



Storage and Use of Newborn Screening Blood Spot Cards

New Requirements – June 1, 2012

HB 1672 and HB 411



Agenda

- History – HB 1672, HB 411
- Comparison of Requirements under Different Laws
- New Forms for HB 411 starting June 1, 2012
- New Healthcare Provider Responsibilities for HB 411
- Logistics of Transition
- HB 411 Points of Contact / Resources

History of Blood Spot Storage and Use Laws

May 2009 - HB 1672

- Outlined allowable uses of residual blood spots
- Required healthcare providers to give a form to the parents when the newborn screen was collected
 - Information about the uses of the blood spots
 - Parental request for destruction of the blood spots

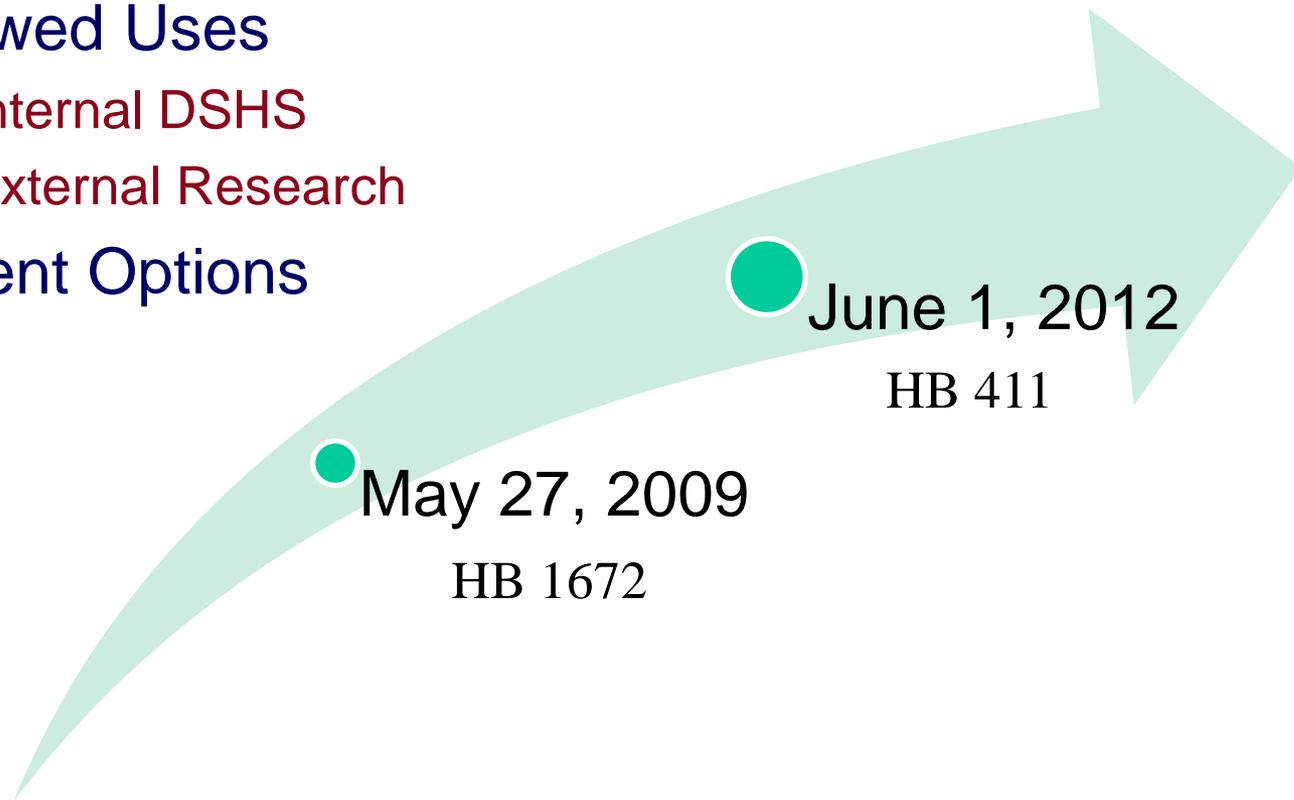
History of Blood Spot Storage and Use Laws

May 2011 - HB 411

- Effective June 2011 - Strengthens the DSHS management review and approval processes of proposed post-screening uses
- Effective June 1, 2012 - Requires parental consent for:
 - Storage longer than 2 years
 - External public health research uses
- New “Decision” Form

Comparison of Timeframe Requirements

- Storage of Residual Blood Spots
- Allowed Uses
 - Internal DSHS
 - External Research
- Parent Options



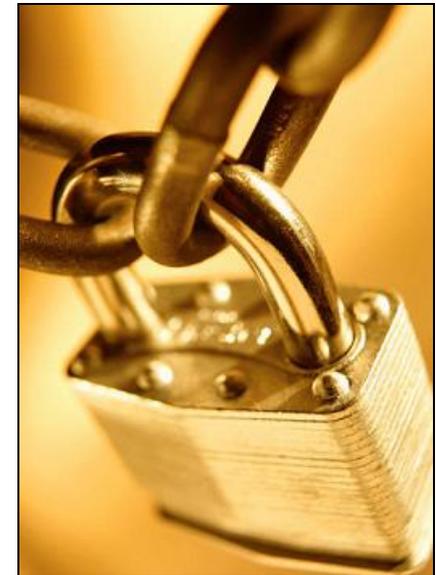
Blood Spot Storage

Length of Storage after Completion of the Newborn Screen Test

Prior to May 27, 2009	May 27, 2009 through May 2012 (HB 1672)	Beginning June 1, 2012 (HB411)
Up to 25 years Destroyed in February 2010 per legal settlement	To be determined	All blood spots are stored for up to 2 years and then destroyed unless the parent submits a completed decision form allowing for longer storage.

IMPORTANT:

- No information that identifies the child or parent can be released outside DSHS without specific written OK from the parent
- Specimens are stored safely and securely



Allowed DSHS Uses

- Allowed uses include:
 - Quality assurance to make sure lab tests, equipment, and supplies are working right
 - Developing new tests; and/or
 - DSHS studies of diseases that affect public health.



Public Health Research Use outside of DSHS

During all timeframes:

- DSHS IRB and management approval required
- De-identified blood spots only

May 27, 2009 through May 2012	June 1, 2012 or Later
Not allowed without study specific parental consent.	Allowed only if parent provides written consent (decision form). Uses must follow DSHS policy for required management and IRB approvals.

Parent Options

<p>May 27, 2009 through May 2012 HB 1672</p>	<p>June 1, 2012 or Later HB 411</p>
<p>Parents may direct DSHS to destroy their child's blood spots within 60 days</p>	<p>Parents may choose to have the blood spots stored for up to 25 years and to possibly be used for de-identified public health research uses outside of DSHS.</p>

New Forms for HB 411

07-060002	Baby's Last Name _____ Baby's First Name _____ Baby's Date of Birth _____ Select Number (31) TX 11- _____	
	Texas Newborn Screening Parent Information	
Parent, Congratulations on your new baby! Take your baby to your baby's doctor when your baby is 7 to 14 days old. Also, take this form. This is important. This will help the doctor get the newborn screening test results.		PROVIDER: Fill out baby's information above. Give this form to a parent.
What is newborn screening? It is a simple blood test to look for some diseases. These diseases can cause a baby to get really sick or die.		What happens to the blood spot card after testing? Starting June 1, 2012: <ul style="list-style-type: none"> • DSHS keeps the blood spot cards in a safe and secure place for up to two years. The blood spot cards may be used to: <ul style="list-style-type: none"> o Make sure the newborn screening tests are working right. o Develop new newborn screening tests, and/or o Study diseases that affect public health. • If you give your OK, your baby's blood spot cards will be stored for up to 25 years, and they may be used for public health research outside of DSHS.
Why should my baby be tested? It is best to treat these diseases early, so we can keep babies from getting sick or dying.		
When is my baby tested? In Texas, babies have a newborn screening test when they are 1 to 2 days old. This test is done again at 7 to 14 days old. The test is done in accordance with Texas law.		Complete, sign, and return the "Parental Decision for Storage and Use of Newborn Screening Blood Spot Cards" form to make your choice. You can change your mind at any time. Call the information number below to get details.
How is newborn screening done? A little blood from your baby's foot is put on a blood spot card. The cards are sent to be tested at the Department of State Health Services (DSHS).		
How do I get results? You can get the test results from your baby's doctor. The results are sent to the doctor from DSHS in one to two weeks.		For more information, call 1(800) 963-7111 ext. 7333 or visit www.dshs.state.tx.us/newbornscreening.shtml
Is more testing available? DSHS screens for many but not all diseases your baby may have. More tests can be done. Ask your baby's doctor and see www.dshs.state.tx.us/newbornscreening.shtml		
Texas Department of State Health Services – Newborn Screening Program P.O. Box 140341, Austin, Texas 78714-0341 (800) 252-8522		Medicaid / CHIP / CLARITY
PARENT COPY		Kit Expires MMDD/YYYY
07-060002		Ve el reverso para Español
Parental Decision for Storage and Use of Newborn Screening Blood Spot Cards		Effective June 1, 2012
you would like DSHS to do with your baby's blood spot cards after testing.		Parent: Please read the form. Select an option. Sign and return.
1. FILL OUT the form below.		Baby's First and Last Name _____ Baby's Date of Birth: _____ Parent Phone Number: _____ Mother's First and Last Name: _____
2. CHECK one box only and SIGN below:		<input type="checkbox"/> 'OK' I give my OK for my baby's blood spot cards to be kept for DSHS after the Newborn Screen tests are complete. They may be used for public health research outside of DSHS.
<input type="checkbox"/> 'NO' I do NOT give my OK for my baby's blood spot cards to be used for any research outside of DSHS after the Newborn Screen tests are complete. I understand the blood spot cards will be destroyed by DSHS within 2 years.		(Parent Signature) _____ (Date) _____
3. RETURN this form to hospital or doctor's office staff with the blood spot cards. Or, you may MAIL it to:		07-060002
Texas Department of State Health Services (DSHS) Newborn Screening Laboratory, MC 940 P.O. Box 140041 Austin, Texas 78714-0041		PROVIDER: Staple form to parent's Blood Spot Card with blood spot cards if requested.
Can information about me or my child be released without my OK? No matter your choice on this form, no information that identifies you or your child can be released outside DSHS without your additional written OK. There are a few exceptions, as provided by law.		07-060002
I've already sent this form. Do I need to send it again? NO. One form applies to all of your baby's newborn screening blood spot cards.		07-060002
For questions or more information: call 1(800) 963-7111 ext. 7333 or call the toll free www.dshs.state.tx.us/newbornscreening.shtml		DSHS Laboratory Order Section 800-963-7111 ext. 7333 (New DSHS)

HB 411 requires the distribution of 2 new forms to parents upon collection of each newborn screen

- Effective date: June 1, 2012
- Explains parent options
- Gives parents a means to allow or refuse long-term storage and use of specimens
- Replaces requirement to distribute current “Parent Copy” and “Disclosure / Directive to Destroy” forms

Goals of Form Development Team

- Ensure parents understand their choices
- Ensure compliance with parental choices
- Streamline healthcare provider distribution
- Ensure compliance with law
- Streamline DSHS processing
- Ensure enough information is requested on forms to match forms to specimens
- Maximize parent / patient privacy
- Improve general Newborn Screening education

Development Summary

- 22 draft versions
- Developed with input from:
 - Professional medical organizations including TMA, TPS, and THA
 - Parents
 - Submitting facility physicians, nurses, and technologists
 - DSHS Laboratory and Clinical Care Coordination staff
 - Legal advisors
- Reviewed by
 - DSHS Executive Leadership
 - Texas Legislative Offices
 - Healthcare Provider Stakeholders

Parent Information Form

- Page 1 of 2012 Kits (Replaces Page 1 of previous kits)
- English / Spanish – Front / Back
- Distribute to parent upon collection of each specimen
- Parents should take form received at collection of first screen to their baby's doctor when the baby is 7 to 14 days of age
- Will be OK to still distribute older version beginning June 1.

07-0600002

Baby's Last Name Baby's First Name Baby's Date of Birth Total Screen TX 11-####

Texas Newborn Screening Parent Information

PROVIDER: Fill out baby's information above. Give this form to a parent.

Parent: Congratulations on your new baby!
Take your baby to your baby's doctor when your baby is 7 to 14 days old. **Also, take this form!** This is important. This will help the doctor get the newborn screening test results.

What is newborn screening? It is a simple blood test to look for some diseases. These diseases can cause a baby to get really sick or die.

Why should my baby be tested? If we find and treat these diseases early, we can keep babies from getting sick or dying.

When is my baby tested? In Texas, babies have a newborn screening test when they are 1 to 2 days old. This test is done again at 7 to 14 days old. The test is done in accordance with Texas law.

How is newborn screening done? A little blood from your baby's foot is put on a blood spot card. The cards are sent to be tested at the Department of State Health Services (DSHS).

How do I get results? You can get the test results from your baby's doctor. The results are sent to the doctor from DSHS in one to two weeks.

Is more testing available? DSHS screens for many but not all diseases your baby may have. More tests can be done. Ask your baby's doctor and see www.baby'sdoctor.org/faq-screening.

What happens to the blood spot card after testing?

- Starting June 1, 2012:
 - Cards keep the blood spot cards in a safe and secure place for up to two years. The blood spot cards may be used to:
 - o Make sure the newborn screening tests are working right
 - o Develop new newborn screening tests, and/or
 - o Study diseases that affect public health.
 - If you give your OK, your baby's blood spot cards will be stored for up to 25 years, and they may be used for public health research outside of DSHS.

Complete, sign, and return the "Parental Decision for Storage and Use of Newborn Screening Blood Spot Cards" form to make your choice.
You can change your mind at any time. Call the information number below to get details.

No matter your choice, no information that identifies you or your child can be released outside DSHS without your additional written OK. There are a few exceptions, as provided by law.

For more information, call 1(888) 963-7111 ext. 2333 or visit www.dshs.texas.gov/newbornscreening.

Kit Expires MM/DD/YYYY

Medicaid / CHIP / CHARITY

Veró de reverso para Español

PARENT COPY

State Department of State Health Services - Newborn Screening Program
P.O. Box 128391 Austin, Texas 78712-8391 (512) 251-2322

Medicaid / CHIP / Charity

07-0600002

Baby's Last Name Baby's First Name Baby's Date of Birth Total Screen TX 11-####

Texas Newborn Screening Parent Information

PROVIDER: Fill out baby's information above. Give this form to a parent.

Parent: Congratulations on your new baby!
Take your baby to your baby's doctor when your baby is 7 to 14 days old. **Also, take this form!** This is important. This will help the doctor get the newborn screening test results.

What is newborn screening? It is a simple blood test to look for some diseases. These diseases can cause a baby to get really sick or die.

Why should my baby be tested? If we find and treat these diseases early, we can keep babies from getting sick or dying.

When is my baby tested? In Texas, babies have a newborn screening test when they are 1 to 2 days old. This test is done again at 7 to 14 days old. The test is done in accordance with Texas law.

How is newborn screening done? A little blood from your baby's foot is put on a blood spot card. The cards are sent to be tested at the Department of State Health Services (DSHS).

How do I get results? You can get the test results from your baby's doctor. The results are sent to the doctor from DSHS in one to two weeks.

Is more testing available? DSHS screens for many but not all diseases your baby may have. More tests can be done. Ask your baby's doctor and see www.baby'sdoctor.org/faq-screening.

What happens to the blood spot card after testing?

- Starting June 1, 2012:
 - DSHS keeps the blood spot cards in a safe and secure place for up to two years. The blood spot cards may be used to:
 - o Make sure the newborn screening tests are working right
 - o Develop new newborn screening tests, and/or
 - o Study diseases that affect public health.
 - If you give your OK, your baby's blood spot cards will be stored for up to 25 years, and they may be used for public health research outside of DSHS.

Complete, sign, and return the "Parental Decision for Storage and Use of Newborn Screening Blood Spot Cards" form to make your choice.
You can change your mind at any time. Call the information number below to get details.

No matter your choice, no information that identifies you or your child can be released outside DSHS without your additional written OK. There are a few exceptions, as provided by law.

For more information, call 1(888) 963-7111 ext. 7333 or visit www.dshs.texas.gov/newbornscreening.

Kit Expires MM/DD/YYYY

INSURANCE / SELF-PAY

Veró de reverso para Español

PARENT COPY

State Department of State Health Services - Newborn Screening Program
P.O. Box 128391 Austin, Texas 78712-8391 (512) 251-2322

Insurance / Self-Pay

Parent Information Form

Parent instructions to take form received at 1st screen to doctor when baby is 7 to 14 days of age

Information about residual specimen storage / use and Parental Decision form (Page 2)

07-0600002	MM/DD/YYYY	Serial Number [SN] TX 11- #####
	Baby's Last Name	Baby's First Name
Texas Newborn Screening Parent Information		
PROVIDER: Fill out baby's information above. Give this form to a parent.		
<p>Parent, Congratulations on your new baby!</p> <p>Take your baby to your baby's doctor when your baby is 7 to 14 days old. Also, take this form! This is important. This will help the doctor get the newborn screening test results.</p> <p>What is newborn screening? It is a simple blood test to look for some diseases. These diseases can cause a baby to get really sick or die.</p> <p>Why should my baby be tested? If we find and treat these diseases early, we can keep babies from getting sick or dying.</p> <p>When is my baby tested? In Texas, babies have a newborn screening test when they are 1 to 2 days old. This test is done again at 7 to 14 days old. The test is done in accordance with Texas law.</p> <p>How is newborn screening done? A little blood from your baby's foot is put on a blood spot card. The cards are sent to be tested at the Department of State Health Services (DSHS).</p> <p>How do I get results? You can get the test results from your baby's doctor. The results are sent to the doctor from DSHS in one to two weeks.</p> <p>Is more testing available? DSHS screens for many but not all diseases your baby may have. More tests can be done. Ask your baby's doctor and see www.babysfirsttest.org/find-condition.</p> <p><small>Texas Department of State Health Services - Newborn Screening Program P.O. Box 140341, Austin, Texas 78714 - 0341 (800) 252-0023</small></p>	<p>What happens to the blood spot card after testing? Starting June 1, 2012:</p> <ul style="list-style-type: none"> DSHS keeps the blood spot cards in a safe and secure place for up to two years. The blood spot cards may be used to: <ul style="list-style-type: none"> Make sure the newborn screening tests are working right; Develop new newborn screening tests; and/or Study diseases that affect public health. If you give your OK, your baby's blood spot cards will be stored for up to 25 years, and they may be used for public health research outside of DSHS. <p>Complete, sign, and return the "Parental Decision for Storage and Use of Newborn Screening Blood Spot Cards" form to make your choice. You can change your mind at any time. Call the information number below to get details.</p> <p>No matter your choice, no information that identifies you or your child can be released outside DSHS without your additional written OK. There are a few exceptions, as provided by law.</p> <p>For more information, call 1(888) 963-7111 ext. 7333 or visit: www.dshs.state.tx.us/lab/newbornscreening.shtml</p>	INSURANCE / SELF-PAY
PARENT COPY		Kit Expires MM/DD/YYYY

Expanded and simplified general newborn screening information

Contact phone number and web address

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Parental Decision for Storage and Use of NBS Blood Spot Cards

Explanation of Choices

Parental Decision for Storage and Use of Newborn Screening Blood Spot Cards Effective: June 1, 2012

Please read below to decide what you would like DSHS to do with your baby's blood spot card when the Newborn Screening tests are finished.

If you check the 'OK' box AND sign this form:

- All of your baby's blood spot cards will be kept safe and secure for up to 25 years.
- The blood spot cards may be used for public health research. The research may take place outside of DSHS. This research would study public health problems like cancer, birth defects, or other illnesses.
- If a card is used for research, DSHS will keep at least one blood spot. This is in case it is needed for your child's medical care.
- You can change your mind at any time. Call DSHS (see number below) for details.

If you check the 'NO' box OR do not sign OR do not fill out OR do not return this form:

- The Newborn Screening tests will still be done in accordance with Texas law.
- Your baby's blood spot cards will be kept safe and secure. They will be destroyed within two years.
- The blood spot cards will NOT be used for public health research outside DSHS.

Can information about me or my child be released without my OK? No matter your choice on this form, no information that identifies you or your child can be released outside DSHS without your additional written OK. There are a few exceptions, as provided by law.

I've already sent this form. Do I need to send it again? NO. One form applies to all of your baby's newborn screening blood spot cards.

For questions or more information: Call 1(800) 963-7111 ext. 7333 or visit the web site: www.dshs.state.tx.us/nbs/newbornscreening.shtm

07-0600002

DSHS Laboratory/Screening Section NBS Form: 0714-0009 (04/14/2012)

PARENT: Please read this form. Select an option. Sign and return

1. FILL OUT the form below.

Baby's First and Last Name: _____
 Baby's Date of Birth: _____
 Parent Phone Number: _____
 Mother's First and Last Name: _____

2. CHECK one box only and **SIGN** below.

'OK' I give my **OK** for my baby's blood spot cards to be kept by DSHS after the Newborn Screen tests are complete. They may be used for public health research outside of DSHS.

'NO' I do **NOT** give my OK for my baby's blood spot cards to be used for any research outside of DSHS after the Newborn Screen tests are complete. I understand the blood spot cards will be destroyed by DSHS within 2 years.

(Parent Signature) _____ (Date) _____

3. RETURN this form to hospital or doctor's office staff. They will send it in with the blood spot cards. Or, you may **MAIL** it to:
 Texas Department of State Health Services (DSHS)
 Newborn Screening Laboratory, MC 1947
 P.O. Box 140045
 Austin, Texas 78714-0045

PROVIDER: Give form to parent & return with blood spot cards if requested

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Forms without a signature or a selection will default to 'No'

Parents only need to complete form once per child

Signature is required to process 'OK' selection

New Healthcare Provider Responsibilities for HB 411





Healthcare Provider Responsibilities

Step 1: Distribute to parents upon collection of each newborn screening specimen.

“Texas Newborn Screening Parent Information” (Page 1 of 2012 Kits)

and

“Parental Decision for Storage and Use of Newborn Screening Blood Spot Cards” (Decision form) (Page 2 of 2012 Kits)

Healthcare Provider Responsibilities

STEP 2: Advise parents that they should :

- Read Page 1 “**Texas Newborn Screening Parent Information**”. Take the form given to them upon collection of the first screen to their child’s healthcare provider when the child is 7 to 14 days of age.
- Read Page 2, “**Parental Decision for Storage and Use of Newborn Screening Blood Spot Cards**”, select an option, and return to DSHS.

Parents may return the form to the healthcare provider at the time of collection or mail it into DSHS at a later date.

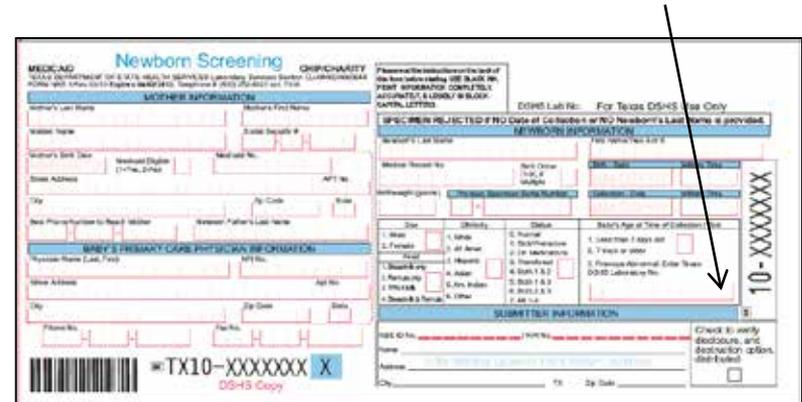


'OK' I give my OK

'NO' I do NOT give my ok

Healthcare Provider Responsibilities

STEP 3: Check the box on the demographic form (**Page 3**) that the “Use and Storage...” form was given to the parent.



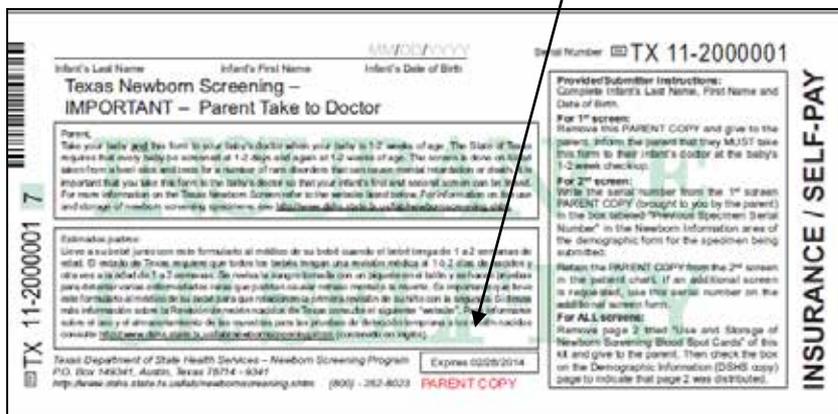
The image shows a 'Newborn Screening' form with several sections. A red arrow points to a checkbox in the 'SUBMITTER INFORMATION' section, which is labeled 'Check to verify specimen and destination when returned'. The form includes fields for mother's and father's information, baby's information, and a barcode at the bottom with the text 'TX10-XXXXXX X DS-43 Copy'.

STEP 4: If requested by parent, return the completed form to DSHS along with any regular newborn screening specimen shipment



What do Healthcare Providers do with the older collection kits (2010 and 2011) starting on June 1, 2012?

Continue to use the 2010 and 2011 collection kits through the kit expiration date.



Serial Number TX 11-2000001

Texas Newborn Screening – IMPORTANT – Parent Take to Doctor

Parent: Take your baby and his form to your baby's doctor when your baby is 1-2 weeks of age. The State of Texas requires that every baby be screened at 1-2 days old and again at 1-2 weeks of age. The screen is done on heel pricks from a heel stick and must be done before 15 days old. If you do not have a heel stick, you must have a heel stick done at the doctor's office. It is important that you take this form to the doctor's office so that your baby's first and second screens can be linked. For more information on the Texas Newborn Screening or to the serial number below. For information on the use and storage of newborn screening specimens, see <http://www.dshs.state.tx.us/lab/nbs/parentinfo.asp>.

Parental Decision for Storage & Use

YES

NO

INSURANCE / SELF-PAY

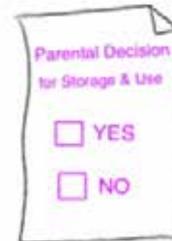
Expires 02/28/2014

Parent Department of State Health Services – Newborn Screening Program
P.O. Box 446347, Austin, Texas 78744-4347
<http://www.dshs.state.tx.us/lab/nbs/parentinfo.asp> (800) 252-8023

STEP 1: Discard page 2 of kit



STEP 2: Print full-page parental decision form



STEP 3: Give to parent

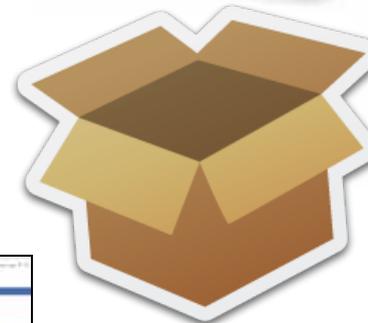


8 ½ X 11 form is available at:

<http://www.dshs.state.tx.us/lab/nbsBloodspots.shtm>

Educational Resources

- Official notification letter
- Monthly NBS listserv updates
- Kit order inserts
- Website updates
<http://www.dshs.state.tx.us/lab/nbsBloodspots.htm>
- Webinars
- CE modules
- Video
- Pamphlets / flyers





Resources

Web

<http://www.dshs.state.tx.us/lab/nbsBloodspots.shtm>

Phone:

1-888-963-7111, ext. 7333, or 512-776-7333

Email:

NewbornScreeningLab@dshs.state.tx.us