

Residual Dried Blood Spot Specimens Educational Toolkit



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Introduction

The residual dried blood spot specimens educational toolkit was developed by the Association of Public Health Laboratories (APHL) with the assistance of the Newborn Screening and Genetics in Public Health Residual Dried Blood Spot Taskforce to address public concerns over related policies and practices and gaps in public education regarding residual dried blood spot specimens. It is designed to assist state newborn screening, legal and public health professionals to shape appropriate policies and communicate the value of retaining newborn screening dried blood spot specimens to protect the public's health. **The material contained in this toolkit may be customized based on the needs of the individual state laboratory or newborn screening program.**

Policy and Policy Statements

This section offers examples of specific state policies regarding the storage and use of residual dried blood spot specimens as well as resources to assist state health departments, newborn screening programs and legal specialists in crafting or updating a policy statement on retention and use of residual dried blood spot specimens. This section includes tips on writing a policy statement, the recommended components of a retention policy, and explicit policy language from state newborn screening programs on this issue.

Tips on Writing a Policy Statement

(See Appendix A for the APHL Residual DBS Policy Statement)

A policy statement describes an organization's stance on a particular topic of concern to stakeholders or the general public and contributes to the policy base of the organization. Policy statements serve to clarify intent as well as to formulate a position with a justification, a description of relevant background and a plan for implementation when appropriate. The policy statement may also serve to shield an organization from misapprehensions that could lead to legal ramifications.

A good policy statement should:

- Express a clear position and a rationale
- Contain a statement of position, preferably in the first paragraph, that should only contain the policy statement (statement of position)
- Include a background section: include any relevant information and, if you cite other documents, make sure to include a link
- Avoid contradictory statements within the statement and with other standing organization policy statements
- Coordinate with other shareholders who may be tackling similar issues

It is suggested that a program review and revise the official policy statement on a routine basis. It may be recommended that a state approved policy statement be translated into a law or statute. The policy statement should be transparent and easily interpreted.

Policy Language from State Programs

(See Appendix B for Current Policy Language Examples from State Programs)

Considerable variety exists in the governance of health department policy. Some states endow authority to the state health department in the development and implementation of policy for state laboratory procedures and protocols. Other states require that changes to governing policy affecting health department practices be approved by state lawmakers. State public health laboratories may either influence newborn screening policy or they may be subject to laws that are enacted without input from the Newborn Screening Program. Policy language examples in Appendix B illustrate both these scenarios. Ideally state laws and statutes should be consistent with program policy. It is also important that, if the state health department's policies be governed by the state legislature, representatives from the health department (and more specifically from the state newborn screening program) be able to engage state law makers wherever

possible in order to educate them about what changes to policy signify to newborn screening program practices.

Suggested Components of Newborn Screening Programs' Residual Dried Blood Spot Specimens Policy Language

- Rationale for storage or destruction
- How newborn screening specimens will be stored (addressing physical conditions, security measures and conditions) after receipt by the Public Health Laboratory or other laboratory
- Length of time that specimens will be stored
- Who will have access to the specimens
- Appropriate uses of specimens (use without consent, only with consent, or a combination)
- Disposal and/or disposition of specimens
- Release of specimens to another entity
- Research or third-party requests
- Parent or patient options relative to storage, retrieval, revocation of consent for storage and destruction.

Education

At a time when privacy issues can generate polarizing debate, state health departments must be active in communicating the benefits of retention of newborn screening residual dried blood spot specimens. A message pallet, FAQ's, and educational brochures from a state newborn screening program, provide examples. These examples can be customized to fit each individual state program based on its unique needs and messaging goals.

Message Pallet

(See Appendix C for sample message pallet)

The message pallet offers a high level summary of messages directed to public audiences, including parents, the media and community-based organizations. **It can be used as a guide while speaking to a reporter or community group.** The main message (center box) of the overall message pallet emphasizes the public health importance of retaining newborn screening residual dried blood spot specimens. The goal of the message pallet is to make a strong, positive and accurate statement.

Newborn screening programs are advised to engage with their public information officer from either the state laboratory or the state health department. This person is typically responsible for engaging with the media as well as developing public messaging.

FAQs for Retention of Newborn Screening Blood Spots

(See Appendix D for FAQs and prepared responses)

There are several frequently asked questions that have been submitted over the years to state newborn screening programs regarding the storage and use of residual dried blood spot specimens. It is important that concise, transparent and thoughtfully crafted responses be made to these inquiries when they are received in order to provide consistent information to the public as well as to deliver a reliable message to those with concerns.

Texas Educational Brochure

(See Appendix E for the Texas Educational Brochure)

The Texas Department of State Health Services (DSHS) produced a brochure (in English and Spanish) designed to educate the public about specific issues related to the use and storage of residual dried blood spot specimens. It serves as an example of educational material produced for this topic.

Appendix A: APHL Residual DBS Policy Statement

Statement of Position

APHL supports the position that public health newborn screening (NBS) programs should be able to store and use residual dried blood spot (DBS) specimens and test results for program activities without requiring parental consent. APHL recommends that NBS programs have policies on the retention and use of residual DBS specimens and test results that are transparent, protect patient privacy, address parental concerns, and promote education and informed public participation.¹

Implementation

1. APHL will share this position statement with key state and federal policy makers.
2. APHL will collect and maintain information on the uses of residual DBS specimens and test results for NBS program activities to inform NBS program policymakers.
3. APHL will collaborate with CDC, newborn screening programs, and partners to collect, evaluate and share best practices, model policies, and parent/provider educational materials in order to develop guidance for public health laboratories regarding secure storage and use of residual DBS specimens and newborn screening results for program activities.
4. APHL will encourage state newborn screening programs to develop policies on retaining, storing, and using residual DBS specimens and test results that are compliant with the recommended Clinical and Laboratory Standards Institute (CLSI) storage conditions and accentuate their compliance with federal and state research privacy rules and regulations.²

Background/Data Supporting Position

Newborn screening is a state-mandated program that screens newborns at birth for a select number of serious conditions, known as a newborn screening panel. Specimens submitted undergo initial testing for heritable and congenital disorders and the results are used for the provision of follow-up services for the infant.

The Association of Public Health Laboratories (APHL) endorses the Committee Report [*Considerations and Recommendations for National Guidance Regarding the Retention and Use of Residual Dried Blood Spot Specimens after Newborn Screening, 2011*](#), put forth by the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC).¹ This report states that every state newborn screening program should have a retention and use policy in place that has been reviewed by a state attorney general or other legal authority. This policy should specify who is responsible for storage, access, use, and secure destruction of residual DBS specimens after testing is completed.¹

Once newborn screening is complete, state programs retain residual DBS specimens for various lengths of time, from several weeks to greater than 18 years.¹ Residual DBS specimens are used to support essential program functions such as program evaluation, quality assurance, result verification, test refinement, and quality improvement initiatives.^{1,2,3,4} Use and analysis of residual DBS specimens is essential for some NBS program activities, which include the following:

1. Laboratory quality control, quality assurance and improvement
2. To verify calibration of equipment
3. Evaluation of equipment, reagents, and methods of newborn screening tests for conditions approved for screening by the program
4. Validation of equipment and screening methods
5. Development, testing, and maintenance of a continuity of operations plan to ensure testing can continue in the event of an emergency
6. Assure competency of testing personnel.

Because newborn screening programs are state-mandated and involve regulated clinical laboratories, program activities related to ensuring the accuracy, quality, and improvement of tests for conditions on the newborn screening panel are considered public health practice, not research.

Newborn screening activities may include studies for the development of new laboratory tests, which are essential for expanding public health's ability to protect newborns from congenital conditions where early detection is key. These studies may or may not be research, and opt-in or opt-out consent may be indicated, depending on the nature and details of the study, the funding source, and applicable State laws on education during the prenatal and postnatal periods. Prenatal education materials should include sufficient information to inform the public about any additional uses of specimens beyond screening including information about possible research in cases where such uses are allowed and the security in place to maintain the confidentiality of identifiable health information. State newborn screening programs have a responsibility to improve public health, while also ensuring privacy and maintaining the public's trust.

References

1. Therrell BL, Hannon WH, Bailey DB, Goldman EB, Monaco J, Norgaard-Pedersen B, Terry SF, Harris A, Vasquez LM, Johnson A, Lloyd-Puryear MA, Howell RR. Committee report: Considerations and recommendations for national guidance regarding the retention and use of residual dried blood spot specimens after newborn screening. *Genet Med*. 2011 Jul;13. Available at: <http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/reportsrecommendations/reports/residualdriedbloodspots.pdf>. Accessed May 17, 2017.
2. Hannon WH, Whitley RJ, Davin B, Fernhoff P, Halonen T, Lavochkin M, Miller J, Ojodu J, and Therrell BL Jr. Clinical Laboratory Standards Institute. Blood collection on filter paper for newborn screening programs - Fifth Edition; Approved Standard. CLSI document LA4-A5. Wayne, PA: CLSI, 2007.
3. American College of Medical Genetics. Position statement on the importance of residual newborn screening dried blood spots. Available at: http://www.acmg.net/StaticContent/NewsReleases/Blood_Spot_Position_Statement2009.pdf. Accessed May 17, 2017.
4. Therrell BL, Hannon WH, Pass KA, et al. Guidelines for the retention, storage, and use of residual dried blood spot specimen after newborn screening analysis: statement of the Council of Regional Networks for Genetic Services, *Biochem Molec Med* 57: 116-124, 1996.

Appendix B: Current Policy Language Examples from State Programs

Rationale for Storage or Destruction of Specimens

Example 1 – Storage

The *Health Department* performs a variety of laboratory tests on DBS samples from newborns. Upon completion of laboratory tests, the samples are stored securely for a period of five years in order to meet record retention policies of the *Health Department* and Centers for Medicare and Medicaid Services. Stored samples may be used for internal purposes, such as for quality control materials, method verification and method validation studies.

Example 1 – Destruction

The standard retention period for blood samples with a negative test result is up to *x* days from the date of receipt of the sample. The standard retention period for blood samples with a positive test result is up to *x* days from the date of receipt of the sample. The standard retention period for all test results is up to *x* days from the last date of reporting. Blood samples with a negative test result will be destroyed within *x* days of the *x* retention period. Blood samples with a positive test result will be destroyed within *x* days of the *x* retention period. All test results will be destroyed within *x* days of the *x* retention period. During the standard retention period, the Department of Health may use blood samples and test results for newborn screening program operations.

(Rationale for destruction in the policy above is to obey the health department policy, state law or statute)

How Newborn Screening Specimens Will Be Stored

Example 1

Upon receipt by the *Laboratory*, DBS samples are stored refrigerated (i.e., 2-6 °C) or at ambient temperature (i.e., 18-25 °C) until testing is completed. After testing is finished, DBS samples are stored in a walk-in refrigerator until disposal.

Example 2

Specimen blotters will be stored at room temperature in a secured access area of the laboratory for no longer than *x* months following receipt, testing, validation, and reporting of results to the patient's healthcare provider. Specimen blotters maintained after testing are hereinafter referred to as residual specimens. *X* months following testing, the DBS sample shall be separated from the patient identifying information, sealed in biohazard bags, destroyed by autoclaving, and disposed of in the general waste. The portion of the DBS sample with the patient identifier is then placed in the sensitive document container for shredding and disposal.

Length of Time Specimens Will Be Stored

Example 1

All DBS samples are retained for *x* weeks after testing is completed in order to allow for re-analysis if questions arise concerning the test results. Specimens that are presumptive positive for any of the diseases included in the newborn screening panel are stored in low gas-permeable, zip-closure bags with desiccant and humidity indicator cards along with CDC quality assurance materials (base and elevated DBS samples) as recommended by CLSI. These presumptive positive DBS samples, required for laboratory quality assurance purposes, may be stored at the laboratory for up to *x* years at 2-6 °C.

Who Will Have Access to the Specimens

Example 1

The *Laboratory* is a secure facility. Access is through key-cards distributed to employees. All visitors must sign in and out with the armed security guard at the front desk, which is manned 24/7. They must be accompanied at all times by a staff member. Access to newborn screening specimens is restricted to staff involved with specimen receipt, testing, data entry and laboratory management.

Example 2

All newborn screening specimens will be handled only by laboratory analytical, receiving, and accessioning staff during all steps of the testing process. All such staff has been trained and has signed documentation to be in accordance with HIPAA requirements. Following accessioning of the specimens by accessioning personnel and laboratory staff, the specimens will be transported to the secure area of the newborn screening laboratory by these aforementioned staff only. The specimen blotters will remain in this secured area during their retained period in the laboratory.

Appropriate Uses of Specimens

Example 1

Retained DBS samples and associated demographic information can be used for the following purposes:

- Re-analysis to confirm the original test results
- Internal method development and method validation studies, including the setting of appropriate cutoffs or normal ranges
- Quality assurance audits and gap analysis
- De-identified DBS aliquots may be sent to another laboratory when the reason for sending the aliquot is:
 - Confirmation of an unusual newborn screening result
 - Participation in a specimen-exchange program designed to improve the quality of testing in newborn screening laboratories
 - Providing assistance to another laboratory in developing or validating a newborn screening method (requires a statement from the laboratory requesting the specimens that specifies how the specimens will be used, and written approval from the Laboratory Director).

Example 2

The main benefits of retention of newborn screening dried blood specimens are:

- Quality assurance and improvement for the newborn screening laboratory
- Research to develop new technologies and detect new disorders
- Research for new treatments and cures for major childhood diseases
- Population incidence research on disorders and environmental contaminant exposures
- Parents can recall specimens to help determine the cause of an unexplained death of their child (e.g., SIDS)
- Parents can recall specimens to aid law enforcement in identifying their missing child

Disposal and/or Disposition of Specimens

Example 1

DBS samples will be autoclaved and then handled as medical waste, which involves off-site incineration.

Example 2

DBS samples from infants whose parents have chosen to have the leftover NBS sample destroyed are retrieved from the storage freezers by the senior scientist that oversees the sample storage process. The NBS laboratory manager then double checks the sample identifiers with the parent opt-out request to assure accuracy, and then acts as witness to the destruction of the sample into medical waste disposal. This is documented by both individuals, initialed and dated in writing on the original parent opt-out letter, of which the parent will receive a copy back in the mail along with a letter stating that their request has been granted.

Release of Specimens to Another Entity

Example 1

DBS samples may be transferred to other entities as delineated below:

- An entity that has a contract with the *Public Health Department* to perform additional (i.e., second tier) testing in response to an out-of-range screening result
- A health care provider at the request of the patient, legal guardian or legal representative after completing and signing a written request form approved by the *Public Health Department*
- A researcher with written, informed consent from the patient, legal guardian, or legal representative as long as the research project has been reviewed and approved by the *Public Health Department*
- A named person in a legally executed subpoena following review and approval by the attorney general or his/her designee
- A person to who release is mandated by order of a court of competent jurisdiction
- Any parent who desires to have his/her child's newborn screening specimen (presumptive positive or confirmed case) destroyed 12 weeks after completion of testing may request such action in writing
- Any parent who desires assurance that his/her child's specimen has been destroyed at or after completion of testing may request confirmation of such action in writing

Example 2

The *Health Department* will release samples upon written request by the parents and guardians to an authorized health care provider. A parental or legal guardian's consent is required.

Research or Third-Party Requests

Example 1

As part of its public health responsibility to support improving newborn screening and the public health, the *Public Health Department* will consider study requests to use DBS samples without patient identifiers, i.e., DBS samples that are either de-identified or anonymized.

De-identified DBS samples are those that are:

- coded and separated from all identifiers; cannot be linked to an individual by an investigator and require a data access agreement under which an investigator agrees not to attempt to re-identify a DBS; and where, if critical to protect the health of an individual, the *Public Health Department* could use the code to re-link a DBS to the individual
- anonymized DBS samples are those that are separated from all possible identifiers and cannot be re-linked to an individual

Requests for samples require:

- A study proposal approved by the Institutional Review Board (IRB) at the investigator's institution
- Purpose of the study
- Anticipated public health or medical benefits
- Whether the proposed study is prospective or retrospective
- If parental or individual consent will be required
- Confidentiality requirements
- Any required demographic characteristics of the specimens
- Time period to be covered by the study
- Analyte(s) to be tested; requested
- Support that would be provided to help retrieve and prepare the requested DBS samples

- The quantity of DBS samples being requested
- Epidemiological/statistical evidence for the number of specimens

Prior to submitting a formal proposal for the *Public Health Department* IRB approval, an investigator must submit the following materials to the Director of the Laboratories Administration so the Director may better understand the request, determine whether the Laboratories Administration will have sufficient resources to meet the request, and respond to the request before the investigator initiates the IRB process: individual consent, will not be approved by the *Public Health Department*.

A request to perform a prospective study using DBS samples found by an IRB to require parental or individual consent for the use of a DBS sample may be considered for approval by the *Public Health Department* Laboratories Administration if:

- Informed consent will be obtained prior to collecting the DBS sample
- Written proof, i.e., a copy of a consent form, for each newborn baby included in the study will be provided to the Laboratories Administration before the DBS samples are provided to the investigator
- Obtaining consent falls fully on the investigator
- The investigator understands that refusal by a parent or individual to consent to the study means no DBS from the baby or individual involved will be provided by the Laboratories Administration for use in the study.

Affirmative responses by the Laboratories Administration to a study request using DBSs also will depend on, but are not limited to: The availability of staff and staff time within the Laboratories Administration to identify DBSs, retrieve DBSs, remove patient identifiers, prepare appropriate documentation, and package and ship the DBSs; and review by the *Public Health Department* IRB to determine that the study:

- Complies with State and federal confidentiality and HSR protection requirements
- Has public health or medical benefit
- Is appropriate for the purpose and intended outcome of the study

Example 2

The *Public Health Department* will release de-identified dried blood spot samples to external agencies for research projects provided that the research project has approval by the agency's IRB. Results from such de-identified samples cannot be linked to the original specimen by the Principal Investigator because the samples are assigned new numbers specific to the study. Any letters of support provided by the *Public Health Department* to an external agency will stipulate that released samples are limited in use for the specifically approved study. Any remaining residual dried blood spot samples should be destroyed upon completion of the study.

The *Public Health Department* will release dried blood spot samples with individually identifiable information to external agencies for research purposes only if parental consent is obtained. The research project must be approved by the agency's IRB. Parental or legal guardian's consent is obtained via the Principal Investigator or designee and copies of these consent forms are provided to the *Public Health Department*. Any letters of support provided by the *Public Health Department* to an external agency will stipulate the released samples are limited in use for the specifically approved study. Any remaining dried blood spots should be destroyed upon completion of the study.

Parental/Patient Options for Extended Storage and Use: Opt-Out Language

Example 1

There are four options available to parents after their child's NBS testing is completed. The first three require action and the last one does not:

- Return the leftover sample to the parents
- Destroy the leftover sample in a scientifically acceptable manner
- Store the leftover sample for *x years* but do not release it for anonymous research
- Do nothing and thereby agree to the default option (storage and anonymous usage).

To opt-out of the sample storage and/or release, the parent must write the *Public Health Department* and request the opt-out choice in writing, and they may do so at any time during the *x year* storage process. If the parent does not choose one of these options, the specimen will automatically be stored at the *Public Health Department* and may be released for approved anonymous research after the first *x months* storage time has transpired and until an opt-out letter is received by the *Public Health Department*. When the *Public Health Department* receives a letter from parents requesting one of the opt-out selections, their request is immediately granted. The *Public Health Department* sends a letter back to the parents stating that their request was fulfilled along with a copy of their original opt-out letter. The *Public Health Department* keeps both electronic and hard copy records of all opt-out cases.

Parental/Patient Options for Extended Storage and Use: Opt-In Language

Example 1

For the purpose of this policy, parental consent can manifest itself in three ways:

- *Department of Health* receives express-written consent from the parent, with instructions to send their child's sample/data to a certain study
- *Department of Health* receives a signed "Parental Decision for Storage and Use of Newborn Screening Blood Spot Cards" form with the check box 'OK' selected
- *Department of Health* receives a research proposal from outside researcher who wish to conduct research on identified residual samples/data, and the study protocol includes obtaining informed parental consent. If the *Department of Health* management and IRB approve the study under this policy and the *Department of Health* IRB policy, samples/data would be released once the signed parental consent forms are received from the researcher.

This policy is not applicable to post-screening uses that are at the express written instruction of the parent/managing conservator/legal guardian, nor those directed by court order (which should be sent to the Office of General Counsel for review), nor those requested by a medical examiner. This policy also does not apply to the Newborn Screening Program clinical care coordination (follow-up) functions related to newborn screening.

Example 2

The parent or legal guardian of an infant otherwise subject to testing under this section may authorize that the infant's blood sample and test results be retained and used by the *Department of Health* beyond the standard retention periods provided in or the purposes described in *x law or statute*.

The *Department of Health* must provide a consent form. The consent form must provide the following:

- Information as to the personal identification and use of samples and test results for studies, including studies used to develop new tests
- Information as to the personal identification and use of samples and test results for public
- Health studies or research not related to newborn screening
- Information that explains that the *Department of Health* will not store a blood sample or test result for longer than 18 years from an infant's birth date
- Information that explains that, upon approval by the *Department of Health's* IRB, blood samples and test results may be shared with external parties for public health studies or research

- Information that explains that blood samples contain various components, including Deoxyribonucleic acid (DNA)
- The benefits and risks associated with the department's storage of a child's blood sample and test results

When authorized in writing by a parent or legal guardian under *x law or statute*, the *Department of Health* may store blood samples and test results for a time period not to exceed 18 years from the infant's birth date, and may use the blood samples and test results in accordance with *x law or statute*.

If Consent is Given How to Revoke Consent

Example 1

A parent or legal guardian may revoke approval for extended storage or use of blood samples or test results at any time by providing a signed and dated form requesting destruction of the blood samples or test results. The *Department of Health* shall make necessary forms available on the department's website.

Request to Destroy the Sample

Example 1

Blood samples must be destroyed within one week of receipt of a request or within one week of the standard retention period for blood samples provided in *x law or statute*, whichever is later. Test results must be destroyed within one month of receipt of a request or within one month of the standard retention period for test results provided in *x law or statute*, whichever is later.

- The benefits and risks associated with the department's storage of a child's blood sample and test results.

Appendix C: Sample Message Pallet

Newborn screening (NBS) blood spots—small drops of a baby’s blood—are vital to quality screening. Samples are collected on cards along with the baby’s demographic data.

Samples are used to:

- Do repeat screening test if needed.
- Develop new screening tests, e.g., SCID.
- Ensure that testing equipment works properly.
- Improve existing newborn screening tests.
- Check accuracy of positive screening results.
- Check screening quality by comparing test results from stored cards with those from cards sent by CDC.

NBS samples are valuable for:

- Making a diagnosis after unexplained death of an infant.
- In research studies of childhood diseases; environmental exposures (like PCB hazards for children in Love Canal) among pregnant women; exposure of pregnant women to infectious agents, e.g., hepatitis B, toxoplasmosis, rubella, HIV
- Guiding management of results for newborns by re-testing older siblings’ samples

Newborn screening blood samples are vital to quality screening. They protect babies’ lives by ensuring accurate and reliable test results.

Some ways states safeguard NBS samples and data:

- De-identify prior to storage.
- Store in locked, secure facilities
- Allow access by few authorized staff
- Destroy cards at end of retention period.
- Ensure IRB oversight where research is allowed
- Require parental consent for use of baby’s card in research

Can my baby be identified through the DNA in the newborn screening sample alone?

- DNA is in all living organisms and all parts of our bodies: e.g., hair, finger nails, skin, blood.
- A baby cannot be identified through the DNA on a collection card alone. A second DNA sample is necessary for comparison. Regulations governing research forbids such comparisons.

Appendix D: FAQs and Prepared Responses

What happens to a baby's blood spots after newborn screening?

After screening is completed, the state newborn screening program saves the unused drops of the baby's blood in case a test needs to be repeated. Newborn screening specialists refer to these drops of blood as "blood spots."

Why do programs keep newborn screening blood spots?

Newborn screening blood spots are vital to quality screening. They protect babies' lives by ensuring accurate and reliable test results. Laboratory scientists rely on them to develop new screening tests, ensure that testing equipment works properly, improve existing newborn screening tests, and to check positive screening results. Programs regularly check the quality of their laboratory by testing spots sent by the Centers for Disease Control and Prevention and comparing these results with those from stored spots.

How long do programs keep newborn screening blood spots?

Each state determines how long it will keep newborn screening blood spots. State statutes, policies and available resources all figure in these decisions. States keep newborn screening blood spots for periods ranging from months to years with some states keeping them indefinitely.

How do programs protect the privacy of stored newborn screening blood spots?

Each state has its own policy for the storage and security of stored newborn screening blood spots including storing in a secured location with limited access, removing demographic information from the card before storage and having laboratory employees sign confidentiality agreements each year.

What happens to newborn screening spots once they reach the end of their retention period?

Newborn screening blood spots and the associated demographic data are destroyed once they reach the end of the state's retention period. Retention periods vary by state. Some states policies require spots to be destroyed by autoclaving, burning or disposing of as medical waste.

How have newborn screening spots been used to support public health?

Blood spots have been used to make a diagnosis after the unexplained death of an infant, to show the effectiveness of a test for conditions being considered for newborn screening and to retest older siblings blood spots in order to determine management of a younger siblings symptoms should a disorder be detected via newborn screening. By testing—with parental consent—the collection cards of children with Severe Combined Immunodeficiency (SCID), also known as "Bubble Boy Disease," researchers were able to determine that the newly developed test worked.

How are newborn screening spots used in research?

In the 1980s and 1990s scientists used newborn screening blood spots to determine the number of newborns exposed to HIV. More recently, blood spots have been used in studies of childhood diseases; environmental exposures (like PCB hazards for children in Love Canal, New York); exposure of pregnant women to infectious agents, e.g., hepatitis B, toxoplasmosis, as well as to guiding management of results for newborns by re-testing older siblings' stored dried blood spot samples.

How is newborn screening blood spots protected when used for research?

Any information that would identify children is removed before newborn screening blood spots are released for use in research. Sometimes parents' consent to release blood spots with the identifying information for a specific study. All research projects are governed by a state Institutional Review Board that evaluates the ethics of a proposed study and its potential to improve health outcomes. Some states also require parental consent before newborn screening blood spots can be used for any research purpose.

Is the identifying information on newborn screening collection cards secure?

Newborn screening aims to achieve the most public health protection with the least intrusion on privacy. Programs seek to do this in a variety of ways. Some states store newborn screening blood spots on cards

that are de-identified and stored in locked, highly secure facilities. Other states allow only authorized staff access to storage facilities.

Some people say that newborn screening will steal my baby’s DNA. Is that true?

There is DNA in a baby’s blood as there is DNA in all living organisms. DNA cannot be used to identify an individual unless there is another blood sample available for comparison. The mission of any newborn screening program is to protect the health and welfare of babies.

Where can I go to find out what conditions my state screens for?

Each state determines the conditions to be screened within its jurisdiction. You can learn about the conditions screened in your state at the [Baby’s First Test site](#). Public health professionals may refer to the [NewSTEPS site](#) for state policies governing retention of newborn screening collection cards.

Parents may also look up their state program’s site directly.



Newborn Screening Blood Tests

A Parent's Guide to Storage and Usage

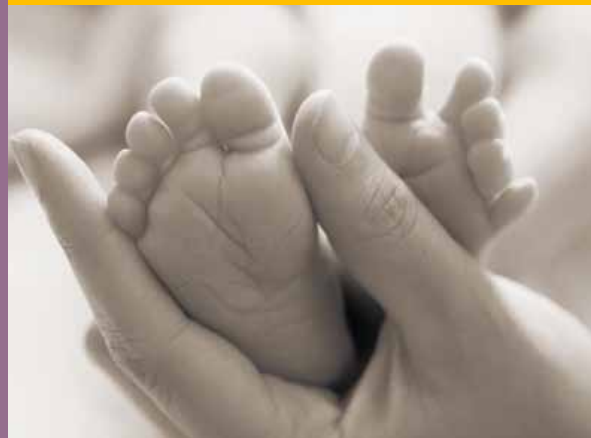
Your Baby's Newborn Screening Blood Test

- Every Texas baby gets a newborn screening blood test soon after birth.
- The screening checks for a number of rare disorders. Many babies with these disorders look healthy when born.
- Finding them early is vital. Prompt treatment can prevent serious illness, physical or mental disabilities, or death.

A sample of blood will be collected from your baby's heel and put on a blood spot card. A second sample will be collected at the doctor's office or clinic 7 to 14 days after birth. The Department of State Health Services (DSHS) lab tests the blood spots.

Safe Storage After Testing

- All blood spot cards are stored safely and securely by DSHS.
- There are many privacy safeguards. All personal information is removed from the card.



You Decide How Long Your Baby's Blood Spot Card is Kept

You have the right to choose how long DSHS keeps your baby's blood spot card and whether it can be used for research purposes outside of DSHS. You can change your mind at any time if you previously chose to allow DSHS to keep the blood spot card.

Each time a newborn screening blood sample is collected, you will get a form to read. The form describes the newborn screening tests. You will have two choices about your baby's blood spot card after the tests are completed:

OK – Allow DSHS to store the card for up to 25 years and possibly release the sample for research, OR

NO – Not allow release of the sample and require that DSHS destroy the card within two years of testing.

You may return the completed and signed Parental Decision for Storage and Use of Newborn Screening Blood Spot Cards form to your health care provider or mail to DSHS as directed on the form.

It is only necessary to complete the form once (unless you change your mind). Your latest decision will apply to all of your baby's blood spots.

No matter your choice, no information that identifies you or your child can be released outside of DSHS without your additional written OK.

How the Blood Spot Cards Might Be Used

Stored blood spots have important possible public health uses. DSHS may use the stored blood spots to:

- Make sure laboratory tests, equipment, and supplies are working right;
- Add newborn screening tests; OR
- Study diseases that affect the health of the public, such as cancer, birth defects, or infectious disease.

If you give your OK, the de-identified blood spots may be used for public health research outside of DSHS. These public health-related research uses must be approved by DSHS management and the DSHS Institutional Review Board whose role is to protect the rights and privacy of people involved in research.



The stored blood spots could also help the child they came from. For example, the child's doctor might ask for other testing on the samples to get more information.

To learn more:
☎ 1-888-963-7111 ext. 7333
🌐 www.dshs.state.tx.us/lab/nbsParentRes.shtml

Texas Department of State Health Services
Newborn Screening Program
P.O. Box 149347
MC 1918
Austin, TX 78756





Guía para padres sobre el almacenamiento

y el uso relacionados con las pruebas de sangre de detección temprana a recién nacidos

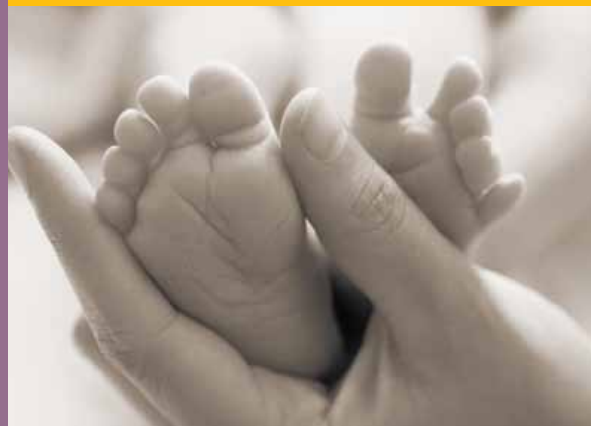
La Prueba de Sangre de Detección Temprana a Recién Nacidos de su Bebé.

- Al poco tiempo de nacidos, a todos los bebés en Texas se les hacen pruebas de sangre de detección temprana a recién nacidos.
- Las pruebas son para detectar distintos trastornos poco comunes. Muchos de los bebés que tienen esos trastornos parecen estar sanos al nacer.
- Es vital encontrar los trastornos a tiempo. El tratamiento rápido puede prevenir enfermedades graves, discapacidades físicas o mentales y la muerte.

Se obtendrá una muestra de sangre del talón de su bebé y esta se pondrá en una tarjeta de recogida de gotas de sangre. Se obtendrá una segunda muestra en el consultorio médico o la clínica 7 a 14 días después de nacido el bebé. El laboratorio del Departamento Estatal de Servicios de Salud (o DSHS) les hace pruebas a las gotas de sangre.

Almacenamiento Seguro Después de las Pruebas

- El DSHS guarda de forma segura todas las tarjetas con gotas de sangre.
- Hay muchas medidas de privacidad preventivas. Toda la información personal se quita de las tarjetas.



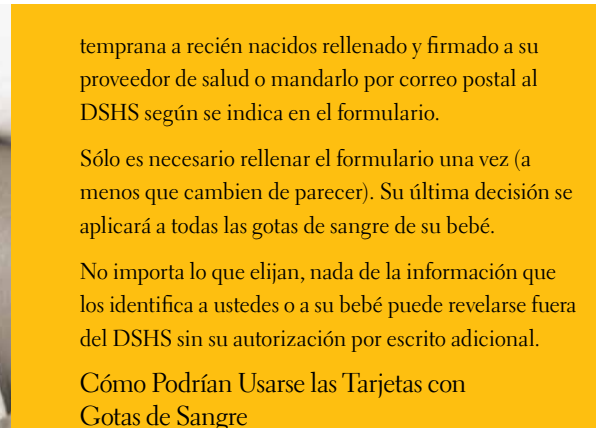
Ustedes Deciden Cuánto Tiempo se Guarda la Tarjeta con Gotas de Sangre de su Bebé

Tienen derecho a elegir cuánto tiempo el DSHS guarda la tarjeta con gotas de sangre de su bebé y si esta se puede usar para fines de investigación fuera del DSHS o no. Pueden cambiar de parecer en cualquier momento si ya han elegido permitir que el DSHS guarde la tarjeta con gotas de sangre.

Cada vez que se obtenga una muestra de sangre para pruebas de detección temprana a recién nacidos, recibirán un formulario para que lo lean. El formulario describe las pruebas de detección temprana a recién nacidos. Tendrán dos opciones para la tarjeta con gotas de sangre de su bebé después de completadas las pruebas:

- SÍ – Permitir que el DSHS guarde la tarjeta hasta por 25 años y posiblemente ceda la muestra para investigaciones, O
- NO – No permitir que se ceda la muestra y requerir que el DSHS destruya la tarjeta en los dos años siguientes a las pruebas.

Pueden devolver el formulario de Decisión de los padres sobre el almacenamiento y el uso de tarjetas con gotas de sangre para pruebas de detección



temprana a recién nacidos relleno y firmado a su proveedor de salud o mandarlo por correo postal al DSHS según se indica en el formulario.

Sólo es necesario rellenar el formulario una vez (a menos que cambien de parecer). Su última decisión se aplicará a todas las gotas de sangre de su bebé.

No importa lo que elijan, nada de la información que los identifica a ustedes o a su bebé puede revelarse fuera del DSHS sin su autorización por escrito adicional.

Cómo Podrían Usarse las Tarjetas con Gotas de Sangre

Las gotas de sangre almacenadas tienen posibles usos de salud pública importantes. El DSHS podría usar las gotas de sangre almacenadas para:

- Cerciorarse de que las pruebas de laboratorio, el equipo y los materiales estén funcionando como deben;
- Agregar pruebas de detección temprana a recién nacidos; O
- Estudiar enfermedades que afecten la salud del público, como el cáncer, los defectos de nacimiento y las enfermedades infecciosas.



Si ustedes lo autorizan, las gotas de sangre sin información identificadora podrían usarse para investigaciones de salud pública fuera del DSHS. Esos usos para investigaciones relativas a la salud pública deben ser aprobados por los directivos del DSHS y la Junta de Revisión Institucional del DSHS, cuyo papel es proteger los derechos y la privacidad de la gente que tiene que ver con las investigaciones.

Las gotas de sangre almacenadas también podrían ayudarle al niño de quien se obtuvieron. Por ejemplo, el doctor del niño podría pedir que les hagan otras pruebas a las muestras para obtener más información.

Pueden informarse más:
☎ por teléfono 1-888-963-7111 extensión 7333
🌐 en la web: www.dshs.state.tx.us/lab/nbsParentRes.shtm

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Association of Public Health Laboratories

The Association of Public Health Laboratories (APHL) works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.



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