

Information for Hospitals

Who's responsible for getting the specimen?

State law requires the newborn's physician to collect or cause the collection of the newborn screening specimen. Most birthing facilities use standing orders for the required newborn screening panel. The ordering physician should be recorded on the filter paper as this functions as the lab test requisition.

Different hospital employees besides the physician, such as clerks, nurses, lab techs and phlebotomists are involved in some aspect of preparing and collecting the newborn screening specimen.

Timing of Specimen Collection

Nebraska regulations require that newborn screening specimens be collected:

- between 24 and 48 hours of age,
- prior to transfer,
- prior to transfusion,
- prior to discharge, whichever occurs first.

Most newborn screening tests and cut-offs are based on specimens collected between 24-48 hours of age. If the baby is to be discharged, transferred or transfused before 24 hours of life, a dried blood spot filter paper specimen must be collected PRIOR to discharge, transfer or transfusion. Regulations require this, and there are many good reasons:

The NNSP has discovered a number of newborns over the years who were discharged without a screen. Dangerous lengthy delays occur in getting these babies screened. They each require a great deal of effort on the part of hospital, physician and NNSP staff in getting the parents to bring the baby back in for an initial specimen collection.

In other cases, newborns have been transferred between three hospitals, with none of them collecting the specimen, assuming another had done so.

Transfused babies who don't have a specimen collected until after the transfusion, are at increased risk because of the significant delays required to get a reliable initial specimen. They also require more than one post-transfusion specimen in order to get all conditions screened. Newborns receiving blood transfusions should always get a specimen collected first, even if before 24 hours of age. The specimen should be collected at the time when blood typing and cross match are done.

Completing the Specimen Card

The dried blood spot filter paper collection cards are three-part forms. All demographic information must be completed, accurately and legibly before collecting the specimen. Every data field is critical to ensure proper testing, and ensure we can get the newborn back in if needed for repeat or confirmatory testing. Certain data elements are also critical to the matching done between NNSP and Vital Birth records (NNSP/Vital Match). This is done to make sure every baby benefits from newborn screening. Some of the data fields are required because they're useful to the interpretation of the laboratory testing result (e.g. TPN, transfused, baby on antibiotics, meconium ileus)

- 1) Complete the form accurately and legibly at the time of specimen collection.
- 2) Pull the center form prior to applying the blood spots, and;
- 3) Keep this in the infant's medical record.
- 4) Do not touch sample area.
- 5) Do not use if damaged.



COLLECTION AND REPORTING (CARE) FORM - NEBRASKA NEWBORN SCREENING PROGRAM

Birth Date _____ / _____ / _____	Time _____ : _____ (Military)
Collection Date _____ / _____ / _____	Time _____ : _____ (Military)
Collector's initials _____	Gestational Age: _____
NICU Admit <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Birth Weight _____
Is this specimen: <input type="checkbox"/> Initial specimen <input type="checkbox"/> 48-72° repeat	
<input type="checkbox"/> Other repeat <input type="checkbox"/> 28 day/ discharge repeat for a < 2000 gram birth	
Has baby EVER been transfused <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
If Yes, Date last transfused: _____ / _____ / _____ Time _____ : _____ (Military)	
Baby receiving TPN <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
If TPN yes, was it interrupted 3 hours before taking this specimen <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
Baby has Meconium Ileus or other bowel obstruction <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
Baby on Antibiotics <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

Baby's last name _____

First name _____ Middle _____

Patient Record Number _____

Place of Birth
Home Birth Yes No Sex M F Unknown

Mother's last name _____

First name _____ Middle _____

Address _____

City _____ State _____ ZIP _____
Mother's Phone (_____) - _____ Mother's DOB / /

Name of Submitter / Facility _____

City _____ State (if other than NE) _____

Name of Ordering Physician _____

(_____) - _____
Ordering Physician's Phone
SN

Name of Physician following baby post-discharge _____

(_____) - _____
Post-discharge Physician's Phone

-Allow to air dry horizontally at least 3 hours.
-Do not let blood spots touch anything before they are dry.
-Ship within 24 hours (when transport available)

SHIP TO:



PerkinElmer Genetics
90 Emerson Lane Suite 1403
P.O. Box 219
Bridgeville, PA 15017
Phone: 412-220-2300



SN 9735502

Date Received	Nebraska Collection and Reporting Form (Care Form) SN 9735502	Date Reported
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Quality Assurance Tip #1: Always check the information on the filter paper card against the information on the newborn's wristband/bracelet prior to collecting the specimen so the right baby's blood is collected on the right filter paper card.

Quality Assurance Tip #2: Always check the expiration date on the filter paper card before collecting the specimen.

Quality Assurance Tip #3: Before sending the specimen to the newborn screening laboratory, filter paper specimens should be checked for:

- legibility,
- completeness,
- accuracy,
- quality of the blood spots,
- and that blood spots have had at least 3-4 hours to dry.

These Data Pieces Must be Completed:

Date and Time of Birth: (enter birth time using military time). This is one of the data elements essential to follow-up to ensure the right baby's information goes with the right baby's records. It is particularly important, for multiple births, in distinguishing "baby A" from "baby B" and "baby C".

Date and Time of Specimen Collection: (Enter collection time using military time). This is crucial to ensuring the baby is at least 24 hours of age. They are entered into the laboratory data system which calculates if less than 24 hours, and flags the specimen as needing a repeat.

Collector's Initials (necessary for legal and quality assurance purposes)

Initial or Repeat: Check the appropriate box. If the specimen is a repeat specimen, checking this correct box will help flag data entry staff at the laboratory to match the testing with the initial screening results.

Transfused Prior to Specimen Collection: Check this appropriate yes/no box relative to the newborn's receive of a transfusion prior to getting the specimen collected. If you mark yes,, be sure to identify date and time of the last transfusion.

TPN: Check the appropriate yes/no box if baby is on total parenteral nutrition, or hyperalimentation. This can have an effect on the

screening results, and having the information may help with laboratory interpretation.

Baby on Antibiotics: If baby is receiving antibiotics, it's important to check this box. Some antibiotics may have an effect on the screening results, which may require repeat testing.

Meconium Ileus: Check this box if the baby had meconium ileus **or other bowel obstruction**. The screening test for cystic fibrosis is done differently for these babies. This improves the reliability of the test. If bowel obstruction or meconium ileus is identified after the specimen has been collected, notify the newborn screening laboratory at (412) 220-2300.

Gestational Age and Birth Weight: This information is essential to interpret certain results. Normal reference ranges are based on birth weight ranges for congenital adrenal hyperplasia. It can also be important to screening for congenital primary hypothyroidism and cystic fibrosis.

Newborn's Information: Last, First and Middle Name: The newborn's information is critical to ensure the right baby's specimen is collected. In the event a repeat or confirmatory specimen needs to be collected, it's essential for getting the baby back in for this testing. In addition the State NNSP/Vital Match uses this information. When the baby is one in a multiple birth, be sure to distinguish between the newborns, e.g. Boy A, Boy B if first names have not been assigned.

Patient Record Number: This should be the newborn's medical record number. This number can be helpful in tracking the information and ensuring it goes with the right medical record. Many Healthcare Providers use this to help access the electronic medical record as well as to help with follow-up.

Place of Birth: It's important to identify the actual place of birth. The hospital collecting the specimen is the "submitter" and may not always be the place of birth. In many cases the newborn is born at one hospital, and transferred to another. In others, the newborn was born at home, or en-route to the hospital. Any out-of-hospital birth should be recorded as a "home birth" for purposes of this form.

Home Birth: Check the appropriate box. Again this is helpful to the NNSP/Vital Match and will help the parents avoid getting a letter from the State NNSP.

Sex: Check the appropriate box, Male or Female. In cases of ambiguous genitalia where the specimen is collected before gender is determined, check the "unknown" box. This could be clinically important in the diagnosis of congenital adrenal hyperplasia as well.

Mother's Information: Full name, address, telephone number and birth date are essential for contacting the mother in the event of a

positive screening result, or the need to get a repeat specimen. These data elements are also crucial to the NNSP/Vital Match in ensuring all newborns receive the screen.

Submitter's Information: The name address and telephone of the contact person (usually the hospital laboratory) should be recorded. This is critical so the newborn screening lab can quickly contact the right submitter in the event of an urgent repeat. Never record an abbreviation without the city where the submitter is located. There are multiple "Community" and "Memorial" hospitals that without the full name and city recorded, can create delays for follow-up.

Newborn's Physician Information:

The first information requested is the name and phone number of **the physician who orders the screening**. Many times this may be a physician on call, a hospitalist or a NICU physician who won't be following the baby long term.

The second physician information requested is that of the physician or other healthcare provider **who will be following the baby post-discharge**.

The ordering physician should ensure the parent(s) have identified a post-discharge physician who will be following the baby. Results for babies in the well-baby nursery are usually available only after discharge, so contacting the correct physician to follow-up is critical information. Without it, the ordering physician will be responsible for follow-up.

Blood Specimen Collection

Collection of dried blood spots on filter paper should be by the direct heel stick procedure only. For very small babies in NICUs, it may be acceptable to collect the specimen from the umbilical catheter line.

Reference the National Committee on Clinical Laboratory Standards (NCCLS), now known as the Clinical Laboratory Standards Institute (CLSI): "Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard (Most recent edition). To obtain copies of contact CLSI at www.clsi.org or e-mail CustomerService@clsi.org or phone 610-688-0100.

 [Blood Specimen Collection and Handling Procedure](#)

 [Simple Spot Check](#)

(PDFs Courtesy of Whatman GE, Inc. and New York State Department of Health)

CAVEAT: Normal reference ranges for the newborn screening tests are based on specimens collected via direct heel stick procedure at 24-48 hrs of age. Cut-offs have not been established for specimens collected by alternate methods such as capillary tube, dorsal hand vein or umbilical catheter.

Hospital tracking of results

The submitter should keep a log of every birth and NICU submission and check-off when:

- Specimen is collected
- Specimen is shipped
- Results are received

If by 10 days the submitter has not received the lab results, they should contact the laboratory (412) 220-2300 to find out the status. The NNSP should be contacted (402) 471-9731 for assistance with any delays encountered.

When Baby Comes Back...Is It a Repeat or Confirmatory?...What to Do

Repeat Filter Paper Dried Blood Spot Specimen.

The newborn screening laboratory will notify the submitter, physician and newborn screening program about any baby needing a repeat dried blood spot specimen. This will be for:

- specimens drawn early,
- unsatisfactory specimens
- specimens collected after transfusion, and
- some abnormal or inconclusive results requiring only repeat dried blood spot specimen testing.

The Newborn Screening Program (NNSP) also notifies the newborn's physician in writing of the need to collect a repeat filter paper specimen in these cases. If despite these efforts, orders are not clear to the hospital staff when the baby is brought back to the hospital lab, they should contact the newborn's physician, or contact the NNSP at (402) 471-9731.

Sometimes the newborn's physician will request the entire panel to be repeated, even though only one or a few tests need to be repeated. The physician's orders for the full panel should be followed. However, there may be additional laboratory charges for this.

Confirmatory Specimen of Another Type

The newborn screening laboratory will notify the submitter, physician and Newborn Screening Program (NNSP) of any abnormal screening result. Some of these will fall in an "inconclusive" range requiring only a repeat filter paper specimen at that point in time. Others will require a different type of specimen to be tested by a different methodology.

The NNSP also notifies the newborn's physician of the specific recommendations to confirm or rule out the condition. The program also helps the newborn's physician connect with a pediatric specialist for the suspected condition (metabolic specialist/geneticist, pediatric endocrinologist, pediatric hematologist, pediatric pulmonology/CF center, pediatric immunologist).

The hospital laboratory may contact the NNSP at (402) 471-0374 with any questions regarding confirmatory specimen collection.

Link to Laboratory Web Site

<http://www.perkinelmer.com/genetics/> (Revvity Omics formerly Perkin Elmer Genetics)

Ordering More Filter Paper Collection Cards

The filter paper dried blood spot collection kits are available from the newborn screening laboratory. Birthing hospitals should have stock rotation of filter paper stored on site. The hospital should also maintain an ongoing inventory of filter paper. At least a 90 day supply should be maintained in the event of disaster causing disruption to services. To order more filter paper, contact Revvity Omics at (412) 220-2300. As an FDA approved medical device the filter paper has an expiration date of 3 years. Any specimen collected on expired filter paper must be rejected, so please check expiration dates on filter paper regularly when collecting specimens.