



Early Check

Expanded health screening for your baby

This permission form is from the Early Check website. Mothers must give permission online at portal.earlycheck.org

Copy of Parental Permission for Early Check Screening

Welcome to Early Check! Let's get started.

Early Check is a research study that checks for a small number of rare but serious health problems in newborns. We call this the Early Check panel. It currently includes muscular dystrophy.

Parents can sign up when pregnant or within 4 weeks after the baby is born. The screening tests are free.

What do babies have to do?

Nothing!

Babies have a heel prick in the hospital for regular North Carolina newborn screening. We don't need any more blood. Early Check simply does extra screening tests on the same drops of blood.

What do parents have to do?

Sign up your baby. That's all!

Parents go through this site to learn more. Then the mother can decide to sign up her baby. Even though the mother has to give permission, we ask that both parents decide when possible.

If you have a family where the birth mother does not or will not have custody of the baby, contact us so we can tell you how to sign up.

Learning about Early Check and signing up is easy, and it is all done on the Early Check website.

Online video script

Congratulations on your baby! You can sign up your baby for Early Check to learn more about your baby's health. This is a special opportunity for babies born in North Carolina.

What is Early Check? Early Check is a research study to check babies soon after birth for rare but serious health problems. The Early Check screening tests are free and no appointments are needed. It is up to parents to decide whether to sign up their babies.

Why join Early Check?

Choosing Early Check gives parents information about the health of their baby. It allows parents to know if their newborn has specific health problems instead of waiting for symptoms to start. Knowing early may help the babies and their families. Right now, there is no cure for the health problems screened for in Early Check. But researchers are looking for better treatments, and there are already ways to help the babies get the best start. Parents can join by giving permission for their babies to enroll in Early Check.

Ready to find out if your baby can join Early Check?

Early Check is for babies born in North Carolina. The babies must have regular North Carolina newborn screening. The babies must live in North Carolina or in South Carolina.

How is Early Check done?

Online video script

How is Early Check screening done?

The Early Check screening tests are done on the newborn screening blood spot. This is the small amount of blood that is taken from a baby's heel shortly after birth in the hospital or birthing center. We use that same blood to do the Early Check screening. We don't need any more blood.

Early Check screening tests are usually done when the baby is between 2 and 6 weeks old.

What happens after the screening?

Most parents get their baby's Early Check results before the baby is two months old.

[Result is normal]

Early Check looks for rare health problems so most parents get a normal result for their baby. When the results are ready, we send parents an email or text telling them to log in to this site to view the results.

[Result is not normal]

The Early Check team calls the parents if the screening test is not normal. Then we do a second test to be sure.

The Early Check team gives parents information, genetic counseling, and helps them find medical care for the baby. We connect parents with specialists and give them information about research studies looking for possible new treatments.

How does Early Check help?

Choosing Early Check gives parents information about the health of their baby. Identifying babies with rare health problems early on can help to give babies a better start.

Explore this graphic to learn more about the Early Check process.

Part 1

Part 2

How Early Check Works

A woman is pregnant or a baby is born in North Carolina

New and expecting parents in the state are invited to join Early Check, a research study that screens newborns for rare health problems.



Parents choose Early Check



Choosing Early Check gives parents information about the health of their baby.

Doctors and researchers learn to find babies with rare health problems and start helping them earlier.

Early Check is free and signing up is easy. Parents sign up their baby online. No appointment is needed.

Early Check does screening tests



Babies have a heel prick in the hospital for state newborn screening.

Early Check does extra screening tests on the same blood spot.



Most parents get Early Check screening results before the baby is 2 months old.

Parents get the Early Check results

Most parents get a normal result for their baby.

Normal result

Not normal result

Most parents get Early Check screening results before the baby is 2 months old.

Parents get the Early Check results

Most parents get a normal result for their baby.

Normal result

Not normal result



A text or email tells parents that the Early Check test results are ready.

Parents view the test results on the secure Early Check website.



The Early Check team calls the parents.



A second test is used to confirm the result of the first screening test.

The baby gets an exam and the family gets information and genetic counseling.



Early Check helps find doctors to care for the baby.

Researchers learn important information



Researchers learn about the screening tests, the screening process, and the rare health conditions to help other babies in the future.

What health problems does Early Check look for in newborns?

Early Check looks for a small number of rare health problems. We change the health problems included on the Early Check Panel as we learn more about them.

The health problems included in Early Check depend on when the baby is born.

All babies born starting December 11, 2021, will be checked for:

Muscular dystrophy. There are several types of muscular dystrophy. The Early Check Panel looks for Duchenne and some related muscular dystrophies. Duchenne causes muscle weakness that is usually first noticed in the preschool years and gets worse over time. Muscular dystrophy could cause early death, often in the young adult years.

If the health conditions on the Early Check Panel change after you sign up your baby, we will contact you by email before your baby's blood is tested to let you know.

Important facts about the Early Check health problems:

- Babies who have these health problems may not have any signs or symptoms at birth. The signs and symptoms can start later.
- Babies who have these health problems can have mild or serious symptoms.
- There are no cures for these health problems but there are things that may help. Researchers are looking for better treatments.
- The Early Check team will connect parents of babies with these health problems to more information and help them find doctors and support for their child.

If you want to learn more about Duchenne and related muscular dystrophies from our experts...



Holly Peay, MS, PhD, CGC

Senior Researcher
Certified Genetic Counselor
Genomics, Bioinformatics, and
Translational Research Center
RTI International



Edward C. Smith, MD

Associate Professor of Pediatrics
Associate Professor of Neurology
Duke University Medical Center

The Early Check muscular dystrophy screening test will find Duchenne muscular dystrophy and several similar health problems. We find these similar health problems because we screen babies' blood spots for a sign of muscle damage called CK-MM. This sign of muscle damage can happen in several muscular dystrophies. Early Check screening will not find all types of muscular dystrophy. All muscular dystrophies are rare.

The most common is Duchenne muscular dystrophy. Duchenne is also one of the most severe muscular dystrophies. It causes weakness that gets worse over time and early death, often in the young adult years. It happens most often in boys. About 1 in every 4,500 boys has Duchenne.

The other muscular dystrophies are even less common and can happen in boys or girls. Some cause severe weakness and early death and some cause mild weakness and result in a normal lifespan.

Muscular dystrophies run in families. Different genes cause the different types. Parents who have one child with a muscular dystrophy can have another child who also has it.

Currently, there is no cure for muscular dystrophies, but there are treatments and early intervention services that can help.

What happens when parents get results from Early Check?

Results from Early Check are Normal

A normal result means that it is very unlikely that your baby has one of the health problems screened in the Early Check Panel.

The conditions screened by Early Check are rare, and most parents will get a normal result for their baby. More than 99% (99 out of 100) babies screened will have a normal test result.

You would get an email and/or text to tell you the results are ready. You would see the results after logging into this Early Check site. You could choose to download a report to share with doctors. You could contact the Early Check team with any questions.

Later on, we may also ask you to share your thoughts and feelings about Early Check. It will be your choice whether to do this.

Results from Early Check are Not Normal

Any baby who has a screening test that is not normal gets a free second test to tell for sure. A member of the Early Check team will call the mother or legal guardian. The Early Check team will also contact the baby's doctor and provide them with information.

Even though the health problems cannot be cured, there may be options to help. The Early Check team will give parents information and genetic counseling. We will help parents find special doctors to take care of their baby, and we will give them information about research studies looking for new treatments. Early Check will also ask parents about their Early Check experience and if they want their baby to be in follow-up projects about the health problems. It will be their choice whether to do these things.

If you are having twins or multiple babies

Mothers can sign up twins, triplets, or any number of multiples for Early Check. If you sign up, each one of your babies will have Early Check screening. The Early Check team will call the mother or legal guardian if **any** of the babies has a screening test that is not normal.

Do you have to pay for Early Check?

The screening tests included in the Early Check Panel will provide **for free**:

- The screening tests included in the Early Check Panel
- A second test for any baby whose screening test is not normal
- Help in understanding what the results mean

If the second test confirms the health problem, Early Check will provide **for free**:

- Genetic counseling and education about the health problem
- An assessment of the baby's development
- Help with finding doctors and support services

Early Check **does not** pay for any other tests, doctor and specialist office visits, or treatments for the baby.

How is Early Check different from regular North Carolina newborn screening?

Early Check is **not** the same as regular North Carolina newborn screening. This table shows the differences.

| | Early Check | Regular newborn screening |
|--|-------------|---------------------------|
| Parents must give permission for their baby to be screened | Yes | No |
| There are treatments for babies with the health conditions, which can greatly improve their symptoms | Maybe* | Yes |
| Type of program | Research | Public Health |

*There are no cures for these health problems but there are things that may help. Researchers are looking for better treatments

You get to choose whether to join Early Check. If you choose not to enroll your baby in Early Check, your baby will still have regular newborn screening just like other babies in North Carolina.

It would be very rare, but it is possible that a baby could have a health problem found on regular newborn screening and also have an Early Check screening test that was not normal. If this ever happens, the Early Check team will tell the newborn screening professionals and doctors caring for the baby to make sure the baby has coordinated care.

If you want to learn more about regular North Carolina newborn screening from our experts...



Scott Shone, PhD, HCLD(ABB)
 Director
 North Carolina State Laboratory
 of Public Health

Most babies are born without health problems. If babies do have health problems, they cannot always be found by a routine exam. Many of these conditions are life-threatening early in life, and others can cause serious long-term problems if they are not treated early. But the newborn screening conditions have effective treatments. If they are caught at birth, the baby can be treated to help reduce or prevent future problems.

In the hospital or birthing center, a healthcare professional will prick the baby’s heel with a small needle to collect a few drops of blood. The hospital sends these drops of blood to the North Carolina State Laboratory of Public Health (NCSLPH) in Raleigh for testing, along with some basic information about the baby such as date of birth, sex, and birthweight. This is the same blood sample that will be used for the Early Check screening tests. Early Check also uses this basic information about the baby to make sure the screening result is as accurate as possible.

Early Check will only use the baby’s blood sample if the parent signs up for the Early Check study. If parents decide not to enroll their baby in Early Check, the baby will still have regular newborn screening and follow up. The baby’s doctor will still receive the results of regular newborn screening.

Are the screening tests perfect?

A screening test is a good, quick way to check lots of babies, but here are some things to know.

- The screening test may miss some babies with the health problems.
- The first screening test could come back not normal even though the baby is fine. That's why Early Check uses a second test to tell for sure. If the second test is normal, then there is no evidence that the baby has the condition, and the screening test result is called a "false positive".

Early Check only screens for the health problems on the Early Check Panel. Early Check will not give you information about any other health problems.

In a few cases, we cannot do the screening test because there is not enough blood left over after newborn screening. If this happens, the Early Check team will let the parent know and talk about options.

Also, it is rare, but the screening process may show something unexpected—something that is not included in the list of Early Check health problems. We would not report these unexpected results.

If you want to learn more about Early Check's false positive rates...

Less than 1% (1 out of 100) babies screened will have a result that is not normal (also known as a "positive" result).

To screen for DMD, Early Check measures a biomarker (CK-MM) associated with muscle damage. Not all babies who have a high CK-MM result will be confirmed with DMD or another muscle disorder because there can be other causes of high CK-MM, including a difficult delivery. The researchers at Early Check have not yet established the false-positive rate for DMD.

If you are having twins or multiple babies

Mothers can sign up twins, triplets, or other multiples for Early Check. If you sign up, each one of your babies will have their own Early Check screening tests. The Early Check team will call the mother if any of the babies has a screening test that is not normal.

If you want to learn more about screening tests from our experts...



Scott Shone, PhD, HCLD(ABB)

Director

North Carolina State Laboratory
of Public Health

1. Screening tests may not find all babies.

Early Check screening tests will catch most, but not all, babies with these health problems. A few babies who have a normal screening test may really have the health problem and may develop symptoms later. **Parents should always share any concerns about their baby's development with the doctor.**

A screening result that comes back as not normal could be wrong. That's why we use the second test to tell for sure. Often babies with a result that is not normal have the health problem. Some do not, because the screening tests are not perfect.

2. Screening tests are targeted to specific health problems.

Early Check screens for a small number of rare health problems. In rare cases, the screening process may show something unexpected—something that is not included in the list of Early Check health problems. We would not report

these unexpected results.

3. There may not be enough blood spot left to do the Early Check screening.

In rare cases, we cannot do Early Check screening because there is not enough blood left over after regular newborn screening. We expect this to happen in less than 1 in 100 babies. If this happens, the Early Check team will let the mother know.

4. When a second test is needed, it is done at a different laboratory. Often the second test will have the same result. Those babies do have the health problem.

Some of the time the second test will have a normal result. Those babies do not have the health problem.

The Early Check team will carefully explain the results to the family.

Parents can contact the Early Check team to answer questions.

Email: support@earlycheck.org

Phone (toll-free): **866-881-2715**

How is your information protected and shared?

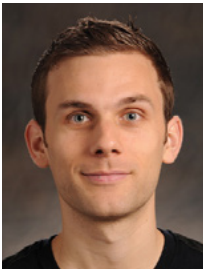
The Early Check team works hard to protect your information.

We are fully committed to protecting your information, but it is never possible to guarantee that a system is completely secure.

Parents' and babies' names and contact information are never sold to anyone, and never given to anyone outside of the Early Check team without your permission.

Early Check may share de-identified information (which means it cannot be traced back to you or your baby) with other researchers and partnering companies. This allows Early Check to help research all over the country. We will not share anything that could connect the de-identified information to you or your baby.

If you want to learn more about protecting information from our experts...



Martin Duparc

Early Check Informatics Expert
RTI International

The Early Check system uses strong measures to protect both parents' and babies' information (such as a secure network, encryption, password management policies, and multi-factor authentication). All Early Check information is stored in a separate area of the network that is held to an even higher security standard, known as the Federal Information Processing Standard (FIPS) "moderate" level of security categorization.

Why might you say Yes to Early Check? Why might you say No to Early Check?

It's OK to decide yes or no to Early Check. All research has benefits and risks. You should make the best decision for your family.

Remember that the health problems screened in Early Check change as we learn more. It is possible the Early Check Panel will change after you sign up your baby. If this happens, we will contact you by email before your baby's blood is tested to let you know.

Online video script

The goal of Early Check is to learn how to use new screening tests for health problems that affect babies to better understand the disorders and speed up finding new treatments.

Early Check can diagnose infants early with health problems that right now cannot be cured. Some parents want to know about the baby's health as soon as possible. Other parents want to wait and see how their baby develops. Parents should make the best choice for their families.

The main benefits to joining are:

- Learning more about a baby's health
- Knowing early could help newborns with certain health problems
- Learning information that may be important to others in the family
- Helping scientists learn about the health problems and create new treatments in the future

The main risks to joining are:

- For a baby whose screening test is not normal, parents may worry and feel uncertain about the baby's future
- Parents may worry about the privacy of their or their baby's information

We do our best to make these risks as small as possible.

Take your time and do what feels right. You can contact the Early Check team to answer any questions you have. Parents can change their mind and withdraw from Early Check at any time. (But if the baby's Early Check screening test has already been done, we will still contact the mother if the screening test is not normal.)

Here's a checklist to help you decide:

- Would you want to know if your newborn has one of the health problems screened in Early Check?
- Are you okay knowing that right now there is no cure for the health problems?
- Do you have the information you need to make the decision?
- Do you feel ready to learn the answer of the screening tests?
- If your baby has a screening test that is not normal are you okay with your baby having a second test to tell for sure?

If you checked most of these questions, maybe you are ready to sign up your baby. If you did not check most of these questions, maybe you are not ready or it is not the right decision for you.

Parents can contact the Early Check team to answer questions.

Let's review

It's our job to explain Early Check to you. Let's review and see how we are doing.

Which babies can be screened in Early Check?

- a. Babies who have regular newborn screening in North Carolina
- b. Only babies at higher risk
- c. Only babies with a family history of rare health problems

The correct answer is a.

Babies are invited to Early Check if they:

1. have regular newborn screening in North Carolina **and**
2. live in North or South Carolina.

We ask mothers of all babies to join Early Check, so babies screened will include those at higher risk and those with a family history. We don't know anything about the health of any baby or about any baby's family history when we invite the mother to join.

Let's review

Which is **not true** about Early Check?

Early Check:

- a. is a research study
- b. checks newborns for rare health problems
- c. screens for health problems that can be cured
- d. uses the same blood spot used for newborn screening

Answer: Item C is not true. Early Check screens newborns for rare health problems that currently cannot be cured, though there may be treatments that can help.

Items a, b, and d are true. Early Check is a research study and you can choose whether or not to join Early Check. Early Check uses the same blood spot used for newborn screening.

Let's review

Which is **true** about Early Check screening test?

- a. It may not find every single baby with the health problems.
- b. It will check for every kind of health problem in newborns.
- c. If the screening result is not normal, the baby definitely has the health problem.

Answer: Item a is true. Screening tests are not perfect and may miss a small number of babies with the health problems.

Item b is not true. Early Check screening will only check for a few specific health problems.

Item c is not true. The screening tests are not perfect. We will use a second test for babies with a screening test that is not normal. A small number of those babies will have a normal second test because they do not have the health problem.

Would you like to join Early Check?

Mothers must sign up on portal.earlycheck.org to give permission for their infant to participate.

In most cases the mother must sign up. Early Check cannot connect the father to the newborn's blood spot for screening.

Are you a legal guardian or have custody of a child you want to sign up for Early Check, but are not the biological mother?

If so please contact Early Check at +1 (866) 881-2715 or support@earlycheck.org.

We want all infants to join, but we ask you to please contact us first to ensure we have the information we need to screen your baby

To learn more, please visit the FAQ page.

The Early Check study has been approved by the University of North Carolina at Chapel Hill Institutional Review Board (IRB). An IRB is a committee that reviews research to protect the rights and welfare of participants. If you have questions about your rights as a research participant, you may contact the IRB at 919.966.3113.

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