

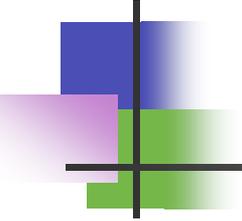
# State Hygienic Laboratory (SHL) University of Iowa



## Newborn Screening (NBS) Training

Mike Ramirez, BS

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# Partnering for the Health of Babies—We all work together

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- State Hygienic Laboratory-Newborn Screening Laboratory
- University of Iowa Children's Hospital
- South Dakota Department of Health
- South Dakota Hospitals
- South Dakota Clinics
- Health Care Practitioners
- Parents

# Newborn Screening Disorders Detected from the Heelstick Blood Collection

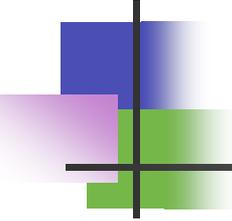
- Congenital Adrenal Hyperplasia
- Congenital Hypothyroidism
- Biotinidase Deficiency
- Galactosemia
- Hemoglobinopathies
- Cystic Fibrosis
- Amino acid, Organic acid, Fatty acid oxidation disorders (Tandem Mass Spectrometry)

# Why Screen?

- Inherited Disorders
  - Collectively about 1 in 700 babies affected
- Can't Cure but Start Treatment Soon
- Health Problems
  - Abnormal Metabolism
  - Developmental Delays
  - Coma and even death



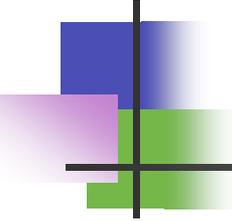
**Newborn screening specimen**



# Components of this Training

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- Application to the Blood Spot (BS) Collection Device (form)
- Techniques for Collection
- Filling Out the NBS collection form
- Transport of specimen
- Specimen Quality/Acceptability



# Specimen Quality

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- Based on Standards written by the Clinical and Laboratory Standards Institute (formerly NCCLS)
- NBS01-A6, Volume 33 No. 9, 2013
  - *Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard—Sixth Edition*
  - Available from South Dakota Department of Health

# Specimen Quality

- Need for a quality specimen
  - Accurate and timely results
  - Screen assesses risk
- Poor Quality (PQ) MUST be recollected



# Recollection

- Adds trauma to the infant
- Causes anxiety to parents
- Burdens the screening laboratory
- Burdens the collecting facility
- Delays testing



# Delays in Testing May:

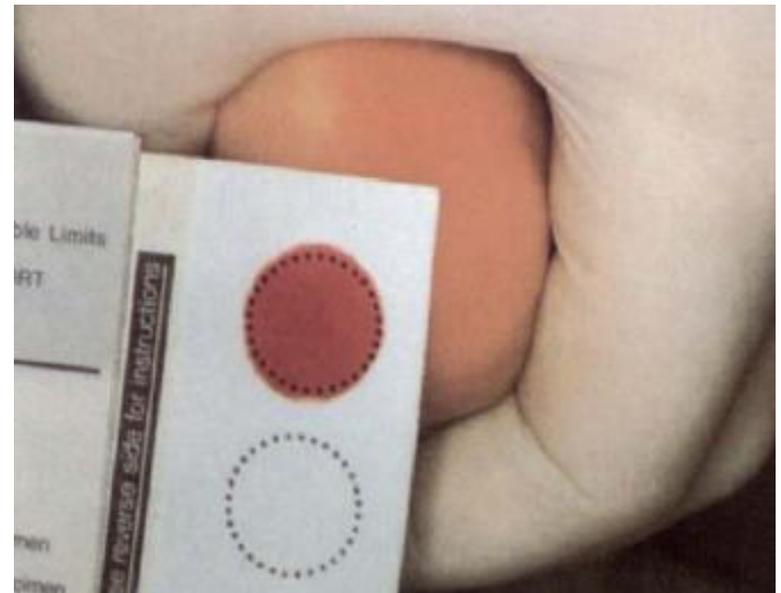
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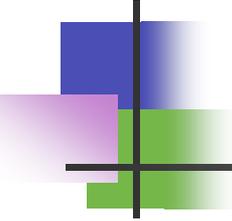


- Delay diagnosis
- Delay treatment
- Lead to potentially irreversible mental retardation, coma or death

# Blood Collection Techniques

- Heel Stick—Method of choice
- Avoid venous collections
- Avoid using syringes
  - clotting,
  - settling, and
  - lysing of cells
- Umbilical cord blood
  - maternal contamination





# Unacceptable Collection Sites

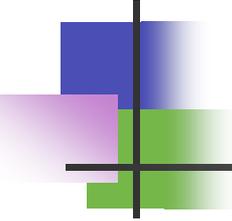
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- Arch of the foot
- Newborn's fingers
- Earlobes
- Previously punctured sites
- Intravenous lines contaminated with interfering substances

# Heel Stick Method Prep



- Check the expiration date on form
- Fill out the form (more on this later) properly and completely



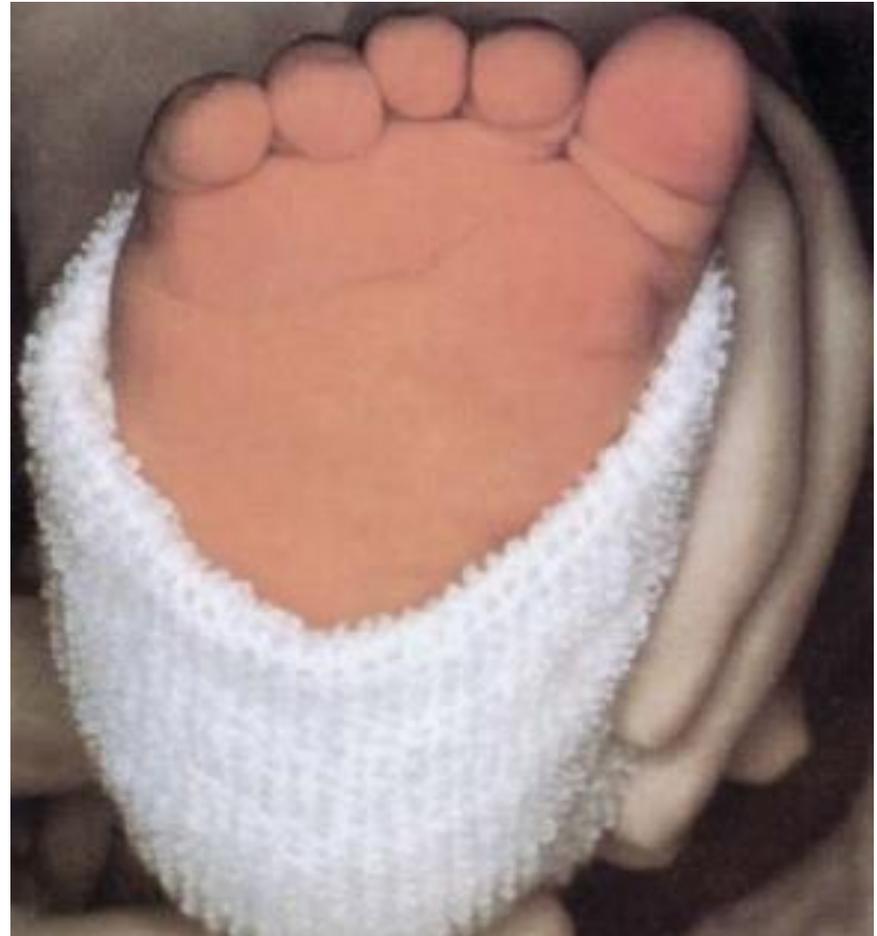
# Precautions

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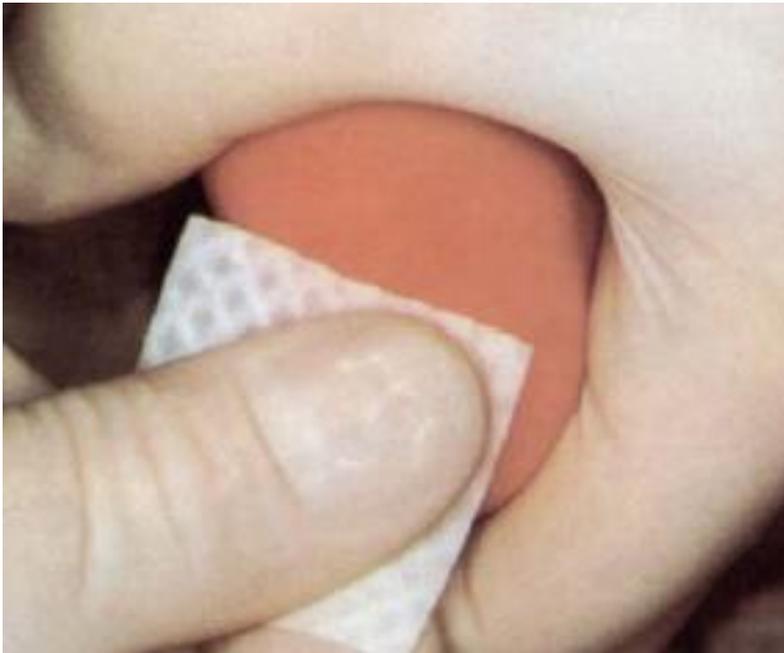
- Confirm infant's identity
- Wash hands
- Wear powder free gloves and change between infants
- Follow safety precautions when handling and disposing of sharps

# Site Preparation

- Warm the newborn's heel
- Use heel warming device or
- Use soft cloth moistened with warm water (less than 42 °C) for 3-5 minutes

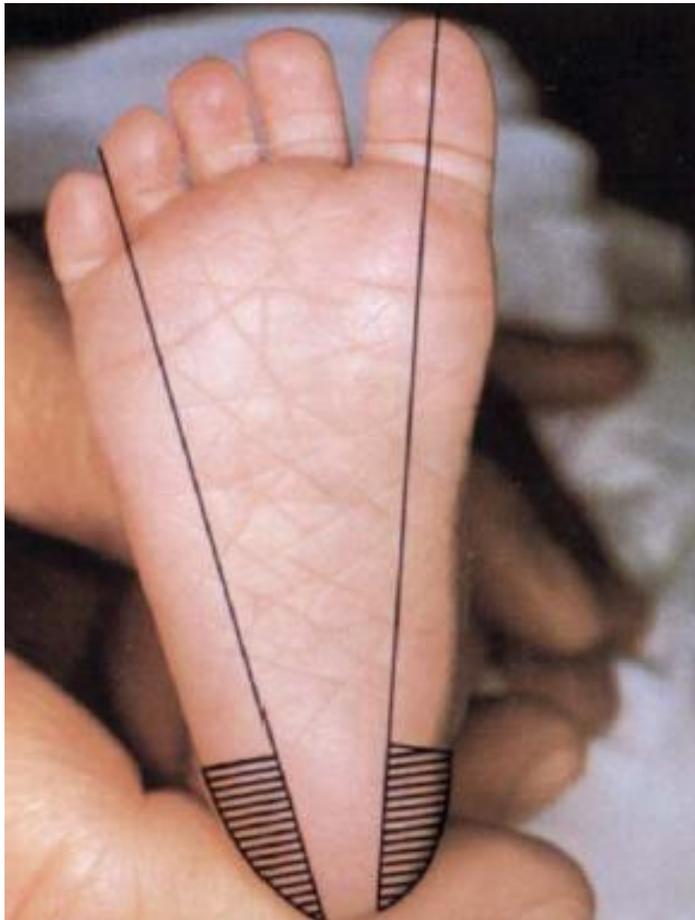


# Positioning foot



- Infant's leg should be lower than the heart
- Increases venous pressure
- Wipe heel with 70% isopropyl alcohol
- Air dry

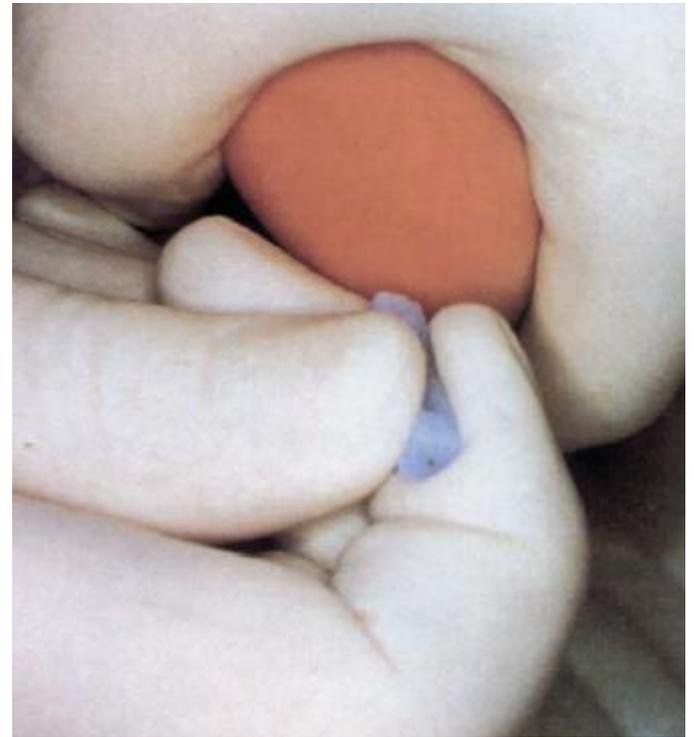
# Puncture Site



- Puncture made WITHIN shaded area
- Plantar surface of the heel

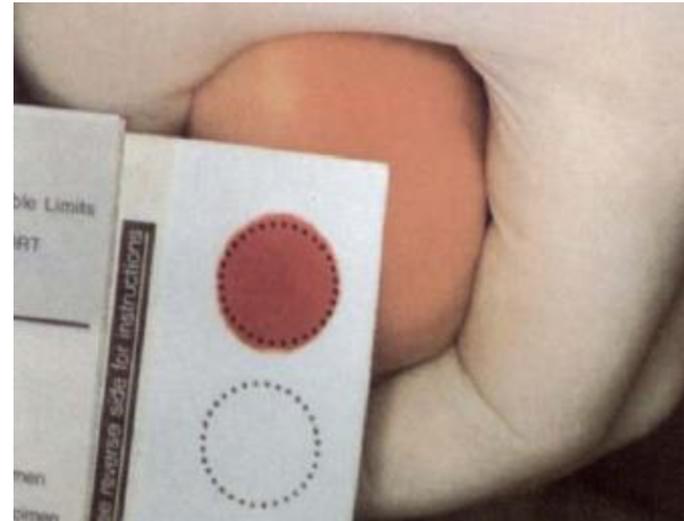
# Puncture

- Use sterile lancet or heel incision device
- 1.0 mm deep by 2.5 mm long
- No scalpel blades or needles



# Direct Application

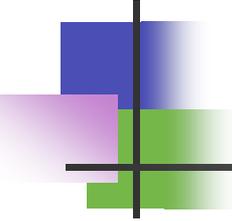
- Wipe away first drop of blood
- Allow a large drop to form (50-75  $\mu\text{L}$ )
- Touch paper to blood ONCE and let soak through



# Apply Blood

- Apply ONE drop on a circle
- Apply to ONE SIDE only
- Continue and fill all circles
- Do not press filter paper against puncture site

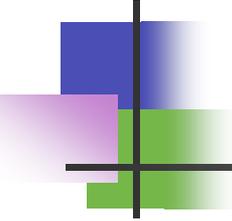




# Take care of puncture site

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- Elevate foot above the body
- Press sterile gauze or cotton swab against puncture site until bleeding stops
- Do not apply bandages that may damage baby's delicate skin



# Examine blood collection

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- Look at both sides of filter paper to assure blood has soaked through
- If blood is not soaking through try again on another circle
- Do not re-apply to same circle

# Air Drying the Specimens

- Do not touch other blood spots
- Keep away from direct heat and humidity
- No direct sunlight
- Horizontally
- Elevate off bench
- Dry at least 3 hours at ambient temperature



# Quality Assurance & You

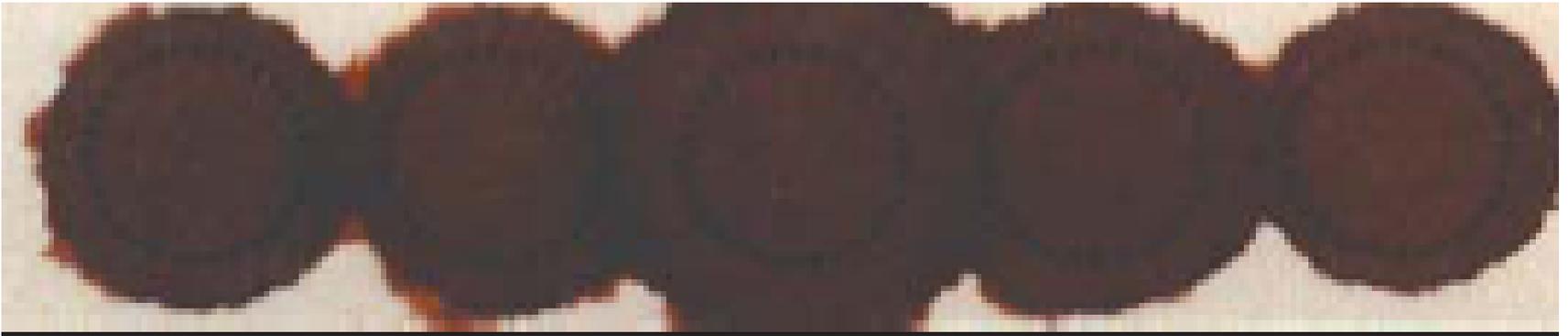
- After collection of the specimen, take time to look at it and determine whether or not it is acceptable.
- If not, recollect it at that time.



# Too much blood

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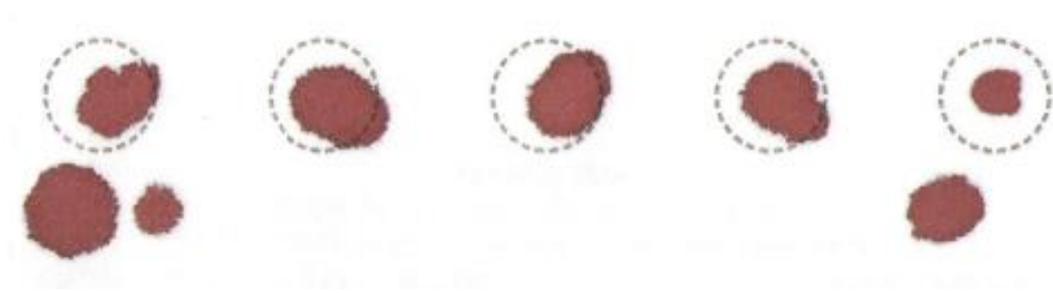
- Over-saturated



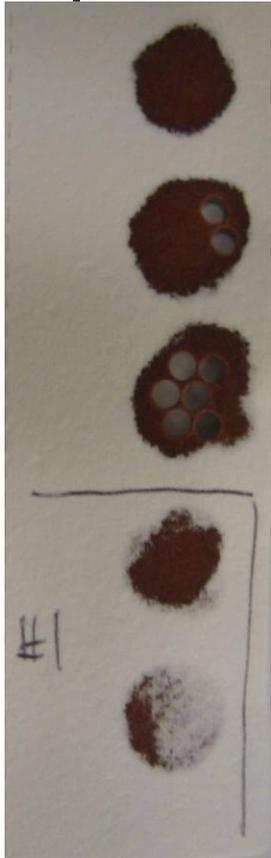
# Insufficient blood:

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- Applying drops that are too small
- Removing filter paper before blood has soaked through to the other side



# Uneven saturation



- Insufficient quantity so blood did not soak through
- Spreading the blood drop over the surface of the circle, contributing to uneven absorption.
- Improperly applying blood to the filter paper with a device.



# Layering-

- Multiple drops added to each circle
- Non-uniform concentrations
- Analyte concentrations variable by amount of blood



# Contamination or dilution

- Alcohol not dried on baby's heel
  - Other fluid/substances
- Substances on bench top
- Not always this noticeable
- May affect analysis



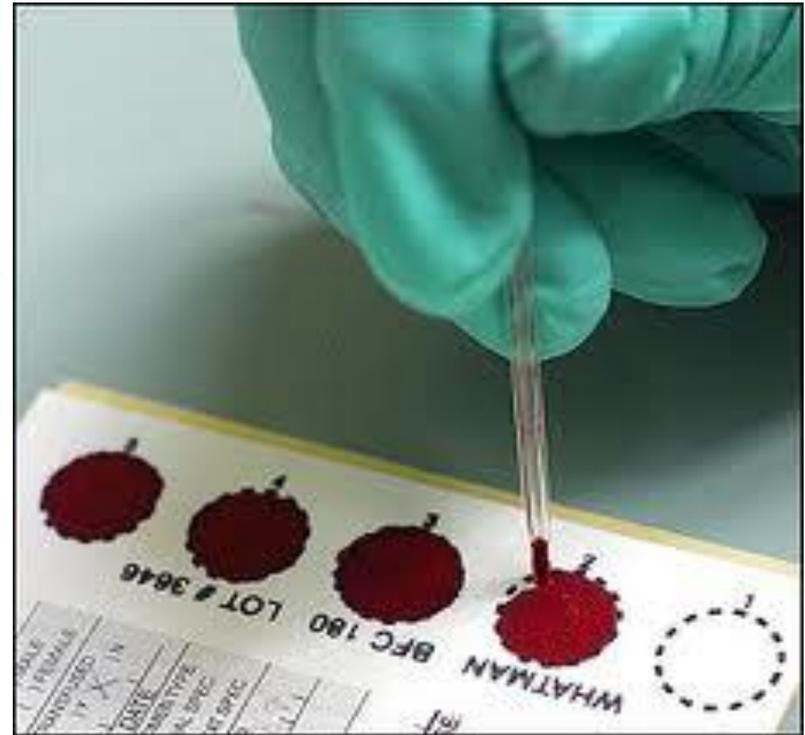
# Inadequate drying

- Putting in envelope before drying
- Folding the flap before dry – air dry for at least 3 hrs.
- Sending with the courier before dry



# Capillary Tube Collection

- Avoid anticoagulants
  - EDTA causes false negatives for TSH & IRT, false positives for 17-OHP
  - Heparin may interfere with PCR analysis for Cystic Fibrosis testing



# More on Capillary Tube Collection

- Apply the blood to the filter paper from each tube as it is collected
- Do not draw or swirl with the capillary onto the filter paper
- Avoid pressing capillary tube into the paper - causes dents or scratches.



# Serum separation

- Serum rings
  - Squeezing or milking the heel causes hemolysis. Use gentle pressure.
  - RBCs have settled in capillary tube.

Completely Fill All Circles with Blood from Healed Site  
ALLOW TO AIR DRY FOR AT LEAST 3 HOURS  
DO NOT HEAT



# Clotting



- Apply blood from each tube as collected
- Don't delay or hold
- Don't "draw" blood on circles

# Filling out the Collection Form

- All requested information must be provided
- Missing information may prevent or delay test results

**Iowa Neonatal Metabolic Screening Form**

W112  
LOT 6918212

South Dakota  
IVD

Whatman 903™  
Expiration Date 2015-02

ATTENDING HEALTH CARE PROVIDER

Feeding Method

<input type="checkbox"/> First Screen	<input type="checkbox"/> Repeat Screen	<input type="checkbox"/> Check if infant is in NICU	Collector's Initials	Chart Number	Feeding Method	
					<input type="checkbox"/> Formula	<input type="checkbox"/> Breast
					<input type="checkbox"/> NPO	<input type="checkbox"/> Parenteral Nutrition
					<input type="checkbox"/> Other	

**BABY**

Infant's Last Name

Infant's First Name

Sex  
 M  F

Birth Date  
Month Day Year

Birth Time (24 hour clock)

Collection Date  
Month Day Year

Collection Time (24 hour clock)

Multiple Births  
 Yes  No

Birth Order  
1, 2, 3, etc.

Current Weight (GMS)

Transfusion ANY blood products  
 Yes  No

If yes, date of transfusion  
Month Day Year

Gestational Age

**MOTHER**

Mother's Last Name

Mother's Maiden Name

Mother's First Name

Mother's Birth Date  
Month Day Year

Mother's Phone Number or Contact's Phone Number  
Area Code Number

Mother's Address  
Street

City

State

Zip Code

**SUBMITTING FACILITY**

Submitting Facility's Name

Facility Number

Submitting Facility's Phone Number  
Area Code Number

Submitting Facility's Address  
Street

City

State

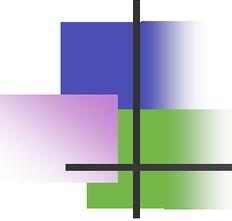
Zip Code

Attending Health Care Provider

DO NOT WRITE IN THIS SPACE

Attending Health Care Provider's Phone Number  
Area Code Number

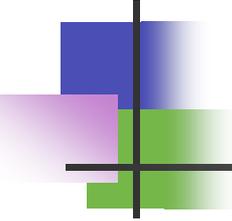
Facility of Birth



# Collection Information

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- Age of baby at time of collection
  - Birth date and Time
  - Collection date and Time
- Early collection (<24 hrs. old) affects results
  - Amino acids
  - 17-OHP, TSH



# Missing Information

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- Early Collection Unknown
  - Date or time is missing
  - No results for tests affected by EC
- Unknown weight
  - CAH results not reported
- Transfusion status
  - Must be marked no
  - Not assumed as no if not marked

# Transfusion Affects

- Biotinidase-plasma
- Cystic Fibrosis-plasma
- Galactosemia-RBC
- Hemoglobin Disorders-RBC
- Platelets carry RBC suspended in plasma



# Submitter Information



- Submitter Receives Report
  - Hospital
  - Clinic
- Infant's Physician & Telephone Number
  - Needed for follow-up for abnormal results

# Quality Assurance

- Daily fax sent from Lab to collecting facility
- Need Secure Fax Line
- Contact Person
- Fill out Info and fax back immediately



Hygienic Laboratory

*The University of Iowa*

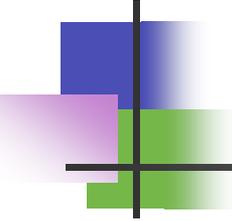
Neonatal Metabolic Screening Laboratory

**Problem:** This sample was rejected for the following reason: "Layered/Clotted"  
**Required Action:** Please submit another specimen immediately.

Specimen & Patient Information	
Patient's Last:	[REDACTED]
Patient's First:	[REDACTED]
Gender:	Male
Birth Date:	03/28/2008
Birth Time:	17:42
Collection Date:	03/29/2008
Collection Time:	18:00
Weight:	3723
Transfused:	No
Transfusion Date:	
Chart #:	685282
Mother's Last:	[REDACTED]
Mother's First:	[REDACTED]
Physician Name:	[REDACTED]
UHL Lab #:	2008019107

Delays in testing the newborn screening panel (due to recollecting and retesting for poor collections) and/or the lack of patient information places the newborn at risk for the delayed diagnosis of a metabolic condition.

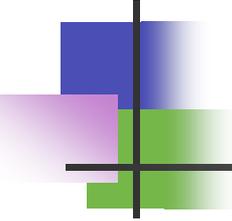
Facility Information	
Attn:	
Phone:	
Email:	



# How are Newborn Screening Forms Monitored?

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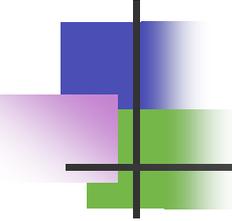
- Are they stored in a clean dry place in a vertical position?
- Is the supply monitored to assure that the availability of forms are within the expiration date?



# Filter Paper on Form:

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- Should NEVER come into contact with anything other than the baby's Blood
- Never let the filter paper touch the bench top
- When filling out the form wear gloves and make sure the flap is closed over the filter paper
- Do not crush the form; take care when storing in charts. The filter paper may not absorb blood if crushed.

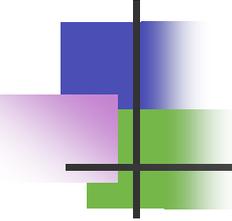


# Who completes the NBS form?

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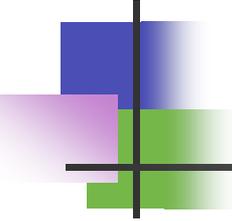
- Demonstrate that your staff completes ALL fields. Is the form checked before sending to screening lab?
  - Complete
  - Legible
  - Accurate

# Who conducts parent education?



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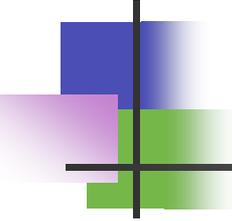
- Is newborn screening education started during the prenatal period?
- Does the nursery or obstetrician provide parents with the NBS pamphlet?



# Who performs heel-sticks at your facility?

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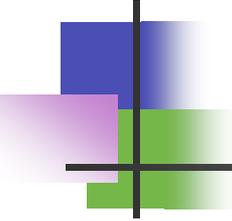
- Are they properly trained in the collection procedure on filter paper?
- Are they able to describe a satisfactory specimen?
- Are they able to describe an unsatisfactory specimen?
- Do you track unsatisfactory specimens back to the individual who collected it and retrain as needed?



# Who sends the specimens?

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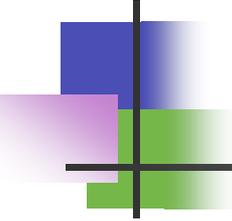
- Are specimens checked for suitable quality prior to sending with the Courier?
- Are all specimens sent within 24 hours of collection using the Courier system?
- Are steps taken to avoid subjecting the specimens to heat and humidity prior to sending?
- Does someone review the demographic information prior to sending to make sure the form is complete and legible?



# Courier Information

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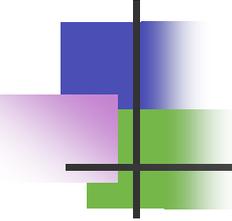
- ICS dispatch
  - 866/442-7247
  - [www.icsair.com](http://www.icsair.com) (website)



# Abnormal Result Reporting

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- All initial presumptive positive results are reported to:
  - Health Care Provider
- With Recommendations for:
  - Re-screening, and/or
  - Diagnostic testing



# Reporting Test Results

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- Reporting Options:
  - Paper Reports
    - Paper reports delivered by USPS.
  - Web Access And Paper Reporting
    - Paper report plus Web Access
  - Web Based – Paperless
    - Totally paperless, web based only

# Advantages of Web Access - Newborn Screening

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- Patient look-up online
- Downloading and printing patient results
- A variety of reports for your facility, i.e., status, turnaround, summary, quality control
- Results available as soon as released by lab

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About the SHL Education/Training Lab Certification Publications News

**State Hygienic Laboratory**  
at The University of Iowa

Limnologists Katie Spoelstra and Eric Cherko

Test Results  
A-Z Test Menu

**Environmental**

- Ambient Air
- Surface Water
- Private Well Water
- Analytical Services

**Newborn & Maternal Screening**

- What is Newborn Screening?
- Description of Disorders
- What is Maternal Screening?
- Abnormalities

**Disease Control**

- Sentinel Lab Training
- General Microbiology
- Molecular Diagnostics
- Serology

**News**

**Harkin calls Hygienic Lab 'one of the best'**  
U.S. Sen. Tom Harkin toured the State Hygienic Laboratory on Friday, Nov. 15, and described the environmental and public health laboratory of Iowa as "one of the best in the nation."

**Newborn Screening cited in national story**  
When Zach Zwirlein took the field at the University of Iowa's Kinnick Stadium on Nov. 23, it was an extraordinary event in a relatively ordinary life, made possible with a process that began shortly after his birth.

**Hygienic Lab, IDPH issue influenza test guidance**  
Influenza virus has been detected in Iowa. Although its prevalence is considered sporadic at this time, the State Hygienic Laboratory and Iowa Department of Public Health provide the following guidance on testing for the 2013-2014 season.

**Events**

*Disability Policy Summit 2013*  
12/5/2013

*Closed: Lakeside*  
12/23/2013

*Closed: Lakeside*  
12/24/2013

*Closed 12pm-5pm: Coralville*  
12/24/2013

*Closed for public sample receipt*  
12/25/2013

*Closed 8am-12pm: Lakeside*  
12/26/2013

*Closed for public sample receipt*  
1/1/2014

[More events](#)

[Explore the Lab](#)

**GIVE NOW**

**Coralville Laboratory**  
State Hygienic Laboratory  
U of I Research Park  
2490 Crosspark Road  
Coralville, IA 52241-4721

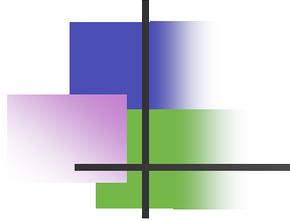
**Ankeny Laboratory**  
State Hygienic Laboratory  
2220 S. Ankeny Blvd.  
Ankeny, IA 50023-9093

**Lakeside Lab**  
1838 Highway 86  
Milford, IA 51351-7267

310.316.4600 515.236.1200 319.333.3660

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THE UNIVERSITY OF IOWA



Patient Lookup

Patient

Gender

Birth From

Birth To

Id #

Chart Number

Lab Number

Region

Run Reset

Patients						
Patient	Birth	Facility	Gender	Lab No.	Collection	Events

Monitor Patient

Download Reports

Samples Received

Quality Control

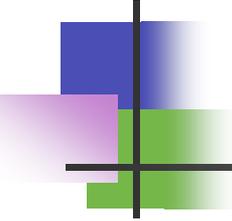
Turnaround Statistics

Feeding Report

Facility Summary

[Web Master](#) | [Site Map](#)

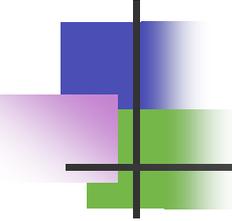
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# Web Access

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- To begin Web access for results:
  - Contact IT Web Access at:
    - 319-335-4358
      - Creation of a unique user id and password
      - Training via phone on “How to use web access.”
  - [www.shl.uiowa.edu](http://www.shl.uiowa.edu)



# Questions?

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- Mike Ramirez, Lab Supervisor
  - 515-725-1630
  - michael-ramirez@uiowa.edu
- Order supplies
  - 515-725-1630
- Computer issues (web access)
  - 319-335-4358