



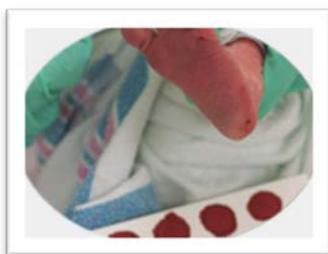
# What Happens to My Baby's Newborn Screening Blood Spots?

## Background on the Newborn Screening Program

Newborn Screening (NBS) is a public health program established by state law to test all babies for many serious disorders. NBS can prevent serious health problems or even save your baby's life. Newborn screening is like other types of health screening. Screening identifies those who are at risk for having a specific disorder even though they may seem healthy.



If a baby is found to be at risk for a certain disorder then further evaluation will need to be done to confirm if the baby has the disorder. NBS enables babies with some rare disorders to be identified early so treatment can be started right away.



## How is NBS Done?

Before the baby is sent home from the hospital, a few drops of blood are taken from the baby's heel. These drops are used to fill small circles on a filter paper card. All six circles are filled to make sure there is enough blood to complete the NBS testing. After the blood dries, the form is sent to a lab for testing.

## What Happens at the Lab?

Using a punching machine, the lab obtains small pieces from the blood spots to perform eight types of tests.



Cells in the human body carry DNA and blood cells are no different. Most of the time, testing does not involve the DNA in the blood cells. However, a very small number of babies need an extra test to determine the NBS results and this test looks at a small piece of DNA for a specific condition. Once the information is obtained for NBS screening results, the DNA sample is destroyed. The Newborn Screening Program stores the dried blood spots but does not store information about your baby's entire DNA or store your baby's "DNA profile." The state does not have a DNA database from the specimens collected.

## What Happens to the Residual Blood Spots?

After NBS testing has been completed, what is left of the paper with the blood spots is carefully stored in a freezer. The freezers are located in a secure storage facility. The filter paper cards are labeled with a unique bar code. They have no other identifying information on them. The codes to match the bar code on the card to your baby's name is secured in a different site.



## Could the Stored Blood Spots Ever Benefit Me or My Baby?



**Yes.** The stored NBS blood spots could provide useful information to you or your family. In the future, the blood spot could be used, with your permission, to detect a disorder not included in the NBS panel. You or your baby's doctor might want to use the remaining blood spots for special testing that otherwise could not be done. You would then need to sign a release form allowing the NBS Program to send the blood spot to the doctor or lab for more testing.

If you choose to enroll your child in a specific research project, the researchers must obtain your written informed consent and only then can identifying information be provided by the NBS Program.

## Are the stored blood spots used in any other way?

The stored blood spots are used to monitor and to improve the current NBS program. They are also used to evaluate and develop new tests to add to the newborn screening panel. New tests, such as the one for cystic fibrosis, were developed by using the stored blood spots.



Use of the stored blood spots has helped not only babies in California but throughout the world. Over the last 35 years, newborn screening in California has gone from testing each baby for 3 disorders to testing for over 75 disorders. By testing for these added disorders, we have been able to prevent serious illness, including death and disability, in many more children.

California law allows the NBS Program to use or provide newborn screening specimens for department-approved studies of disease in women and children, such as research related to identifying and preventing diseases like birth defects or exposure to toxins or infections. If the blood spots are used for this type of study, they are used without any information that would identify the blood spot as coming from your baby. Because identifying information is not provided to the researchers, you would not be notified of any study test results for your baby.

## Is Extra Blood Taken From My Baby for Research?

**No.** In most cases, after Newborn Screening testing has been completed, one or more spots have some residual blood. California law<sup>1</sup> allows for the use of the remaining blood spots for studies approved by the California Department of Public Health. The goal of these studies is to prevent disease and/or improve treatment.



If a baby's remaining specimen is selected for research, every effort is made to make sure that part of the specimen is saved in case it is later requested by the parent or individual. Most often, only a small amount from a single blood spot is provided for research. Extra blood spots or specimens will not be collected from your baby just to use for research.

## How Are the Studies Approved?

There are several steps taken to be sure the dried blood spots are only used for approved research. All research projects are required to be approved by the State Committee for the Protection of Human Subjects (also called state institutional review board or IRB) to be sure the study is well-designed, ethical and protects patient confidentiality. Prior to being submitted to the State IRB, the studies often need to also be approved by a community Institutional Review Board. Only after the IRB approvals have been obtained can a researcher apply to the CDPH for use of newborn screening blood spots for a specific research project. The public health department also makes sure the study is related to preventing disease and/or improving the health of the public. Researchers must comply with very strict California Biobank Regulations.<sup>ii</sup>

## Is the Information Confidential?



Yes. After a study has been approved, CDPH gives the researchers only the minimum amount of data and remaining specimen needed to conduct the research. There is no personal information on the dried blood spot card, only a unique non-identifying number. Researchers are **not** provided with any information that would allow them to identify the baby whose blood spots they are given.

## How is Privacy Protected?

Many safeguards are in place to protect the privacy of babies and families. California state and federal laws outline security measures which must be in place to protect privacy.



The blood spots are never sold or given away. Researchers are charged a processing fee for limited use of the spots, but do not own the spots. Researchers who receive data and blood spots from CDPH are required to meet all federal and state privacy laws. They must sign a “use agreement” that prevents them from using or sharing the blood spots for any purpose except the approved research project. This includes any products or information that comes from the blood spots. When the project has been completed, any remaining blood must be destroyed. It is illegal for the specimen to be used for any other purpose.

## Can Health Plans, Insurance Companies or Employers Gain Access to the Stored Blood Spots?



**No.** Under state law the blood spots are considered confidential.<sup>iii</sup> They are protected and are not subject to forced disclosure to third parties.

Law enforcement officials can only obtain access to the specimens with a court order signed by a judge, but court orders are rarely granted. They are limited to special circumstances such as in cases of a missing child. In the 30 year history of the program only a few court orders have been received.

## Can I Request that my Baby's Blood Spots be Destroyed?

**Yes.** If you do not want your baby's or your own spots to be stored, you can request that they be destroyed after newborn screening has been completed. Keep in mind that if you request that the blood spots be destroyed, they will not be available to you or your baby in the future for any additional testing.

*To request that your baby's or your own NBS blood spots be destroyed you can:*

Complete and submit the request form ([CDPH 4410](#) located at the [NBS Forms Page](#))

## Questions?

Call or email the California Biobank Program Coordinator at 510-412-1500 or [CaliforniaBiobank@cdph.ca.gov](mailto:CaliforniaBiobank@cdph.ca.gov) if you have any questions.



## Acknowledgement

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<sup>i</sup> Health and Safety Code, Division 106, Personal and Health Care, Part 5 Hereditary Diseases/Congenital Defects, Chapter 1 Genetic Prevention Services, Article 2 Newborn Screening, Section 125002(e) and (f)

<sup>ii</sup> Title 17, California Code of Regulations, California Biobank Program, DPH-09-020E

<sup>iii</sup> Health and Safety Code, Division 102, Vital Records and Health Statistics, Part 2 Population and Public Health Surveillance, Chapter 1 Birth Defects Monitoring Program 103850(g)