Newborn Screening

Oklahoma State Department of Health

Newborn Screening Program

Phone: (405) 426-8310

Toll Free: 1 (800) 766-2223

Fax: (405) 900-7556

NewbornScreen@health.ok.gov

OKLAHOMA
State Department of Health

Why Newborn Screening

Allow me to Introduce….

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Lainey's Story – MCADD

History of Newborn Screening

Then and Now

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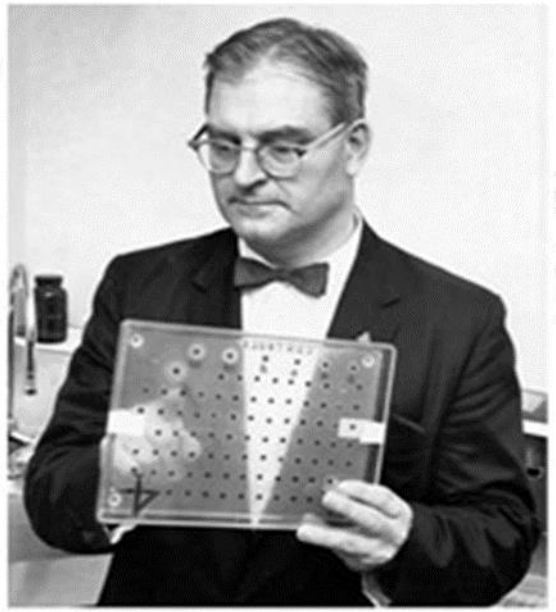
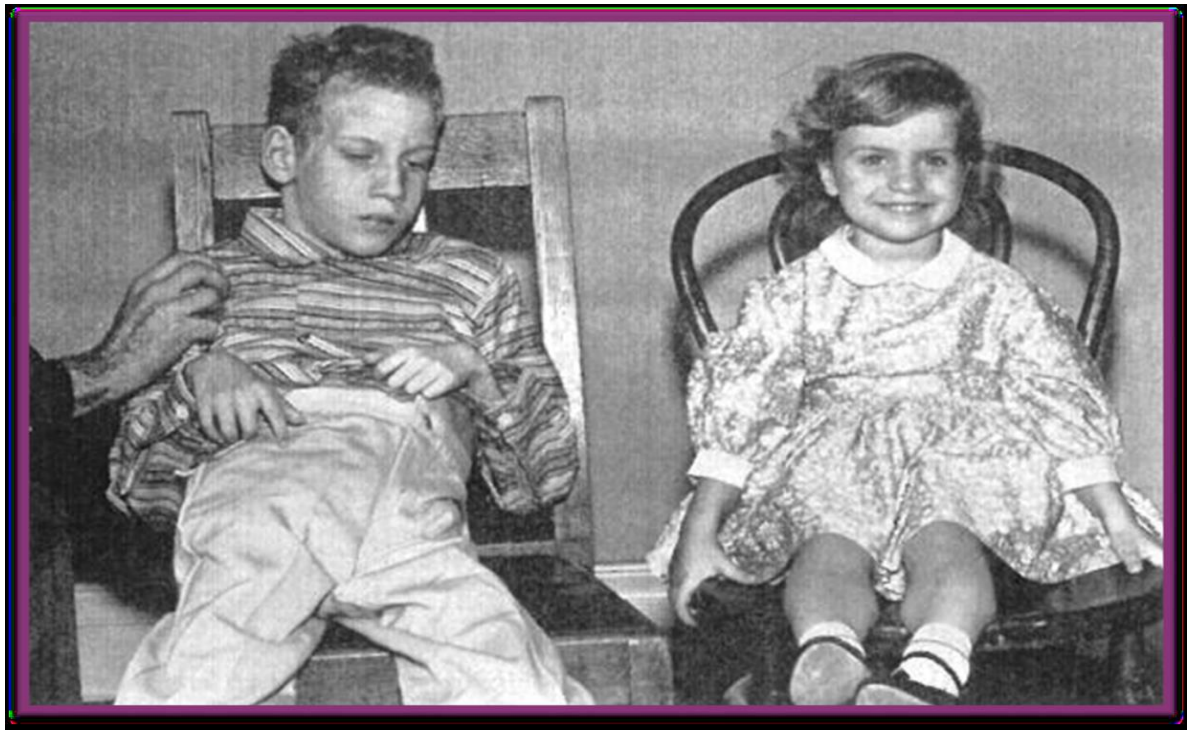
History of Newborn Screening

- Newborn screening **originated** with Dr. Robert Guthrie who developed a test for elevated phenylalanine in dried blood spots in **1960**. (PKU Disease)
- **Before** the blood test existed, most children with PKU were not diagnosed until after they had irreversible brain damage.
- **Early** test > **Early** diagnosis > **Early** treatment > Mitigated brain damage.
- PKU was the first condition identified by NBS, so some people still refer to all NBS as the "PKU test." However, **this term is not accurate as the newborn screen now tests for 57 total disorders, not solely PKU.**

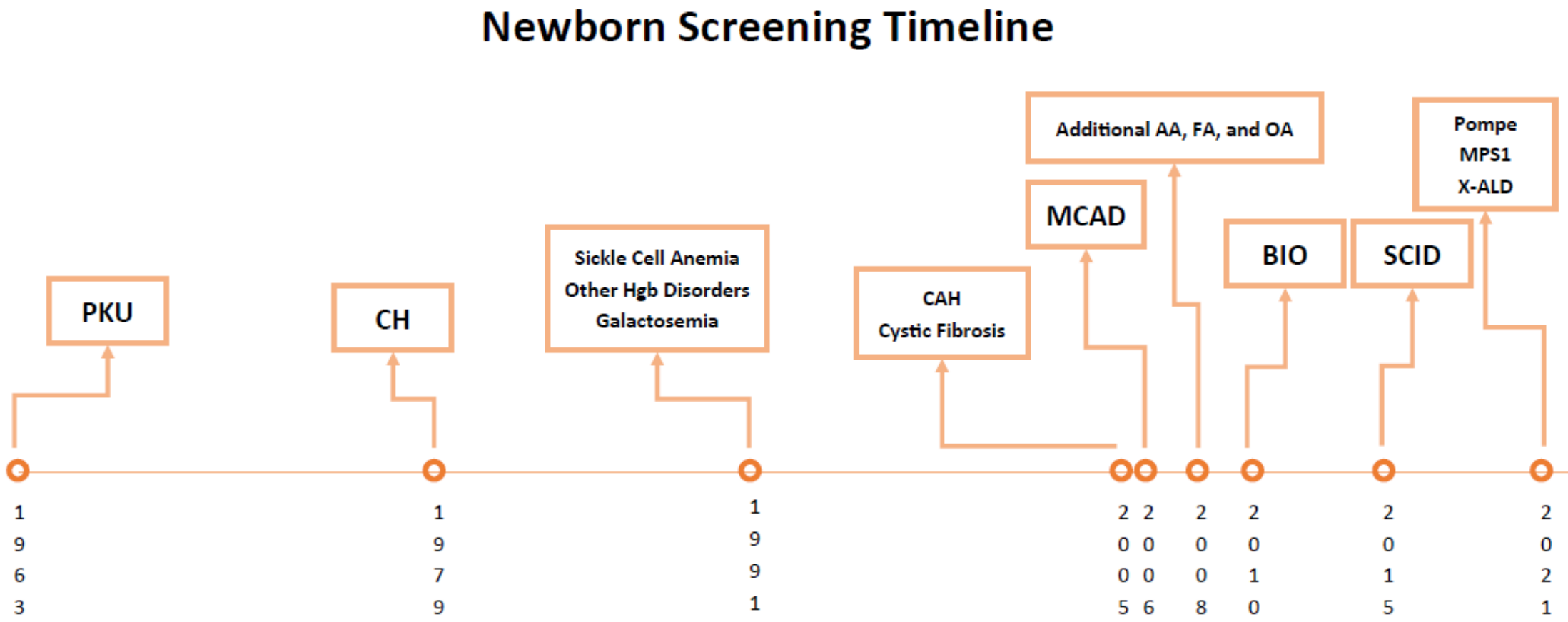


Before NBS: Parents Had to Lose One to Save One



Untreated versus Treated PKU

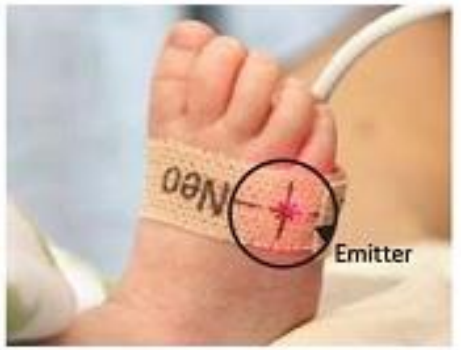
Scientific Progress Translates to More Infant Lives Positively Impacted



More to Come….

Newborn Screening Today: A Three-Part Process

- Newborn screening checks a baby for certain conditions present at birth that benefit from early treatment or intervention.
  - Blood spot screening, which determines if a baby might have one of many serious conditions.
  - Pulse oximetry screening, which determines if a newborn might have certain heart conditions.
  - Hearing screening, which determines if a newborn might be deaf or hard of hearing.



PURPOSE – Every Baby Deserves A Newborn Screen

- Newborn screening (NBS) is the practice of testing **every** newborn for harmful or potentially fatal disorders that are not otherwise apparent at birth.
- **Early detection** and **prompt treatment** can make the difference between healthy development or lifelong impairment and possible death.

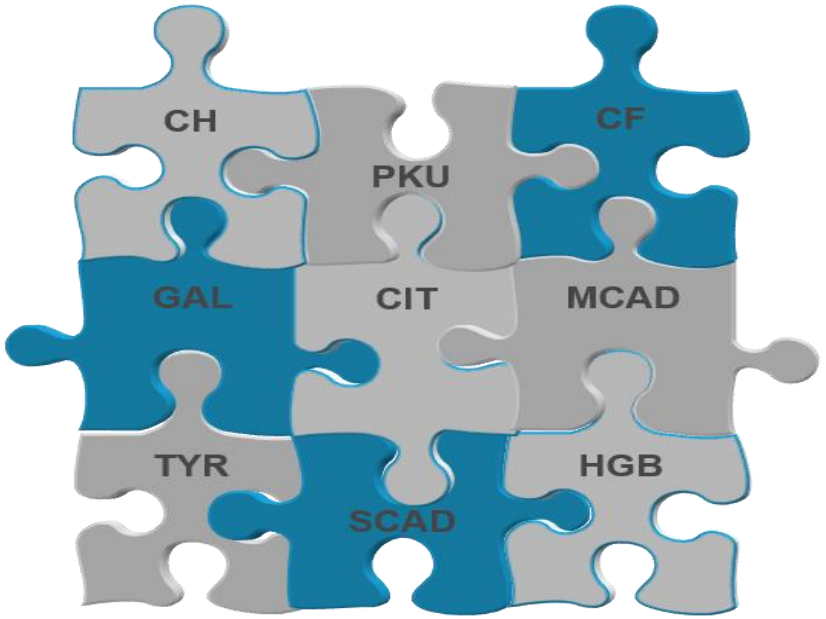
Screening VS Diagnostic

- **Screening results**, by themselves, cannot determine the presence or absence of a disorder. The purpose of a screen is to detect risk factors for disease in large numbers of apparently healthy individuals – in this case, newborns.

- **Diagnostic results** refers to the combination of signs, symptoms, and test results that allows the provider to confirm the diagnosis of the respective disease.

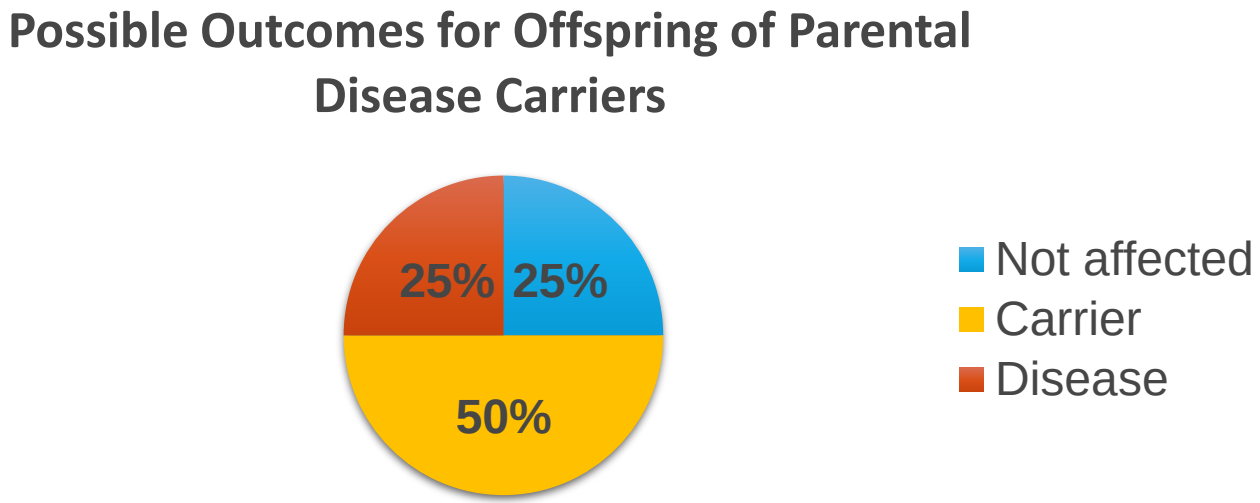
Who Decides?

- In 2022, the Oklahoma legislature passed a statute stating that the Oklahoma NBS panel will match the national Recommended Uniform Screening Panel (RUSP) to the extent practicable.
- Once a condition is added to the RUSP the NBS Program (lab and follow-up) will determine practicability and readiness.
- The Infant and Children's Health Advisory Committee will provide recommendations to the Commissioner of Health to add the disorder.
- The Commissioner of Health will give final approval.
- Oklahoma currently screens for 57 possible hidden disorders.
- Oklahoma will continue to expand.
- Three disorders added to RUSP in the last year (MPS2, GAMT, and Krabbe) that OK will work to add to our state panel.



Autosomal Recessive

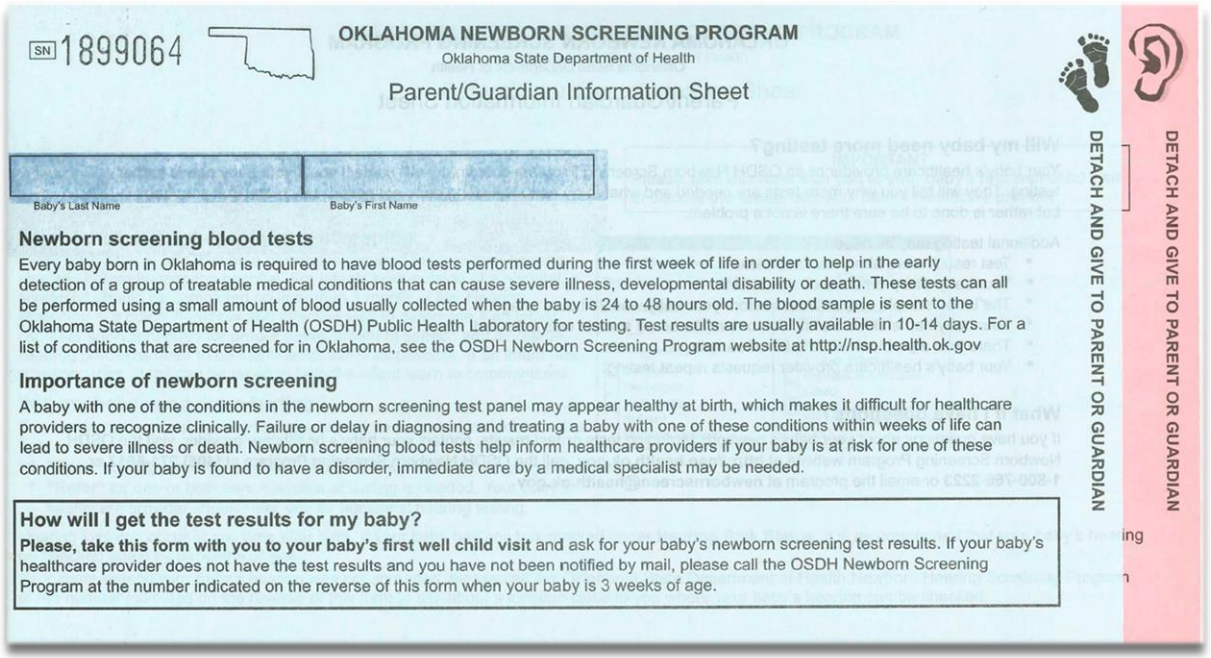
- Most NBS disorders are autosomal recessive with the exception of:
  - Congenital Hypothyroidism (CH)
  - Some forms of Severe Combined Immunodeficiency (SCID)
  - X-Linked Adrenoleukodystrophy
- Usually no prior family history
- Risk for <u>each</u> pregnancy if both parents are carriers of a disorder:



Parent Education

- Instruct parents to ask for their baby's newborn screening results:
  - Baby's Pediatrician
  - Local County Health Department
  - OSDH Newborn Screening Program

- Tell parents to hang onto the Blue or Pink slip from their baby's filter paper for reference.



SN 1899064

OKLAHOMA NEWBORN SCREENING PROGRAM

Oklahoma State Department of Health

Parent/Guardian Information Sheet

Baby's Last Name | Baby's First Name

Newborn screening blood tests

Every baby born in Oklahoma is required to have blood tests performed during the first week of life in order to help in the early detection of a group of treatable medical conditions that can cause severe illness, developmental disability or death. These tests can all be performed using a small amount of blood usually collected when the baby is 24 to 48 hours old. The blood sample is sent to the Oklahoma State Department of Health (OSDH) Public Health Laboratory for testing. Test results are usually available in 10-14 days. For a list of conditions that are screened for in Oklahoma, see the OSDH Newborn Screening Program website at http://nsp.health.ok.gov

Importance of newborn screening

A baby with one of the conditions in the newborn screening test panel may appear healthy at birth, which makes it difficult for healthcare providers to recognize clinically. Failure or delay in diagnosing and treating a baby with one of these conditions within weeks of life can lead to severe illness or death. Newborn screening blood tests help inform healthcare providers if your baby is at risk for one of these conditions. If your baby is found to have a disorder, immediate care by a medical specialist may be needed.

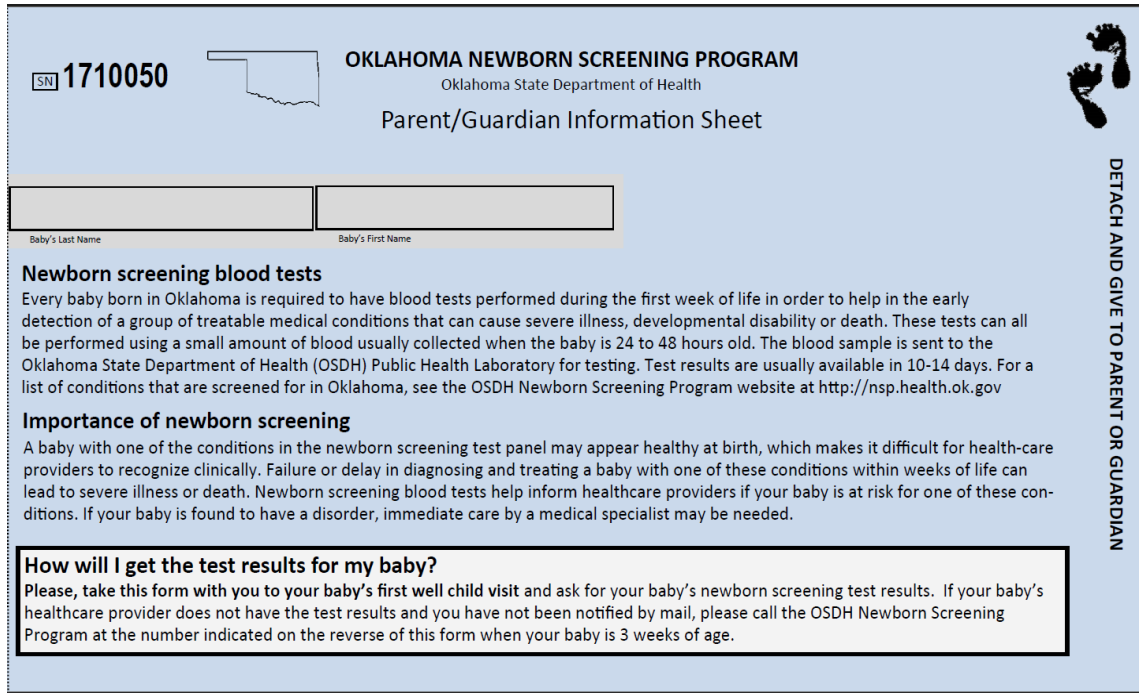
How will I get the test results for my baby?

Please, take this form with you to your baby's first well child visit and ask for your baby's newborn screening test results. If your baby's healthcare provider does not have the test results and you have not been notified by mail, please call the OSDH Newborn Screening Program at the number indicated on the reverse of this form when your baby is 3 weeks of age.

DETACH AND GIVE TO PARENT OR GUARDIAN

DETACH AND GIVE TO PARENT OR GUARDIAN

Oklahoma State Rules and Statutes – Filter Paper Education Pages
Blood spot



SN 1710050

OKLAHOMA NEWBORN SCREENING PROGRAM
Oklahoma State Department of Health
Parent/Guardian Information Sheet

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DETACH AND GIVE TO PARENT OR GUARDIAN

OKLAHOMA NEWBORN SCREENING PROGRAM
Oklahoma State Department of Health
Parent/Guardian Information Sheet

Will my baby need more testing?
Your baby's healthcare provider or an OSDH Newborn Screening Program coordinator will contact you if your baby needs further testing. They will tell you why more tests are needed and what to do next. Retesting does not necessarily mean that your baby is sick, but rather is done to be sure there is not a problem.

Additional testing may be needed if:

- Test results were abnormal or unclear.
- Your baby was premature or sick at birth.
- The blood sample was collected before your baby was 24 hours of age.
- Your baby had a blood transfusion before the blood sample was collected.
- There was a problem with the blood sample.
- Your baby's healthcare provider requests repeat testing.

What if I have questions?
If you have questions about your baby's newborn screening tests or test results, contact your baby's healthcare provider, visit the OSDH Newborn Screening Program website at http://nsp.health.ok.gov, call the OSDH Newborn Screening Program at **(405) 271-6617** or **1-800-766-2223** or email the program at newbornscreen@health.ok.gov

Oklahoma State Rules and Statutes – Filter Paper Education Pages
Hearing Screen

SN 1710050

OKLAHOMA NEWBORN HEARING SCREENING PROGRAM
Oklahoma State Department of Health

Parent/Guardian Information Sheet

Baby's Last Name | Baby's First Name

IMPORTANT
Please, take this form with you to your baby's first well child visit to discuss the results with your baby's healthcare provider.

DETACH AND GIVE TO PARENT or GUARDIAN

Importance of newborn hearing screening

Every baby born in an Oklahoma hospital is required to have their hearing checked before leaving the hospital. For infants born outside of a hospital, a screening should be completed no later than 1 month of life. Hearing screening is a quick, harmless and effective way to determine if an infant can hear sounds needed for proper development of speech and language. Hearing problems need to be identified as early as possible. If an infant has a hearing loss, steps can be taken to help the infant learn to communicate.

HEARING SCREEN

Date of Final Screen ____ / ____ / ____

Right Ear: ☐ Pass ☐ Refer Left Ear: ☐ Pass ☐ Refer

Screen Method
☐ ABR ☐ OAE

If not screened, reason
☐ Delayed
☐ Discharged
☐ No Supplies
☐ Refused
☐ Technical Problem

Hearing Risk Status
(Select all that apply)
☐ Family History
☐ In Utero Infection
☐ Craniofacial Anomalies
☐ ECMO
☐ Both Hyperbilirubinemia AND Exchange Transfusion
☐ NICU

Will my baby need more testing?

The hearing screen results for your baby should be indicated in the box to the right.

- **"Pass"** for both ears = your infants hearing is sufficient for language development.
- **"Refer"** for one or both ears = additional testing is needed. Your baby's healthcare provider should refer you for additional hearing testing.

Hearing loss can occur at any time after birth. If your baby has any box marked under **Hearing Risk Status**, it is recommended that your baby's hearing be checked again by 6 months of age.

If for some reason your baby's hearing was not screened, please call the Oklahoma State Department of Health Newborn Hearing Screening Program at the number indicated on the reverse of this form to ask about a location close to you where your baby's hearing can be checked.

OKLAHOMA NEWBORN HEARING SCREENING PROGRAM
Oklahoma State Department of Health

Parent/Guardian Information Sheet

Your baby's hearing

Your child's most important learning and speech development will take place during the first few years of life. In these early years of development, your child learns how to communicate — first to understand what people say, and then to start talking. Any degree of undetected hearing loss can negatively impact a child's speech, language, social and emotional development.

Your baby should be able to achieve the following milestones around the ages listed below. As the weeks and months go by, check to see if your baby can do most of the things listed. *If your baby can't, don't wait— have your infants' hearing tested.* If you suspect a hearing loss or have a concern about your child's hearing, contact your healthcare provider, an audiologist, or your county health department to find out about hearing testing.

Hearing checklist

Birth to 3 months
- startled by loud sound
- quiets to your voice
- makes cooing sounds

3 to 6 months
- turns eyes toward sounds
- responds to mother's voice
- enjoys rattles
- babbles "ba-ba" or ga-ga"

6 to 10 months
- turns head towards sounds
- begins to imitate speech sounds
- babbles more frequently

9 to 12 months
- responds to own name
- understands "no no" & "bye-bye"
- turns head toward soft sounds

12 to 15 months
- correctly uses "ma-ma" and "da-da"
- points to familiar objects when asked
- responds to singing/music

What if I have questions?

If you have questions about your baby's newborn hearing test results, contact your baby's healthcare provider, visit the OSDH Newborn Screening Program website at **http://nsp.health.ok.gov**, call at **(405) 271-6617** or **1-800-766-2223**, or email the program at **newbornscreen@health.ok.gov**.

Parent Education

- NBS is collected on **every** baby born in Oklahoma.
- Importance of **correct** contact info and PCP for follow-up.
- *No news is not good news!* Update NBS Program with changes in home address and/or PCP.
- Review hidden disorders, using NBS pamphlet as a guide.
- Specimens are kept by the OSDH lab for 42 days before being destroyed.
- Explain that most affected newborns do not exhibit signs & symptoms early on.
- Prompt identification and treatment of disorders is critical.

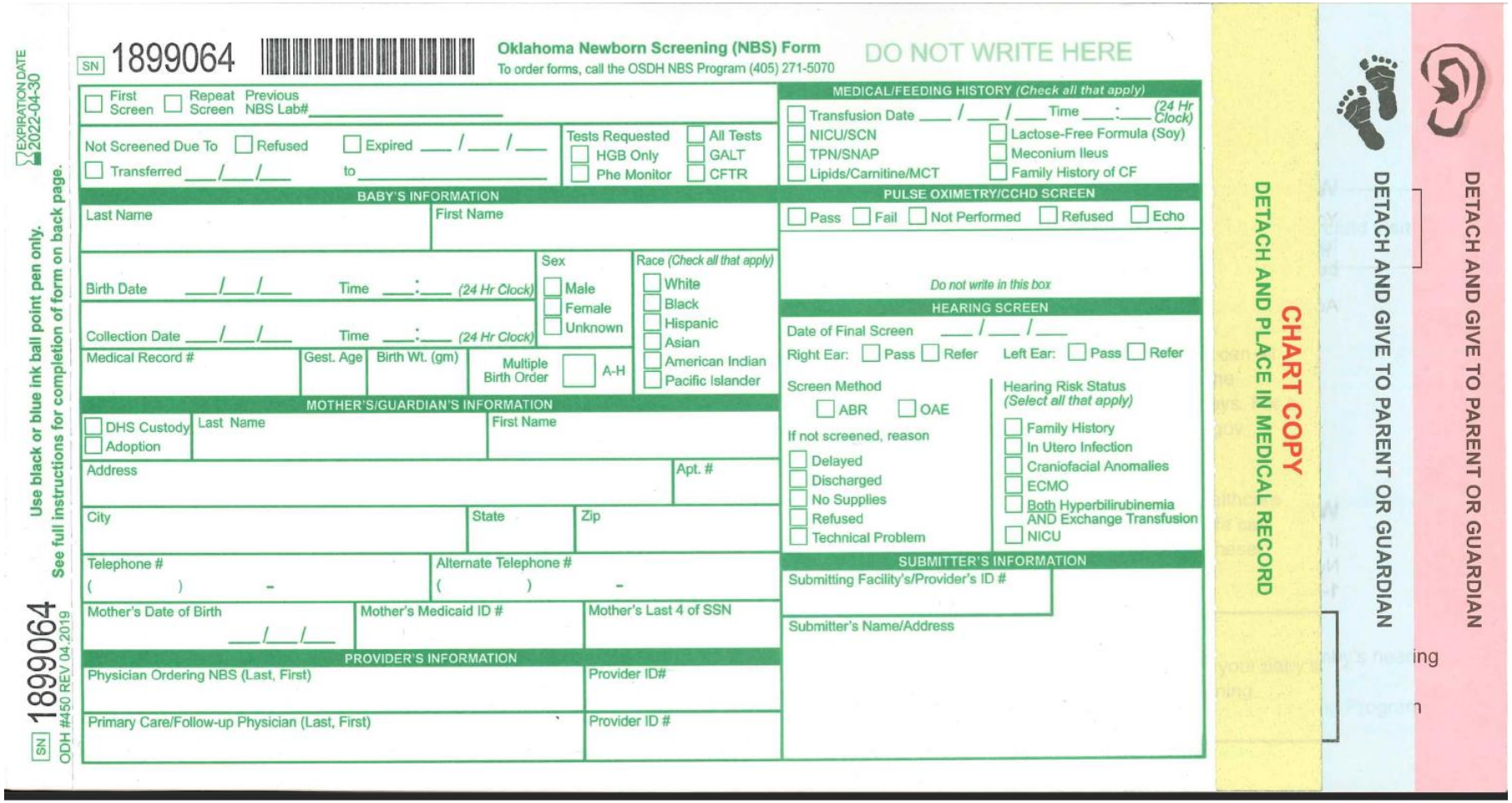
Indications for Repeat Screen

- The NBS testing results are out of range for one or more disorders – PCP notified by phone, parent by mail.
- The NBS sample was damaged or is otherwise unsatisfactory for testing – PCP and parent notified by mail.
- The infant received a transfusion prior to NBS collection – usually in NICU, will notify PCP when time for recollection.
- The infant's screen was collected prior to 24 hours old – if normal result, this report will be on the portal, if out of range, PCP notified by phone, parent by mail.
- The infant is premature or sick (TPN and antibiotics could affect results).

Filling Out the Demographic Form

OKLAHOMA
State Department
of Health

Filling out the Form



Specimen testing will be delayed if the form is incomplete!

Filling out the Form

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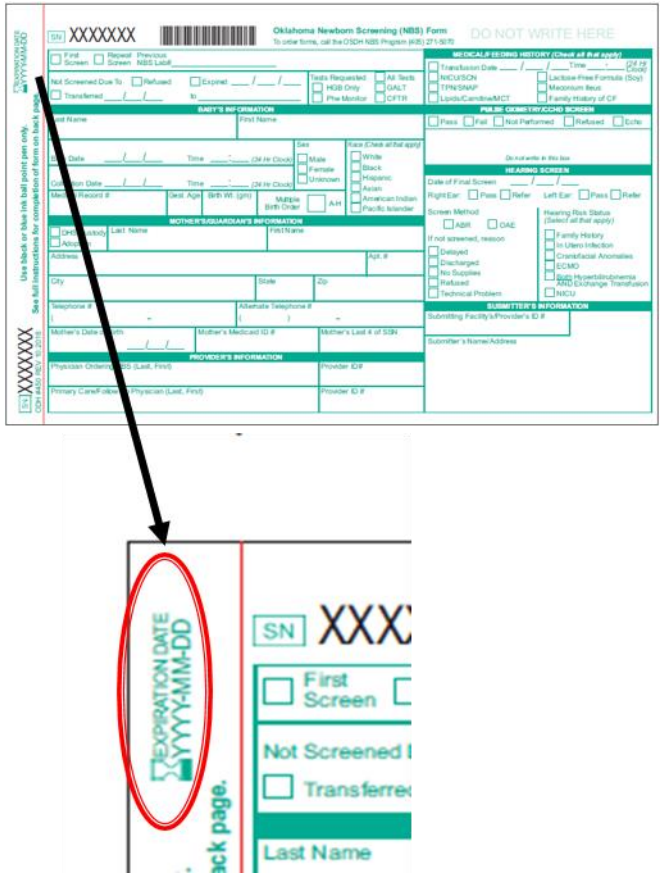
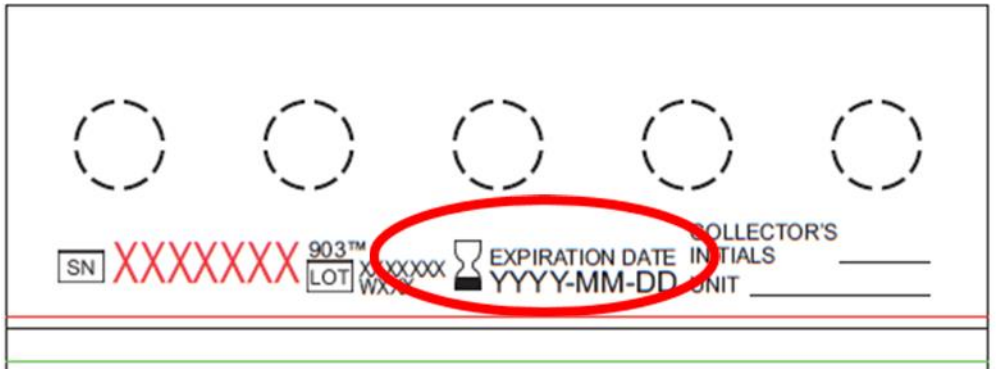


- **Check expiration date**
  - If the filter paper is expired, discard the paper, and check the stock of filter paper kits and discard all expired kits.
  - Collect the specimen on a kit that is not expired.



Filling out the Form: Specimen Information

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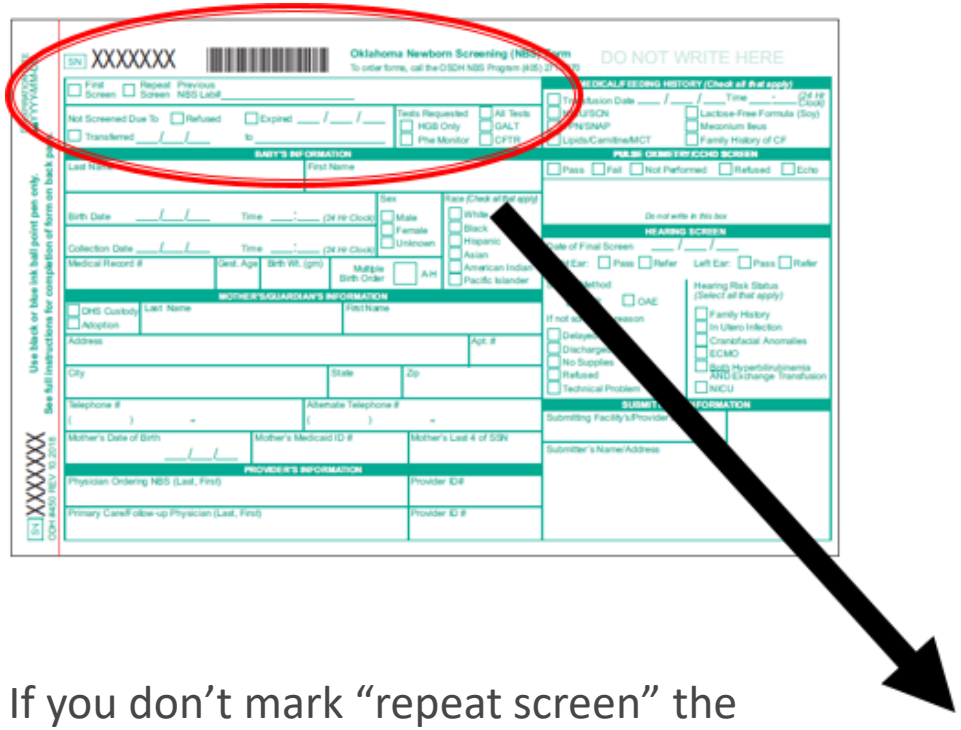

If you don't mark "repeat screen" the correct linking to the original screen could be delayed.

- If this is the first specimen collected for the baby, check the "First Screen" box.
- If baby has had a previous screen, check the "Repeat Screen" box**.**
  - List the previous OSDH Lab Number, if you have it.

Filling out the Form: Specimen Information

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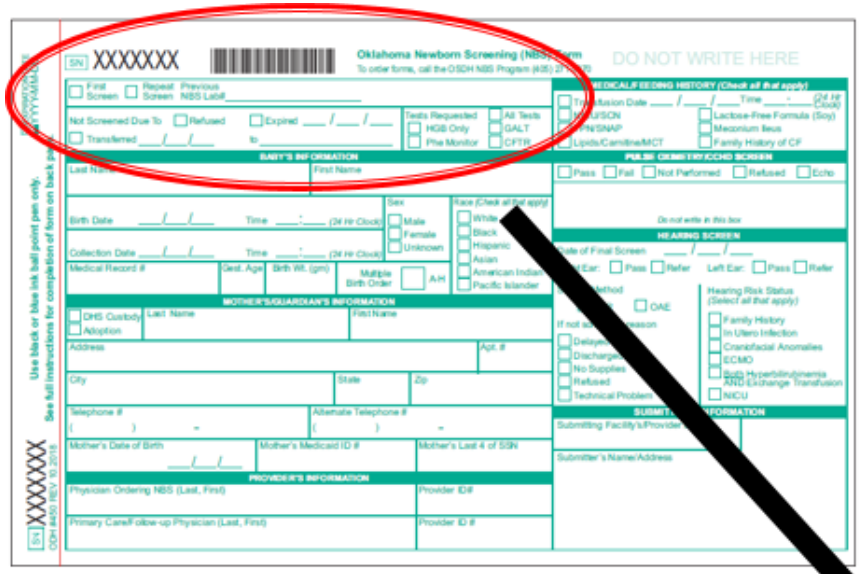

- If baby expires before a screen can be collected:
  - Check the “Expired” box.
  - Enter the date that baby passed away.
  - Submit the filter paper form to the OSDH PHL.

Filling out the Form: Specimen Information

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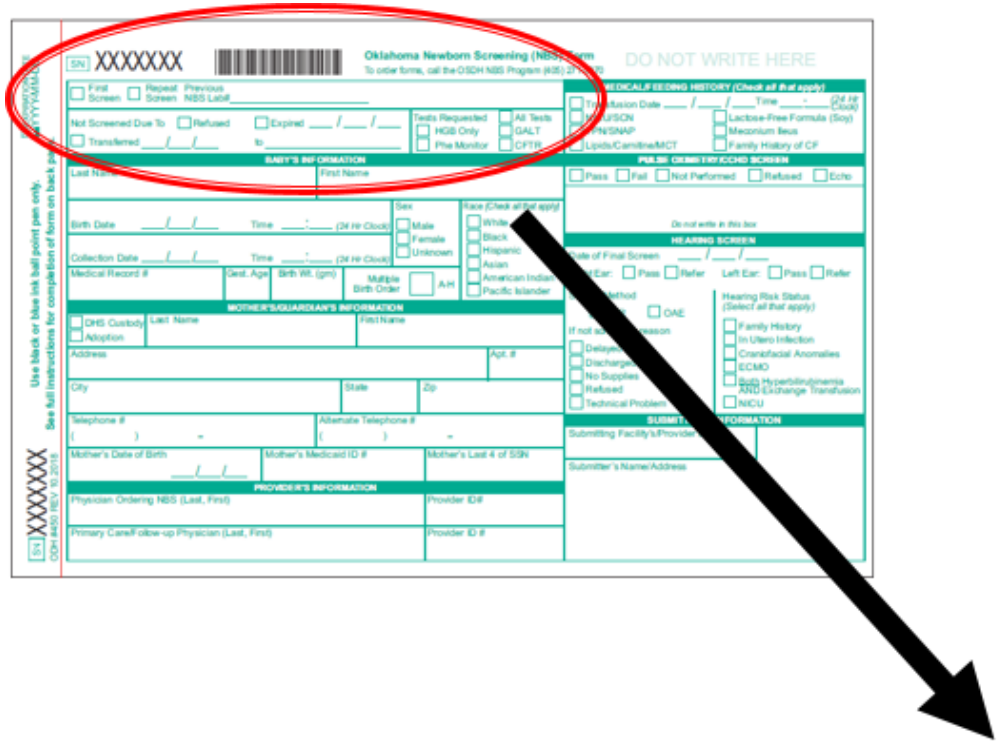

If baby is transferred prior to specimen collection:

- Check the “Transferred ” box.
- Enter the date that baby transferred and the facility that baby was transferred to.
- It is the responsibility of the receiving facility to collect the newborn screen.

Filling out the Form: Specimen Information

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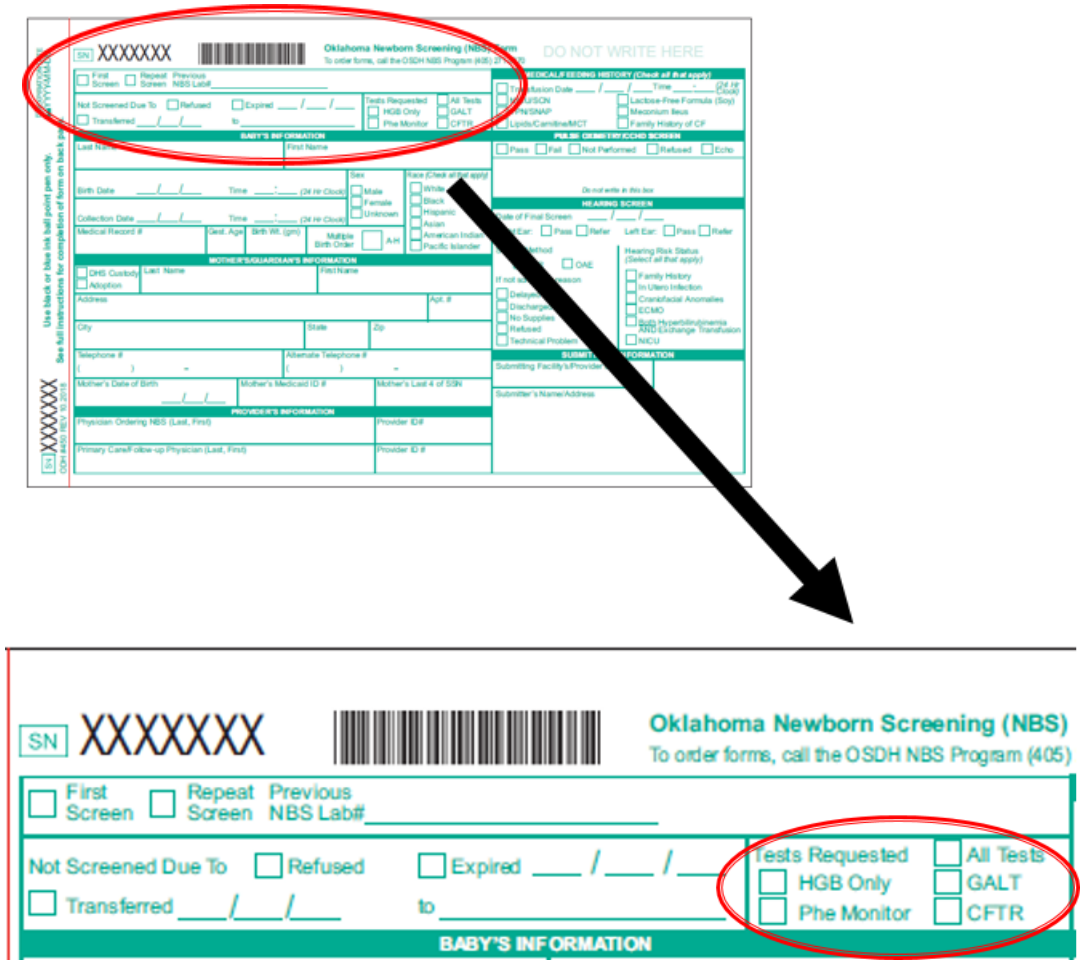
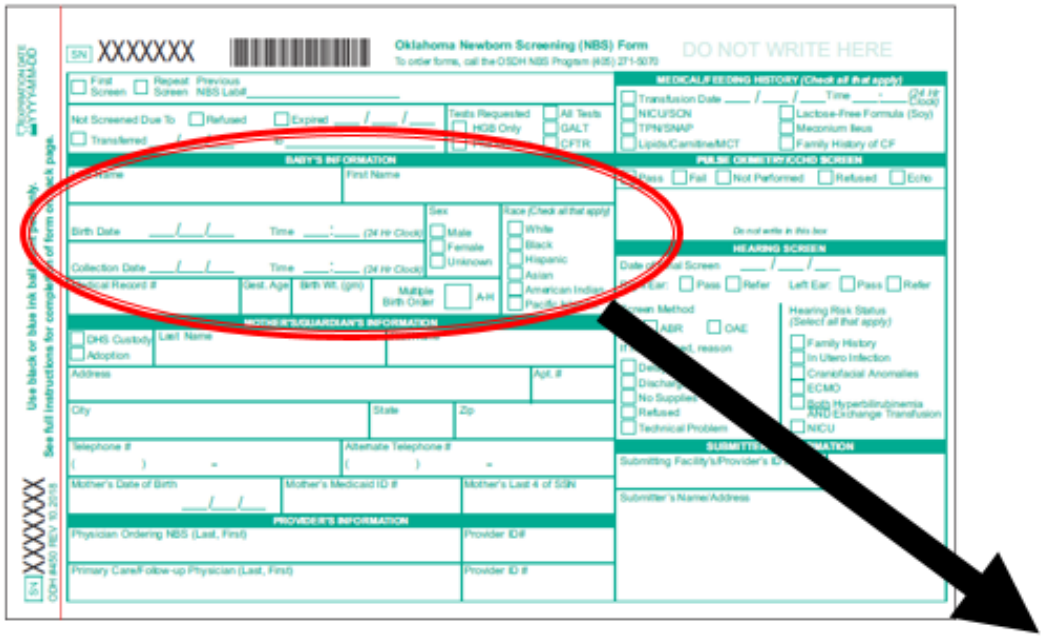


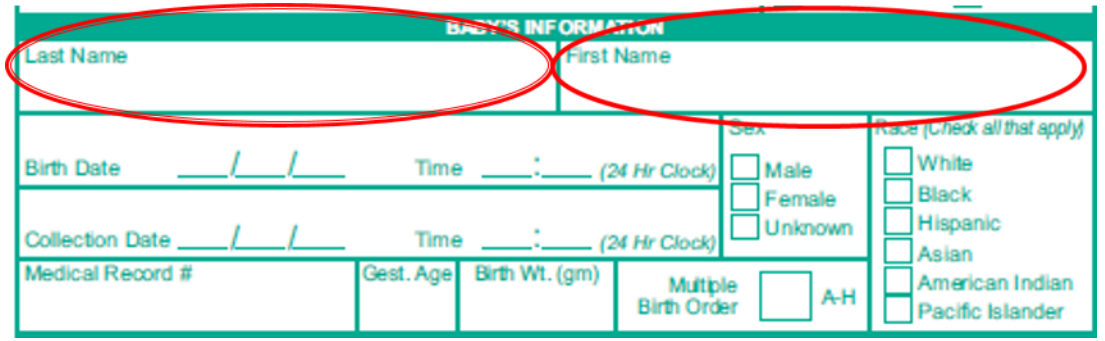
- Tests Requested: Check all that apply.
  - **All Tests-** always check unless test is for HGB only. This ensures that the lab screens for all disorders on the NBS panel.
  - **HGB Only-** Check if the repeat screen is for a follow-up of the initial abnormal HGB result.
  - **GALT**- Check GALT in addition to All Tests if there is a family history of galactosemia or if baby is on lactose-free (soy) formula at time screen is collected.
  - **Phe Monitor-** Check only if baby has been diagnosed with PKU (typically metabolic specialists only).
  - **CFTR**- Check in addition to All Tests if baby has clinical concerns for CF, meconium ileus, and/or family history of CF.

Filling out the Form: Infant's Information – Initial screen

Specimen testing will be delayed if the form is incomplete!

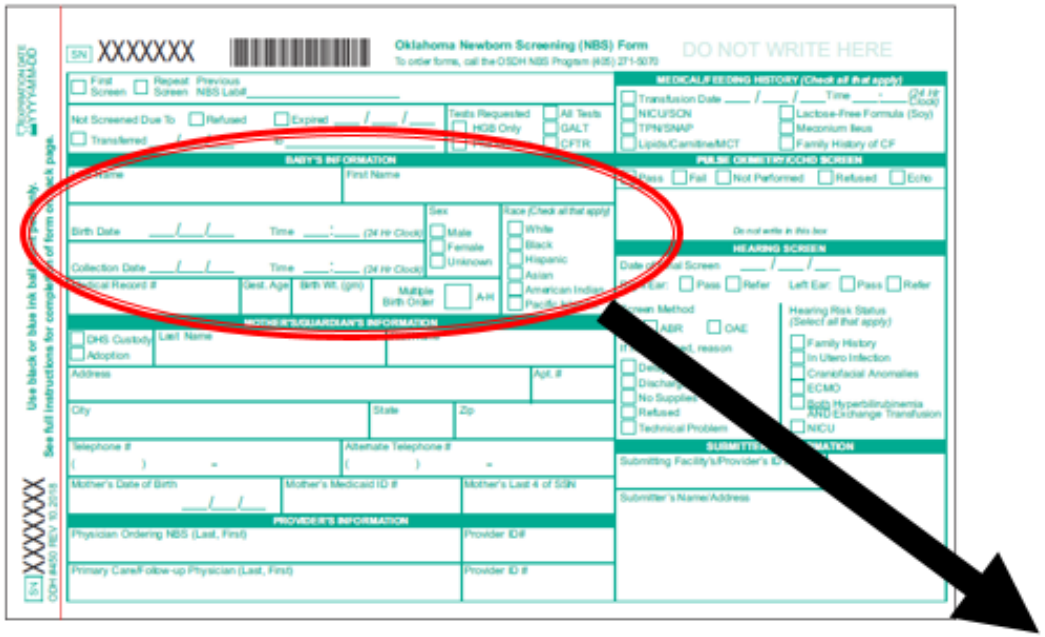


- Baby's first and last name (use legal name as displayed on the birth certificate).
- If baby's first name is unknown, "BG" or "Female", "BB" or "Male" may be used.

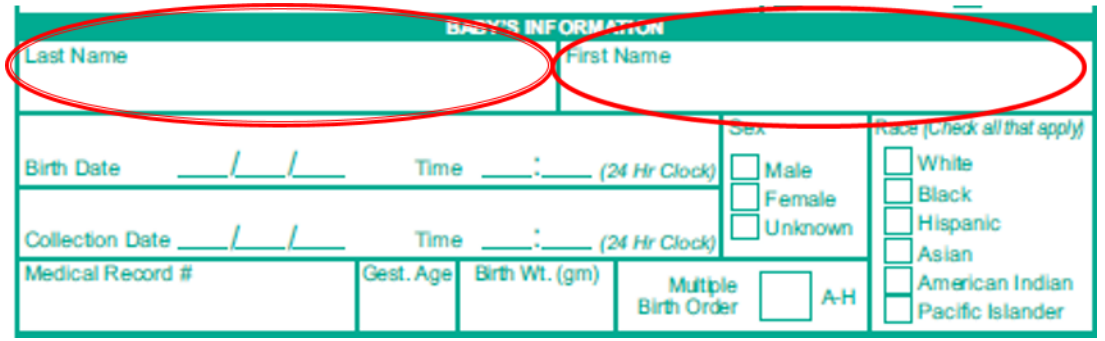


Filling out the Form: Infant's Information – for repeat screen

Specimen testing will be delayed if the form is incomplete!



- Baby's first and last name
- If baby's name was updated after hospital discharge, screens will be linked using the DOB, previous specimen #, mom's name, address and/or phone.



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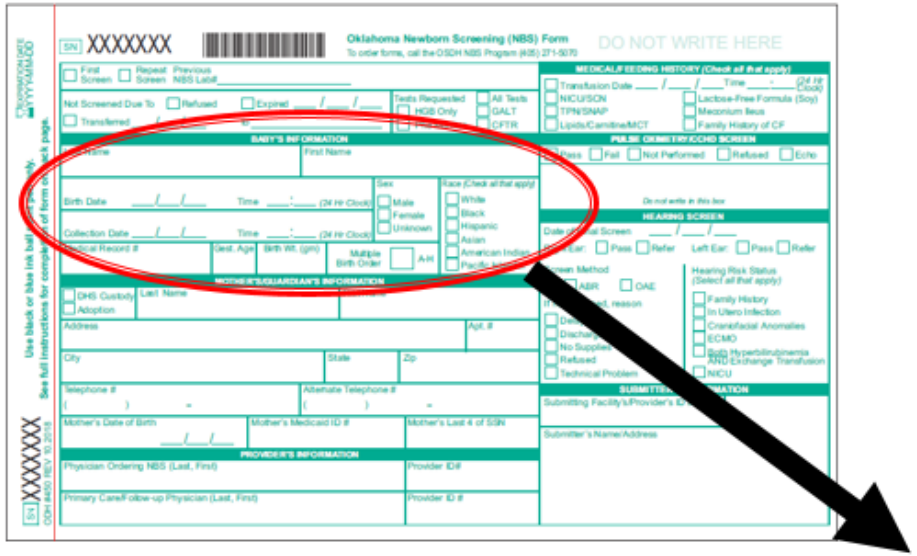
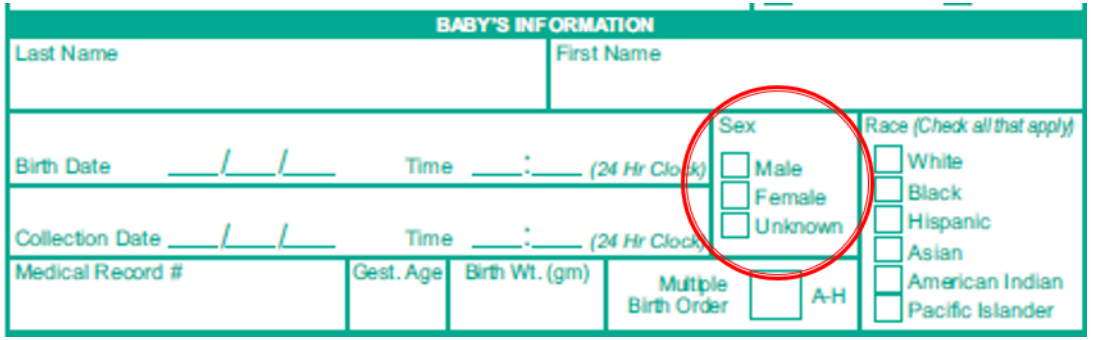


- Sex/Gender
  - Check "Male", "Female", or "Unknown"



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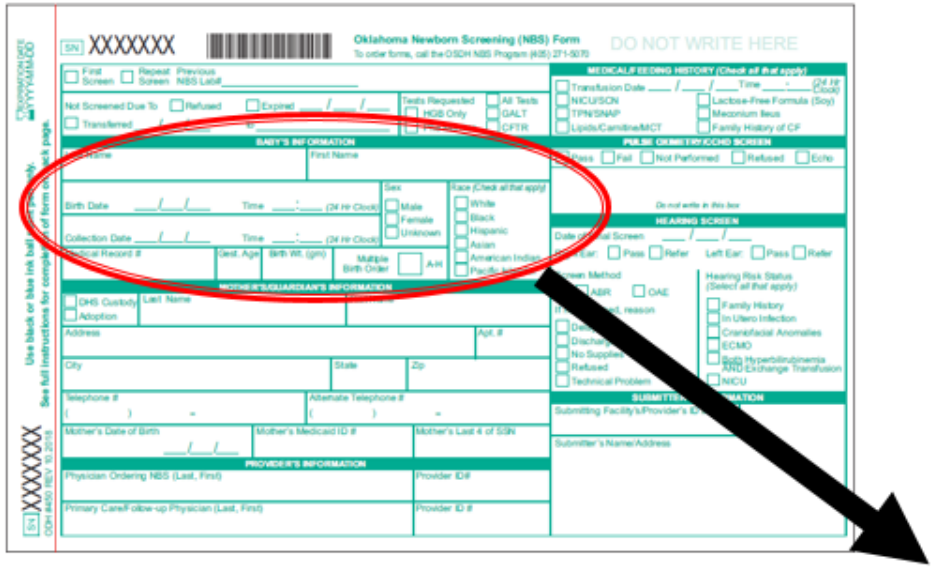
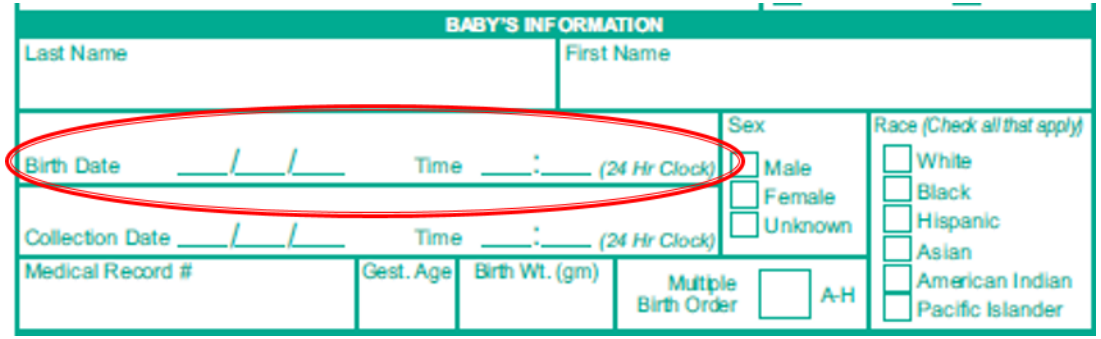


- Date & Time of birth
  - Enter the time using the 24-hour clock. For example, 1PM would be entered as 13:00.
  - For a repeat screen, outside of hospital, if time is not known, this box can be left empty.



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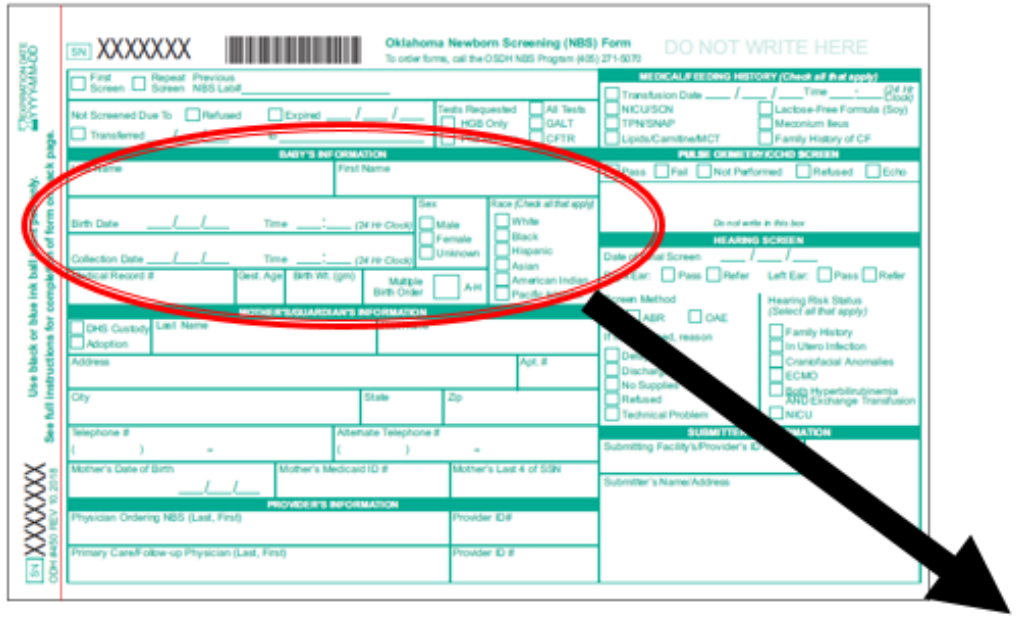
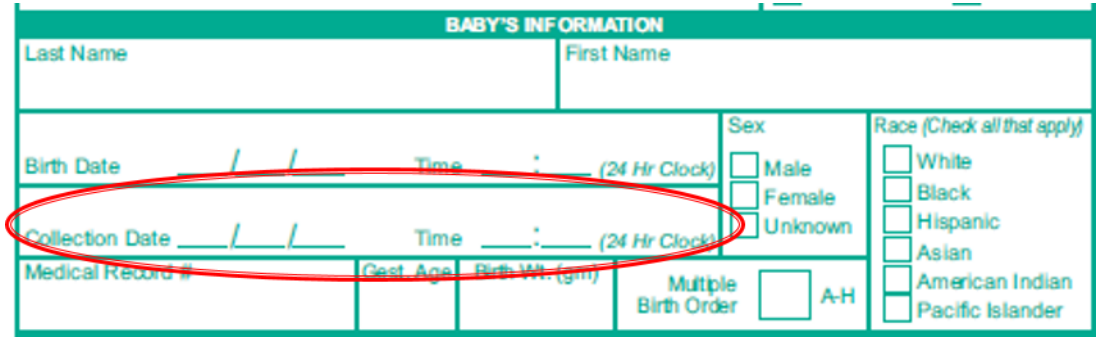


- Date & Time of specimen collection
  - Ideal time for well, term newborn:

    24 hours + 1 minute of age
  - Enter the time using the 24-hour clock. For example, 1PM would be entered as 13:00.
  - Ideal date of repeat is determined by follow-up recommendations.



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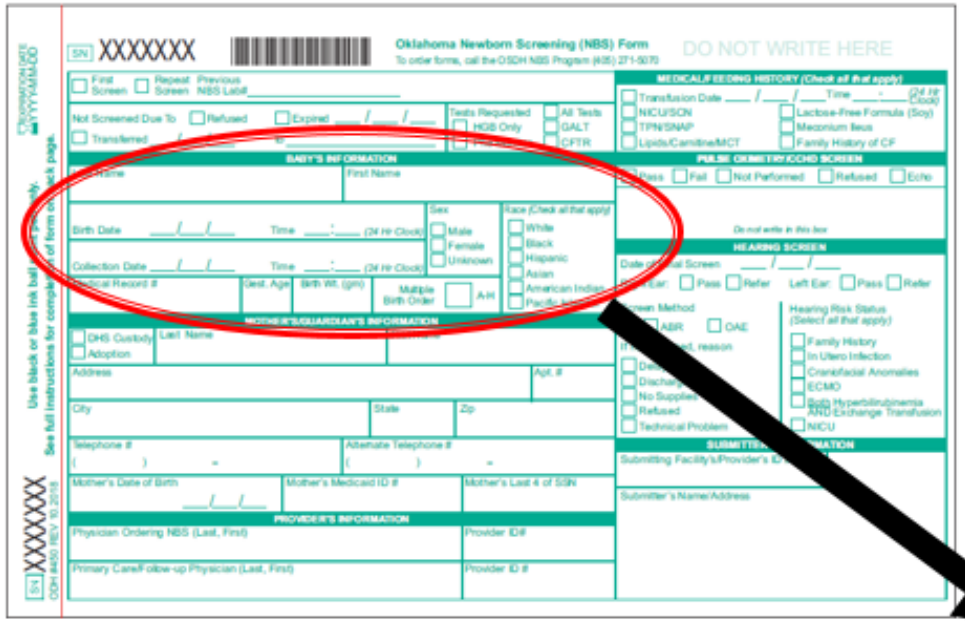

- Medical record number
  - Baby's medical record number
  - If a multiple birth, take extreme care here

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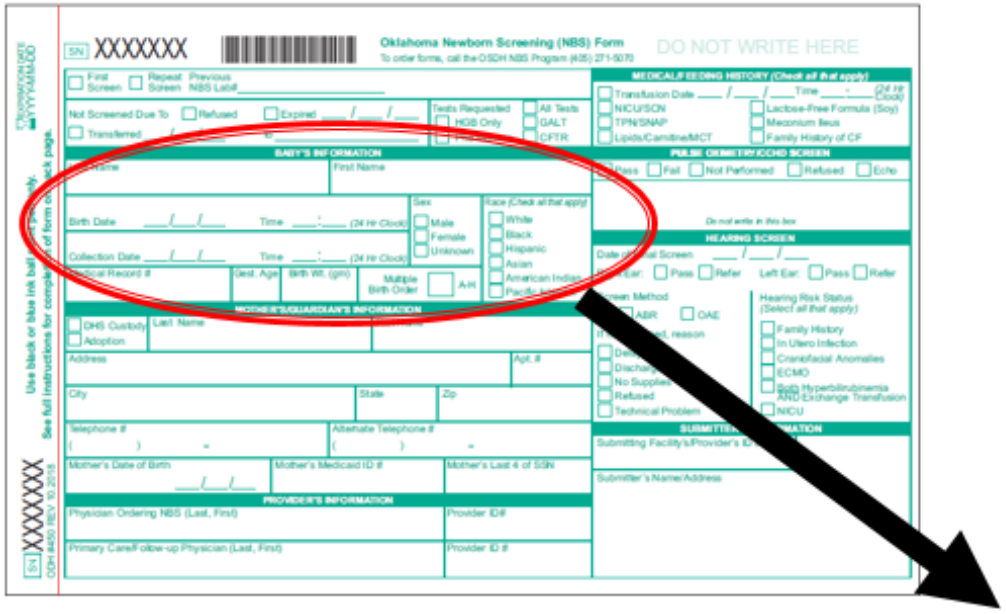
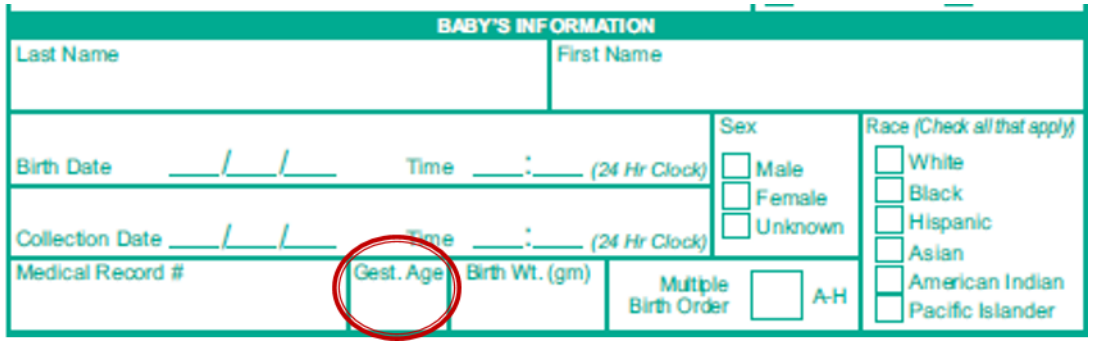
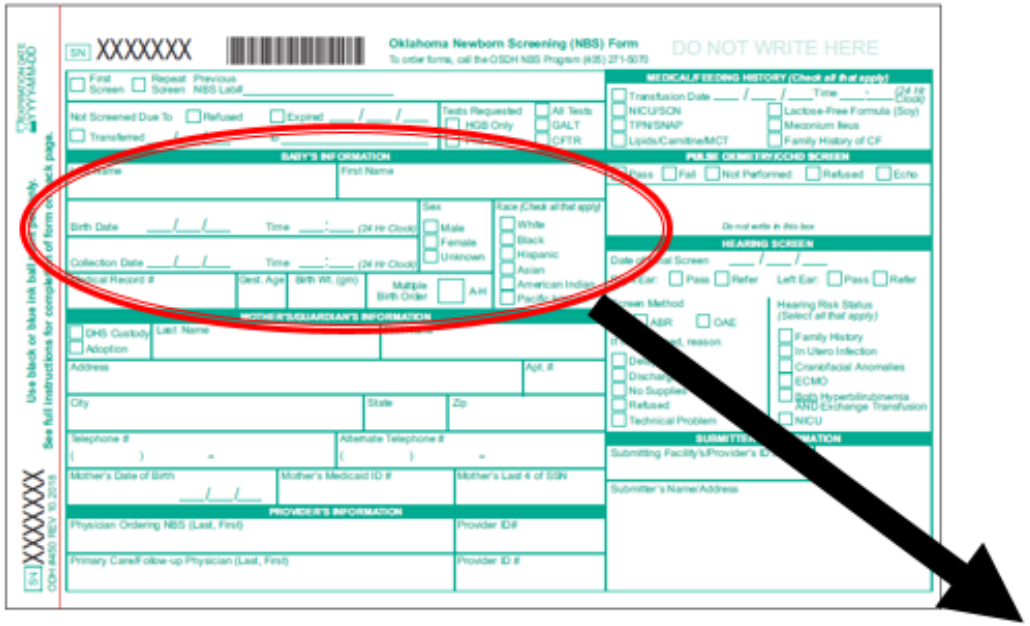


- Gestational Age
  - List gestational age at birth, may leave blank on a repeat collection.
  - Lab cut off values for abnormal severe combined immunodeficiency (SCID) are gestational age dependent.

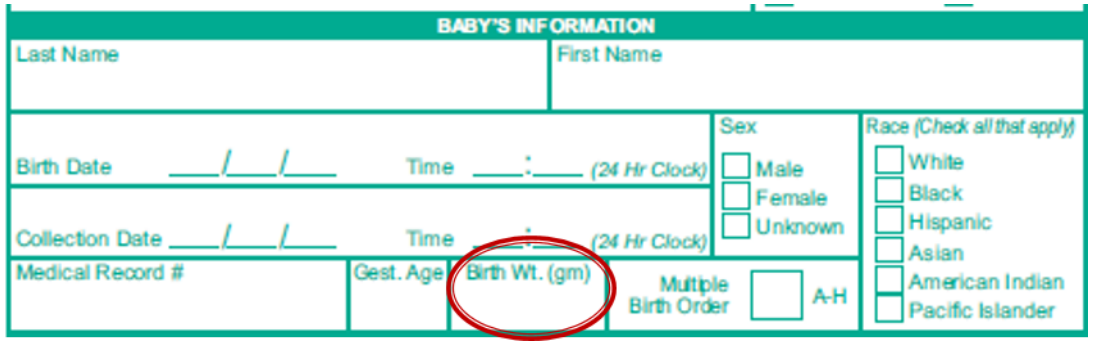


Filling out the Form: Infant's Information

Specimen testing will be delayed if the form is incomplete!

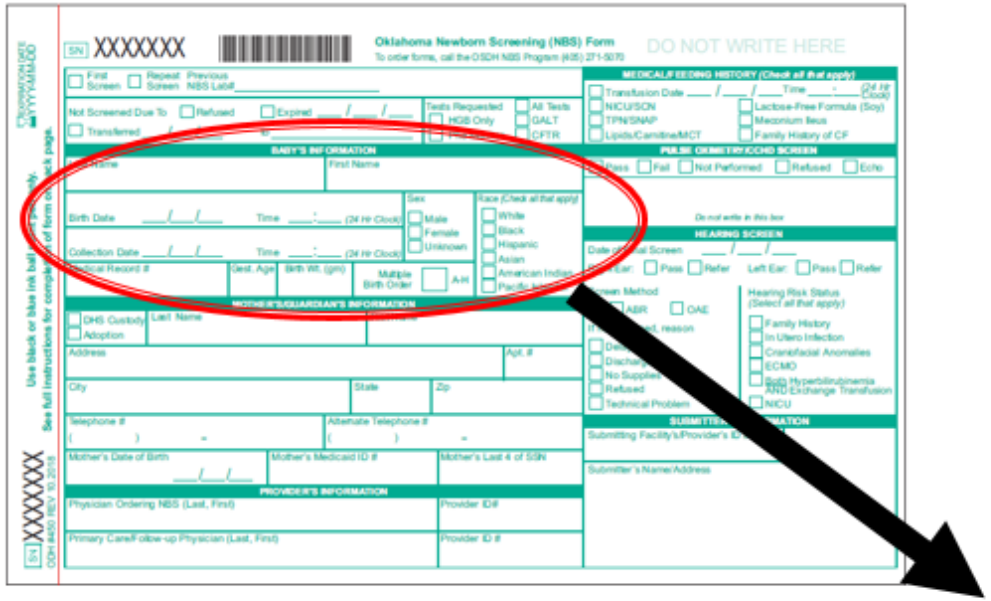


- Birthweight (in grams), leave blank if unknown (for repeat screen out of hospital).
  - Lab cut off values for abnormal congenital adrenal hyperplasia (CAH) results are dependent on birth weight.

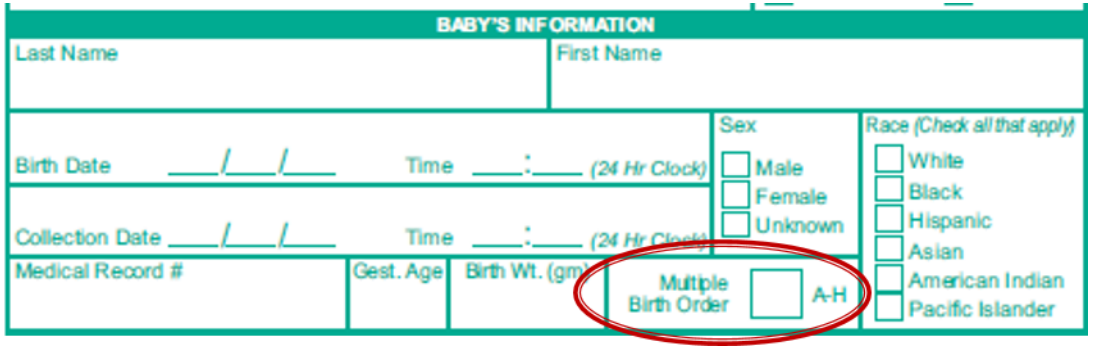


Filling out the Form: Infant's Information

Specimen testing will be delayed if the form is incomplete!

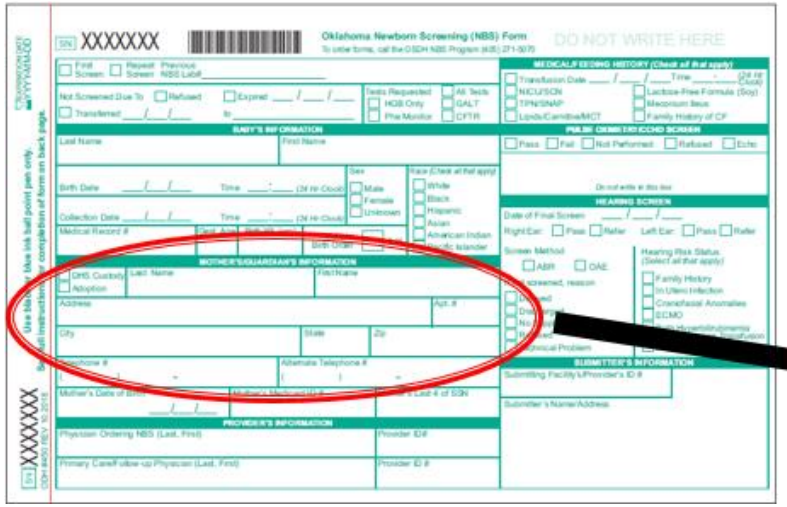


- Birth order (if multiple birth is present)
  - Indicate "A", "B", "C", etc. if baby is of multiple birth (twin, triplet, etc.).
  - Do NOT mark anything in this space if baby is a single birth.

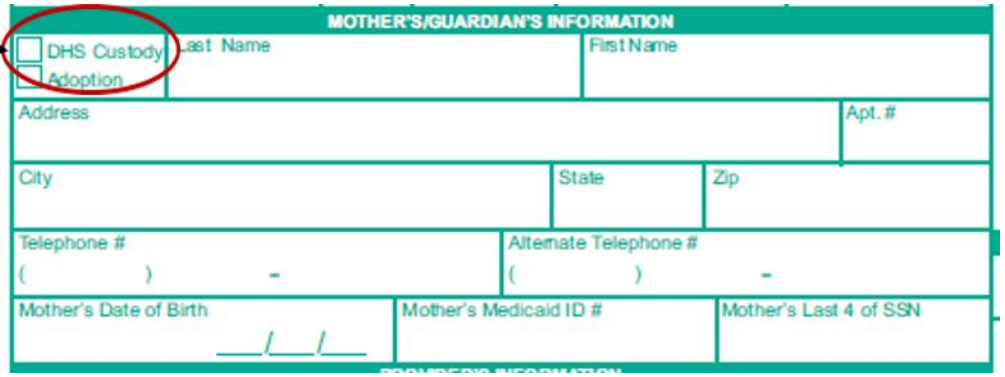


Filling out the Form: Mom's Information

Specimen testing will be delayed if the form is incomplete!



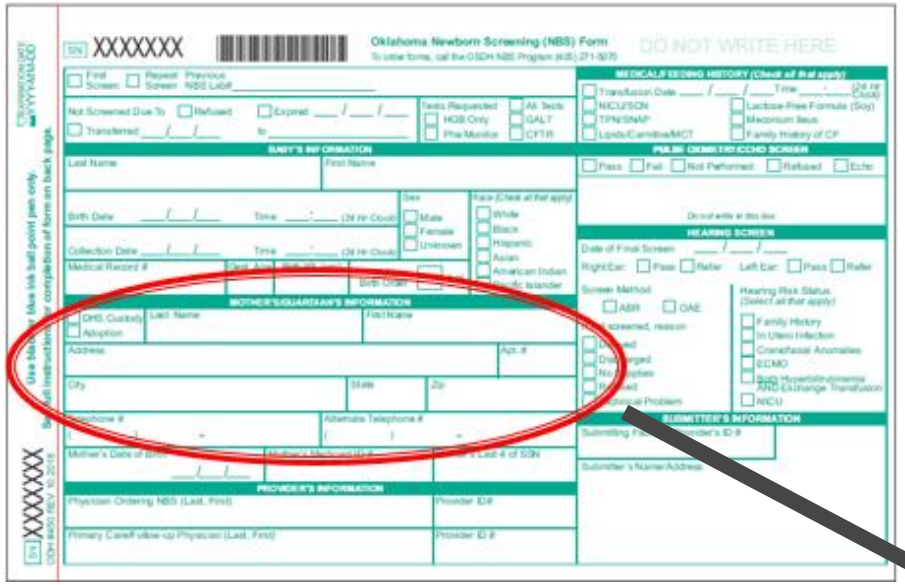
- DHS Custody or Adoption



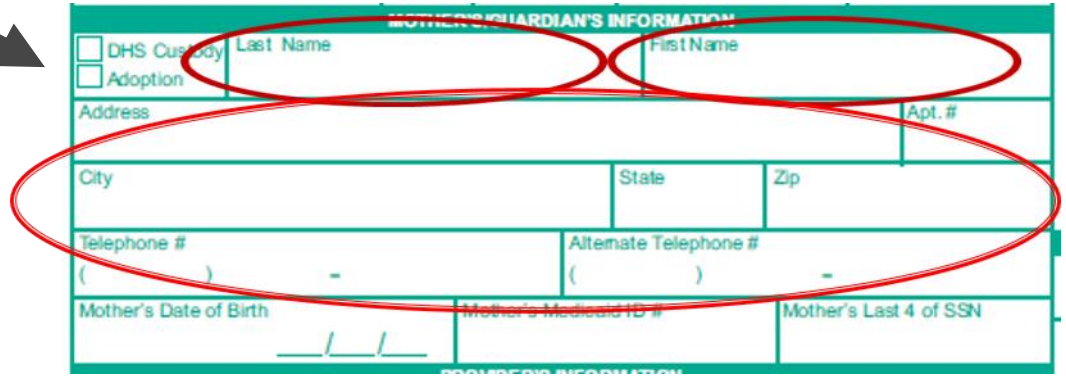
Note: If baby is adopted, be sure to check the **Adoption** box on the filter paper form and enter the agency/law firm information in this section. If DHS is involved, enter case worker information in this section and check the **DHS Custody** box.

Filling out the Form: Mom's Information

Specimen testing will be delayed if the form is incomplete!



- Mom's first and last name
- Mom's mailing address:
  - Street, Apt # (if applicable), City, State, Zip
- Mom's telephone number:
  - <u>Extremely important</u> to include in case newborn screen results are abnormal and require follow-up.



Filling out the Form: Provider's Information

Specimen testing will be delayed if the form is incomplete!

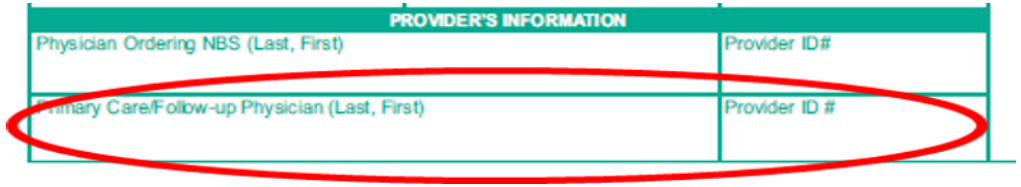
- Physician <u>Ordering</u> the NBS:
  - Include first and last name
  - Enter the NBS Provider ID #, if known
  - May leave blank if ordering Physician unknown on a repeat collection, outside of hospital

PROVIDER'S INFORMATION	
Physician Ordering NBS (Last, First)	Provider ID#
Primary Care/Follow-up Physician (Last, First)	Provider ID #

Filling out the Form: Provider's Information

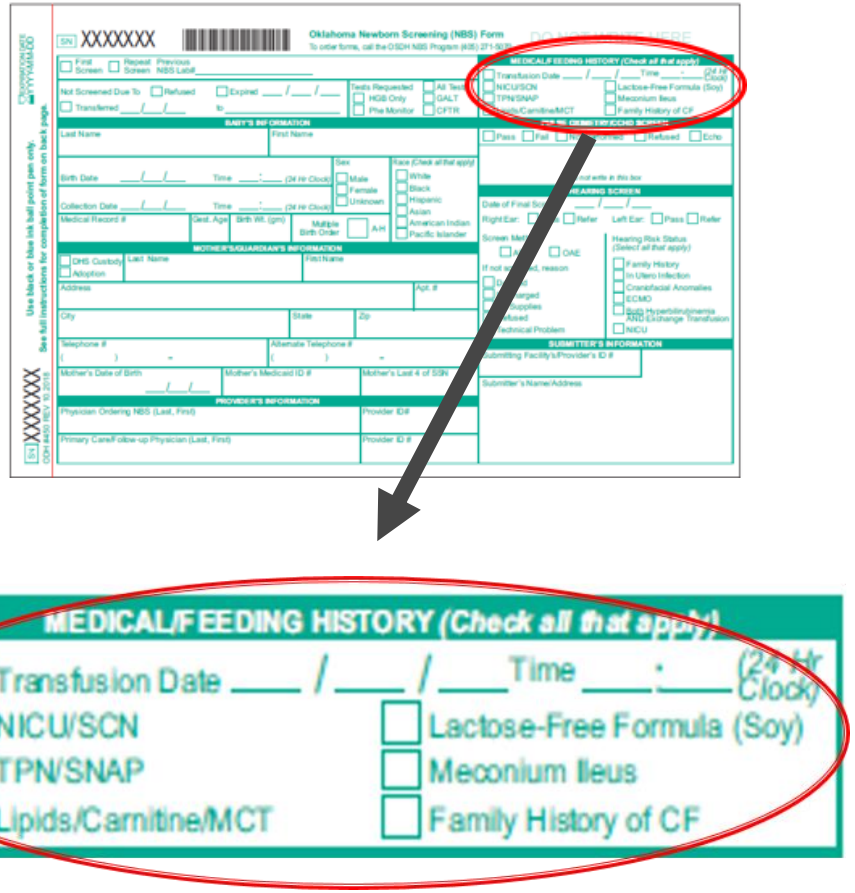
Specimen testing will be delayed if the form is incomplete!

- Primary Care/Follow-up Physician:
  - Planned health care provider upon discharge from birthing facility
  - Include first and last name
  - Enter the NBS Provider ID #, if known
  - **<u>Extremely important</u>** that this is correct in case newborn screen results are abnormal and require follow up



Filling out the Form: Medical/Feeding History

Specimen testing will be delayed if the form is incomplete!

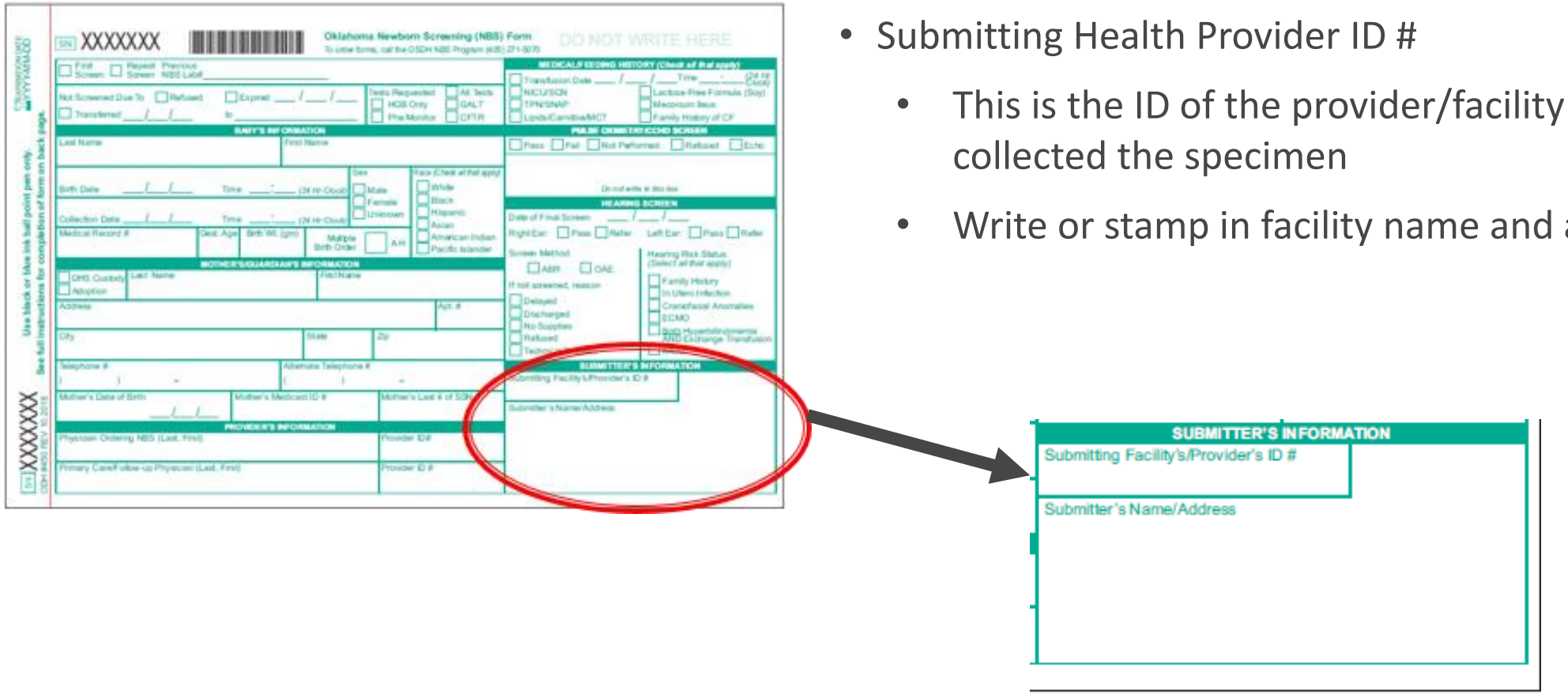


Check all that apply for baby at the time of specimen collection

- If transfused enter the date and time of transfusion
- NICU/Special Care Nursery
- TPN/SNAP
- Lipids/Carnitine/MCT
- Lactose-Free (Soy) Formula
- Meconium Ileus
- Family History of Cystic Fibrosis (CF)

Filling out the Form: Submitter ID

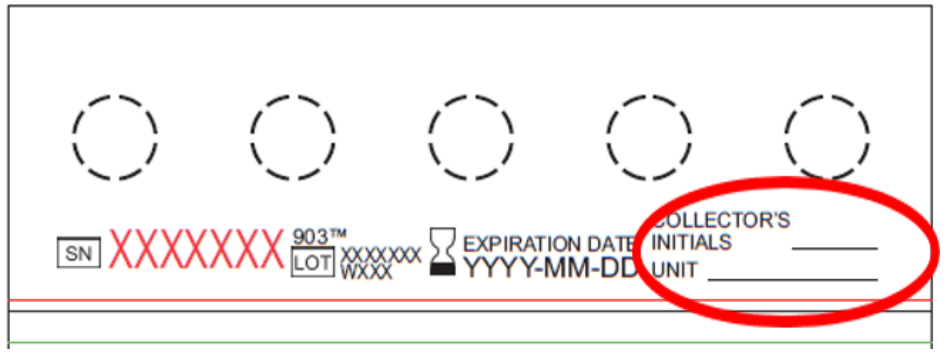
Specimen testing will be delayed if the form is incomplete!



- Submitting Health Provider ID #
  - This is the ID of the provider/facility who collected the specimen
  - Write or stamp in facility name and address

Filling out the Form: Collector's Initials

Allows for thorough follow-up of an unsatisfactory screen



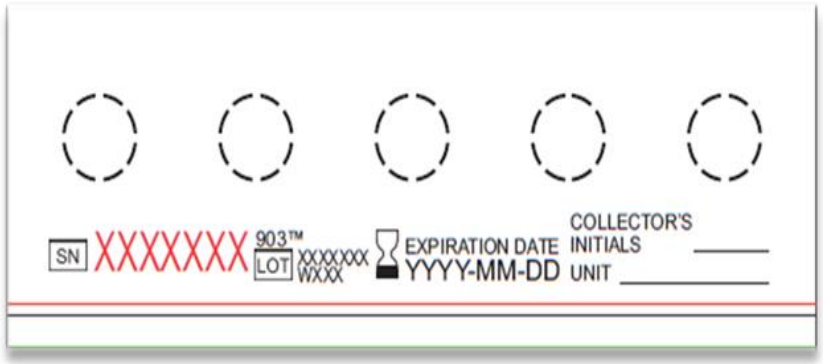
Note: Do not touch the filter paper in any other area when writing initials and unit.

- **Unsatisfactory Specimen Follow-up**
  - Specimen collectors can place their initials and unit in the area below for identification purposes, in the event of an unsatisfactory specimen. This allows for easier identification of the individual who collected the specimen so that further education and/or training can be provided.

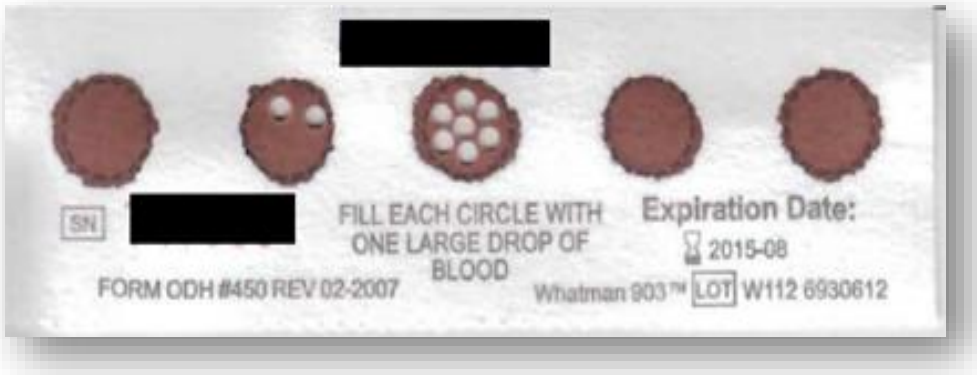
Collecting the Specimen

OKLAHOMA State Department of Health

How Is An Infant Screened?



- Blood spot screen-heel stick
- Performed when the infant is “24 hours plus one minute” or prior to discharge, whichever comes first
- A small amount of blood is placed on a small card and sent to the OSDH Newborn Screen lab.
- Newborn screening specimens are picked up from birthing hospitals and county health department via a contract courier service and then brought to the PHL for testing.



Time of Screening: Healthy Newborn

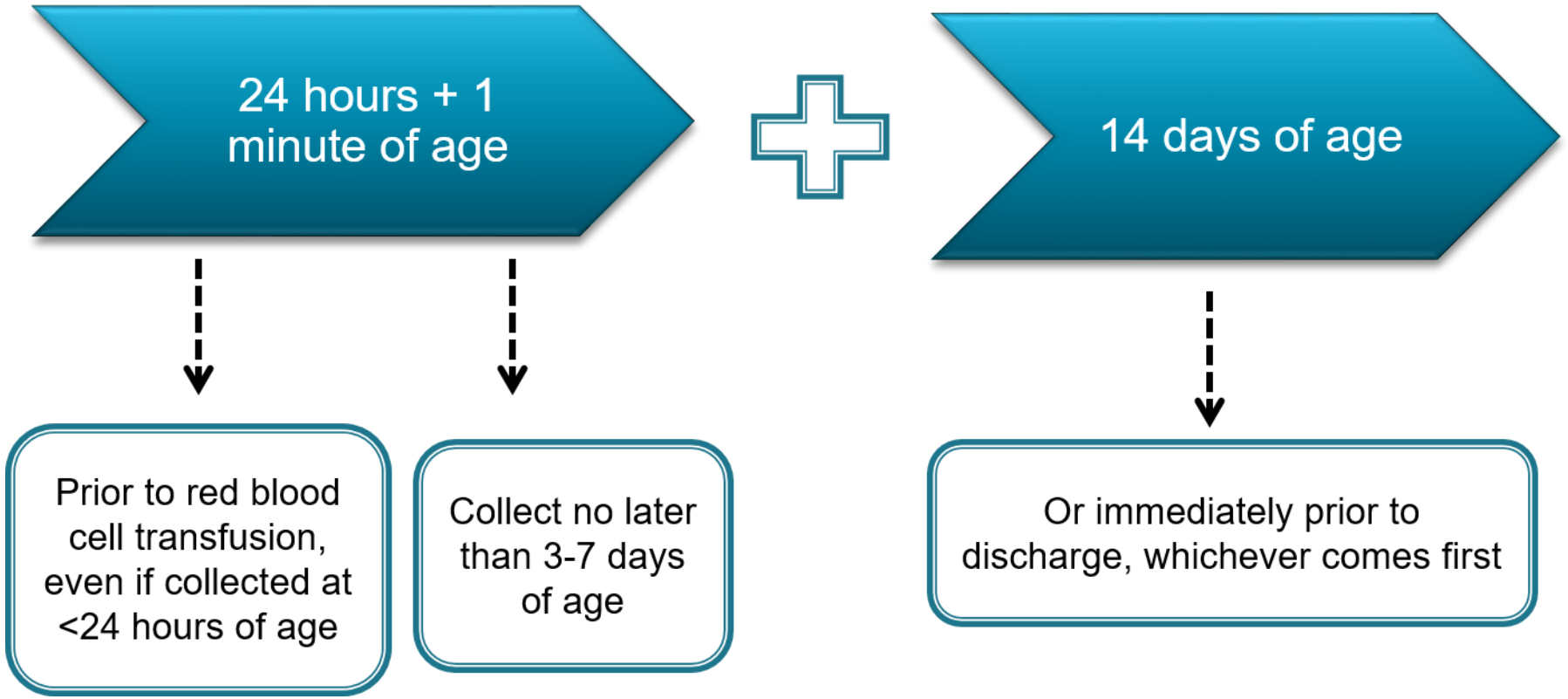
"**24 hours** plus one minute" of age

Or

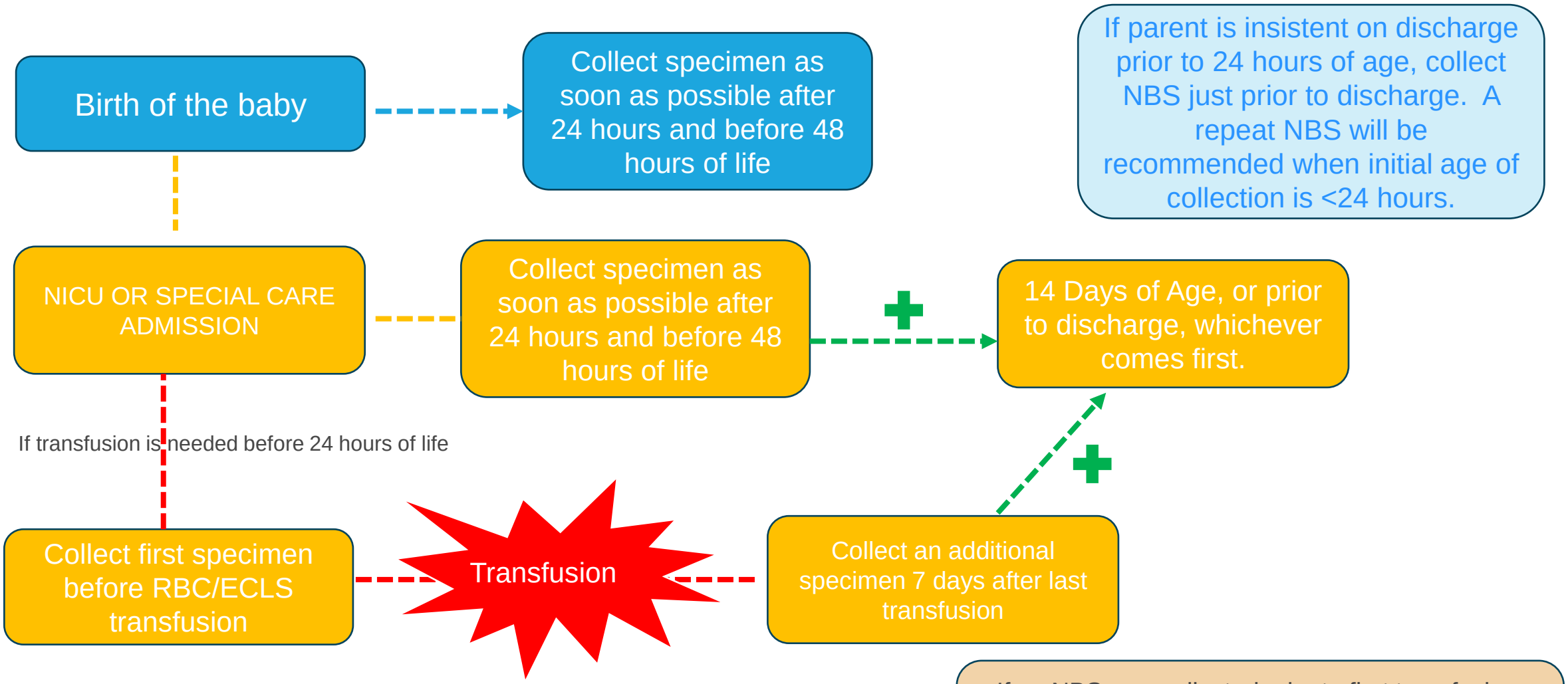
Prior to discharge

WHICHEVER COMES FIRST

Time of Screening: Premature or Sick Newborns

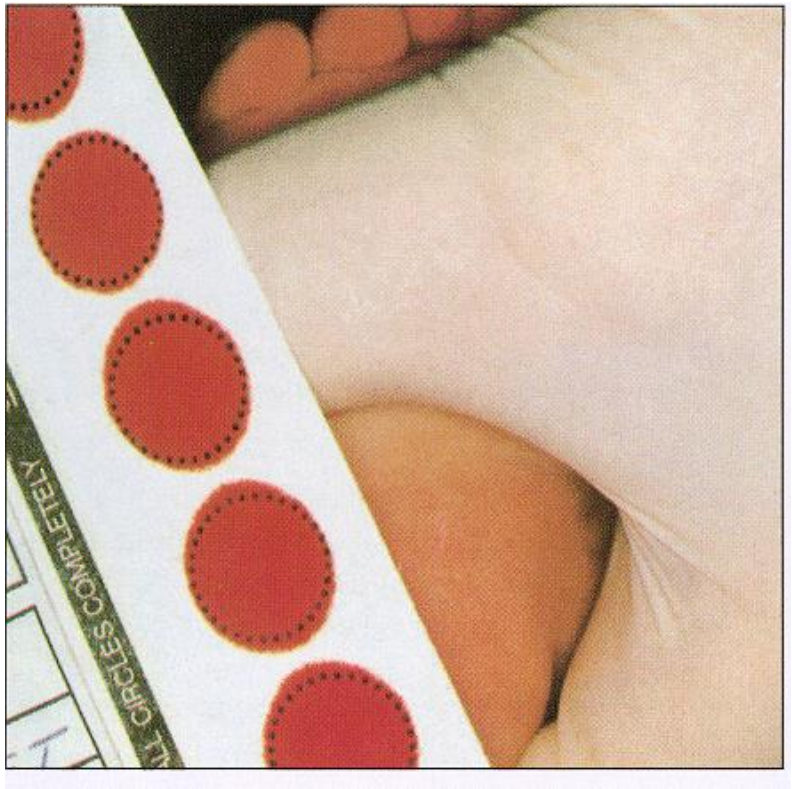


Optimal Time of Bloodspot Collection – Well Baby and NICU

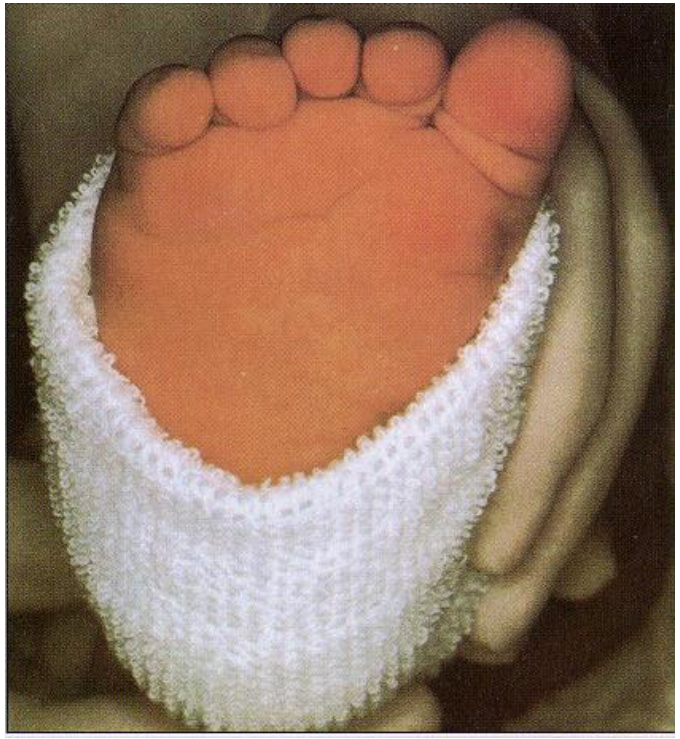


Specimen Collection

- **Heel Stick / Direct Application**
  - Preferred, recommended method
  - Start with clean, dry hands before handling the filter paper.



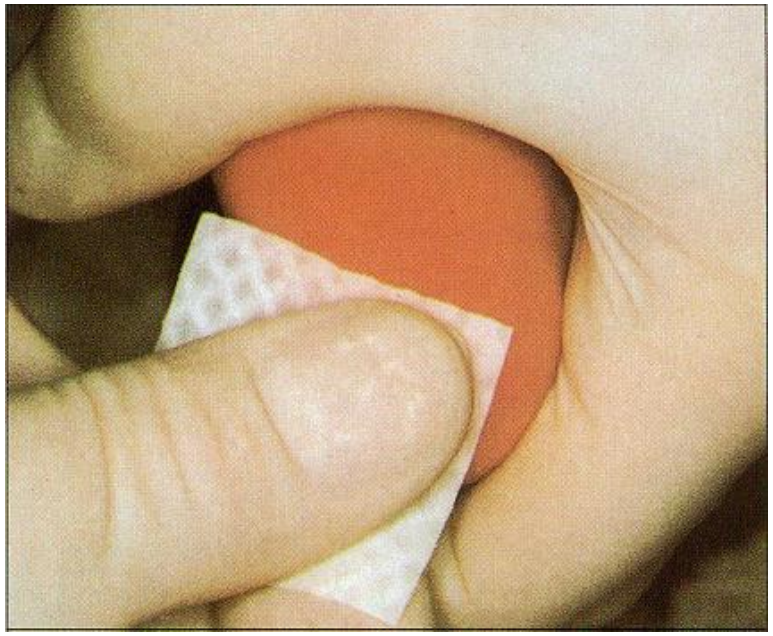
Direct Application



Prepare the Site

- Warm the heel with a heel warmer or a soft cloth, moistened with warm water up to 41 C for 3-5 min.
- Warmth leads to vasodilation, which increases blood flow and chance of collection success.
- **Follow your facility protocol regarding which warming device to use.**

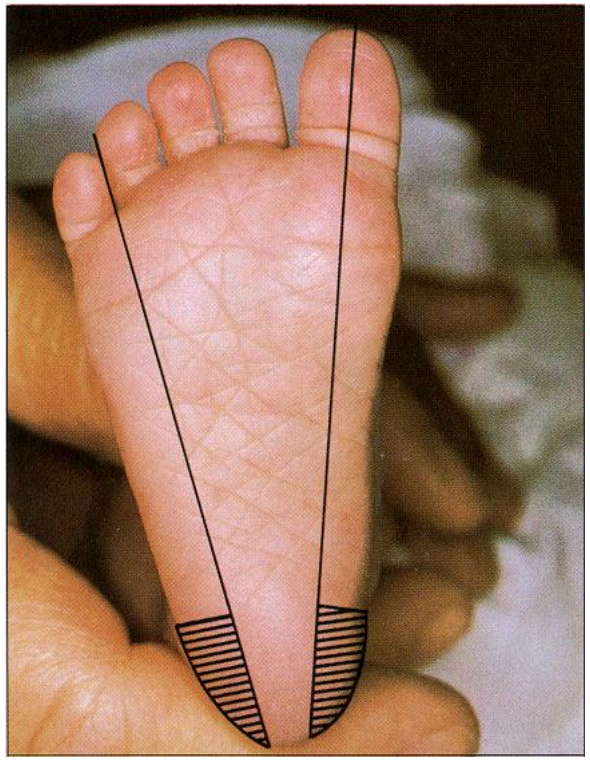
Direct Application



Prepare the Site

- If desired, parent may hold infant during collection.
  - Decreases stress response in newborn
  - Encourages bonding
- Position the infant's leg lower than the heart.
  - This increases venous pressure, which results in increased blood flow and a greater chance of collection success.
- Wearing gloves, wipe the infant's heel with 70% isopropyl alcohol.
- Allow the heel to air dry!
  - Residual alcohol can affect NBS results and/or lead to unsatisfactory specimens.

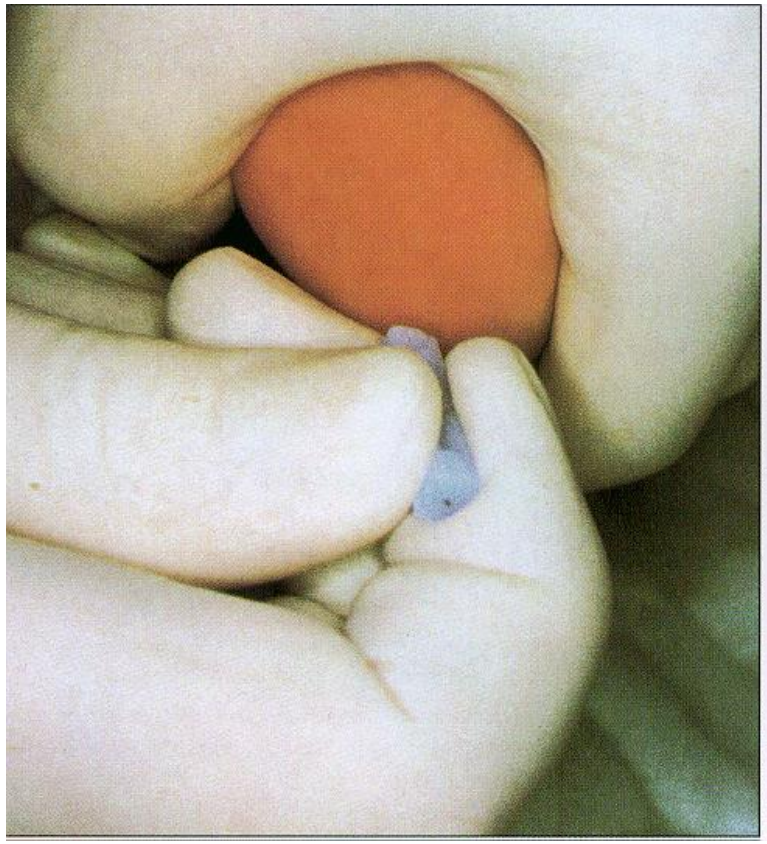
Direct Application



Lancet Placement

- Hatched areas are safe for puncture.
  - Damage to nerves and/or the heel bone may occur for punctures outside of the hatched region.

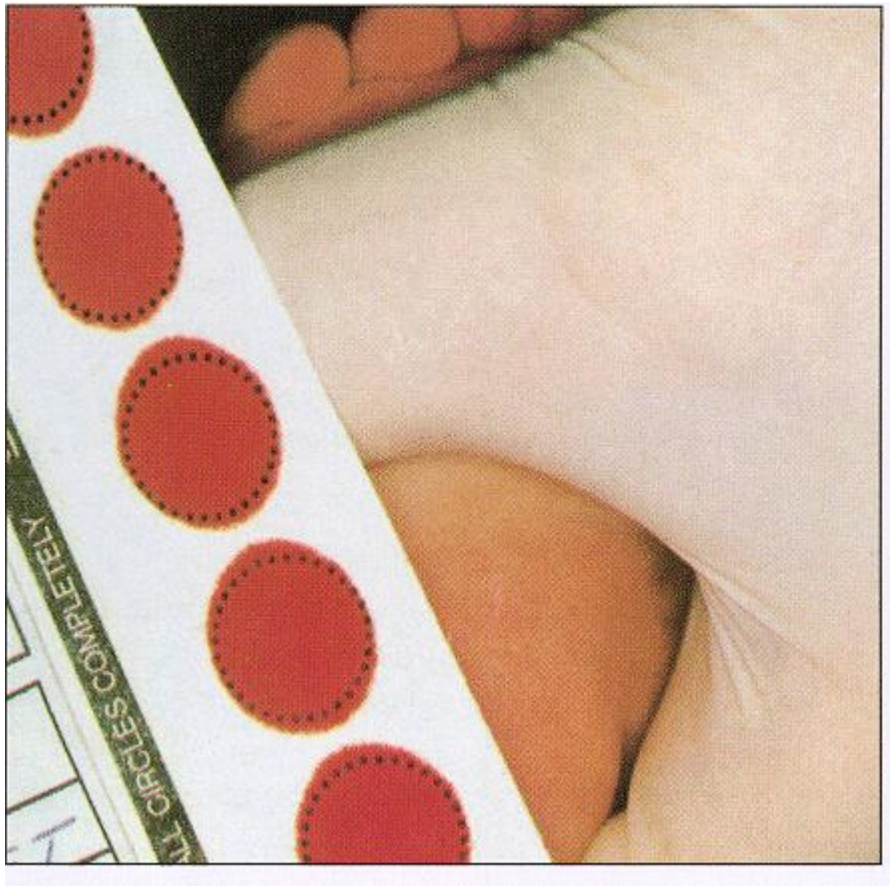
Direct Application



Perform the Puncture

- Using a sterile lancet, perform the puncture.
- Gently wipe off the first drop of blood with a sterile gauze or cotton ball.
- Apply gentle pressure with thumb and around heel but not near the puncture site; ease intermittently as drops of blood form.
- Avoid “milking” the puncture site.

Direct Application



Application

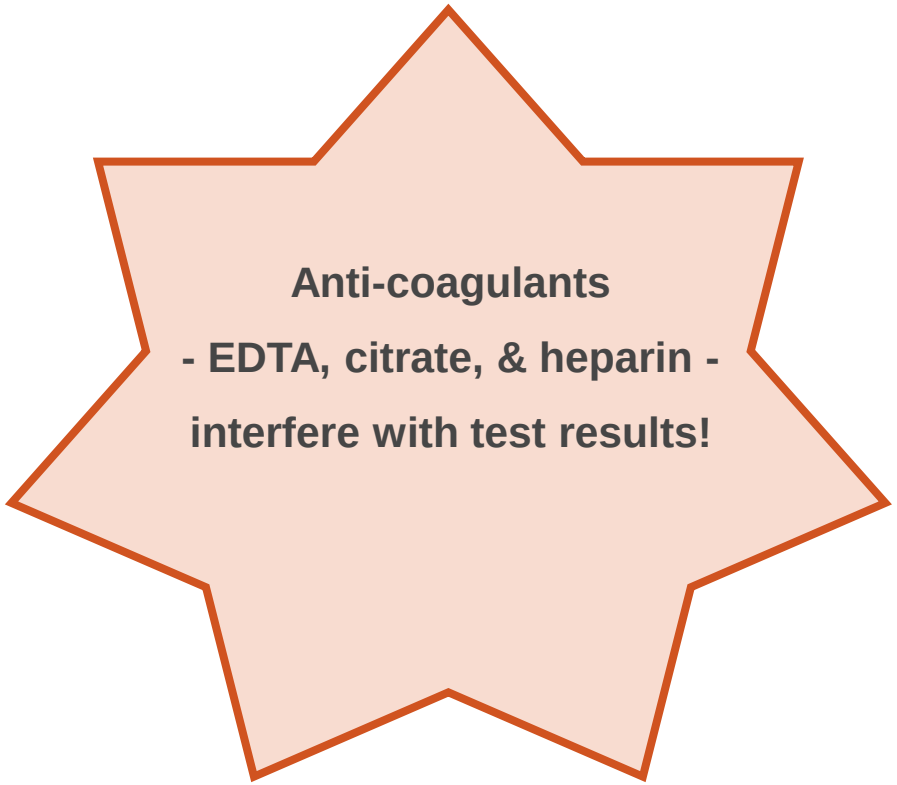
Gently touch the filter paper card to the blood drop and fill each printed circle with **one** large drop of blood.

- Apply blood to **one** side only.
- Observe the saturation of each printed circle as the blood flows through the filter paper.

Alternative Specimen Collection

What about capillary tubes? >> **Not preferred**

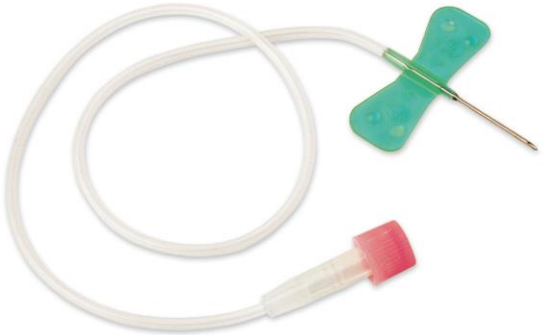
- Higher risk for collection error
- If used, must be sterile/clean and plain.
- No additives, must be anticoagulant free, however no anti-coagulants = risk of clotting.
- Risk of scratching the filter paper, avoid touching tip of tube to the paper.
- Use a new tube for EACH printed circle.



Alternative Specimen Collection

What about venous samples? >> **Discouraged**

- May be appropriate under certain circumstances (e.g. NICU).
- More invasive than a heel stick.
- Do not draw blood from extremity with infusing IV fluids.
- Please refer to CLSI guidelines for more information.



Only in certain circumstances

Alternative Specimen Collection

What about umbilical catheters? >> **Discouraged**

- May be appropriate under certain circumstances (e.g. NICU).
- Ensure the line is cleared byb withdrawing 2-2.5 cc (ml) of blood to collect a specimen for newborn screen.
- Please refer to CLSI guidelines for more information.

Alternative Specimen Collection

What about umbilical cord blood? >> **Discouraged**

- May be appropriate under certain circumstances (e.g. NICU).
- Risk for maternal blood contamination.
- Repeat the newborn screen using the heel stick method when indicated.
- Please refer to CLSI guidelines for more information.

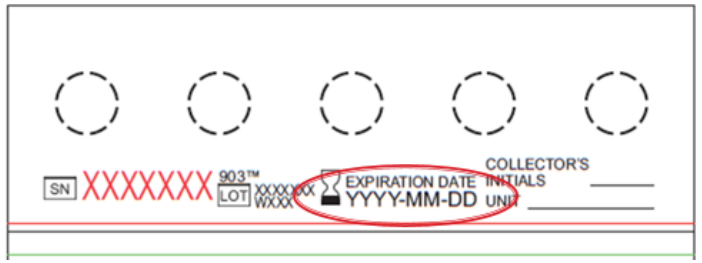
Specimen Collection: What NOT to Do

- Do NOT dab or “color in” the filter paper circles.
- Do NOT apply multiple drops of blood per circle.
- Do NOT scratch the filter paper.
- Do NOT contaminate specimens.
  - insufficient drying of alcohol, oils on hands, lotions, compressing the circles, spills, etc.
- Do NOT stack specimens.
  - risk for leaching and cross-contamination between specimens
- Do NOT submit wet specimens.
- Do NOT place specimens in direct sunlight or in front of air vents or other sources of moving air.
- Do NOT place specimens in plastic bags.
- Do NOT batch (hold onto) specimens.

Collection Reminders

Pre-collection:

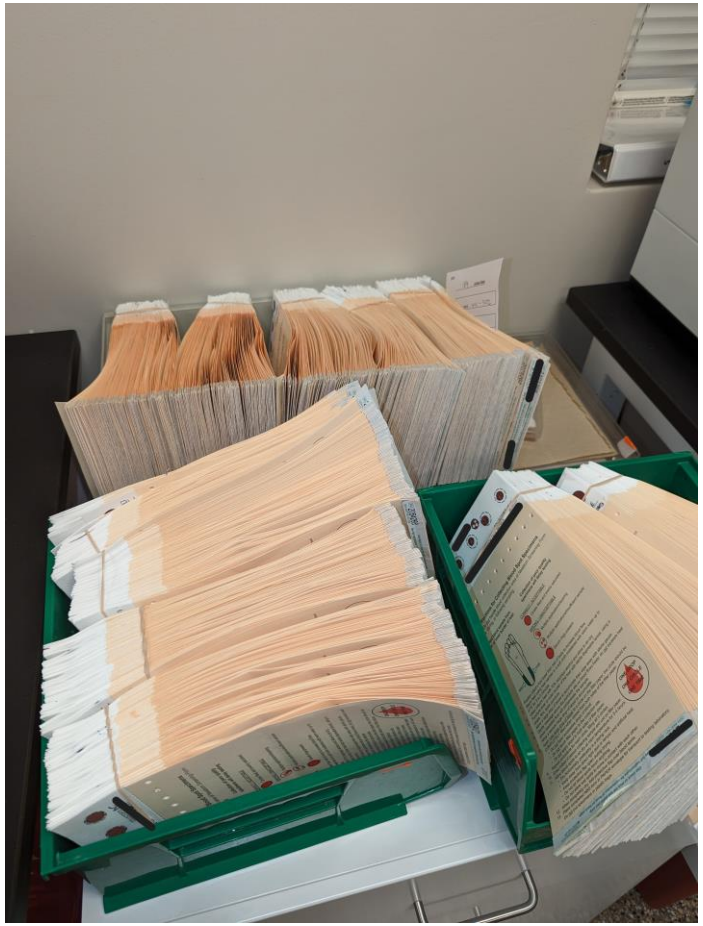
- **Check the Expiration Date of the filter paper.**
  If filter paper is expired, discard the paper, check the stock of filter paper kits it came from to ensure they are not all expired, and collect on a kit that is not expired.

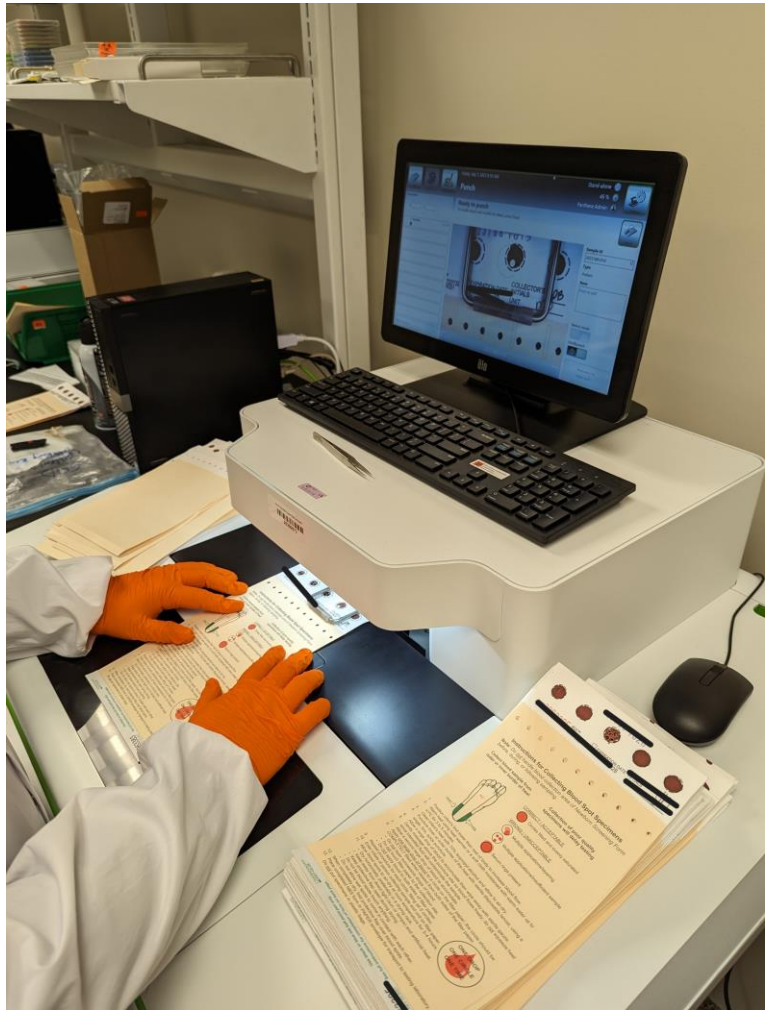


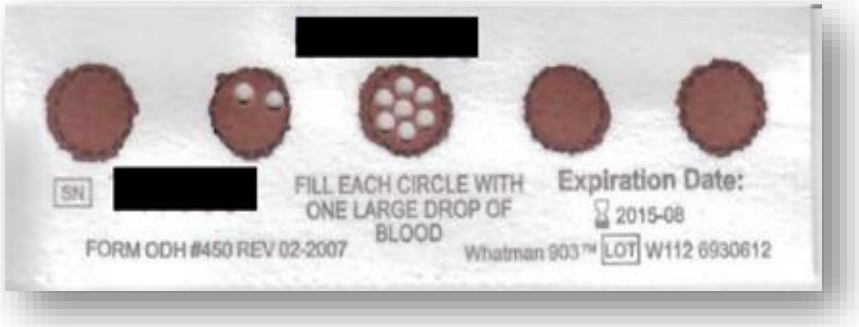
Post-collection:

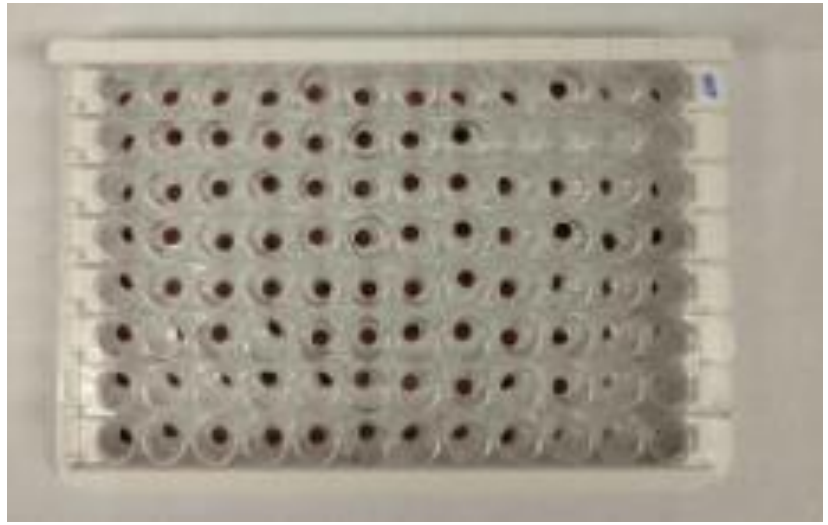
- **Air dry specimen horizontally for 3-4 hours.**
  - Transporting wet specimens can make them unsatisfactory for testing.
- **Send specimen with Courier within 24 hours of collection.**
  - Delayed receipt of specimens to the Public Health Laboratory can delay identification of and treatment for a disorder, which can result in lifelong disability or even death for Oklahoma newborns.
  - Know the courier schedule and location for your facility! Ensure all staff involved in newborn screening are also aware of the process.
- **Maintain specimen collection log and ensure screening results are received and recorded.**
- **Ensure that everybody who handles the filter paper or is involved in the newborn bloodspot collection process is trained.**

A Peek Inside the Laboratory…..



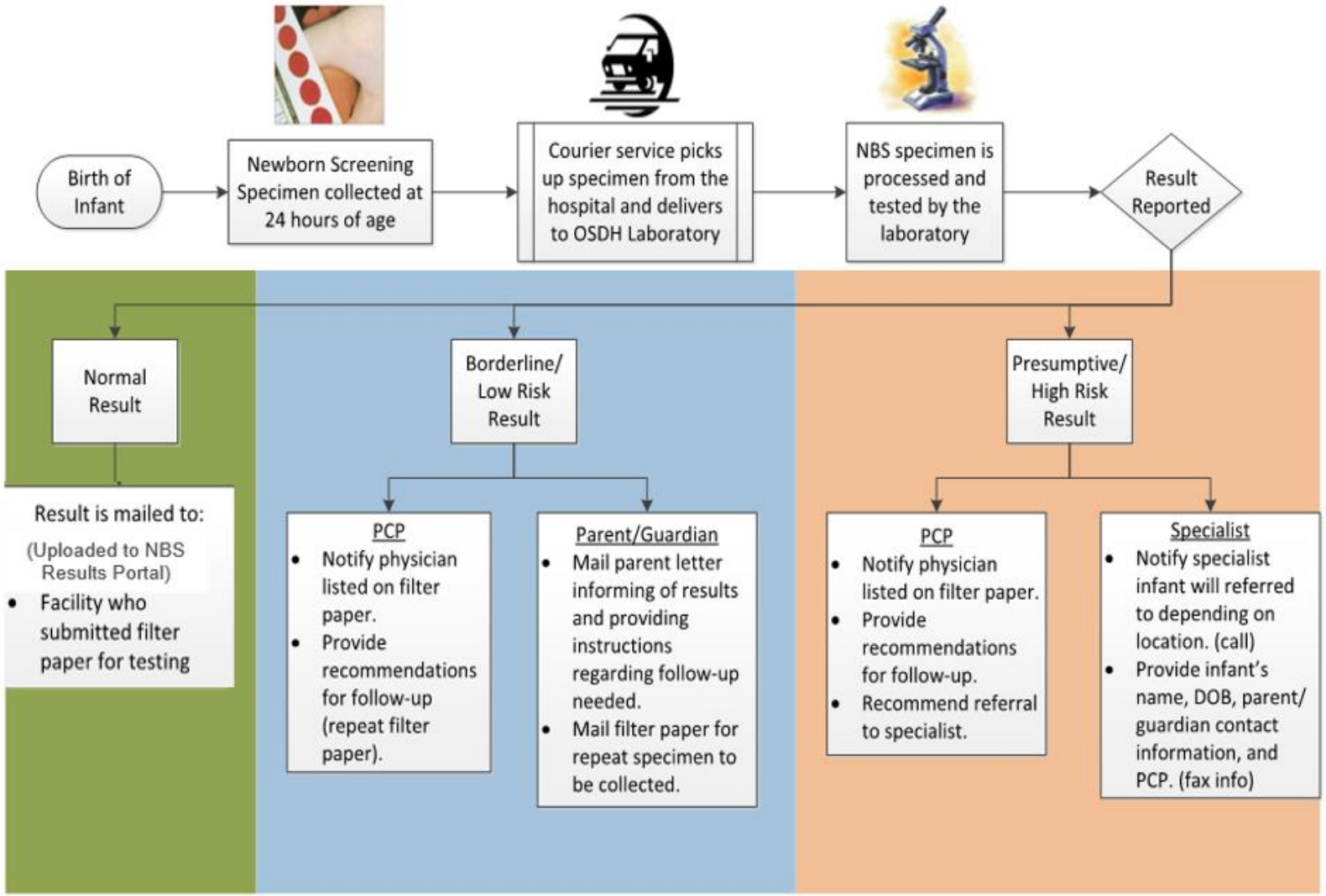






Blood Spot Screening is a system, not an event.

Pre-Testing: Education



*Short-term Follow-up continues tracking case until confirmed normal or diagnosed with a disorder.

Diagnostic Testing, Potential Diagnosis and Long Term Follow-Up

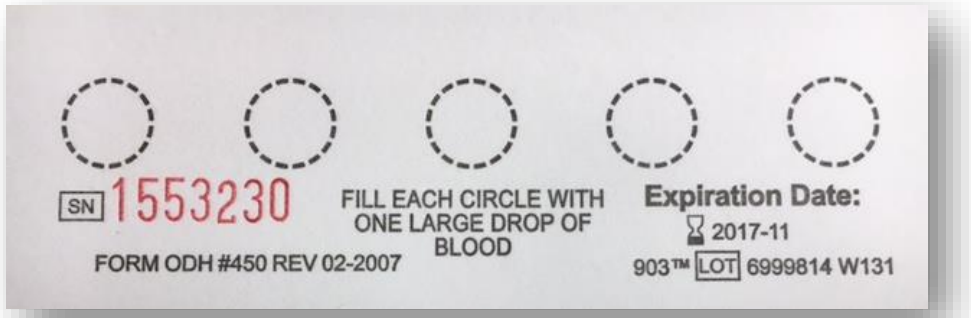
NBS Filter Paper Review

Unsatisfactory (Unsat) Specimen Examples

OKLAHOMA State Department of Health

Filter Paper

- The filter paper is part of the NBS Form. It is a medical device designed to absorb a specific volume of blood within each pre-printed filter paper circle.
- If an analyte for any disorder is either too high or too low, this is an indication that additional testing is needed.
- Accurate results depend upon proper absorption of blood onto the filter paper.
  - Too much or too little blood may result in inaccurate results.



Multiple Application

Front

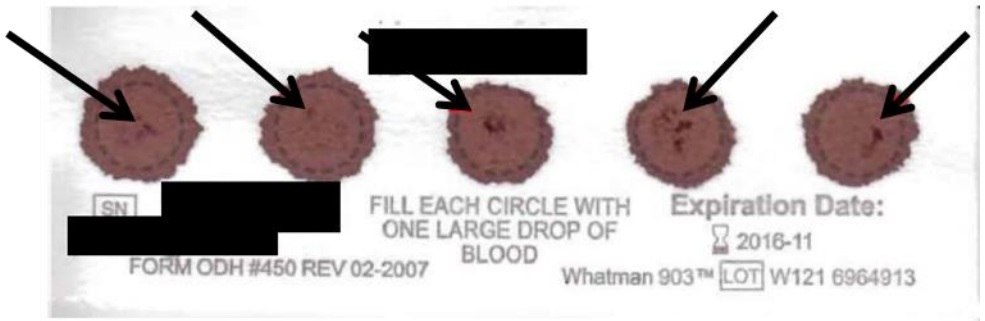
Back

Why Unsat?

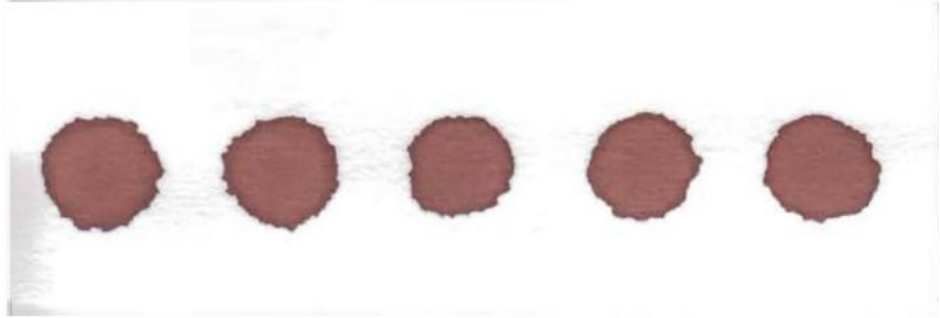
- When bloodspots overlap or touch, as is the case in the sample above, it creates an uneven absorption of blood.
- Analyte levels cannot be accurately measured.
- Testing these specimens will result in inaccurate results.

Clotted or Caked Blood

Front



Back



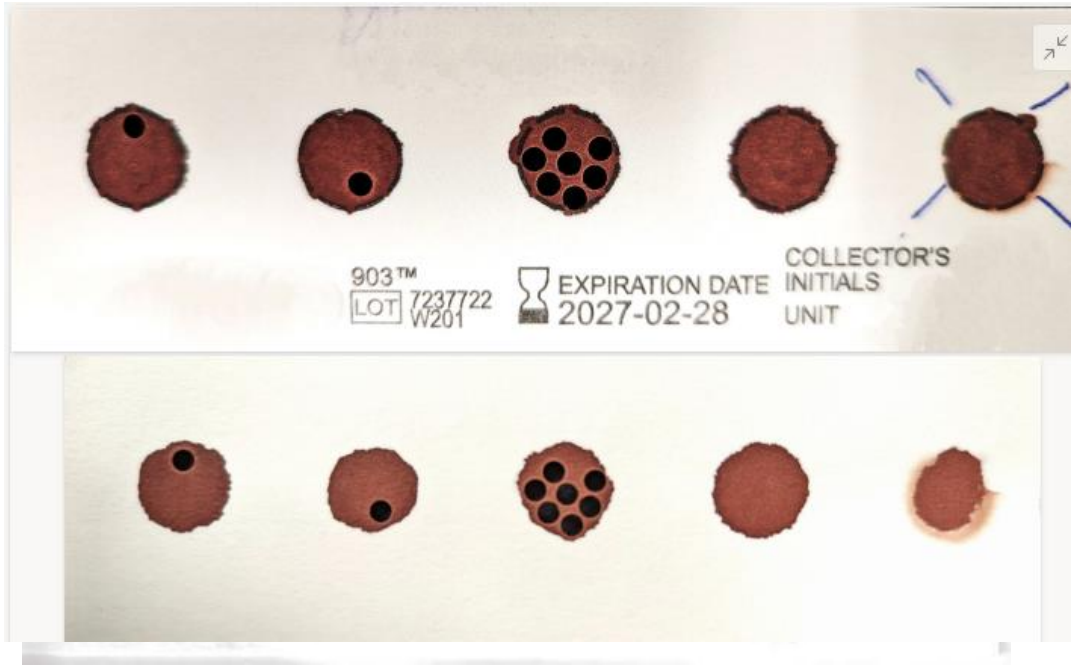
Why Unsat?

- Clots can occur using capillary tubes or if too much blood is applied to the pre-printed circles.
- Samples with clots are not suitable for testing.

Serum Rings

Front

Back



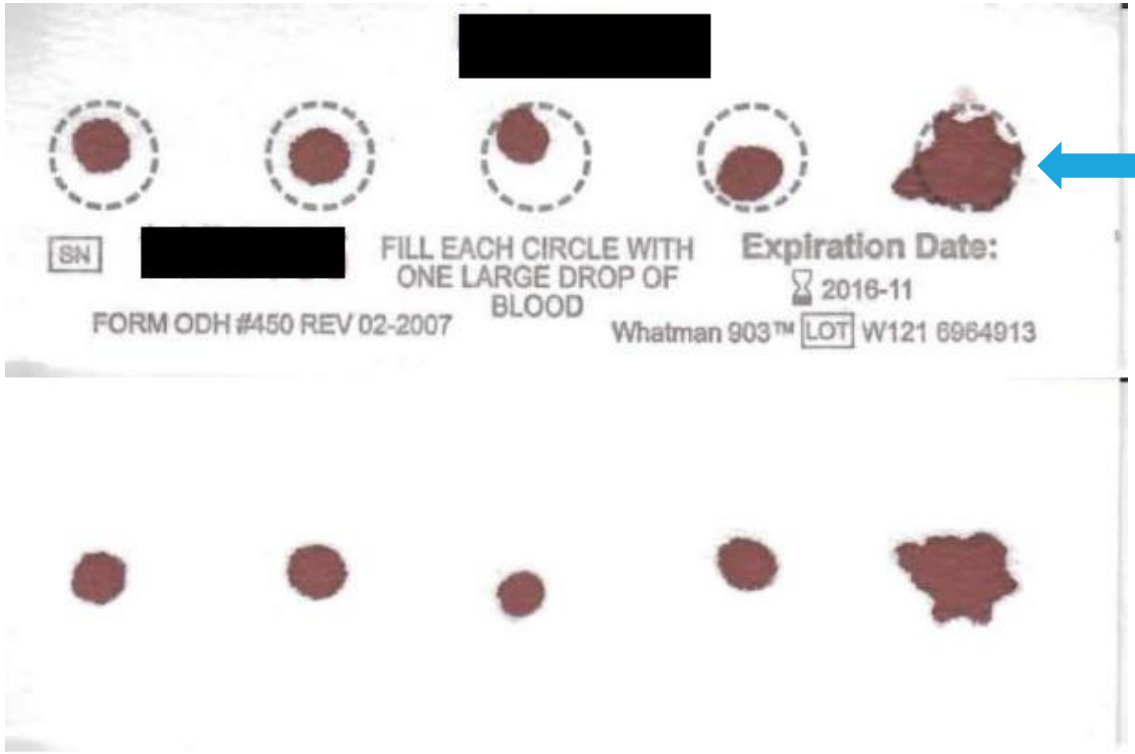
Why Unsat?

- Notice the halos around the periphery of some of the pre-printed circles above. This can occur due to the following:
  - Insufficient drying of alcohol on the baby's heel prior to heel stick
  - Drying the specimen vertically instead of horizontally
  - Closing the flap of the filter paper on top of the circles while the specimen is still wet
  - Placing wet specimens in plastic bags
  - Milking or squeezing the puncture site

Inadequate Amount of Blood

Front

Back



Why Unsat?

- The above filter paper circles are not sufficiently filled with blood for testing.

Under-Saturation

Front

Back

Why Unsat?

- Notice how the blood has not soaked all the way through the filter paper. There simply is not enough blood in this sample for testing.

Acceptable Filter Paper

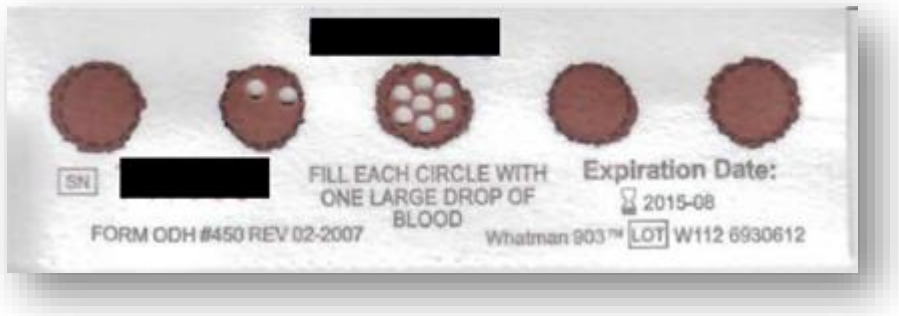
Front

Back

Why Acceptable?

- Pre-printed circles are completely filled with blood
- Blood has soaked all the way through the filter paper
- Absence of clots or caked blood
- Absence of serum rings

Are All Five Circles Needed?



Why?

- If a result is flagging out-of-range, the specimen will be retested, and the final result will be an average of three results. Each test requires an additional punch to be taken from the pre-printed circles.
- If the results for Congenital Adrenal Hyperplasia (CAH), Pompe Disease, MPS1 or X-ALD are out-of-range, ***one or two entire circles*** will be removed and shipped to another laboratory for steroid profile testing. These are overnighted to Mayo laboratory in Minnesota or Revvity Labs in Massachusetts. Screen results are not final until second tier is complete.
- Disorders will continue to be added to the newborn screening panel.
- The specialist and family may request for the specimen to be sent to another laboratory for additional testing to assist in determining diagnosis.

For Reference…

- Refer to *Clinical and Laboratory Standards Institute* (CLSI) for collection guidelines.

NICU and Special Considerations

NICU Special Considerations

Infant

- Prematurity and LBW may affect TSH & 17-OHP results
- Hypoxia, CMV, septicemia, trisomies, biliary atresia may affect IRT levels
- Liver immaturity may affect amino acid results
- Carrier status may affect all NBS results

Treatment

- TPN, SNAP, and carnitine may affect amino acid, fatty acid, or organic acid results
- Steroids may affect 17-OHP results
- ECLS and blood transfusions may affect all NBS results

Maternal

- PTU therapy or radioactive iodine may affect infant TSH results
- Steroids may affect infant 17-OHP results

Collection Issues

- Contamination: oils/lotion from hands, spills, standing water, residual alcohol, heat/humidity
- Early/delayed specimen collection
- Transit time delays
- Unsatisfactory specimens

Additional Information

Hospital Responsibilities

- Ensure **ALL** infants are screened prior to discharge. (Keep a log book to ens
  compliance.)
- Ensure specimens are received in a timely manner to the OSDH PHL for testing.
- Infants who are transferred: >> The **RECEIVING** hospital is to ensure that the NBS has been collected.
- Submit **SATISFACTORY** specimens:
  - Collected properly
  - All requested information is documented on the demographic form attached to filter paper
  - Submitted timely

Annual NBS Summary (All Submitters)

Total Specimens

52,320

Total Unsatisfactory Specimens

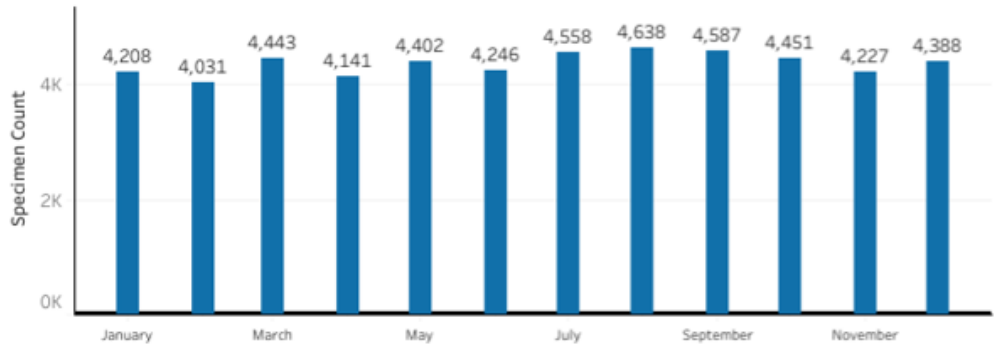
1,569 3.00%

GOAL: The number of unsatisfactory specimens < 2%

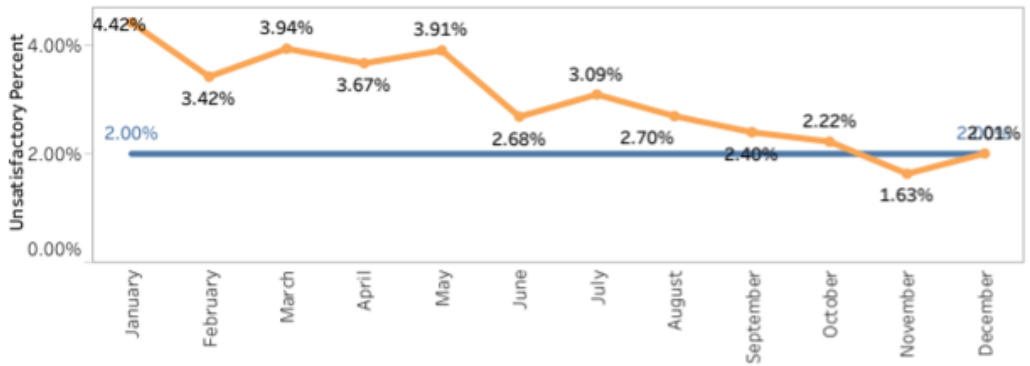
Total Initial Specimens

45,303 97.50%

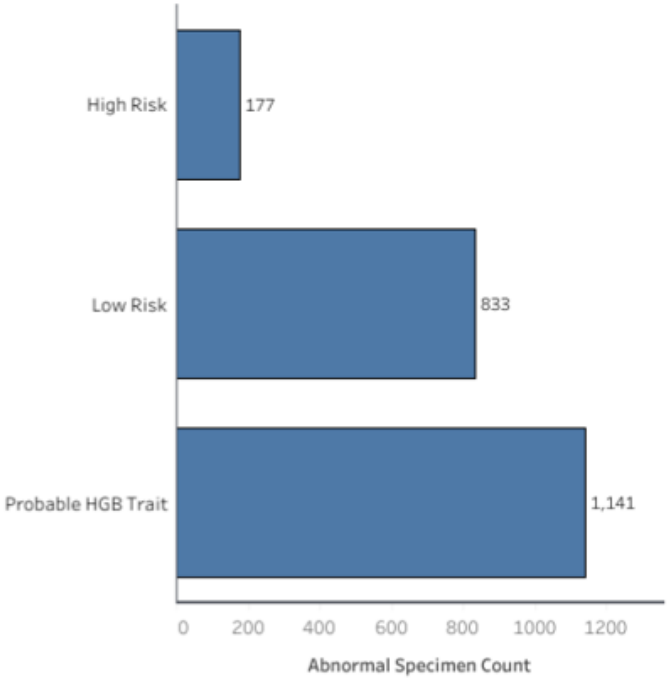
GOAL: The number of initial specimens collected between 24.01 - 48 hours ≥ 95%



Unsatsifactory Specimens



Abnormal Specimens



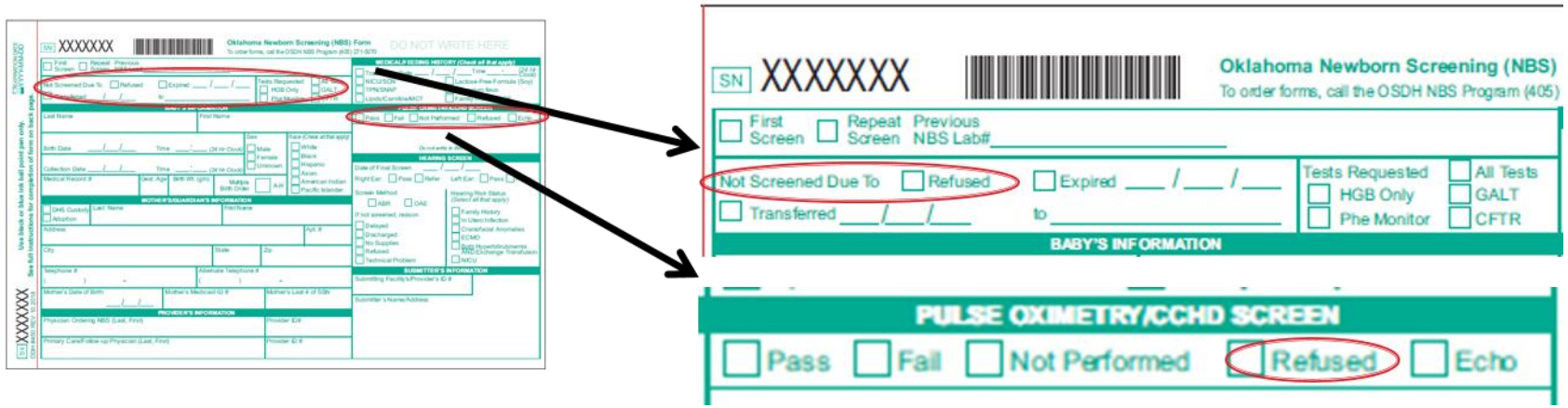
Total Abnormal Specimens 2,151

Refusal of screening

- Parents may refuse screens based on Religious Tenets and Practices.
- Refusal form must be signed and placed in the medical record with a copy mailed to the Newborn Screening Program.
- Please note that a parent must indicate which of three portions of the screen are being refused: Hearing, bloodspot, and/or CCHD.
- Demographic form with no specimen on filter paper should be sent into PHL with courier, with “X” marked in refusal box.

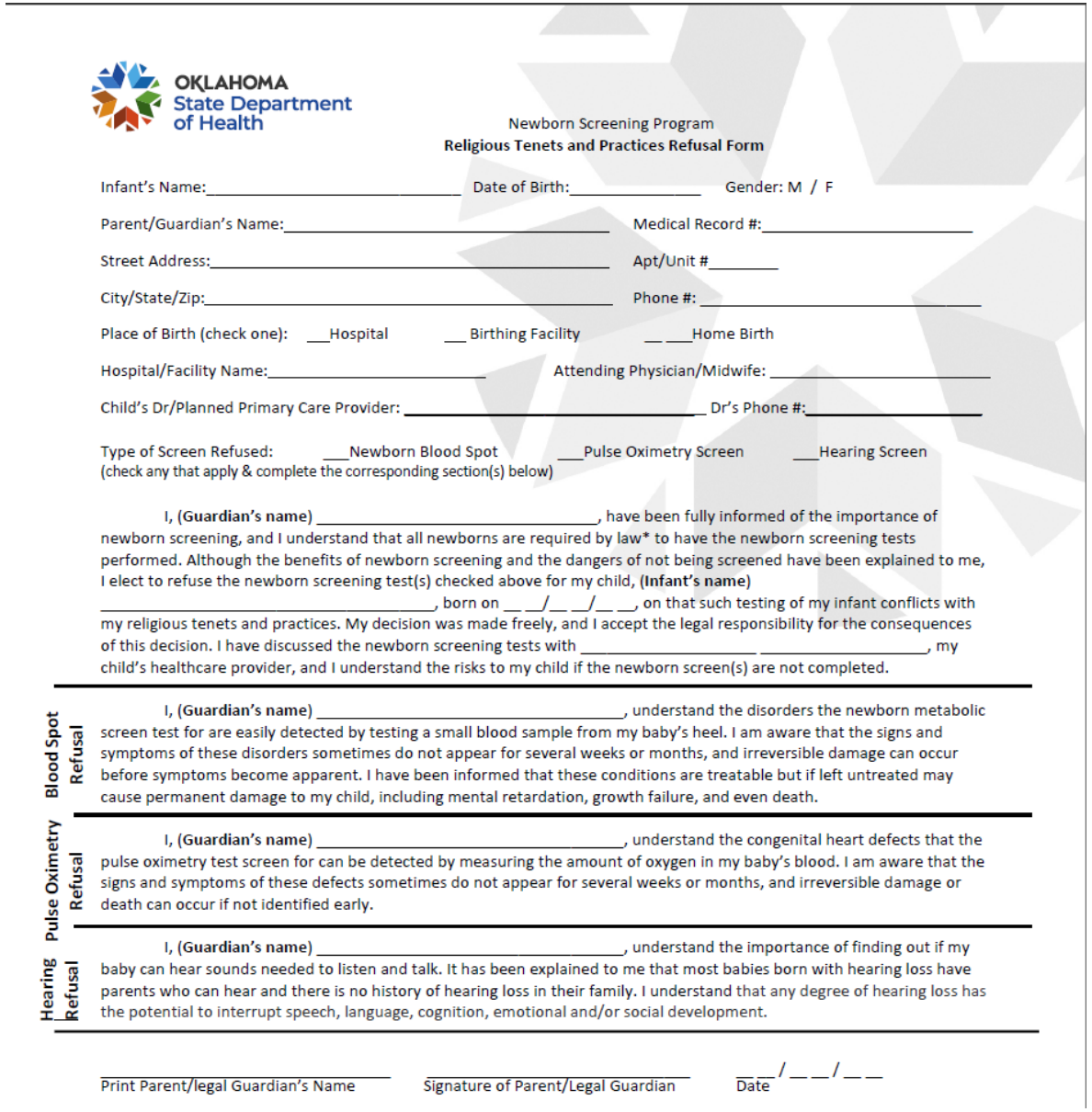
Refusal

- Religious Tenets and Practices only.
- **Check the box(es) on the filter paper form if parents refuse the NBS and/or the pulse oximetry screen.**
  - Provide parents with a NBS blood spot and/or pulse oximetry brochure(s) and answer any questions they might have about the screen(s).



- Ensure the parents fill out a Refusal Form. Keep a copy for baby's record and fax a copy to the NBS Program using fax number 405-900-7556.

Refusal Form



OKLAHOMA State Department of Health

Newborn Screening Program

Religious Tenets and Practices Refusal Form

Infant's Name:_____ Date of Birth:_____ Gender: M / F

Parent/Guardian's Name:_____ Medical Record #:_____

Street Address:_____ Apt/Unit #_____

City/State/Zip:_____ Phone #: _____

Place of Birth (check one): ___Hospital ___ Birthing Facility __ ___Home Birth

Hospital/Facility Name:_____ Attending Physician/Midwife: _____

Child's Dr/Planned Primary Care Provider: _____ Dr's Phone #:_____

Type of Screen Refused: ___Newborn Blood Spot ___Pulse Oximetry Screen ___Hearing Screen
(check any that apply & complete the corresponding section(s) below)

I, **(Guardian's name)** _____, have been fully informed of the importance of newborn screening, and I understand that all newborns are required by law* to have the newborn screening tests performed. Although the benefits of newborn screening and the dangers of not being screened have been explained to me, I elect to refuse the newborn screening test(s) checked above for my child, **(Infant's name)** _____, born on __ __/__ __/__ __, on that such testing of my infant conflicts with my religious tenets and practices. My decision was made freely, and I accept the legal responsibility for the consequences of this decision. I have discussed the newborn screening tests with _____ _____, my child's healthcare provider, and I understand the risks to my child if the newborn screen(s) are not completed.

Blood Spot Refusal

I, **(Guardian's name)** _____, understand the disorders the newborn metabolic screen test for are easily detected by testing a small blood sample from my baby's heel. I am aware that the signs and symptoms of these disorders sometimes do not appear for several weeks or months, and irreversible damage can occur before symptoms become apparent. I have been informed that these conditions are treatable but if left untreated may cause permanent damage to my child, including mental retardation, growth failure, and even death.

Pulse Oximetry Refusal

I, **(Guardian's name)** _____, understand the congenital heart defects that the pulse oximetry test screen for can be detected by measuring the amount of oxygen in my baby's blood. I am aware that the signs and symptoms of these defects sometimes do not appear for several weeks or months, and irreversible damage or death can occur if not identified early.

Hearing Refusal

I, **(Guardian's name)** _____, understand the importance of finding out if my baby can hear sounds needed to listen and talk. It has been explained to me that most babies born with hearing loss have parents who can hear and there is no history of hearing loss in their family. I understand that any degree of hearing loss has the potential to interrupt speech, language, cognition, emotional and/or social development.

_____ _____ ___/__ __/__ __
Print Parent/legal Guardian's Name Signature of Parent/Legal Guardian Date

Transit Time

Prompt delivery of specimens to the Public Health Laboratory for testing can make all the difference.

Transit Time: What is it?

- “The time between the collection of a newborn screening specimen to its receipt at the OSDH Public Health Laboratory for testing.”
- Specimens should be received at the OSDH Lab within 48 hours from time of collection. *Oklahoma Law: OS 63 Sections 1-533 and 1-534*

“Practically Speaking…. How is that Consistently Possible?”

If a specimen is collected anytime (up to 11:59 PM) on “day one”, there is no reason that specimen can’t be dry, in the lab and ready for pick up on “day two”.

With every hospital having seven day a week courier service, every specimen should be able to arrive at the PHL the next day, regardless of the day of the week. The exception would be holidays or the very occasional weather-related delay.

Transit Time: Tips for Improvement

- Ensure everyone involved in NBS collection/handling knows about courier pick-up time, location, and importance.
- Do not batch specimens.
- Ensure the NBS is collected at 24 hr + 1 min of age and goes out with the courier as soon as possible after it has dried (~3-4 hours of drying time).
- Set timelines and goals specific for your facility.
- Maintain a courier/transport log.
- Review transit time reports.
- Contact the PHL if the courier does not present to pick up the NBS specimens.

Impact

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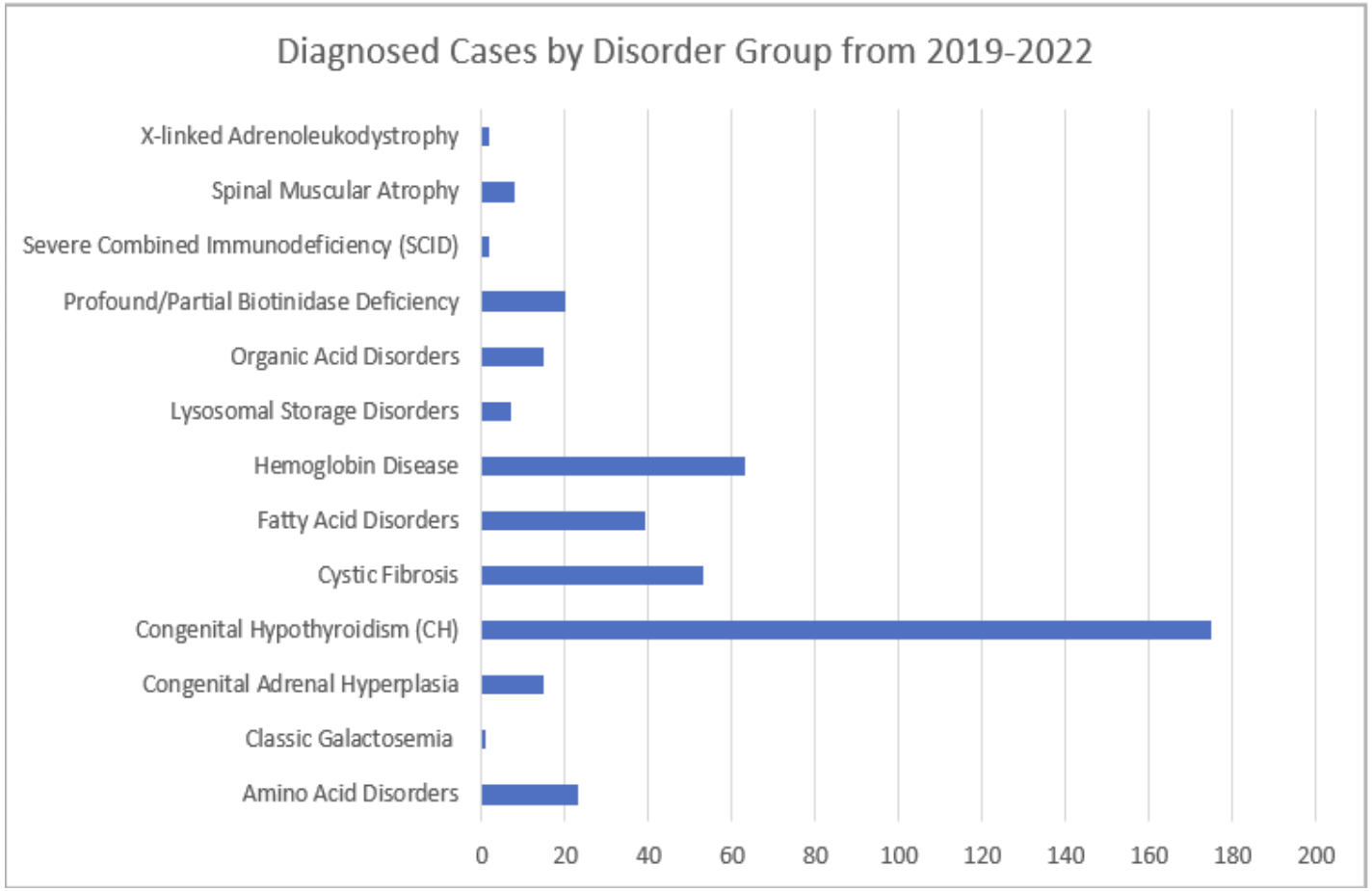
Blood Spot Screening Statistics in Oklahoma

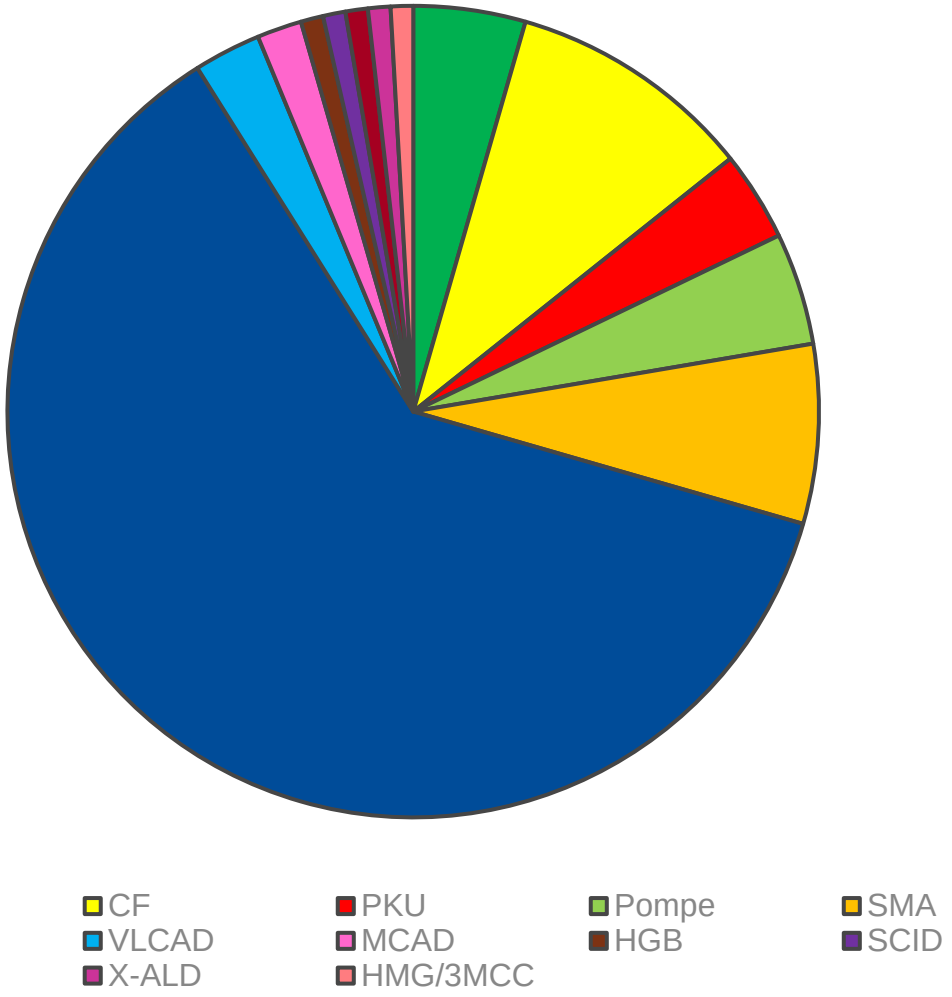
- In 2023, **50,294** dried bloodspot specimens were collected.
- Three in 50 infants will have an abnormal screen that requires further testing.
- One in 450 infants will be identified with a disorder.
- Specimens are kept by the OSDH lab for 42 days before being destroyed.



**LSD Disorders began screening in June 2021.

Diagnosed Bloodspot Cases – Preliminary Data 2024

Congenital Hypothyroidism (CH) - 69
Cystic Fibrosis (CF) – 11
Spinal Muscular Atrophy (SMA) – 8
Biotinidase Deficiency (BIO) – 5
Glycogen Storage Disease Type II (Pompe Disease) – 5
Phenylketonuria (PKU) – 4
Very long-chain acyl-CoA dehydrogenase deficiency (VLCAD) – 3
Medium-chain acyl-CoA dehydrogenase deficiency (MCAD) - 2
Hemoglobinopathy (SS) – 2
Severe Combined Immunodeficiency (SCID) – 1
Congenital Adrenal Hyperplasia (CAH) – 1
X-linked Adrenoleukodystrophy (X-ALD) – 1
3-Methylcrotonyl-CoA carboxylase deficiency (3MCC) - 1



Newborn Screening WINS – True Story Timeline

Case Study from 2023

- Born on a Tuesday at 0121
- NBS collected Wednesday at 0150
- Specimen arrived at PHL Wednesday at 1900
- Preliminary critical result called to NBS follow-up nurse on Thursday at 1210
- Baby was found to still be in hospital, in Mother/Baby unit. Mother/Baby nurse was notified, Genetic specialist notified and confirmatory labs were ordered. Feeding precautions initiated, decision made to delay discharge another night.
- NBS critical result finalized on Friday, called to NBS follow-up nurse who promptly notified Mother/Baby staff and Genetics Specialist. Emergency management protocol in place, confirmatory labs are pending. Geneticist speaks with infant's parents at bedside for initial consultation. Treatment is initiated on Friday (3 days after birth), in anticipation of confirmatory testing results.
- Confirmatory lab results are finalized eight days after birth. Ongoing care has been established with geneticist with plans for life-long management in place.
- Delay of diagnosis or lack of treatment for this fatty acid disorder would have resulted in infant mortality.

Newborn Screening Loss – In Oklahoma in 2023

Case Timeline:

- Born on a Tuesday at 1904
- NBS collected Wednesday at 1951
- Specimen arrived at PHL Friday at 1900 (that Friday was a state recognized holiday)
- Friday 9 AM: NBS follow-0up team received word that infant was hospitalized in critical condition for R/O Sepsis, suspected seizures and was found to have elevated ammonia level. Geneticist requesting if NBS results were available? (Day three of life)
- Friday 4:12 PM: Infant passed on day three of life, screen and labs collected prior to passing indicated Citrullinemia to be cause of death

What do we learn from this family's experience?

- It was important to be able to trace the timeline, so that we knew that we had done all that we could to prevent this outcome for this family. (Courier logs are a part of this)
- Even when we control all the parameters within our scope, we will lose some infants to these disorders.
- We are compelled to address specimen quality and timeliness for every baby as if a disorder of this gravity hangs in the balance. We do have babies in Oklahoma diagnosed and living with Citrullinemia, due to early identification through newborn screening.

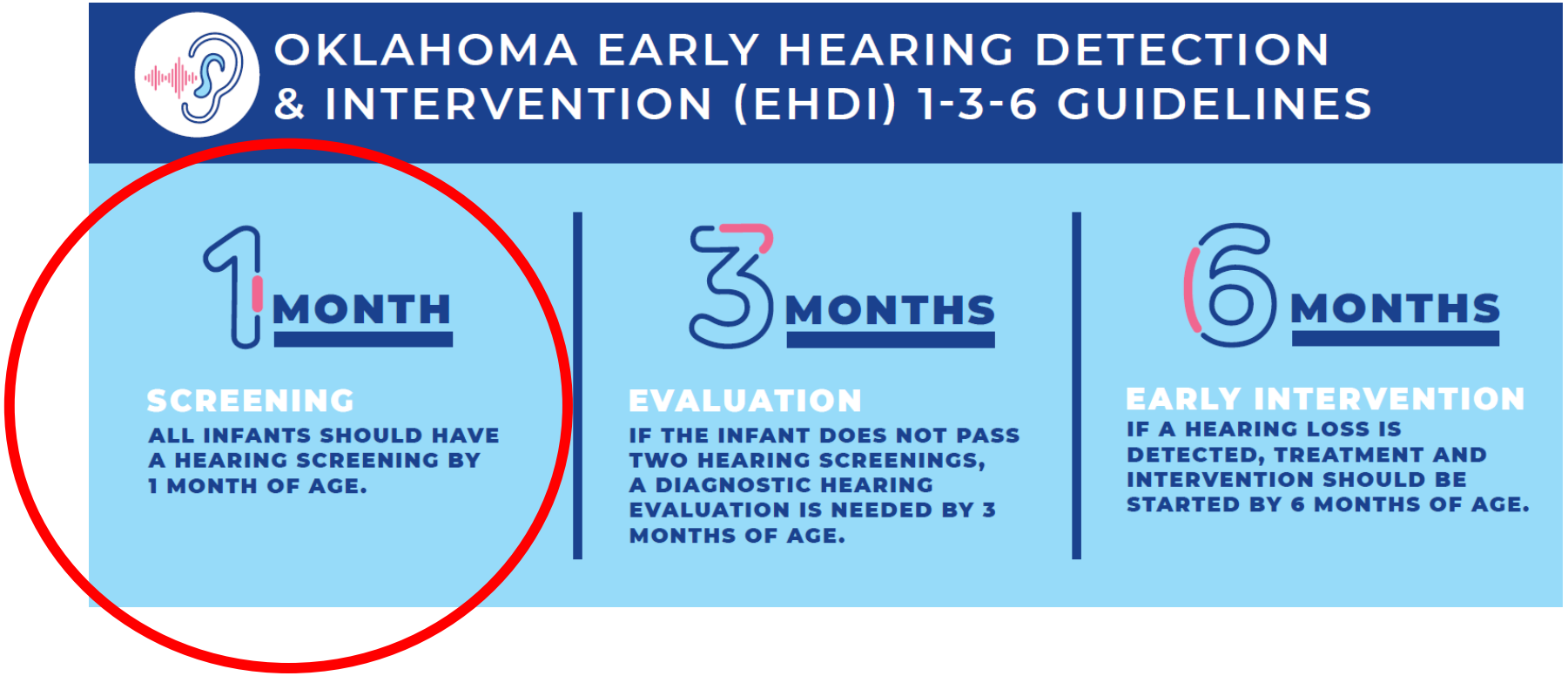
Newborn Hearing Screening

Why Newborn Hearing Screening is Important

- Cannot always “see” a hearing loss
- 92% of children with hearing loss are born to hearing parents
- ½ of children identified with a hearing loss do not have a risk factor
- The prevalence of permanent hearing loss in 2022 was 1.7 per 1,000 births
- A total of 6,272 infants were diagnosed with permanent hearing loss in 2022 following NBHS

2022 Summary of National CDC EHDI Data | Annual Data EHDI Program | CDC

Newborn Hearing Screening



Newborn Hearing Screening – When and How

- At least 34 weeks of age
- Close to discharge while still having time to rescreen if possible
- If needed, the second screening should *not* be immediately after the first screen – ideally it should be several hours later

Two High Quality Screens

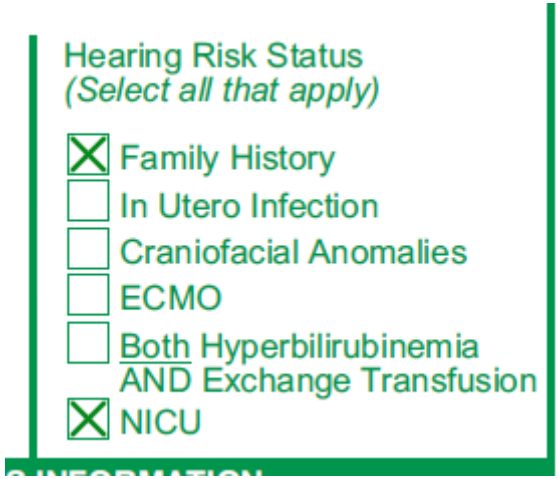
- Want a quiet environment
  - Can use a sign on the door or inside
  - Okay to ask people to step out/ turn the TV off/etc.

- Ensure the baby is relaxed
  - Sleeping
  - Quiet
  - Well Fed
  - Dry
  - Comfortable
- Swaddle can help
  - Helps them relax
  - Keeps hands away from equipment

- Can be done bedside
- Can be done while baby is held by family
- Can be done while nursing

Risk factors for Hearing Loss

- Family history of childhood hearing loss
- NICU stay of longer than five days
- Hyperbilirubinemia with exchange transfusion
- Aminoglycoside administration for more than five days
- Asphyxia or Hypoxic Ischemic Encephalopathy
- Extracorporeal membrane oxygenation (ECMO)
- In utero infections (herpes, rubella, syphilis, toxoplasmosis)
- Congenital Cytomegalovirus (CMV)
- Caregiver Concern
- Maternal Zika, COVID-19
- Craniofacial abnormalities
- 400 Syndromes are associated with hearing loss
- Events associated with hearing loss (head trauma, fracturs)
- Chemotherapy
- Not meeting speech and language milestones
- Balance difficulties (walking, changing surfaces)



Sharing Hearing Screen Results

- Make sure family understands results <u>prior to discharge</u>

- **Pass** – No follow-up needed unless concerns arise
- **Pass with risk** – Another screening at six months or as recommenced by their provider
- **Refer** – Repeat screening or have a diagnostic test
- **Missed screening** – Complete a NBHS by one month of age

Things to Say

- Did not pass / refer
- Does not mean there is a hearing loss
- Just means we need more testing
- Can do another screening or go to a pediatric audiologist

Things to not Say

- It is just fluid
- It is our equipment /equipment is old
- I am sure it is nothing
- It was just loud

Pulse Oximetry Screening

CCHD – Critical Congenital Heart Disease

OKLAHOMA State Department of Health

Critical Congenital Heart Disease (CCHD)

- Screening began in 2014.
- Screening is done by utilizing pulse-oximetry.
- Critical congenital heart defects are conditions that are present at birth and can affect the structure of a baby's heart and the way it works.

Pulse Oximetry Screening

Purpose:

- Screen **all** newborns between 24-48 hours of life with pulse oximetry to detect select defects related to critical congenital heart disease.

Rationale:

- Some newborns may appear healthy at first *despite* having a CCHD. Early detection and prompt treatment can prevent lifelong disability and early death.

Pulse-Oximetry Screening

- Simple and painless way to measure the amount of oxygen in the baby's blood.
- Congenital heart disease is the **most common** birth defect
- One in 110 infants will have a heart defect, 25% of those cases will have CCHD.
- Most affected will not have symptoms early on.
- Most will require surgery shortly after birth.

Normal Heart: Blood Flow

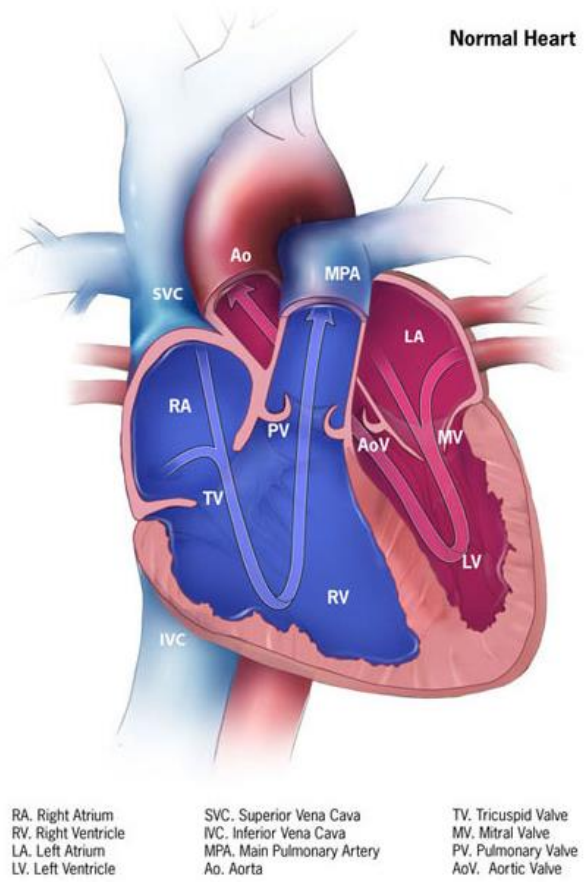


Image credit: CDC (2014)

- Blood from body tissues goes to the right side of the heart and enters the lungs, where the blood becomes oxygenated. The blood is then delivered to the left side of the heart, which is responsible for pumping the oxygenated blood out to provide oxygenation to the body tissues. After being utilized, the deoxygenated blood is returned to the right side of the heart, and the cycle continues. Valves within the heart help to prevent backflow of blood during this process.

- Fetal openings between the atria, ventricles, and blood vessels begin to close shortly after birth.

Fetal-Neonatal Circulation

- The first *breath of life* leads to important changes in neonatal circulation:
  - Makes way for use of neonatal lungs (The lungs were not utilized in utero, as the placenta provided oxygenation to the fetus; after birth, however, an enormous amount of pressure is necessary for the newborn to close the diversions used to bypass the lungs in utero and instead allow for use of the lungs.)
  - Increased pressure change in the left side of heart compared to the right (The left side becomes the body's "pump") resulting in:
    - Closure of the Ductus Arteriosus (fetal opening between aorta and pulmonary artery)
    - Closure of the Foramen Ovale (fetal opening between the right and left atria)

❖ Failure of closure of fetal openings can result in complications.

CCHD: Screening Targets & Symptomatology

CCHD Targets - Most likely detected by pulse oximetry screening

- Hypoplastic Left Heart Syndrome (HLHS)
- Pulmonary Atresia
- Tetralogy of Fallot
- Total Anomalous Pulmonary Venous Return
- Transposition of the Great Arteries
- Tricuspid Atresia
- Truncus Arteriosus

❖ These heart defects lead to low levels of oxygen in the blood.

CCHD Targets - Potentially detected by pulse oximetry screening

- Double Outlet Right Ventricle (DORV)
- Ebstein's Anomaly
- Coarctation of the Aortic Arch
- Interruption of the Aortic Arch
- Single Ventricle

❖ Also potentially detected by pulse oximetry screening: other hypoxic cardiac or non-cardiac conditions.

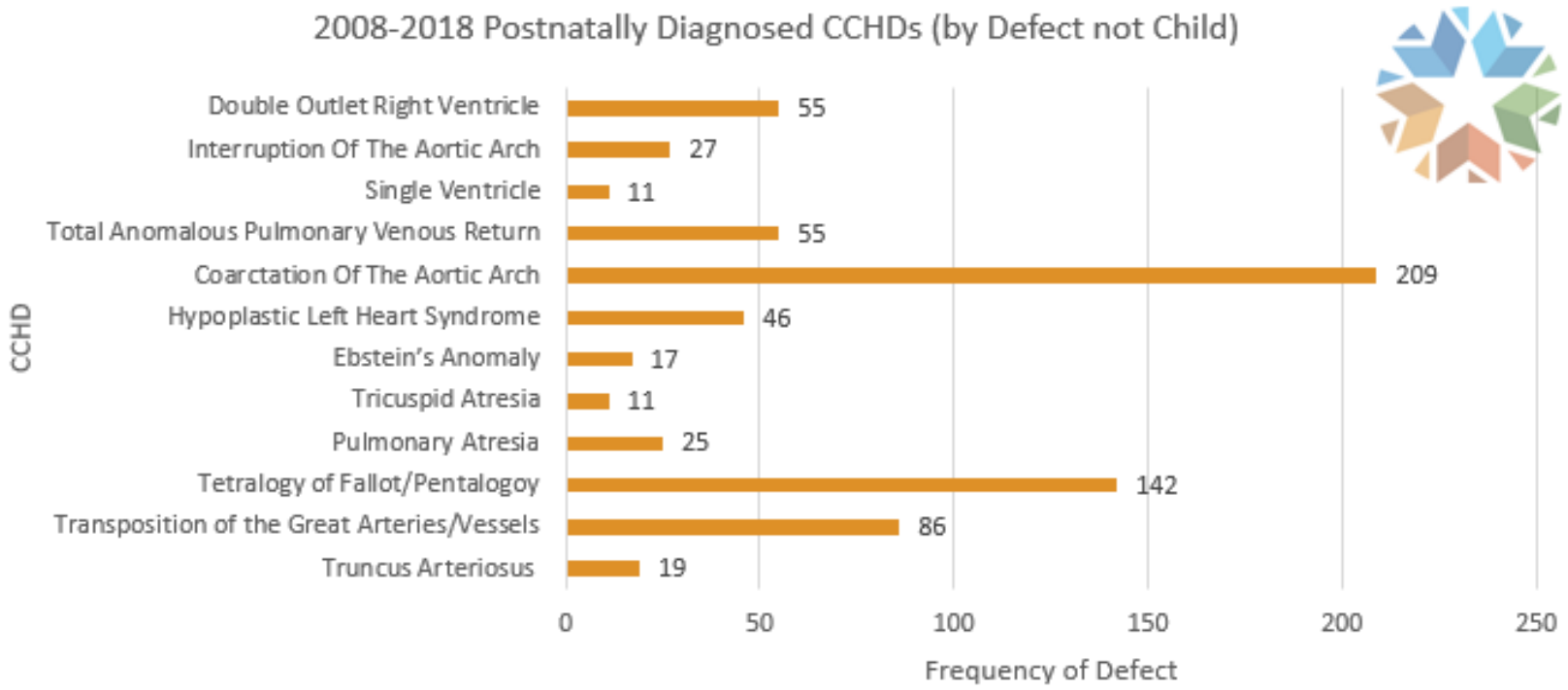
CCHD: What to Watch For

Signs

- Cyanosis
- Tachypnea
- Increased work of breathing
- Swelling
- Tires easily during feeds
- Sweating
- Poor weight gain

❖ **If at any time, the newborn should become symptomatic, the family should *immediately* take the baby to the closest emergency room for evaluation.**

CCHDs in Oklahoma



Data provided by the Oklahoma Birth Defects Registry. Data does not reflect cases identified solely through pulse oximetry screening for CCHDs.

Pulse-Oximetry

The Screen and the Oximeter

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State Department
of Health

Pulse Oximetry: Context

Who is screened?

- **All** newborns:
  - Must be calm and well; not crying
  - Warm extremities (temperature affects readings)
  - Skin clean and dry (dried blood affects readings)
  - Using room air; not on supplemental oxygen

When is screening performed?

- **Healthy Newborn**: Between 24-48 hours of life
- **Sick Newborn**: Between 24-48 hours of life
  - May delay if on supplemental oxygen

- **Before 24 hours*:*** higher risk for false positives (fetal-neonatal circulation transition not fully established)
- **After 48 hours*:*** delayed identification & treatment of affected newborns

Points to Consider

- Pulse oximeter must be FDA approved (AAP, 2015)
- Regular calibration of the oximeter is required
- Pulse oximetry readings are averages
- Skin color and jaundice **do not** affect pulse oximetry readings

❖**Continuous pulse oximetry monitoring does not replace the pulse oximetry screen.**

Screening How-to, Protocol and Guidelines

How is the Screen Performed?

1. **Select site:** right hand; either foot.
2. **Place** photodetector on outer aspect of hand/foot (under 4th-5th finger/toe).
3. **Wrap** sensor tape around extremity.
4. **Ensure** light emitter is **directly opposite** the photodetector.
5. If using a reusable sensor, secure the sensor using wrap recommended by vendor; **do not tape** or use hand to secure sensor to site.

Photo credit: Masimo 2011

Guidance for Screeners

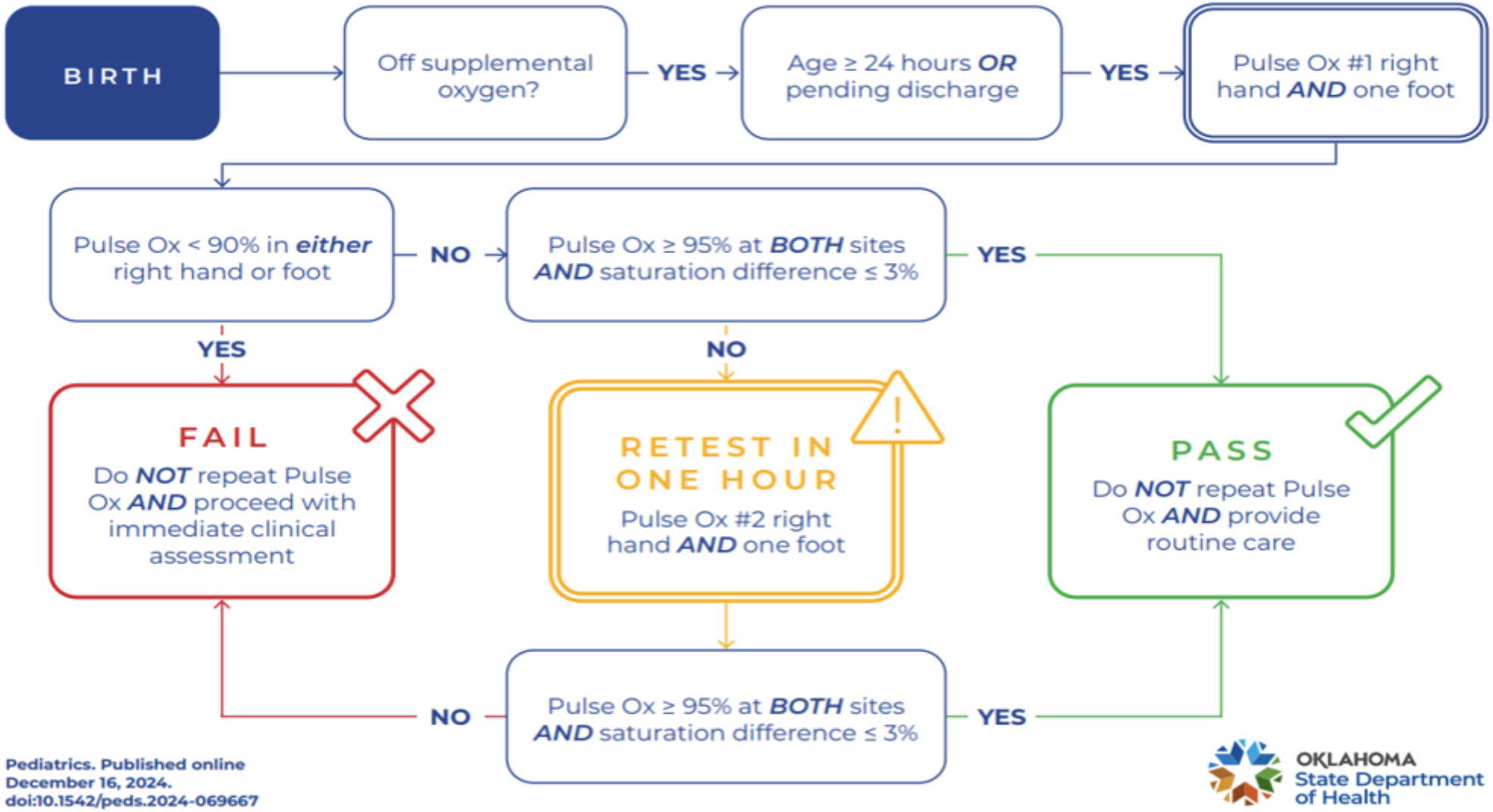
Pulse Ox Dos

- If disposable, use a new, clean sensor; if reusable, clean between use
- Clean according to manufacturer recommendations
- Ensure newborn is calm and warm, not crying; encourage family involvement
- Ensure newborn skin is clean and dry
- Ensure no gaps between sensor and newborn's skin
- Light emitter and photodetector should be **directly opposite** of one another
- Use alongside physical examination
- Ensure pulse: no pulse, no oximetry!

Pulse Ox Don'ts

- Do not use an adult probe
- Do not tape pulse oximeter in place (use disposable wrap as indicated)
- Do not use your own hand to hold sensor in place
- Do not obtain reading from same extremity with blood pressure cuff
- Bilirubin lamps and surgical lights can affect accuracy of reading; cover pulse oximetry sensor with a blanket if such instruments are in use
- Do not use in isolation

Pulse-Oximetry Screening – Updated Algorithm, January 2025



Pediatrics. Published online December 16, 2024. doi:10.1542/peds.2024-069667

OKLAHOMA State Department of Health

Screening Results

Negative Screen (Pass):

- Oxygen saturation ≥ 95% in Right Hand and/or Left or Right Foot

AND

- Difference between the Right Hand and Left/Right Foot ≤ 3%

Positive Screen (Refer/Fail):

- Oxygen saturation < 90% in Right Hand or Left/Right Foot during **any** screen
- Oxygen saturation 90 - 94% for **both** screens (one hour between each screen)
- Difference between the Right Hand and Left/Right Foot > 3% for **both** screens (one hour between each screen)

Interpretation of Results

Negative = Pass

- Results are in-range
- Blood oxygen level WNL
- CCHD still possible (if symptomatic, a cardiac evaluation is warranted)
- Monitor baby's status:
  - Heart rate – too fast/slow?
  - Energy – overly sleepy/fussy/lethargic?
  - Appearance – pale/blue skin?
  - Respiration – too fast/slow?
  - Temperature – cold to touch?
  - Feeding – difficulties?

Positive = Fail/Refer

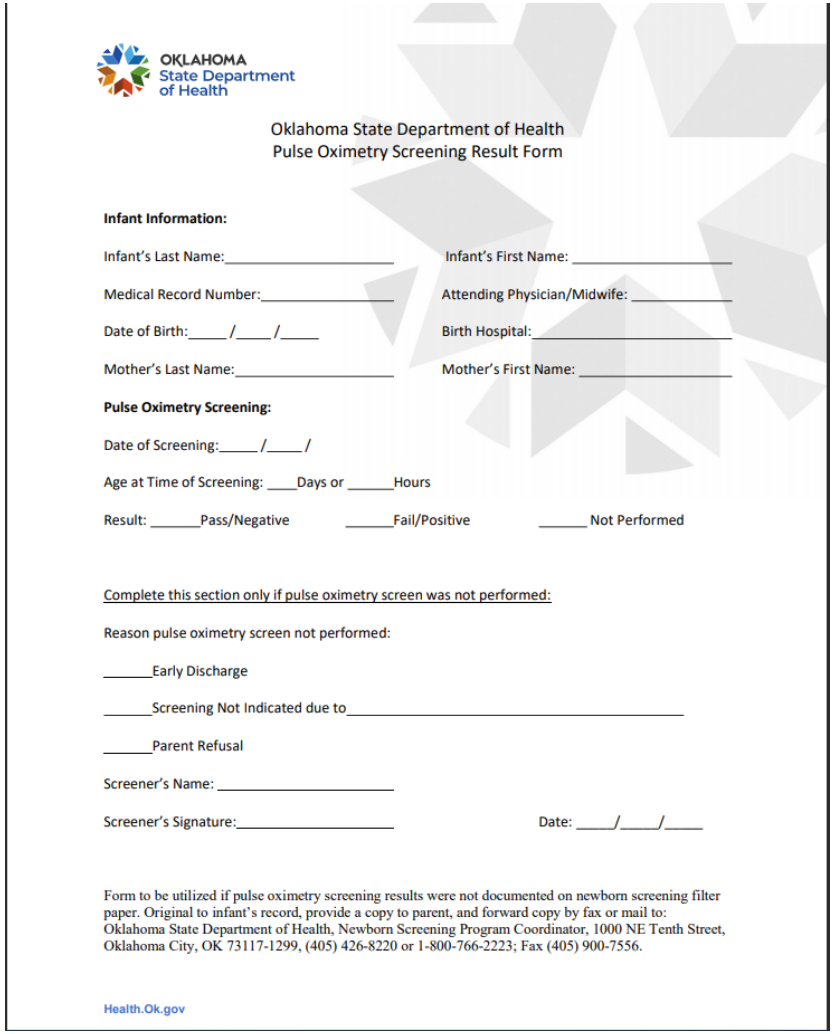
- Results are out-of-range
- Blood oxygen level is low
- High risk; not diagnostic
- Confirmatory procedures & referral for treatment are warranted

Reporting Results for CCHD: Filter Paper

Note: If parents refuse the pulse oximetry screen, provide them with a pulse oximetry brochure and answer any questions they might have about the screen. Ensure the parents fill out a Refusal Form; keep a copy for baby's record and fax a copy to the NBS Program using fax number 405-900-7556.

- Pulse Oximetry Screen: Check Only ONE, do not leave blank
  - Pass
  - Fail
  - Not Performed
  - Refused
  - Echo

Reporting Results for CCHD - Pulse Oximetry Result Form



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State Department
of Health

Oklahoma State Department of Health
Pulse Oximetry Screening Result Form

Infant Information:

Infant's Last Name:_____ Infant's First Name: _____

Medical Record Number:_____ Attending Physician/Midwife: _____

Date of Birth:_____/____/_____ Birth Hospital:_____

Mother's Last Name:_____ Mother's First Name: _____

Pulse Oximetry Screening:

Date of Screening:_____/____/

Age at Time of Screening: ____Days or _____Hours

Result: _____Pass/Negative _____Fail/Positive _____ Not Performed

Complete this section only if pulse oximetry screen was not performed:

Reason pulse oximetry screen not performed:

_____Early Discharge

_____Screening Not Indicated due to_____

_____Parent Refusal

Screener's Name: _____

Screener's Signature:_____ Date: _____/_____/_____

Form to be utilized if pulse oximetry screening results were not documented on newborn screening filter paper. Original to infant's record, provide a copy to parent, and forward copy by fax or mail to: Oklahoma State Department of Health, Newborn Screening Program Coordinator, 1000 NE Tenth Street, Oklahoma City, OK 73117-1299, (405) 426-8220 or 1-800-766-2223; Fax (405) 900-7556.

Health.Ok.gov

Newborn Screening Contacts

- **Bloodspot, Pulse Oximetry, & Hearing Screening**

Screening & Special Services
123 Robert S. Kerr
Oklahoma City, OK 73102-6406

Phone: 1-405-426-8220
Toll Free: 1-800-766-2223
Fax: 1-405-900-7556
NewbornScreen@health.ok.gov

- **Public Health Laboratory**

Newborn Screening Section
Public Health Laboratory Service
4615 W. Lakeview RD
Stillwater, OK 74075

Phone: 1-405-564-7750
Toll Free: 1-800-766-2223
Fax: 1-405-900-7611
Publichealthlab@health.ok.gov

Thank you for your time!

Questions?