



Newborn Metabolic Screening Information, Authorization, and Waiver

The Newborn Metabolic Screening Test checks for 37 rare but serious conditions your baby could have. In all of these disorders there are no symptoms at birth, and in most of them by the time you have symptoms severe, irreversible damage has been done. However, if caught early, all can be treated to prevent the majority of the damage. There are three general types of disorders tested on the Newborn Metabolic Screening Test. They are: Metabolic Disorders (where the body does not produce an enzyme required by the body, and substances normally metabolized build up in dangerous, even lethal amounts), Endocrine Disorders (where the baby does not produce certain hormones required by the body), and Hemoglobin Disorders (where the body does not correctly construct the hemoglobin in red blood cells, thus affecting how oxygen is used by the body, whether enough oxygen is usable by the body, or other problems). Four of the most common individual diseases found by this test are described in the table below (remember these are just 4 of the 37 conditions tested for):

Disorder	What causes the disorder?	How often does it occur?	What happens if it is not found and treated?	How is it treated?
Phenylketonuria (PKU) (metabolic disorder)	The body cannot break down certain parts of proteins (the amino acid phenylalanine)	One in 15,000 newborns	Children become mentally retarded.	A special diet
Galactosemia (metabolic disorder)	The body cannot break down a certain sugar (galactose) found in dairy products and breast milk	One in 50,000 newborns	Children become very sick (and may die). Mental retardation, cataracts, and liver damage can occur in untreated infants.	A special diet.
Congenital Hypothyroidism (endocrine disorder)	The thyroid gland does not produce enough of a special hormone (thyroxine)	One in 5,000 newborns	Children become mentally retarded and growth is slow	Supplement of a pill (thyroxine)
Sickle Cell Anemia (hemoglobin disorder)	An inherited abnormality in the structure of hemoglobin in red blood cells affects the body's ability to utilize oxygen and may cause several other problems.	One in 3,000 newborns	Children could have a range of problems; from mild anemia to a life-threatening crisis.	Sometimes education, sometimes special care.

How and When The Test Should Be Performed:

The test is performed by pricking the heel of your baby and obtaining a small amount of blood which is put on a test card and submitted to a state laboratory. The timing of the test is important. Before 24 hours of age parts of the test may not be accurate. After 28 days damage to an affected child may already be occurring. The ideal time to perform the test is twice, once between 24 and 48 hours of age, and again at 14 days of age. If only one test is done, the ideal timing is between 5 and 14 days of age.

Risks of Not Performing the Test:

The risks of not performing the tests are: 1) Your child may be affected by one or more of these conditions, and may suffer the effects of the disorder(s) if not treated. These effects include brain damage, mental retardation, illness, and death.

Risks of Performing the Test:

The risks of performing the test are: 1) Anytime you break the skin, as you must with this test, there is a chance of infection. This complication is rare, and the risk is minimized by using a sterile lancet and cleaning the skin before it is performed. In most cases infections that do develop can be treated (usually with topical or oral antibiotics). 2) If the puncture is too deep and nicks the heel bone, the resulting injury can develop gangrene and ultimately require amputation of the foot. This complication is extremely rare, and is prevented by carefully selecting the site to be used, and using a lancet device that does not allow a puncture deep enough to reach the bone. 3) We do not know what affect the pain caused by this procedure may have on a newborn's psychological development. 4) As with any test, the result can be a false positive (indicating your baby has one of these conditions when in fact he or she does not) or a false negative (indicating your baby is fine when in fact he or she has one of these conditions). A false positive will likely cause stress and worry to you, and would be dealt with by performing further testing to confirm the result. You may be required to suspend breastfeeding and formula feed your baby while awaiting confirmatory testing. A false negative would be devastating since no further testing would be done and the condition would likely progress to symptoms before it were caught. In this case providers may delay investigation or diagnosis of one of these conditions because you have a test result that says the baby does not have it. False positives are more common than false negatives, and are particularly common in the summer (heat affects the test paper). 5) If your baby has an undiagnosed bleeding disorder (for example, hemorrhagic disease of the newborn or hemophilia), bleeding from the puncture site may be

profuse, or in rare cases, result in severe injury or death. A vitamin K injection at birth may reduce this risk, but does have risks of its own.

What Happens If My Baby Tests Positive?

If your baby has an abnormal result, further testing is necessary to confirm the diagnosis. Additional testing *does not* necessarily mean that your baby has one of these diseases. The provider identified on the screening form will be notified of the abnormal results and s/he will notify you of the need for further testing. Normal test results are mailed to the provider who performed the test.

If your baby is identified as having phenylketonuria (PKU) or galactosemia, you will be referred to the Metabolic Clinic. The Metabolic Clinic provides diagnostic and consultative services for children and adults with PKU, galactosemia, and other metabolic disorders. Evaluation and management services are provided by a team which included a pediatrician/geneticist, nutritionist, psychologist, social worker, genetic counselor, nurse, and secretary. Other consultants, such as neurology, ophthalmology, and speech and hearing specialists, are available if needed. The Metabolic Clinic staff helps coordinate efforts to purchase special metabolic formulas and medications with pharmacies, the WIC Program and other community agencies when needed. The Metabolic Clinic is administered by the Division of Medical Genetics, Department of Pediatrics, University of Utah Medical Center. The clinics are held at Primary Children’s Medical Center. Call 801-585-2457 for more information. If your baby has a hemoglobinopathy, you will be referred to the Hematology clinic. The hematology clinics are held at the Primary Children’s Medical Center.

Is This Test Required By Law?

Utah law states that all newborns must be tested (Utah code 26-10-6), however it also provides that parents may refuse the test for religious reasons. As a provider of maternity care, BetterBirth, LLC must require you to either authorize us to perform this test on your baby, or refuse it in writing. Please read the following options and sign the one you select:

_____ (Initial) I certify that I have read the preceding information regarding the Newborn Metabolic Screening test and that all my questions have been answered to my satisfaction.

Test Refusal

I understand that Utah law requires that each newborn infant undergo the Newborn Metabolic Screen. I understand that failure to detect and treat any of these conditions within the first two weeks of life can result in the effects listed in this document, which I have read and understood.

Knowing and understanding the risks, I hereby refuse the Newborn Metabolic Screening test for my infant and declare that I am a member of a religion opposed to this test, or that I have personal objections to newborn screening.

I release and hold harmless BetterBirth, LLC and it’s agents from the outcome of this decision.

Signature

Date

Witness

Test at Health Department or other provider

I prefer to have my baby tested at the Health Department or with my child’s physician rather than by my maternity care provider, therefore I refuse it from BetterBirth, LLC. I hereby assume all responsibility for obtaining the test and release and hold harmless BetterBirth, LLC it’s agents, and all other related parties from the outcome of this decision. I understand that the test can be obtained for a minimum fee at my local health department and I plan to have my baby tested within the recommended 14-day limit.

Signature

Date

Witness

NOTE: If you want this test done by your physician, please contact him or her prior to the birth of the baby. Some physicians will not do this test for you, and all must special-order the test kit.

Test Authorization

Knowing and understanding the risks of the Newborn Metabolic Screening test, I authorize my midwife at BetterBirth, LLC or her designee to perform the test on my infant. I hereby release and hold harmless the midwife, BetterBirth, LLC, and all other related parties from the outcome of this decision, except in the case of gross negligence. I understand there is a fee for this procedure that is not included in my other maternity care fees. I understand that it is my responsibility to immediately notify BetterBirth, LLC if I change address or phone numbers within 60 days of the test so that I can be notified of the results.

Signature

Date

Witness