COLLECTION OF NEWBORN SCREENING SPECIMENS

Newborn Screening is Mandatory

Newborn screening has the potential to save or greatly improve the life of a newborn; therefore, Newborn Screening is mandatory in New York State (Public Health Law Section 2500-a, 10 NYCRR Section 69-1.4). Written consent from the parent(s) is not required. There is only one circumstance where Newborn Screening is exempt.

When the parent or guardian of the infant is a member of a recognized religious organization whose teachings are contrary to the testing requirement, s/he may choose to opt out of testing of their child. If a parent or guardian objects to testing based on religious grounds, the hospital administrator, or another person designated to register the birth of a child (as defined by Public Health Law Section 4130) has the following responsibilities: a) Fully inform the parent or guardian of the consequences of refusal and b) inform the Newborn Screening Program of such parental refusal by submission of a signed “Refusal of Newborn Screening for Religious Reasons” form (available on our website at www.wadsworth.org) or similar a document. This form must include a statement indicating that the parent or guardian is a member of a recognized religious organization and has been fully informed of the benefits of screening as well as the possible consequences of not having the newborn tested. Submit the Newborn Screening Blood Collection form with complete demographic information, but without the blood sample, to the screening program. “Declined testing” should be written across the top of the form and; the green copy should be retained by the hospital, and the pink copy given to the parents.

If a newborn is receiving compassionate (comfort) care only, and is not expected to survive, screening may be declined by the parent or guardian. As above, the attending physician must submit a Newborn Screening Blood Collection Form with complete demographic information, but without a blood sample. This is to be, accompanied by written documentation of the reason for compassionate care and parental declination of screening. It should be explained to the parent or guardian that even in such a case, there may be a benefit to newborn screening. Screening results may shed light on the cause of the newborn’s medical condition and the remaining blood spots would be stored, providing the opportunity for future testing if the diagnosis remains unclear.

Resources for Specimen Collection Education

- A video on specimen collection:
  - The New York State Newborn Screening Program has produced an updated video demonstrating proper specimen collection technique. This is viewable on our website and is available as a DVD (see below).

- The poster, “Simple Spot Check” lists possible causes of unsuitable specimens and illustrates examples of unsuitable specimens.

- Instructions for specimen collection can also be found on the back of the specimen collection form.

To obtain a DVD of the video and/or copies of the poster:

- Visit our website at www.wadsworth.org and fill out a supply request form
- E-mail a request to NBSinfo@health.ny.gov
- Call (518) 473-7552
- Call the Voice Response System (VRS) at (800) 535-3079
Blood Spot Collection Cards

The New York State Newborn Screening Program tests dried blood specimens collected via heel stick. Drops of blood from the heel stick are used to saturate the marked circles of the specimen collection form. The blood spot is often called the Guthrie spot. The specimen collection card may be referred to as: DOH-1514, the filter paper card, the MCH3 form, the blood collection form, and (although now outdated) the “PKU” card. Specimen cards are shipped quarterly to most birth hospitals, to the attention of the designated hospital employee.

To obtain additional blood specimen cards at no charge:
- Visit our website at www.wadsworth.org and fill out a supply request form
- E-mail a request to NBSinfo@health.ny.gov
- Call (518) 473-7552

Completion of the Blood Collection Form

Every effort should be made to use a current form. Therefore, take notice of the expiration date on the collection form. A specimen collected on expired filter paper will be unsuitable for testing. Any questions regarding the forms can be directed to the Newborn Screening Program by calling (518) 473-7552 or e-mailing NBSinfo@health.ny.gov.

Verify the identity of the infant. All information requested on the blood collection form should be filled in using only blue or black ballpoint pen. This information must be accurate and legible. The information is vital to identify and locate infants with invalid or screen positive test results. Inaccurate or illegible information could result in delays in diagnostic testing and treatment of affected infants.

The SUBMITTER COPY of the specimen form (the green copy or a scanned version of it) remains in the infant’s permanent medical record. The PARENT COPY (the pink top copy) should be given to the mother along with the brochure, "Newborn Screening: For Your Baby's Health" in the mother’s native language, as available, from the Newborn Screening Program (available in: English, Spanish, Chinese, French(Haitian) Creole, French, Vietnamese, Korean and Italian).

Birthing centers may opt to submit demographic information in an electronic format by using either a web based Remote Demographic Entry (RDE) system, HL7 transfer of demographic data or a combination of the two. These applications are used in combination with a label printer to create a label to affix to the blood collection form prior to submission.

Timing of Specimen Collection

The American Academy of Pediatrics recommends that the specimen be collected after the newborn is at least 24 hours old.1 A specimen collected prior to 24 hours of age can be used to screen for some of the disorders but is not reliable for amino acid disorders, cystic fibrosis, hypothyroidism, urea cycle disorders or Krabbe disease. Analyses of screening results suggest that a specimen taken on the second day of life is suitable for all testing, with a slightly increased risk of not detecting certain abnormal conditions. Never discharge an infant without collecting a specimen or with intent to collect it later, as this will greatly increase the risk of not identifying an infant who has one of the screened conditions.
Responsibility for Specimen Collection

Hospital and Birthing Centers
The birthing facility is responsible for collecting a satisfactory specimen for each baby born at their facility. The specimen should be collected after the baby is 24 hours old. Newborns discharged at less than 24 hours of age must have a specimen collected at discharge and a second specimen collected when the baby is between 24 hours and 120 hours of age (Day 2 through Day 5 of life). The hospital or birthing center is responsible for the collection of both specimens.

Home Births
It is the responsibility of the birth attendant (the medical professional attending the birth) to arrange for collection and submission of a specimen from the newborn after the baby is 24 hours old.

Readmission of Newborns
If a newborn is admitted to a hospital within the first 28 days of life, the admitting hospital is required to submit a specimen for screening unless proof of a screen negative result is available.

Inter-Hospital Transfers
The transferring hospital should provide written notification to the receiving hospital indicating whether or not a newborn specimen has been submitted. Following transfer, the receiving hospital assumes responsibility for fulfilling collection requirements including securing documentation from the transferring hospital.

Special Circumstances Surrounding Specimen Collection

Premature and/or Sick Infants
Guidelines on specimen collection for premature and/or sick infants, approved by the Clinical and Laboratory Standards Institute (ILAC31-A), recommend specimen collection upon admission to a neonatal intensive care or special baby care unit. If the specimen is collected when the infant is less than 24 hours of age, collect another specimen when the infant is 48 - 72 hours of age. A third specimen is required at discharge or 28 days of age; whichever comes first. Every effort should be made to obtain a specimen prior to transfusion and/or administration of Total Parenteral Nutrition (TPN) or other treatments which can affect screening results.
Guidelines for Collecting Specimens for Babies in the NICU

**First Newborn Screening Specimen**
- Collect upon admission to the Neonatal Intensive Care Unit if not already collected
- Newborn will probably be less than 24 hours of age
- Ensure specimen is collected prior to starting TPN or Transfusion

**Second Newborn Screening Specimen**
- Collect at 48 to 72 hours of life
- Collect if first specimen was collected at <24 hours of age or if newborn weighed <2000 grams at birth

**Third Newborn Screening Specimen**
- Collect at 28 days of life, or discharge, whichever comes first
- Collect if newborn weighed <2000 grams at birth

**Transfusion**
The optimum specimen collection time is when the newborn is older than 24 hours of age. However, transfusions may invalidate some screening results by masking the presence of a hemoglobinopathy or galactosemia. If the infant is to receive a transfusion, every effort must be made to collect a specimen prior to transfusion. Infants receiving transfusions with no prior newborn screening test need two specimens collected: one at three days or more after the most recent transfusion and one at four months after the final transfusion.

**Total Parenteral Nutrition (TPN) - Hyperalimentation**
The optimum collection time is when the newborn is older than 24 hours of age. However, even small amounts of TPN may invalidate some screening results for the acylcarnitines and amino acids. If the infant is to receive TPN, every effort must be made to collect a specimen prior to treatment. Infants receiving TPN with no prior newborn screening test need a collection three days or more after the last administration of TPN.

**Newborn Screening Laboratory Request for Another Specimen**
The Newborn Screening Laboratory will request another specimen when the initial specimen is:
- Unsuitable (invalid) for testing
- Obtained when the infant was less than 24 hours of age at first collection
- Borderline abnormal (having a slightly elevated or decreased amount of a particular analyte)
Collection of Blood Specimen

Materials

- Sterile lancet, with a tip not to exceed 2.0 millimeters in length
  - Standardized incision devices are available that produce a 1.0 mm deep incision
  - Devices are also available that have been developed specifically for premature infants
- Sterile 70% alcohol pads or other appropriate cleansing agent
- Sterile gauze pads
- Warm moist cloth or compress
- Filter paper blood collection form with a future expiration date
- Gloves
- Supplies for heel stick aftercare as per your institution’s policy

Procedure

Specimen quality can be compromised by: incorrect timing of specimen collection, incorrect method of collection and/or mishandling of the specimen post-collection. In these instances the specimen is rendered invalid or unsuitable.

Since laboratory analysis of the specimen depends on a standard amount of blood in the filter paper circle, it is imperative to carefully follow these procedures. Do not touch the area within the circles on the filter paper with gloved or un gloved hands before or after specimen collection since skin oils, latex and powder may affect test results. Avoid contamination of the filter paper with feeding formulas, antiseptic solutions, water, lotions, powder, etc. These may invalidate the blood specimen.

1. Inform parents about the purpose and need for newborn screening.

2. Place infant's leg in a position that will increase venous pressure (e.g. heart above feet).

3. Warm the heel to increase blood supply to the area by covering the puncture site for three to five minutes with a warm, moist towel which has been run under tap water at a temperature of not more than 42°C.
Note: The heel puncture should be made on the plantar (sole) surface, at the heel. The best area for heel puncture is toward the sides of the heel as shown in the cross hatched areas in the photo to the left. Do not puncture on the posterior curvature of the heel, or on a previous puncture site.

4. Wash hands and put on gloves. Cleanse the puncture site with a sterile alcohol pad. Wipe dry with a sterile gauze pad. Residual alcohol may cause hemolysis of the blood specimen resulting in an invalid specimen.

5. With a lancet or specialty device, puncture the heel skin with one continuous, deliberate motion at a slight angle (a little less than 90°). Wipe away the first drop of blood with a dry sterile gauze pad, as it is likely to contain tissue fluids that will contaminate the specimen.

6. Allow a second, large drop of blood to form.

7. Lightly touch the filter paper to this large drop of blood. Allow the blood to soak through and completely fill the preprinted circle. To enhance blood flow, very gentle intermittent pressure may be applied to the area surrounding the puncture site. Do not "milk" the area surrounding the puncture site. Milking may cause an admixture of tissue fluids with blood specimen, resulting in an invalid specimen. Apply blood to one side of filter paper only. Either side may be chosen for this procedure. Do not use capillary tubes or other devices (syringes etc.).
8. Fill remaining circles in same manner as steps 6 and 7 with successive drops of blood.

Note: If the first drop of blood does not fill the circle or most of the circle immediately, express another blood drop and continue to fill the circle. This must be done within a few seconds of the placement of the first drop. Alternatively, allow a larger drop to form and move on to the next four circles. If more than two drops are required to fill a single circle, or there is more than 10 seconds of time between drops, follow the steps above to repuncture a different site with a sterile lancet. This time, ensure that the baby’s heel has been properly warmed and that you firmly press the lancet against the skin prior to activating the device. Most often, these steps will allow blood to flow more freely for sampling. Multiple contacts to the same circle, over a period of greater than 10 seconds, can result in layering which renders the circle unsuitable for testing.

9. Care of the skin puncture site should be consistent with your institution's procedures.

A Valid Specimen

The perfect specimen:

- Has all information legibly recorded on the blood collection form
- Is collected from an infant after the first 24 hours of life
- Has no foreign contaminants on the filter paper
- Has all printed circles completely filled with blood that is applied evenly on one side of the filter paper; free of layering and clots
- Is dried for at least four hours on a flat, clean, non-absorbent surface, away from direct heat and sunlight
- Is covered by the safety flap after proper drying and before mailing
- Is delivered to the appropriate pick-up site within the hospital for delivery to the screening laboratory the next morning. If your site does not participate in the NYS delivery program, the specimen must be sent to the Newborn Screening Program by first class mail or its equivalent within 24 hours of collection.
**Unsuitable Specimens**

Approximately 2-3% of the specimens received by the Newborn Screening Program are unsuitable for testing. Certain types of specimens are known to give erroneous laboratory results. In accordance with Newborn Screening laboratory policy, these specimens cannot be tested and are deemed unsuitable or invalid for testing (see figure below). If an unsuitable specimen is submitted, the submitter must repeat the collection procedure. This delays the screening process and puts the newborn at unnecessary risk should he or she have one of the disorders on the screening panel.

If you would like to know your facility’s rate of unsuitable specimens, contact the Newborn Screening Program at 518 473-7552.

**Examples**

*Quantity Not Sufficient*

Circles not completely filled or blood did not soak through

*Wet Specimen*

Specimen not dried for a minimum of four hours prior to mailing

*Supersaturated*

Excess blood applied (usually by capillary or needle) or blood applied to both sides of the card
Milked/Exposed to Direct Heat/Contaminated

Puncture site squeezed or “milked” to expel blood; exposure to direct heat; contamination of filter paper before or after specimen collection

Serum Rings

Alcohol not wiped off puncture site before skin puncture; filter paper contaminated with water or lotion, puncture site excessively squeezed; improperly dried; blood applied with a capillary tube containing an anticoagulant

Clotted or Layered

Same circle touched with blood several times; circle filled from both sides of the paper; protective flap in contact with wet blood spots

No Blood Applied
Post Collection

Do not place the protective flap over the blood spots until the blood is completely dry. Allow blood spots to air-dry thoroughly for at least four hours in a horizontal position on a clean flat, non-absorbent surface away from direct heat and sunlight. Do not refrigerate specimens after collection. Both sides of the dried specimen should be inspected to ensure suitability. If the specimen is deemed unsuitable by the hospital staff, and the newborn is still in-house, another specimen should be collected. Forms have a built-in flap which should be placed over and cover the dried blood spots before the form is inserted into an envelope. The envelope itself serves as the second barrier. **Do not** place the specimens in a plastic bag. Each day, gather all the specimens to be shipped together. Record each specimen’s laboratory identification number (Lab ID) on the Newborn Screening Transport Form. The Lab ID can be found in the upper left hand corner of the blood collection card. Count the number of specimens that will be placed in the envelope and write that number in the large circle on the Transport Form. Fill out the rest of the information on the form including the courier tracking number. Keep a copy of the Transport Form for your records.

Transport forms may be printed from our website
  - Visit our website at [www.wadsworth.org](http://www.wadsworth.org) and download the form
  - E-mail a request for a template form to [NBSinfo@health.ny.gov](mailto:NBSinfo@health.ny.gov)
  - Call (518) 473-7552 for a template form you can use to make copies at your site

NYS has arranged with an overnight delivery service to collect specimens daily (except Sunday) from a pre-arranged pick-up site at most birthing hospitals. If pick-up is not available, mail dried specimens as soon as possible using the mailing address that is printed on the back of the blood collection form. **Do not retain specimens more than 24 hours in order to accumulate or “batch” them, since several of the conditions on the screening panel can begin to cause irreversible damage to the infant in the first few days of life.**

References:


Appendix: Refusal of Newborn Screening for Religious Reasons

June 2013
Refusal of Newborn Screening for Religious Reasons

Infant’s name ___________________________ Infant’s Date of Birth ___________________________

Infant’s Place of Birth ___________________________________________________________________________

I, the undersigned parent or legal guardian of infant ___ boy ___ girl ________________________________ born at
Last name __________________________________________________________
Hospital of birth have made the decision not to have the above infant
screened by the New York State Newborn Screening Program because ____________________________________
_____________________________________________________________________________________________

I understand that the New York State law mandates that all infants shall be screened for disorders listed on the following
page and only exempts infants from this requirement if the parent or guardian of the infant advises the physician or
nurse-midwife attending the birth or the administrative officer of the hospital that the parent or guardian is a member
of a recognized religious organization whose teachings and tenets are contrary to this testing.

I have been advised of the benefits of the newborn screening and the risks and consequences of refusal of
screening. I accept the legal responsibility for the consequences of this decision.

Signed: ___________________________________ Dated: ____________________________
Parent or legal guardian

Printed: ___________________________________

Witnessed by: ______________________________
Medical personnel (signature)

I have explained the means by which the newborn screening tests are done, the meaning of the results, the possible
consequences to this infant of not performing these tests and have answered any questions the above parent/legal
guardian had about these tests.

_____________________________
Name (print)

_____________________________
Title

Signature

Send original to:
NYS Newborn Screening Program
Wadsworth Center
New York State Department of Health
P.O. Box 509
Albany, NY 12201-0509

Retain copy for permanent record of this child

FOPARF June 2013
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For more information on the New York State newborn Screening Program and the disorders in the panel please visit our webpage at www.wadsworth.org/newborn/index.htm