Oklahoma State Dept of Health

Amendment of Solicitation

Date of Issuance: 03/26/19 **Solicitation No.** 3400001619

Requisition No. **Amendment No.** 2

Hour and date specified for receipt of offers is changed: ☐ No ☒ Yes, to: 4/4/2019 3:00 PM CDT

Pursuant to OAC 260:115-7-30(d), this document shall serve as official notice of amendment to the solicitation identified above. Such notice is being provided to all suppliers to which the original solicitation was sent.

Suppliers submitting bids or quotations shall acknowledge receipt of this solicitation amendment prior to the hour and date specified in the solicitation as follows:

(1) Sign and return a copy of this amendment with the solicitation response being submitted; or,

(2) If the supplier has already submitted a response, this acknowledgement must be signed and returned prior to the solicitation deadline. All amendment acknowledgements submitted separately shall have the solicitation number and bid opening date printed clearly on the front of the envelope.

ISSUED BY and RETURN TO:

U.S. Postal Delivery:

Donna Dodson
OSDH
1000 NE 10th St

OKC , OK 73117 - 1299

or

Personal or Common Carrier Delivery:

SAME

,OK -

Donna Dodson
Contracting Officer

405 - 271 - 4042
Phone Number

donnad@health.ok.gov
E-Mail Address

Description of Amendment:

a. This is to incorporate the following:

1.) EXTEND CLOSING DATE TO 4/4/2019
2.) ATTACHMENT A - SPECIFICATIONS FOR NBS BLOODSPOT KITS
3.) ATTACHMENT B – REPLACES IN IT'S ENTIRETY THE ATTACHMENT ON THE ORIGINAL SOLICITATION 3400001619

PLEASE NOTE THERE IS NO WORD DOCUMENT AVAILABLE

b. All other terms and conditions remain unchanged.

Supplier Company Name (**PRINT**) Date

Authorized Representative Name (**PRINT**) Title Authorized Representative Signature

ATTACHMENT A

SPECIFICATIONS FOR OKLAHOMA METABOLIC DISORDER SCREENING KIT Rev. 10/2018

Methodology for evaluating this acquisition will be "lowest and best" bid. Responses not complying with any of the requirements listed in this ITB will be considered non-responsive and eliminated from further consideration for award.

Vendor requirements:

1. Vendor must be registered with the Food and Drug Administration (FDA) for printing an in vitro medical diagnostic device (N. 1,281,317) and must comply with FDA's "Good Manufacturing Practices" regulations and provide documentation.
2. Vendor must provide documentation, if requested, of a satisfactory FDA inspection and authorization for printing and production of this collection kit.
3. Vendor must provide at least four physical properties of the filter paper listed below:
    a. Absorption capacity
    b. Homogeneity
    c. Retention volume of 1/8 inch punch, and
    d. Absorption time for filling blood collection circles
4. Vendor must provide with the bid a Certificate of Quality Control Testing post printing of the filter paper.
5. Vendor must provide a proof of the form for examination, revision, and approval by the Public Health Laboratory prior to printing.
6. Vendor shall not print or manufacture the form until the final proof is approved by the Public Health Laboratory Service.
7. Vendor must acknowledge compliance with all specifications listed below.

Filter paper Matrix Specifications – before printing

1. Filter paper shall be a recent lot of S&S 903 or equivalent 100% pure cotton fiber, filter paper with no wet-strength additives or equivalent. Lot number to be printed on the filter paper attachment of page 3.
2. Basis weight should be 110 lb. +/- 5% per read (550 sheets 24 x 35 inches).
3. Densitometer reading by Gurley method on one sheet with a 5 oz. Cylinder, 0.1 sq. orifice and 100 cc of air (Test method, modified ASTM D7266-58).
4. pH should be 5.7 to 7.5
5. Ash% 0.2 maximum (Test method, modified ASTM D726-63)
6. Kelmn: Tappi modified useful method – UM451
7. Wet strength (ASTM D-774-67), usually around 4/5 lbs./inch sq.
8. Absorption rate: The absorption time and the diameter of blood spot produced by 100 uL. Of a fresh whole blood sample (hematocrit 55 +/- 1%). Absorption time target: 12 seconds; range 5-30 seconds. Diameter target: 16mm; range 15-17 mm volume. Ragged edges or mottling or dried blood spot should not be observed. 1/8

inch punch of the dried blood spot should equate to a blood volume of 1.54 +/- 0.17 uL.

9. Lithographic printing is not an acceptable printing process for the filter paper. A dedicated ink delivery system used only for filter paper printing is recommended.

Ink specifications:

1. Printing ink must not interfere in analytical test procedures. Data must be available, if requested to validate the compatibility of the ink for the following tests: Phenylalanine, Amino Acid disorders, Galactose, Galactose 1- phosphate Uridyl Transferase, Thyroxine, Thyroid Stimulating Hormone, Cystic Fibrosis, Congenital Hyperplasia, Medium Chain Acyl CoA Dehydrogenase, Fatty Acid oxidation disorders, Organic Acid disorders, SCID and others.
2. Circles on the filter paper must be a thin black broken line and must be same dimensions as shown on Attachment B (0.5 inches or 13 mm in diameter)
3. Page 1. Print using green ink with white headings and green check boxes and all other printing in black ink. See Attachment B.
4. Page 2. Print on yellow paper with green ink with white headings and green check boxes and all other printing in black ink. Use red ink for wording on CHART COPY. See Attachment B.
5. Print serial numbers on filter paper in black ink.
6. Page 5 Collecting specimens. Use red ink for expiration date on filter paper. Drawings outlined in black ink with foot having green ink showing the area for collection in green and red no designation for where not to draw sample. Use red ink in correct /acceptable circle as well as wrong/unacceptable circles as shown on Attachment B. Use red tear drop in circle marked with one drop, one circle, one time.
7. Page 6 front and back print use red ink to print first lines of text. See Attachment B. All other printing in black ink.

Packing specifications:

1. Forms shall be packaged in protective loose wrap in bundles of approximately 100 in numerical order.

   NOTE: Shrink wrap or use of heat in packaging is not acceptable and will affect the absorption capacity of the filter paper.

2. Bundles shall be boxed in number order with bundles (forms) flat and not shipped on their side.
3. Boxes shall be number on the exterior with the serial number sequence.

Certificate of Post Printing Quality Control Testing of Filter Paper Matrix:

Random samples of the printed form are to be taken for quality control testing. Sampling to be based on the Military standard 105-E. Vendor must be able to provide a certificate,

if requested, to verify that changes have not taken place during the printing process. Item to be tested on samples is as follows:

1. Dimensional testing, including caliper to insure that the thickness of the filter paper hasn't changed during the printing process. See section on filter paper specifications.
2. Text check versus the approved proof.
3. Blood absorption time for 100 uL of blood. Absorption rate: The absorption time and the diameter of blood spot produced by 100 uL. Of a fresh whole blood sample (hematocrit 55 +/- 1%). Absorption time target: 12 seconds, range 5-30 seconds.
4. Blood circle size for 100 uL. of blood. Diameter target: 16 mm, range 15-17 mm volume.
5. Circle quality: Ragged edges or mottling or dried blood spot should not be observed.

Vendors bidding substitutions to the specification must provide proofs prior to printing approval.

Contact Persons: After award of this ITB for changes, modifications, or approval of proofs:

Steve Johnson, Director Lab Administration
PO Box 24106
Oklahoma City, OK 73124-0106
Phone 405 271 5070 Fax 405 271 4850
E-mail: stevej@health.ok.gov

For delivery:
Oklahoma State Department of Health
Public Health Laboratory
1000 NE 10th Street
Oklahoma City, OK 73117-1299

Vendor Contact is : _____ (name)
_____ (address)
_____ (city, state, zip)
_____ (phone)
_____ (fax)
_____ (FEI/FIN)

ATTACHMENT A

Newborn Metabolic Disorder Screening Kit Format Specifications:
See Attachment B for example of the collection kit.

1. **SIZE**: Collection kit finished – height 5.5 x length 12.625 in.
Note: All measurements include 0.5 inch perforation on left side

Page 1 Demographic Entry Form 5.5 x 8.5 inch Printing on front
Page 2 Newborn Metabolic Disorder Screen – Chart copy (yellow) 5.5 x 9.25 inch printing on front
Page 3 Newborn Metabolic Disorder Screen – Parent information (pastel Blue) 5.5 x 9.875 inch, printing Front and Back
Page 4 Newborn Hearing Screening – Parent information (Pastel Pink) 5.5 x 10.5 inch, Printing Front and Back

Page 5 Blood Collection Instructions and Filter Paper Cardstock 10.625 x 5.5

Page 6 Completion of NBS form and Flap Cardstock back cover-OUTSIDE 12.625 x 5.5
Hearing instructions Cardstock back cover –INSIDE 12.625 x 5.5

Page 6 Overlay 5.5 x 12.625 inch, printing on front and back

2. **Print font:** Arial or equivalent

3. **Print size:** Readable for average individual and to fit information to designated areas of the form.

4. **Print Format:** Minor changes in format of print fields may be allowed but must be approved in advance with a proof for approval and prior to printing.
Page 1 – Print must fit in designated areas.
Page 2 – Print must fit in designated areas.
Page 3&4 – Instructions may be re-arranged to fit into space.
Page 5 – Data must be in designated area.
See Attachment B Page 1 – Demographic Entry Form – Layout

5. **Barcode & serial number:** Each kit to be serially numbered with corresponding barcode (3 of 9 mod 43) (checksum digit) as shown in Attachment B.

The serial number will appear on page 1, 2, 3, 4 and the filter paper starting with the number **1823206**

A. Location of Serial number:
Page 1: Demographic – Serial number to appear top left side of sheet and perforated stub.
Page 2: Chart copy – serial number to appear top left side of sheet.
Page 3: Parent Instructions (blue), top left side of sheet.

Page 4: Parent copy (pink), top left side of sheet.
Page 5: Filter paper attached on right side as shown.

B. Location of barcode:
Page 1: Demographic, to appear top left side of sheet and stub; barcode to be perforated for removal as shown.

6. **Print Media & Ink**

Page 1: Print in green, white and black ink on white 20# bond.
Page 2: Print front in green, white and black ink on pastel yellow NCR 20# bond, specific areas to be in register with page 1.
Page 3: Print front and back, in black ink, on pastel blue NCR 20# bond, specific areas to be in register with page 1.
Page 4: Print front and back, in black ink. On pastel pink NCR 20# bond, specific areas to be in register with page 1. Coat face of page 4 to allow impressions.
Page 5: Print on 100# buff tag with 903 filter paper or equivalent attached to right side.
Page 6: Print on 100# buff tag.

7. **In register Printing: (pages 1,2,3,4) – coated NCR**

Fields required to be in register and coated
"Baby's Last Name" Page 1 with page 2,3,4
"Baby's First Name" Page 1 with page 2,3,4
Check all that apply at time of screening boxes of page 1 must be in register with boxes on **Check all that apply** page 2

Page 1 with page 4
All boxes on page 1 in the **Hearing Screening Results Section** that are completed be submitted must be in register with page 4.

8. **Designated location of boxes**

In the "Specimen Information Section"

Location 1 – Top right corner of form. This area of the box must be 2 inches wide and ½ inch high from edge of form.
Location 2 – The top of the box is 1 ½ inches from the top edge and is 3/8 inches in height by 2 7/8 inches in length.
Note: Each box to have **"Do not write in this box"** in small print.
See Attachment B Page 1- Demographic Entry Form- Layout

9. **Perforation:** All pages to perforate 0.5 inches on left side and glued on left side.
Page 5 – Filter paper attachment to be perforated for removal

Page 6 – Overlay – perforated at 3 ½ inches form the right side for easy removal.

10. **Fold:** Page 6 – fold 1.5 inches from right side to cover the circles of filter paper.

11. **Drawings:** Page 6 Printed on folded panel – add drawing or facsimile of drawing. Add international Biohazard symbol on folded panel in black ink.

12. **Mylar coating:** Page 6 – A three inch area starting ½ inch from the right side of the paper to be coated with mylar. The coated area to be in register with the front and back side of the circles of the filter paper to prevent specimen contamination by the paper stock.

13. **Filter paper attachment:** 903 filter paper attached (butts) to the right side of page. Glue page 2, 3, and 4 on left side so all pages can be removed at the same time.

14. **Circles on Filter paper:** Circles ½ inch or 13 mm in diameter printed with a broken or dotted line. Edge of circle must be printed ½ inch from the right edge of the filter paper.

15. **Expiration Date:** Expiration date XX/XX/XX to be printed in front of the filter paper attachment of page 5 in 10 or 12 bold print.

16. **Identifiers:** Manufacturer's name (or identifier) and lot number of filter paper must be printed on the filter paper attachment.

Attachment B

EXPIRATION DATE 2020-02-28

Use black or blue ink ball point pen only. See full instructions for completion of form on back page.

SN 1710050 ODH #450 Rev 10-2018

SN 1710050

Oklahoma Newborn Screening (NBS) Form

To order forms, call the OSDH NBS Program (405) 271-5070

DO NOT WRITE HERE

☐ First Screen ☐ Repeat Screen Previous NBS Lab #_____

Not Screened Due To ☐ Refused ☐ Expired ____ / ____ / ____

☐ Transferred ____/____/____ to _____

Tests Requested ☐ All Tests ☐ HGB Only ☐ GALT ☐ Phe Monitor ☐ CFTR

BABY'S INFORMATION

Last Name | First Name

Birth Date ____ / ____ / ____ Time ____:____ (24 Hr Clock)

Collection Date ____ / ____ / ____ Time ____:____ (24 Hr Clock)

Sex ☐ Male ☐ Female ☐ Unknown

Race (Check all as apply) ☐ White ☐ Black ☐ Hispanic ☐ Asian ☐ American Indian ☐ Pacific Islander

Medical Record # | Gest. Age | Birth Wt. (gm) | Multiple Birth Order ☐ A-H

MOTHER'S/GUARDIAN'S INFORMATION

☐ DHS Custody ☐ Adoption | Last Name | First Name

Address | Apt. #

City | State | Zip

Telephone # ( ) -

Alternate Telephone # ( ) -

Mother's Date of Birth ____ / ____ / ____ | Mother's Medicaid ID # | Mother's Last 4 of SSN

PROVIDER'S INFORMATION

Physician Ordering NBS (Last, First) | Provider ID #

Primary Care/Follow-up Physician (Last, First) | Provider ID #

MEDICAL/FEEDING HISTORY (Check all that apply)

☐ Transfusion Date ____ / ____ / ____ Time ____:____ (24 Hr Clock)

☐ NICU/SCN ☐ TPN/SNAP ☐ Lipids/Carnitine/MCT

☐ Lactose-Free Formula (Soy) ☐ Meconium Ileus ☐ Family History of CF

PULSE OXIMETRY/CCHD SCREEN

☐ Pass ☐ Fail ☐ Not Performed ☐ Refused ☐ Echo

Do not write in this box

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

SUBMITTER'S INFORMATION

Submitting Facility's/Provider's ID #

Submitter's Name/Address

SN 1710050

Oklahoma Newborn Screening (NBS) Form

To order forms, call the OSDH NBS Program (405) 271-5070

DO NOT WRITE HERE

☐ First Screen ☐ Repeat Screen Previous NBS Lab #_____

Not Screened Due To ☐ Refused ☐ Expired ____ / ____ / ____

☐ Transferred ____/____/____ to _____

Tests Requested ☐ All Tests ☐ HGB Only ☐ GALT ☐ Phe Monitor ☐ CFTR

BABY'S INFORMATION

Last Name | First Name

Birth Date ____ / ____ / ____ Time ____:____ *(24 Hr Clock)*

Collection Date ____ / ____ / ____ Time ____:____ *(24 Hr Clock)*

Sex ☐ Male ☐ Female ☐ Unknown

Race *(Check all as apply)* ☐ White ☐ Black ☐ Hispanic ☐ Asian ☐ American Indian ☐ Pacific Islander

Medical Record # | Gest. Age | Birth Wt. (gm) | Multiple Birth Order ☐ A-H

MOTHER'S/GUARDIAN'S INFORMATION

☐ DHS Custody ☐ Adoption | Last Name | First Name

Address | Apt. #

City | State | Zip

Telephone # ( ) -

Alternate Telephone # ( ) -

Mother's Date of Birth ____ / ____ / ____ | Mother's Medicaid ID # | Mother's Last 4 of SSN

PROVIDER'S INFORMATION

Physician Ordering NBS (Last, First) | Provider ID #

Primary Care/Follow-up Physician (Last, First) | Provider ID #

MEDICAL/FEEDING HISTORY *(Check all that apply)*

☐ Transfusion Date ____ / ____ / ____ Time ____:____ *(24 Hr Clock)*

☐ NICU/SCN ☐ TPN/SNAP ☐ Lipids/Carnitine/MCT

☐ Lactose-Free Formula (Soy) ☐ Meconium Ileus ☐ Family History of CF

PULSE OXIMETRY/CCHD SCREEN

☐ Pass ☐ Fail ☐ Not Performed ☐ Refused ☐ Echo

Do not write in this box

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

SUBMITTER'S INFORMATION

Submitting Facility's/Provider's ID #

Submitter's Name/Address

CHART COPY

DETACH AND PLACE IN MEDICAL RECORD

SN 1710050

OKLAHOMA NEWBORN SCREENING PROGRAM

Oklahoma State Department of Health

Parent/Guardian Information Sheet

DETACH AND GIVE TO PARENT OR GUARDIAN

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 health-care 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.

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

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

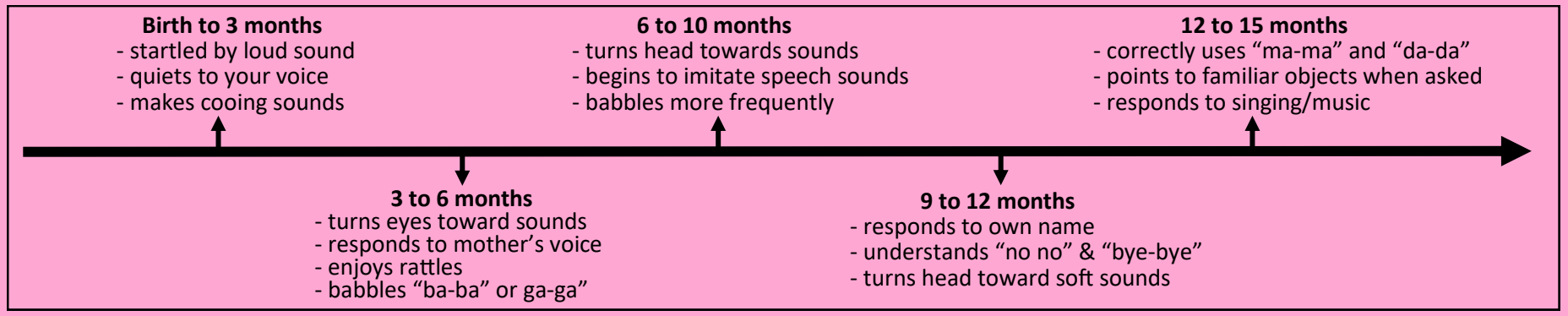
Parent/Guardian Information Sheet

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



What if I have questions?

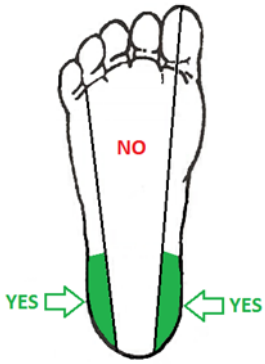
If you have questions about your baby's newborn hearing test results, contact your baby's healthcare provider, visit the OSDH Newborn Screening Program website at **http://nsp.health.ok.gov**, call at **(405) 271-6617** or **1-800-766-2223**, or email the program at **newbornscreen@health.ok.gov**.

SN 1713049 903™ 7069917 LOT W161 EXPIRATION DATE 2020-02-28 COLLECTOR'S INITIALS _____ UNIT _____

Instructions for Collecting Blood Spot Specimens

Note: *Do not handle blood collection area of Newborn Screening Form before, during, or following sampling.*

Collect blood sample from outer or inner border of heel



Collection of poor quality specimens will delay testing

CORRECT / ACCEPTABLE

Circles filled and evenly saturated

WRONG / UNACCEPTABLE

Multiple applications/layering

Multiple applications/insufficient sample

Serum rings present

1. Position infant's foot lower than rest of body to increase blood flow.
2. Warm heel using heel warmer or a soft cloth moistened with warm water up to 41°C for 3 to 5 minutes.
3. Clean infant's heel with 70% isopropyl alcohol and allow to air-dry.
4. Puncture inner or outer border of the heel with sterile disposable lancet, using a single, firm, quick puncture.
5. Allow a large drop of blood to accumulate then wipe away with sterile gauze.
6. Gently massage above the puncture site so blood flows freely; do not squeeze heel since interstitial fluid will contaminate the sample.
7. Allow a second large drop of blood to accumulate.
8. Apply one large drop of blood to a circle on the filter paper; the circle should be COMPLETELY filled when viewed from both sides of the filter paper.
   - Do not layer successive drops of blood.
   - Do not touch filter paper to the collection site.
   - Do not apply blood to both sides of filter paper.

9. Repeat procedure for each circle, filling all 5 circles.
10. Enter initials of person collecting sample and unit on filter paper.
11. Allow blood spots to air-dry at room temperature for 3-4 hours.
    - Dry horizontally, preferably in a drying rack.
    - Keep away from direct light (sun or lamps) and artificial heat.
    - Keep protective flap open during drying.
    - Do not let blood spots touch anything.
    - Do not allow wet spots to come in contact with each other.
12. When completely dry, fold protective flap over blood spots.
13. Place completed NBS form in PAPER envelope for transport to testing laboratory. Do not put specimens in plastic bags.

INSTRUCTIONS FOR COMPLETION OF NBS FORM

Print **legibly** using a **black or blue ball point pen**; press hard to ensure transfer to all copies of form.
Illegible writing and incomplete information may delay test results.
Complete form, even if specimen is not collected.

Top-left Portion of Form

Indicate if this is a First or Repeat newborn screen. Provide previous NBS Lab #, if known.
If infant not screened, indicate reason. If deceased, provide Date Expired.
If transferred to another hospital, provide Date Transferred and Receiving Hospital.
Indicate Tests Requested, as appropriate.

Baby's Information (as entered on birth certificate, as applicable)

Provide infant's Last Name and First Name(s).
Write "Male" or "Female" as First Name ONLY if first name is unknown.
Provide Birth Date and Time of Birth (use 24 hour clock, e.g., 8:30 AM is 0830 and 9:01 PM is 2101).
Provide Date and Time of Collection of specimen (use 24 hour clock).
Note: *Specimens should be collected as early as possible after 24 hours of birth, prior to blood transfusion, or immediately prior to discharge, whichever comes first.*
Indicate Sex of infant.
Indicate Race of infant, by selecting all that apply.
Provide infant's Medical Record number, as used by facility collecting specimen.
Provide Gestational Age (in weeks) of infant at time of birth.
Provide Birthweight (in grams) of infant.
If multiple birth, provide birth order for infant, using A (1st) through H (8th).

Mother's/Guardian's Information

Mark whether infant is in DHS Custody or is up for Adoption, as appropriate.
Provide Mother's/Guardian's Last Name and First Name.
Note: *If infant is to be adopted, document the name of the Agency or Law firm handling adoption, or Legal Guardian responsible for infant's care at time of discharge.*
Provide full address of Mother/Guardian.
Provide primary and secondary Telephone #s in the event that follow-up is required.
Secondary phone can be that of father or other close relative.
Provide Mother's Date of Birth, Medicaid ID# and Last 4 Digits of her Social Security #.

Provider's Information

Provide Last Name and First Name and NBS Provider ID# of physician (or midwife) who is ordering this screen. Refer to OSDH NBS Provider's ID list for full listing of providers.
Provide Last Name and First Name and NBS Provider ID# of physician who will be responsible for follow-up care of infant after discharge. If infant will be hospitalized for an extended period of time then provide name of attending physician.

Submitter's Information

Provide Submitting Facility's or Provider's NBS ID #.
Provide the Submitter's Name and Address (e.g., birthing hospital).

Medical/Feeding History

If infant has been transfused, provide Date and Time of Transfusion.
Indicate if infant is in NICU or Special Care Nursery (SCN).
Indicate feeding and medical history, as appropriate.

Pulse Oximetry/CCHD Screen

Indicate pulse oximetry result, as appropriate.
Note: *A response should be provided on every filter paper.*
If not screened, mark "Not Performed." If echo is performed in lieu of screening, mark "Echo."

Hearing Screen

See Hearing Screen Instructions section of this form.

SEND SPECIMENS WITHIN 24 HOURS OF COLLECTION

Use OSDH Courier Service or mail via USPS to:
Newborn Screening
Oklahoma State Dept. Health
Public Health Laboratory
P.O. Box 24106
Oklahoma City
OK 73124-0106

INQUIRIES

NBS Public Health Lab:
(405) 271-5070
NBS Follow-up:
(405) 271-6617 or
(800) 766-2223

ORDERING NBS FORMS

Call (405) 271-5070
http://phl.health.ok.gov

STORAGE

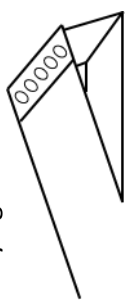
Store NBS forms vertically in a clean, dry area, away from direct sunlight before and after sample collection.

DO NOT REMOVE THIS COVER FLAP

OPEN this flap to uncover the circles for blood collection. DO NOT touch circles.

OPEN this flap while blood spots are drying.

- Air-dry blood spots at room temperature for 3-4 hours.
- Flap can be used to support filter paper horizontally while drying.



CLOSE this flap over blood spots when completely dry.

BIOHAZARD

INSTRUCTIONS FOR COMPLETION OF HEARING SCREEN SECTION OF NBS FORM

Hearing screening results should be submitted at the same time as the blood specimen whenever possible. No more than 2 quality screening attempts should be performed. If the hearing screen will be delayed, DO NOT delay sending the blood specimen. ALL BLOOD SPECIMENS MUST BE SENT WITHIN 24 HOURS OF COLLECTION.

Hearing Screen

1. Screen the infant's hearing using the available technology.
2. Enter hearing screen information on the right side of the NBS Form under "Hearing Screen".
3. Provide Date of Final Screen.
   Note: *Hospitals should only provide the final hearing screening results. If a second screen is required, report ONLY the second/final screen results.*
4. Indicate Right Ear and Left Ear results utilizing "x."
   Note: *Ensure only one result is selected per ear. To make corrections, use a single line through the incorrect result. Print the word "error" and initial the change. (e.g., x Refer Error AB)*
5. Indicate Screen Method used.

Reason Not Screened

Note: *If infant is screened, disregard this section.*

1. If hearing screen cannot be performed, indicate the reason by selecting the appropriate box in the "If not screened, reason(s)" section.
   a. Delayed – if a hearing screening cannot be completed before the blood specimen is sent and it is anticipated that hearing will be screened prior to discharge (e.g., infant in NICU).
   b. Discharged – if infant discharged before a hearing screen can be performed.
   c. No Supplies – if no supplies are available for the hearing screen.
   d. Refused – if the parents/guardian refused a hearing screen.
   e. Technical Problem: if a technical issue prevented performance of a hearing screen.
   Note: *If a technical problem occurs, report issue to the Newborn Hearing Screening Program.*
2. Complete the "Hearing Risk Status" section (see below).
3. Ensure there are no marks in the "Screen Method" box.
4. Detach and retain the Chart copy (yellow sheet) and Hearing Screening Parent/Guardian Information Sheet (pink sheet) of the NBS form.
5. Submit the NBS Form and blood specimen for testing.
6. Perform the hearing screening prior to discharge.
7. Record the hearing screen results in the appropriate boxes on both the yellow Chart copy and pink Parent/Guardian copy.
   a. If a new Hearing Risk Status becomes available, indicate in appropriate boxes on both copies.
   b. Photocopy the front of the completed yellow Chart copy; photocopy is used to fax results.
   Note: *Be certain infant's name and NBS Form Serial Number are legible on the photocopy.*
8. Fax a copy of the results to the Newborn Hearing Screening Program at 405-271-4892.

Hearing Risk Status

Complete the "Hearing Risk Status" section by selecting all that apply, if known.
Note: *This may require reviewing the patient's chart or asking about family history.*

a. Family History – if blood relatives of the infant have a permanent hearing loss that began in early childhood (e.g., parent, grandparent, cousin, etc.).
b. In Utero Infection – if infant exposed to CMV, herpes, rubella, syphilis, toxoplasmosis, Zika, etc.
c. Craniofacial Anomalies – if infant displays pinna/ear canal malformations (microtia, atresia, ear dysplasia), cleft palate, microcephaly, hydrocephalus, etc.
d. ECMO – if extracorporeal membrane oxygenation administrated to infant.
e. Both Hyperbilirubinemia AND Exchange Transfusion - if infant has hyperbilirubinemia requiring exchange transfusion; must have both to select this risk factor.
f. NICU – if infant in NICU or special care nursery.

Parent Education

Detach the Hearing Screening Parent/Guardian Information Sheet (pink sheet) and give to the infant's parent or guardian at discharge. Discuss taking form to the baby's healthcare provider.