0.05	umol/L (<0.180)
Pompe Disease	Normal	
MPS1	Normal	

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 healthcare provider. If glucocorticoids are administered to an infant or mother, use caution when interpreting the CAH result.

SMA, SCID, amino acids, acylcarnitines, MPS1, MPS2, Pompe and X-Linked Adrenoleukodystrophy tests were developed and their performance characteristics determined by the Utah Public Health Laboratory. They have not been cleared or approved by the FDA.

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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 birth hospital 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.

Utah Newborn Screening Miscellaneous Specimen
SEE BACK FOR BLOOD SPOT COVER

GENERAL INSTRUCTIONS

- FIRST SPECIMENS:**
 - Collect specimen between 24 and 48 hours of life.
 - If newborn is discharged before 24 hours, collect specimen as close to discharge as possible.
- SECOND SPECIMENS:** A second screen is required between 7 and 16 days of age.

COLLECTION INSTRUCTIONS

- Legibly print ALL information in spaces provided using black capital letters in blue or black ink. A B C D E F G H I J K L M N O P Q R S T U V W X Y Z 1 2 3 4 5 6 7 8 9 0
- Mark "TEST REQUESTED" box to indicate which screen (FIRST or SECOND) needs to be run.
- If using this form to replace a lost or unusable kit form, cross out the miscellaneous number and write in original kit number.
- Collect specimen with heel stick.
- Fill all 7 circles. Use one large drop of blood per circle.
- Dry 3-4 hours before mailing.

MAILING INSTRUCTIONS:
See Back For Blood Spot Cover

- 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. Do not use plastic bags.
- If using the postal service, place form with blood spots covered into envelope. **One sample per envelope.**

Mail to: UTAH PUBLIC HEALTH LABORATORY
NEWBORN SCREENING
SMDS BOX 144300
PO BOX 31431
SALT LAKE CITY UT 84131-9988

For more information, call, refer to your handbook or visit our website:
newbornscreening.health.utah.gov

Retain this sheet for your records.

SN **UT459M339** ID Number

PEEL AWAY THIS PART HERE

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 birth hospital.

2 Check expiration date.
Do not use if expired.

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

Only 1 large drop per circle
FOR UDOH LAB ONLY - DO NOT MARK

UT459M339

FOR UDOH LAB ONLY - DO NOT MARK

UT459M339

FOR UDOH LAB ONLY - DO NOT MARK

UT459M339

FOR UDOH LAB ONLY - DO NOT MARK

UT459M339

FOR UDOH LAB ONLY - DO NOT MARK

UTAH DEPARTMENT OF HEALTH
MISCELLANEOUS NEWBORN SCREENING FORM
COMPLETE ENTIRE FORM
FORM EXPIRES APRIL 30 2028

Medical Record Number _____ Sample collection date MM/DD/YYYY M

Baby's last name _____ Baby's first name _____

Birthplace/Hospital _____ Birthdate MM/DD/YYYY

Feeding: ☐ Breast ☐ Formula ☐ Transfusion Date: _____
☐ Bottle ☐ Steroids ☐ Meconium Stool ☐ Multi-Birth (Circle one): A B C D
☐ TPN ☐ Antibiotics

Mother's legal last name _____ Mother's legal first name _____

Mother's maiden name _____

Mother's mailing address _____ City _____ State _____ Zip _____

Mother's birthdate MM/DD/YYYY _____ Mother's Area Code & phone _____

Baby's Medical Home Doctor's Name / Clinic Name _____ 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 1st / 2nd ☐ 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 7-16 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.

		FOR UDOH LAB ONLY - DO NOT MARK	
000A111			
UTAH DEPARTMENT OF HEALTH FIRST NEWBORN SCREENING FORM			
BLOCK PRINT ALL CAPITALS - COMPLETE ENTIRE FORM			
FORM EXPIRES December 2007		0 1 - 0 2 - 2 0 0 7	
2 3 4 5 6 7 8		Sample collection date MM/DD/YYYY	
Medical Record Number			
S M I T H		Baby's last name	
		Baby's first name	
Y O U R H O S P I T A		0 1 - 0 1 - 2 0 0 7	
Birthplace/Hospital		Birthdate MM/DD/YYYY	
☐ Breast ☐ Adopted ☒ Transfusion date: 01-01-2007		1 2 3 6	
☐ Bottle ☐ Premature/sick		BIRTHWEIGHT (gms)	

SICK, PREMATURE, NICU INFANTS

The ideal time to collect the first newborn screen is 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.
 - 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 16 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:
☐ Breast	.	☐ Preterm/sick
☐ Bottle		☐ Steroids
☐ TPN		☐ Adoption
		☐ Transfusion Date:
		☐ Meconium Ileus
		☐ 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 healthcare provider 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.
- **Never draw a routine second screen if an unsatisfactory first screen hasn't been repeated yet.** Keep these two collections separate and spaced out.
 - **Separate the dates:** Ensure you collect the repeat specimen and the routine second specimen on different days, **at least 5 days apart.**
 - **Verify before you draw:** If the laboratory hasn't received the repeat first specimen yet, do not collect the second specimen.
 - **Track it down:** Call the facility that collected the first specimen to find out exactly when they drew the repeat.
- When sending in a recall specimen, you will be instructed to mark the recall screen box.

Neonatal Screening

Blood Specimen Collection and Handling Procedure



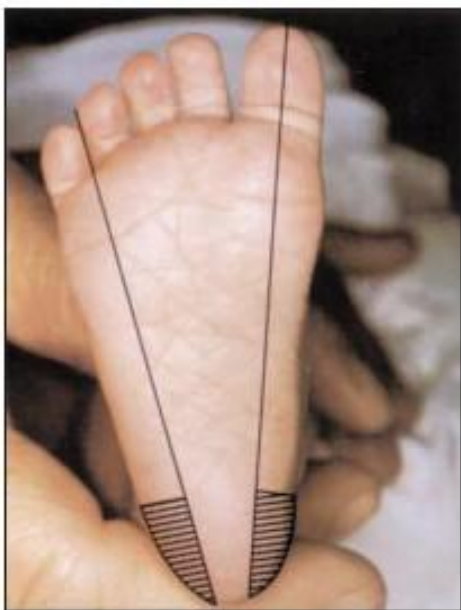
- 1 Equipment: Sterile lancet with tip approximately 2.0 mm, sterile alcohol prep, sterile gauze pads, soft cloth (or disposable heat pack), blood collection form, gloves.



- 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.



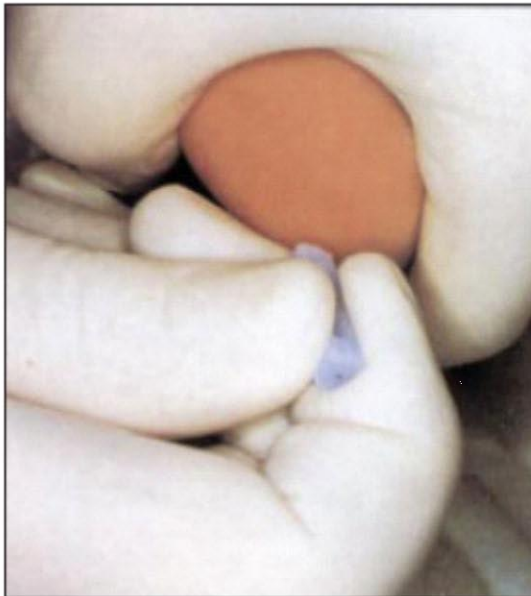
- 4 Warm site with a soft cloth moistened with warm water (up to 41° C), or a disposable heat pack, for three to five minutes.



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



- 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.



- 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.

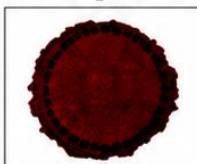
Information provided by The New York State Department of Health.

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: salediagcomp@s-und-s.de

Simple Spot Check

Check your specimen before sending!

Valid Specimen



Allow **enough** 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 Specimen	Example	Possible Causes
1. Specimen quantity insufficient for testing		- Removing filter paper before blood has filled circle or before blood has soaked through to second side. - Applying blood to filter paper with a capillary tube. - Touching filter paper before or after blood specimen collection with gloved or ungloved hands, hand lotion, etc. - Allowing filter paper to come in contact with gloved or ungloved hands or substances such as hand lotion or powder, either before or after blood specimen collection.
2. Specimen appear scratched or abraded		Applying blood with a capillary tube or other device.
3. Specimen not dry before mailing		Mailing specimen before drying for a minimum of four hours.
4. Specimen appears supersaturated		- Applying excess blood to filter paper with a device. - Applying blood to both sides of filter paper.
5. Specimen appears diluted, discolored or contaminated		- Squeezing or "milking" of area surrounding the puncture site. - Allowing filter paper to come in contact with gloved or ungloved hands or substances such as alcohol, formula, antiseptic solutions, water, hand lotion or powder, etc., either before or after blood specimen collection. - Exposing blood spots to direct heat.
6. Specimen exhibits serum rings		- Not wiping alcohol from puncture site before making skin puncture. - Allowing filter paper to come in contact with alcohol, hand lotion, etc. - Squeezing area surrounding puncture site excessively. - Drying specimen improperly. - Applying blood to filter paper with a capillary tube.
7. Specimen appears clotted or layered		- Touching the same circle on filter paper to blood drop several times. - Filling circle on both sides of filter paper.
8. No blood		Failure to obtain blood specimen.

*Information provided by
The New York State Department of Health*

CONSENT FOR RETENTION FORM

The State of Utah requires that every newborn has completed the consent for retention form and that educational materials are given to the family. Both items are included directly inside the Newborn Screening kit. This form legally directs the Utah Public Health Laboratory on what to do with the child's dried blood spot after testing is complete.

The parent needs to read and select one box to allow UPHL to retain the sample for 7 years or destroy the sample after 90 days. Attach one of the labels provided that includes the bar code to the top of the consent for retention form and send it with the kit. Consent for retention forms may also be sent by fax, 801-536-0966, or email, newbornscreening@utah.gov to the Newborn Screening Program.



**Department of Health
& Human Services**

Utah Public
Health Laboratory

Attach NBS kit barcode
sticker here:

Assigned kit number:	
Child's full name:	Child's date of birth:
Parent/legal guardian's full name:	Phone number:

Utah Public Health Laboratory (UPHL) newborn screening blood spot card retention consent form

The Utah Public Health Laboratory (UPHL) tests newborn blood samples to screen for genetic health disorders. With your consent, we keep the samples for 7 years after testing is complete. If you do not consent, we will destroy your baby's bloodspot cards after 90 days.

We keep bloodspot cards for these reasons:

- If your child needs more testing in the future for a diagnosed health condition. We will always get your consent before doing any tests.
- To improve our current testing procedures or develop new tests for other diseases.
- Quality control and assurance.
- If you consent to using your child's blood sample for research on newborn screening diagnosis and treatment. We will never use your child's blood sample for research without your consent.

We keep your personal information safe by:

- Deidentifying the samples. This means that we remove all personal information from the sample before we store it, including names, birthdays, or contact information.
- Storing your contact information in a separate location than the bloodspot cards and test results.
- Storing the bloodspot cards in a secure walk-in freezer that only authorized staff can enter.

Choose 1 option for the amount of time UPHL can store your child's bloodspot cards:

Note: if both boxes are checked or neither box is checked, the sample will be destroyed after 90 days

- ☐ I consent to my child's bloodspot cards to be stored for 7 years then destroyed.
☐ I do not consent and want my child's blood spot to be destroyed after 90 days.

Parent/legal guardian signature:

Date:

Give this form to hospital staff or your midwife or mail/fax it directly to:

Newborn Screening Program
4431 South 2700 West
Taylorsville, UT, 84129
Fax: 801-536-0966

Utah Public Health
Laboratory Updated 5/2026



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 Heel Stick 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 kit ID 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 kit 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'.
- 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" into 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	Healthcare Provider
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 clinic 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.

Birth Record Number/Newborn Screening Log

NBS Program – 801-584-8256

[illegible]

Effective 5/7/2025**26B-4-319 Testing of newborn infants.**

(1)

(a) 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:

(i) phenylketonuria (PKU);

(ii) other heritable disorders which may result in an intellectual or physical disability or death and for which:

(A) a preventive measure or treatment is available; and

(B) there exists a reliable laboratory diagnostic test method;

(iii) hearing loss; and

(iv) critical congenital heart defects using pulse oximetry.

(b)

(i) Prior to conducting newborn infant testing under this section, information shall be provided to the newborn infant's parent or guardian explaining relevant facts and information about newborn infant testing and sample storage under this section.

(ii) Prior to conducting a newborn infant heel stick screen under this section, a copy of the privacy consent form described in Subsection (5) shall be provided to the newborn infant's parent or guardian.

(iii) The department may retain, in accordance with the department's retention policy, a biological sample and any genetic data, as those terms are defined in Section 13-60-102, collected under this section, only if a parent or guardian consents to the retention policy on the privacy consent form.

(c) A biological sample and any genetic data collected under this section shall be destroyed:

(i) according to the department's retention policy; or

(ii) if the newborn infant's parent or guardian does not consent to the department's retention policy, upon completion of the newborn infant's testing under this section.

(2) In accordance with Section 26B-1-209, 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 created in Section 26B-1-432, including:

Utah Code

- (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) The department shall publish a privacy consent form containing:
- (a) relevant facts and information about:
 - (i) the purposes for which the department retains biological samples or any genetic data obtained through newborn infant testing; and
 - (ii) the department's retention policy for biological samples or any genetic data obtained through newborn infant testing; and
 - (b) the option for a parent or guardian to indicate consent to the department's retention policy.

Amended by Chapter 397, 2025 General Session

R438. Health and Human Services, Disease Control and Prevention, Laboratory Services.

R438-15. Newborn Screening.

R438-15-1. Authority and Purpose.

- (1) Sections 26B-4-319 and 26B-1-202 authorize this rule.
- (2) This rule facilitates early detection, prompt referral, and treatment through screening of newborns for certain conditions.

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 Section R438-15-9.
- (3) "Blood spot" means a clinical specimen submitted on the paper of the newborn screening form using the heel stick method.
- (4) "Department" means the Department of Health and Human Services.
- (5) "Follow up" means tracking any newborn 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) "Health care provider" means a person licensed by the Department of Commerce, Division of 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 ongoing health care of a newborn.
- (7) "Inadequate specimen" means a specimen determined by the Newborn Screening Laboratory to be unacceptable for testing.
- (8) "Indeterminate result" means a result that requires another specimen to determine normal or abnormal status.
- (9) "Institution" means a hospital, alternate birthing facility, or midwife service in Utah that provides maternity or nursery services.
- (10) "Metabolic disease" means a disease screened by the department which is caused by an inborn error of metabolism.
- (11) "Newborn screening form" means the department's demographic form with the attached Food and Drug Administration (FDA)-approved filter paper medical collection device.
- (12) "Quantity not sufficient specimen" or "QNS specimen" means a specimen that the laboratory has partially tested but that does not have enough blood available to complete the full testing.
- (13) "Unsatisfactory specimen" means an inadequate specimen.

R438-15-3. Implementation.

- (1) The health care provider shall submit a sample for each newborn in the state for newborn screening testing, except as provided in Section R438-15-12.
- (2) The department, after consulting with the Newborn Screening Advisory Committee, shall determine the disorders on the Newborn Screening Panel, based on demonstrated effectiveness and available funding. The laboratory shall screen infant blood for the following disorders:
 - (a) amino acid metabolism disorders:
 - (i) argininemia;
 - (ii) argininosuccinic aciduria;
 - (iii) citrullinemia;
 - (iv) homocystinuria;
 - (v) hyperprolinemia type II;
 - (vi) maple syrup urine disease;
 - (vii) phenylketonuria;
 - (viii) tyrosinemia type I;
 - (ix) tyrosinemia type II; and

- (x) tyrosinemia type III;
- (b) biotinidase deficiency;
- (c) congenital adrenal hyperplasia;
- (d) congenital hypothyroidism;
- (e) cystic fibrosis;
- (f) guanidinoacetate methyltransferase deficiency;
- (g) fatty acid oxidation disorders:
 - (i) carnitine acylcarnitine translocase deficiency;
 - (ii) carnitine palmitoyl transferase I deficiency;
 - (iii) carnitine palmitoyl transferase II deficiency;
 - (iv) long chain 3-OH acyl CoA dehydrogenase deficiency;
 - (v) medium chain acyl CoA dehydrogenase deficiency;
 - (vi) multiple acyl CoA dehydrogenase deficiency;
 - (vii) short chain 3-OH acyl CoA dehydrogenase deficiency;
 - (viii) short chain acyl CoA dehydrogenase deficiency;
 - (ix) primary carnitine deficiency;
 - (x) very long chain acyl CoA dehydrogenase deficiency;
- (h) galactosemia;
- (i) hemoglobinopathy;
- (j) mucopolysaccharidosis type I;
- (k) mucopolysaccharidosis type II;
- (l) organic acids disorders:
 - (i) 2-methyl-3-OH-butyryl-CoA dehydrogenase deficiency;
 - (ii) 2-methylbutyryl CoA dehydrogenase deficiency;
 - (iii) 3-methylcrotonyl CoA carboxylase deficiency;
 - (iv) 3-hydroxy-3-methyl glutaryl CoA lyase deficiency;
 - (v) 3-ketothiolase deficiency;
 - (vi) glutaric acidemia type I;
 - (vii) holocarboxylase synthase deficiency;
 - (viii) isobutyryl CoA dehydrogenase deficiency;
 - (ix) isovaleric acidemia;
 - (x) malonic aciduria;
 - (xi) methylmalonic acidemia; and
 - (xii) propionic acidemia;
- (m) pompe disease;
- (n) severe combined immunodeficiency syndrome;
- (o) spinal muscular atrophy; and
- (p) x-linked adrenoleukodystrophy.

R438-15-4. Responsibility for Collection of the First Specimen.

- (1) If the newborn is born in an institution, the institution shall collect and submit an appropriate specimen, unless the newborn is transferred to another institution before 24 hours of age.
- (2) If the newborn is born outside of an institution, the practitioner or other person primarily responsible for assisting the mother at the birth shall 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 shall arrange for the collection and submission of an appropriate specimen.
- (4) If the newborn undergoes a transfer to another institution before 24 hours of age, the receiving health institution shall collect and submit an appropriate specimen.

R438-15-5. Timing of Collection of First Specimen.

- (1) The first specimen shall be collected between 24 and 48 hours of the newborn's life, except as outlined in Subsection (2).
- (2) If the newborn is discharged from an institution before 24 hours of age, a specimen shall be

collected within two hours of discharge.

(3)(a) If the newborn is to receive a blood transfusion or dialysis, a specimen shall be collected before the procedure, unless an emergency situation prevents sufficient time for collection.

(b) If the newborn receives a blood transfusion or dialysis before collecting the appropriate specimen, the health care provider shall:

(i) collect initial screen no later than the seventh day of life;

(ii) collect second screen seven to ten days after last transfusion or dialysis for a second screening specimen; and

(iii) if a hemoglobin pattern is abnormal on the first screen, collect a repeat screen after 120 days of life to evaluate the hemoglobin pattern.

R438-15-6. Parent Education.

The person who has responsibility under Section R438-15-5 shall:

(1) inform and provide educational material to the parent or legal guardian of the required collection, submission, and the screened disorders;

(2) provide a copy of the privacy consent for retention form describing the purposes for retained dried blood spot and the newborn screening retention policy for the dried blood spot sample for parent or legal guardian signature;

(3) return the signed consent for retention form to the Newborn Screening Program; and

(4) 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.

R438-15-7. Timing of Collection of the Second Specimen.

(1) A health care provider shall collect a second specimen from the newborn between 7 and 16 days of age.

(2) The parent or legal guardian shall arrange for the collection and submission of the appropriate second specimen through an institution, health care provider, or local health department.

(3) If the health care provider obtains a newborn's first specimen before 24 hours of age, the second specimen must be collected by 14 days of age.

(4) If the newborn is to be hospitalized beyond the seventh day of life, the institution must arrange for the collection and submission of the appropriate second specimen.

R438-15-8. Criteria for Appropriate Specimen.

(1) The institution or health care provider collecting the appropriate specimen:

(a) shall use only the newborn screening form purchased from the department;

(b) shall correctly store the newborn screening form in a cool, dry place, away from direct sunlight or heat source;

(c) shall complete each part of the newborn screening form, except as described in Subsection (4);

(d) shall collect blood in such a way as to not cause serum or tissue fluids to separate from the blood;

(e) shall apply sufficient blood to the filter paper;

(f) shall apply blood evenly to one side of the filter paper and ensure it soaks through to the other side;

(g) shall apply blood to the filter paper in a manner that does not cause caking;

(h) shall dry the specimen properly;

(i) may not alter the newborn screening form in any way;

(j) may not contaminate the filter paper with any foreign substance;

(k) may not tear, perforate, scratch, or wrinkle the filter paper;

(l) may not remove the filter paper from the newborn screening form; and

(m) may not use the newborn screening form beyond the form's date of expiration.

(2) The institution or health care provider shall submit the completed newborn screening form to the Utah Department of Health and Human Services, Newborn Screening Laboratory, 4431 South 2700 West, Taylorsville, Utah 84129.

(a) The newborn screening form shall be placed in an envelope large enough to accommodate the form without folding the form.

(b) If mailed, the newborn screening form shall be provided to the US Postal Service within 24 hours of the

appropriate specimen's collection.

(c) If hand-delivered, the newborn screening form shall be delivered within 48 hours of the appropriate specimen's collection.

(3) The Legislature sets the fee for newborn screening and the newborn screening form.

(4) If the infant is undergoing adoption, the following may be omitted from newborn screening form:

(a) infant's last name;

(b) birth mother's name;

(c) address; and

(d) telephone number.

(5) The institution or health care provider shall include an identifying name and a contact person on the newborn screening form.

R438-15-9. Abnormal Result.

(1)(a) If the department finds an abnormal result consistent with a disease state, the department shall send written notice to the health care provider 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 health care provider based on the results on the second screening specimen.

(2) The department may require the health care provider to collect and submit additional specimens for screening or confirmatory testing. The department may pay for the initial confirmatory testing on the newborn requested by the department. The department may recommend additional diagnostic testing to the health care provider. The cost of additional testing the department recommends is not covered by the department.

(3) The health care provider shall collect and submit specimens within the timeframe and in the manner instructed by the department.

(4) As instructed by the department or the health care provider, the parent or legal guardian of a newborn identified with an abnormal test result shall promptly take the newborn to the health care provider to have an appropriate specimen collected.

(5) The health care provider 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.

R438-15-10. Inadequate or Unsatisfactory Specimen or QNS Specimen.

(1) If the department finds an inadequate or unsatisfactory specimen or a QNS specimen, the department shall inform the institution or health care provider noted on the newborn screening form.

(2)(a) The institution or health care provider that submitted the inadequate or unsatisfactory specimen or QNS specimen shall submit an appropriate specimen, in accordance with Section R438-15-9.

(b) The responsible institution or health care provider shall collect and submit the new specimen within two days of notice, and the responsible institution or health care provider shall label the form for testing as directed by the department.

(3) 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 health care provider to have an appropriate specimen collected.

R438-15-11. Testing Refusal.

(1) A parent or legal guardian may refuse to allow the required testing for religious reasons.

(2) The health care provider 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 guardians.

(3) The practitioner or institution shall submit a copy of the refusal to the Utah Department of Health and Human Services, Newborn Screening Program, P.O. Box 144710, Salt Lake City, UT 84114-4710.

R438-15-12. Access to Medical Records.

(1) The department shall have access to the medical records of a newborn to identify the health care provider or any reason an 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.

R438-15-13. Noncompliance by Parent or Legal Guardian.

If the health care provider or institution has information that leads the provider or institution to believe that the parent or legal guardian is not complying with this rule, the health care provider or institution shall report such noncompliance as medical neglect to the department.

R438-15-14. Confidentiality and Related Information.

(1) The department releases test results to the institution of birth for first specimens and to the health care provider for the second specimen, as noted on the newborn screening form.

(2) The department notifies the health care provider noted on the newborn screening form of any results that require follow up.

(3) The department releases information to the health care provider or other health practitioner on a need-to-know basis. Release may be oral, by a hard copy of results, or electronically by authorized access.

(4) Upon request from the parent or guardian, the department may release results as directed in the release form.

(5) Each request for test results or records is governed by Title 26B, Chapter 8, Part 4, Health Statistics.

(6) The department may release information in summary, statistical, or other forms that do not identify an individual.

(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.

R438-15-15. Blood Spots.

(1) Once received by the laboratory, each blood spot becomes the property of the department.

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

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

(4) The department may release blood spots for research to a person if the person submits a written proposal to the department for approval.

(a) The proposal 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.

(b) The department shall de-identify each blood spot that the department releases unless the department obtains informed consent from a parent or guardian to release identifiable samples.

(c) The department's internal review board shall approve any blood spot research.

R438-15-16. Retention of Blood Spots.

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

(2) Before disposal, the department shall de-identify the blood spots.

(3)(a) On a form provided by the department, the parent or legal guardian shall indicate:

(i) consent to the storage of the specimen for seven years, after which the specimen shall be destroyed;

(ii) that the parent or legal guardian does not consent to the storage of the specimen, and the sample will be destroyed after 90 days.

(b) If the parent or legal guardian does not return the form or indicate a preference, as described in Subsection (3)(a), the department retains the blood spot for 90 days and destroys the blood spot after 90 days.

R438-15-17. 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 health care provider shall report the diagnosis to the department.

R438-15-18. Statutory Penalties.

Any health care provider or institution responsible for submission of a newborn screening that violates this rule may be assessed a civil money penalty, as provided in Subsection 26B-1-224(2).

KEY: health care, newborn screening

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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 birth hospital 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 must use a miscellaneous form; how do we get the baby's original Kit ID number?

- This original kit number was issued by the birth hospital 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, 801-584-8256.

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, and the family has already paid for the screening in that state.

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. The adoptive parent or adoptive agency information should be entered. A contact person must be entered. [R438-15-9 (e)] The second screening form, consent for retention form, and education material 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. Mark adoption on the card and write in surrogate next to the adoption bubble. Provide the intended parents' contact details so they can be notified immediately of any abnormal results.

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 does 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 has 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 healthcare provider 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 healthcare provider 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.