Newborn Bloodspot Collection
2024

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Training Objectives

By the end of the training the participant should be able to:

- Explain why newborn bloodspot screening is important
- Identify 3 types of disorders screened for on the NBS panel
- List 3 pre-collection steps to improve blood flow for bloodspot specimen collection
- List 2 attributes of an acceptable bloodspot specimen
- List 2 attributes of an unsatisfactory bloodspot specimen

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What is Newborn Bloodspot Screening?

Newborn screening is a **state public health program** that identifies infants with **treatable conditions**, which may otherwise go **unrecognized**, to avoid or **prevent adverse outcomes**.

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Why bloodspot screening is important:

- Prevents death and/or disability
- Babies may look and act healthy at birth
- The disorders are not very common
- The disorders screened for have treatments
- There are currently 45 disorders screened for on the NBS panel
- Approximately 20 disorders can kill or severely harm an infant if untreated in the first two weeks of life
- New Mexico is a 2-screen state. If you only screen once some disorders may be missed.

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Newborn Bloodspot Screening

- The screening should not be called the ‘PKU test’ or ‘PKU screening’. This implies that only one disorder is being screened for.

- Newborn bloodspot screening is a more accurate term. It is important to educate families about the screening prior to the collection.

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Newborn bloodspot screening includes:

- Cystic Fibrosis
- Endocrine disorders
- Congenital hypothyroidism
- Fatty acid disorders
- Amino acid disorders
- Organic acid disorders
- Immune disorders
- Galactosemia
- Hemoglobin disorders
- Lysosomal storage disease
- SMA was added in 2022 and X-ALD was added in 2023

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Newborn Screening Stats

97% of the nearly four million newborns born in the United States each year are screened

https://www.newsteps.org/about-newsteps

Saves or improves the lives of over **12,000 babies** in the United States each year

https://www.newsteps.org/about-newsteps

In New Mexico, **approximately 20,000 babies are screened** each year and **more than 50** are diagnosed and treated for one of the conditions on the newborn screening panel.

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Bloodspot screening saves lives

- Maisie was born in Oregon last summer. This was the parent's third child after two healthy children.
- Mom was aware of and thankful for newborn screening but did not have any concerns. "*The things the NBS test for were rare and not likely to be anything I ever had to worry about*".
- Maisie weighed 9 lbs 12 oz and needed glucose to stabilize her blood sugars for the first 24 hours.
- Maisie's NBS screening was positive for MCADD (Medium-chain acyl-CoA dehydrogenase deficiency)

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Goals for specimen collection

- First specimen collected as soon as possible after 24 hours of age, but before 48 hours.
- The second screening for a typical newborn should be collected between 10-14 days of age (typically at the 2 week follow up visit with PCP).
- Receive specimens to state lab within 48 hours of collection.
- Minimize unsatisfactory specimens. The goal is to reduce the unsatisfactory rate to less than 3% statewide. Unsatisfactory specimens may cause delays in screening results, confirmatory testing, diagnosis, and subsequent treatment for affected babies.
- **The goal is to have lab results to PCP as soon as possible and no later than 7 days of life.**

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Monthly Quality Assurance Report for First Submitters

State: Oregon

Facility Name / ID:

Select Date Filter

Filter by Date Received — Year: All — Month: All

Filter by Date of Birth — Year: All — Month: All

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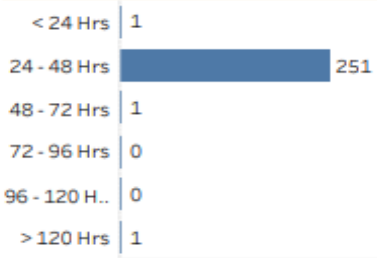
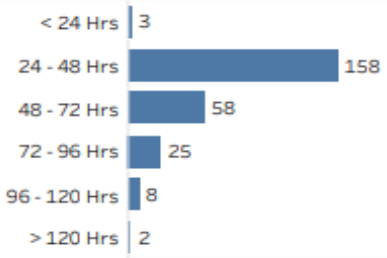
Practice Profile for First Specimens

Total Specimens	% Collected 24-48 Hours	Average Hours to Collect	% Transit Under 48 Hours	Average Transit Hours
254	98.8%	27.1	63.4%	49.4
State Total: 39,769	State Percentage: 94.5%	State Average: 27.0	State Percentage: 60.8%	State Average: 48.8

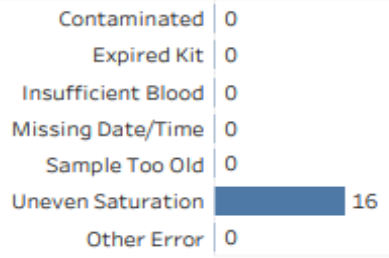
Collection Hours



Transit Hours



Specimen Errors

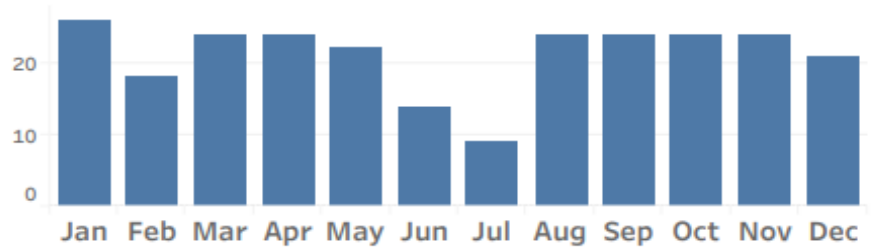


State Errors

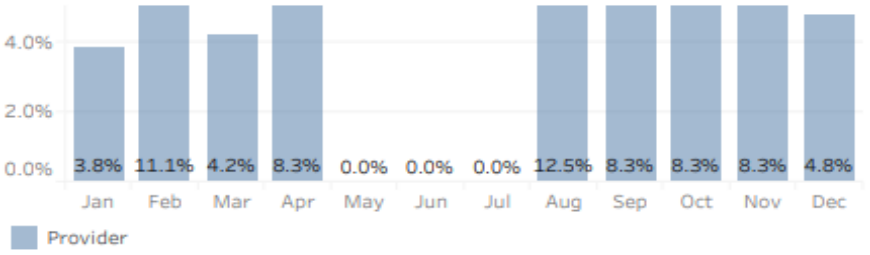
Contaminated	6
Expired Kit	4
Insufficient Blood	170
Missing Date/Time	0
Sample Too Old	18
Uneven Saturation	1,800
Other Error	7

Previous 12 Months Trending

Monthly Totals for First Specimens



Unsat Sample Percentage by Month



Goals in action: Maisie

- First NBS specimen was collection at 24 hours + 3 minutes of life.
- Specimen was received to the state lab 32 hours after collection.
- Screening results came back on day 5 of life.
- The time critical result was called out to the PCP and the OHSU consultants.
- OHSU reached the PCP that day to review results and the plan of care.
- Family was notified by the PCP that day of screening results and scheduled confirmatory testing.
- Maisie is healthy and doing great!

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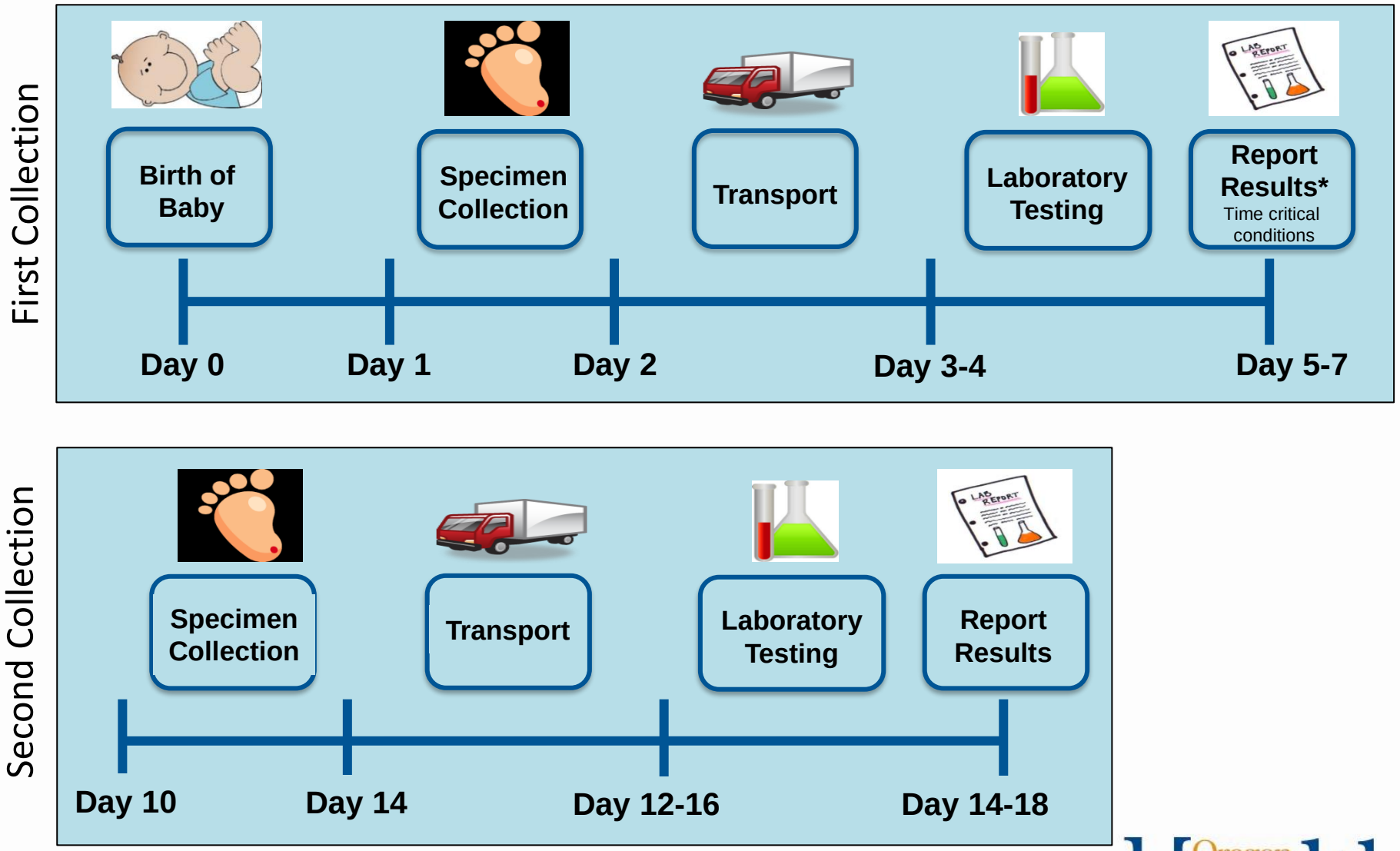
Newborn bloodspot screening timeline



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Timing of specimen collection

Table 2 — Age of infant at specimen collection

	Collection Kit	First specimen	Second specimen	Third specimen
Routine Birth	Double Kit	As soon as possible after 24 hours of age but before 48 hours of age	10-14 days	Not Collected
NICU infants transfused prior to 24 hours of age	Triple Kit	Prior to transfusion	48-72 hours after birth	~ 1 month, no sooner than 28 days
NICU infants **not** transfused prior to 24 hours of age	Triple Kit	As soon as possible after 24 hours of age but before 36 hours of age and prior to transfusion	10-14 days of age (11-15 days of life)	~ 1 month, no sooner than 28 days

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First screen collection scenarios

- A first screen must be collected before the baby is discharged from the birth facility for any reason; early discharge to home or a transfer to another facility.
- If a baby is transferred to another facility, send the rest of the kit to the facility.
- This may mean the first NBS screen is obtained prior to 24 hours of life. If this is the case, check the appropriate box on the card.
- If a collection cannot be done for a specific medical reason, this must be documented in the chart and the accepting facility must be notified.
- The goal is to prevent a missed first screen.

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NBS screening results follow up

- Unsatisfactory specimen: requires an ***urgent*** repeat screen
- Non-critical positive results: may require an *urgent* repeat screen, or early 2nd screen
- Critical positive results: follow up coordinators outreach to PCP asap and no later than 5 days of life and consult with OHSU consultants to coordinate follow up

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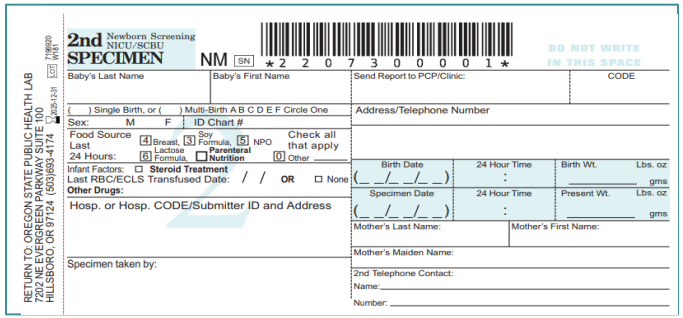
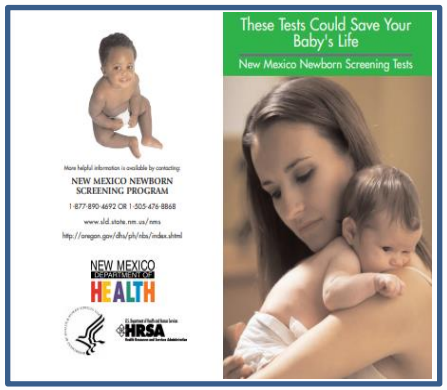
The second specimen collection card

The 2nd specimen card/envelope needs to be available at the location where the 2nd specimen collection will take place.

- **PCP Clinic:** store specimen card on site until collection time
- **Hospital lab:** If the hospital lab collects the 2nd specimen, store card on site.
- Send family home with newborn bloodspot screening pamphlet





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Specimen collection supplies:

You will need:

- Specimen card
- Gloves
- Alcohol wipe and gauze
- Heel warmer
- Sterile retractable puncture device specific to newborn screening and size based on newborn's weight and gestational age

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Puncture device size

- Average weight newborn: do not exceed a puncture device depth of 2.0 mm

- Preterm and low birth weight newborn (<37 weeks gestation or weight less than 2500 grams): do not exceed a puncture depth of 0.85 mm

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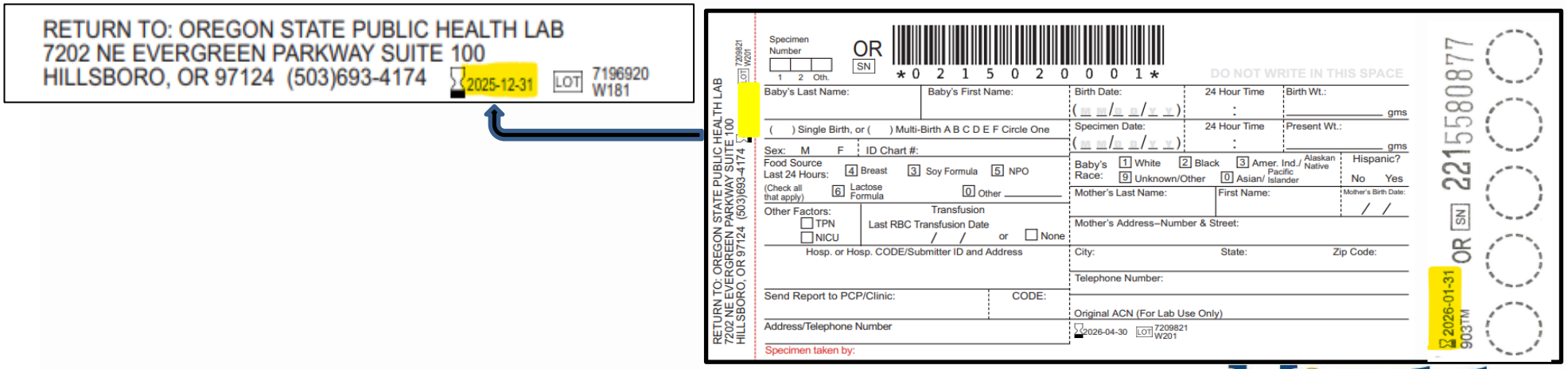
Specimen card

- Check expiration date of card
- Use the correct specimen card (Card 1, 2 or 3 if NICU)
- Fill in the demographic information **completely** before collecting the specimen
- Make sure to include the full name of the PCP/Clinic. Use the provider code if known. This is needed to follow up on results
- Include all of mother's demographic information



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Specimen card

- Specimen cards have a submitter code label on them that is unique to each submitter (including MBUs and NICUs)
- It is not recommended to share cards with other departments or facilities
- If it is absolutely necessary to share a card with a different department or facility, completely cross out the submitter code label and the appropriate information should be written in.

Specimen card

- Avoid touching the filter paper prior to collection
  - DNA sequencing for second tier screening is , and it is important to prevent contamination with extraneous DNA from handlers
- Store unused specimen cards upright (for example: in an accordion file folder or filing cabinet)
- Do not crush, fold, compress or place anything on top of the specimen cards as it can prevent the blood from saturating the filter paper properly

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Pre-collection tips:

- Dress baby warmly
- Massage baby's leg from proximal to distal
- Swaddle baby in upright position with foot exposed
- Use commercial heel warmer or warm wet washcloth/diaper
- Oral sucrose per facility protocol
- Breastfeed during specimen collection
- Do not use anesthetic creams due to possible interference with the analytic testing
- Let parents know that it may take more than one heel stick to collect the specimen

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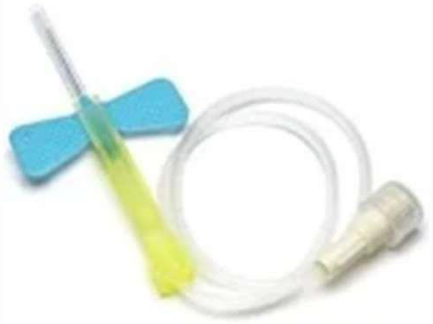
Avoid capillary tubes or needles for collection

- Scratches or tears filter paper
- Causes uneven saturation
- Needles and cap tubes lyse the red blood cells, which leads to false negative or positive results



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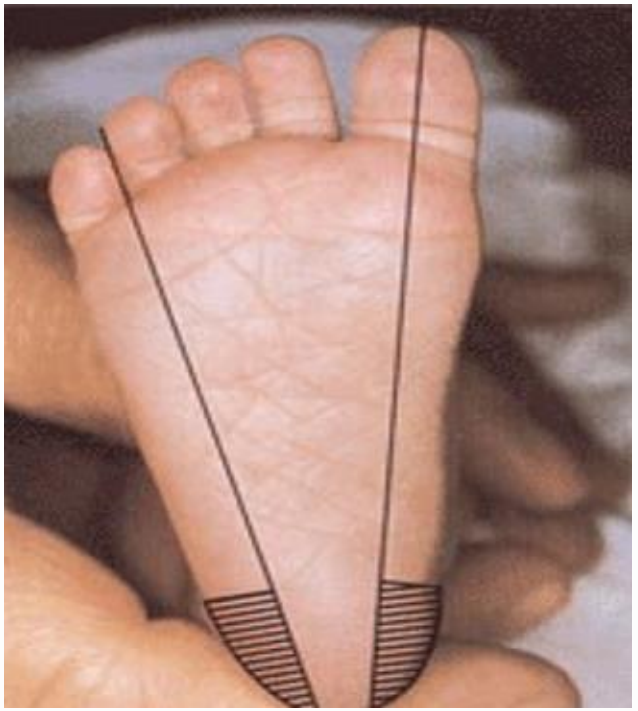
Specimen collection steps

Either side of the heel (hatched areas) is the specimen collection preferred site



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Specimen collection steps

Apply heel warmer to improve your blood flow and decrease pain.	
Cleanse the site on the baby's heel with alcohol swab and air dry.	

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Specimen collection steps

Follow the directions on the puncture device for angle orientation of device and apply gentle pressure to heel stick site.	
Puncture the site and wipe away the first drop of blood as it will be contaminated.	

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Specimen collection steps

Allow **one** large drop to collect and drop onto the filter paper so that it fills up the circle **and** saturates the filter paper evenly-the front and back of the card should look the same.

Gently apply and release pressure around the heel to promote blood flow without squeezing or milking right at the puncture side.

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Specimen collection steps

Repeat for each circle and check for even saturation on the back of card.

When the collection is complete, ask yourself:

- Are the circles completely filled?
- Is there good saturation on the other side of the card?

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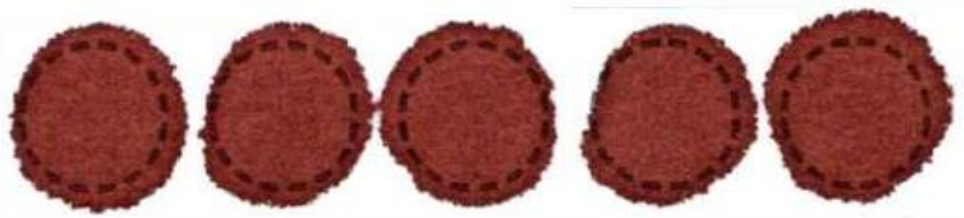
Specimen collection steps

Yes: proceed to drying specimen

Yes

Front:



Back:

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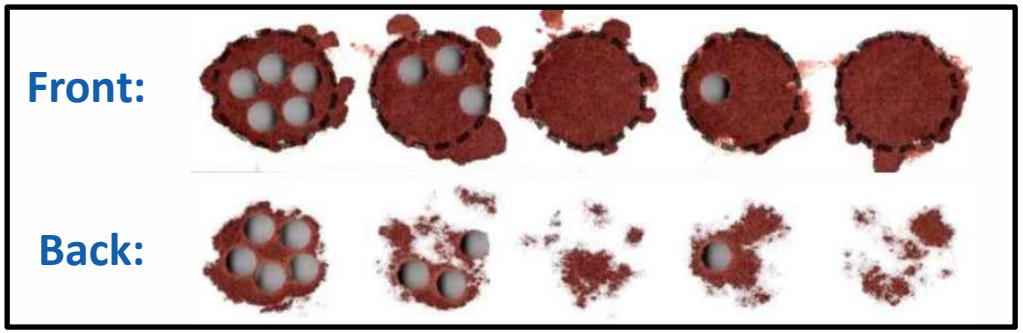
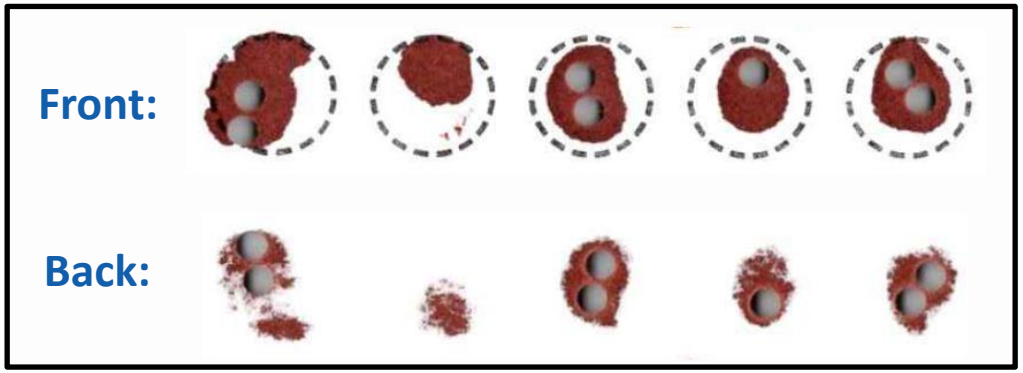
Specimen collection steps

No: Does it look like this?



Or this?



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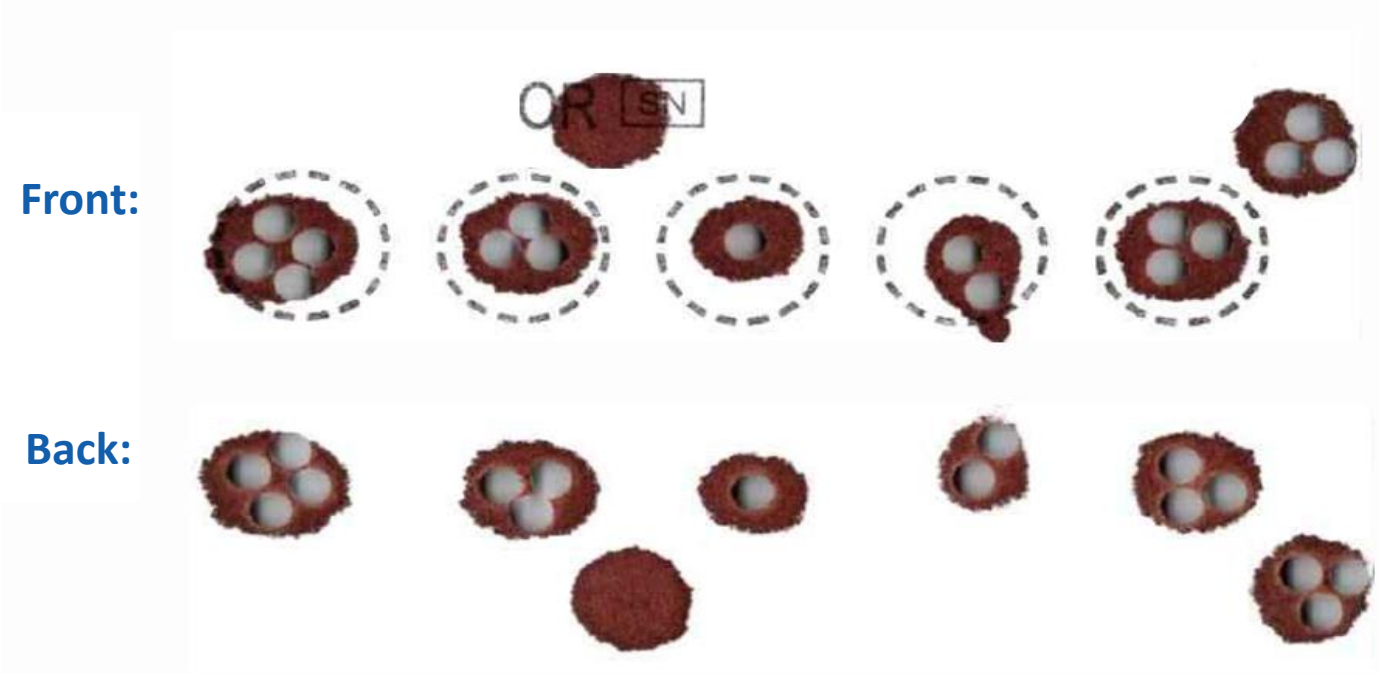
Specimen collection steps

If the circles are not completely filled with one large drop of blood in each, or there is poor saturation on the other side of the card, add two or three extra blood drops outside of the circles.



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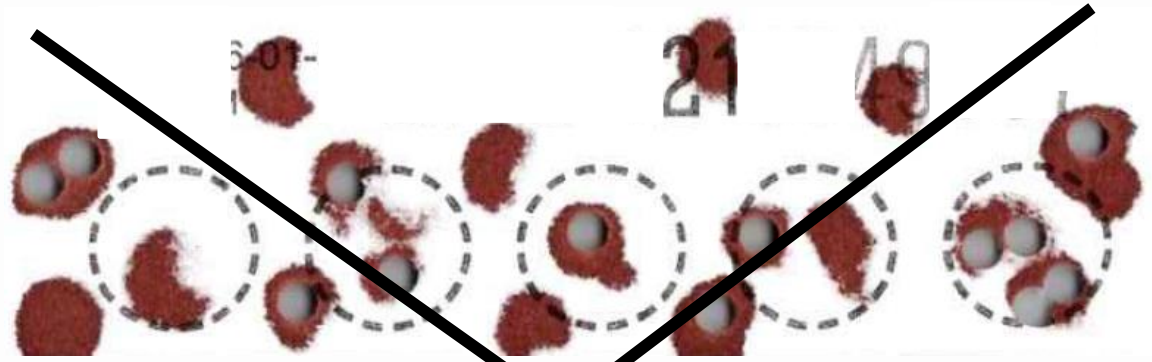
Specimen collection steps

No leopard print!

Front



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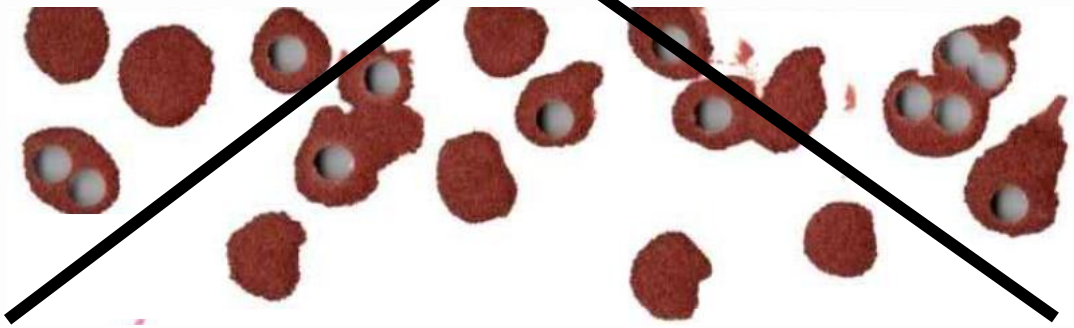

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Collection tips:

- You can use either side of the filter paper to fill, but only fill from one side
- Do not apply blood drops on top of each other or let them connect-this is layering/uneven saturation
- You may apply additional drops outside of the circles if needed
- If the blood flow is slow, restick heel in a different location

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How much blood is needed?

- First specimens: need enough blood for at least 10 punches, plus more if repeat or additional screening is needed

- Second specimens: need enough blood for at least 7 punches, plus more if repeat or additional screening is needed

- Each punch is 3.2 millimeters in diameter

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After collection

- Allow to air-dry **horizontally** for 3-4 hours at room temperature
- Keep away from direct sunlight.
- **Do not fold card or staple/paper clip/tape anything to the card**
- Do not heat, stack or allow the blood spots to touch other surfaces during the drying process
- Do not hang filter paper vertically
- Do not cover blood spots with protective cover until dry
- Do not store or ship in plastic bags

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Ship to the state lab

- After drying, place the protective cover over the circles. Double check that all demographic fields are completely filled out
- Prepare a packing list of the specimens and keep a log of specimens sent to the state lab
- Put the specimens into their sealable paper envelopes or a large mailing envelope (when sending multiple specimens)
- Ship the same day by courier or express mail
- Specimens that arrive at the state lab by 10:30am will begin screening same day
- Do not accumulate or wait to ship batches of specimens

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Weekends and Holidays

- Keep your specimens in a cool, dry, room temperature location until they are shipped. Avoid sunlight, heat, humidity, hot mailboxes, or similar conditions.
- Send by overnight or express mail on the following business day
- Even with holidays, the goal is always to have the specimen received by the state lab within 48 hours of the specimen collection
- The state lab is open on Saturdays and can receive specimens until noon

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Example: an acceptable specimen collection

Front:

Back:

- The circles are completely filled with one drop of blood
- Blood is evenly saturated
- Looks the same on both sides of filter paper
- No contamination evident
- Card was laid flat to dry

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Unsatisfactory example: uneven saturation

Front:

Back:

This can occur when:

- Blood is applied with a needle or capillary tube
- Multiple small drops of blood are applied to fill each circle
- Damage to filter paper
- Hanging cards to dry

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Unsatisfactory example: uneven saturation

Front:

Back:

This can occur when:

- Layering of blood drops: multiple drops of blood are applied to each circle and layered over each other

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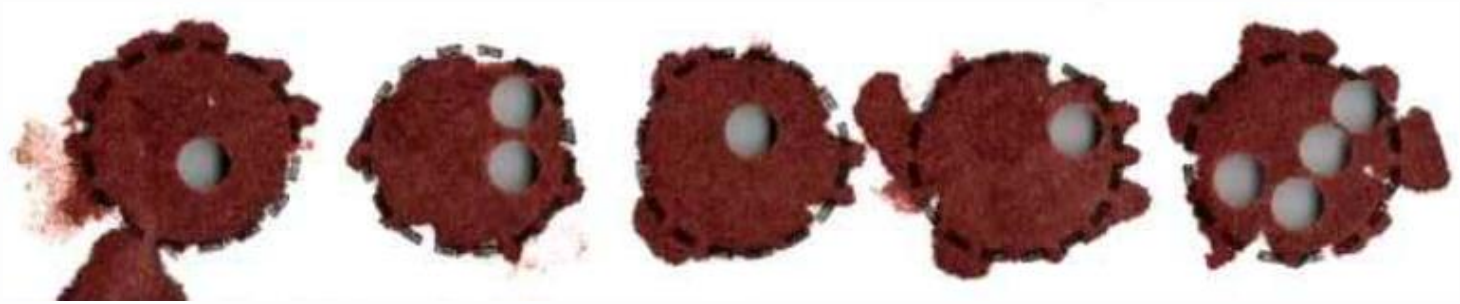
Unsatisfactory example: uneven saturation

Front:



Back:

This can occur when:

- Layering of blood drops: multiple small drops of blood are applied to each circle

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Unsatisfactory example: insufficient blood

Front:

Back:

This can occur when:

- The blood drop is too small to fill the circle
- The drops of blood are too small to saturate through to the back of the filter paper

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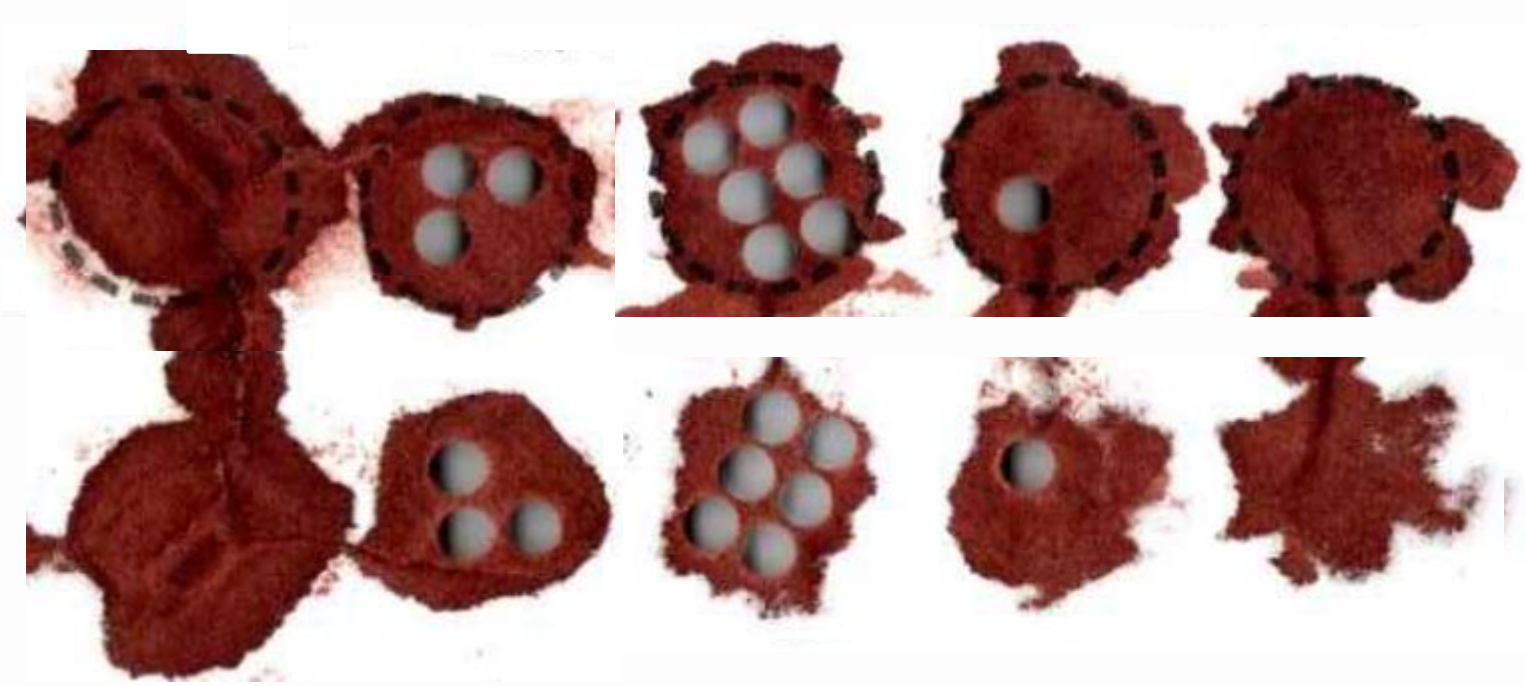
Unsatisfactory example: scratched or abraded

Front:

Back:



This can occur when:

- Applying blood with a capillary tube or a needle
- Layering of blood drops can abrade and tear the filter paper

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Unsatisfactory example: Serum rings and contamination

This can occur when:

- Not letting the alcohol dry
- Not wiping away the first drop of blood
- Specimen is contaminated with fluid
- Milking heel: tissue fluid is pushed into the blood drop
- Improper drying: specimen is exposed to heat, humidity or sunlight
- Capillary tubes: can separate blood components

Unsatisfactory specimen: what is the concern here?

Front:

Back:

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Unsatisfactory specimen: what is the concern here?

Front:

Back:

Answer: Uneven saturation: multiple blood drops were applied to each circle.

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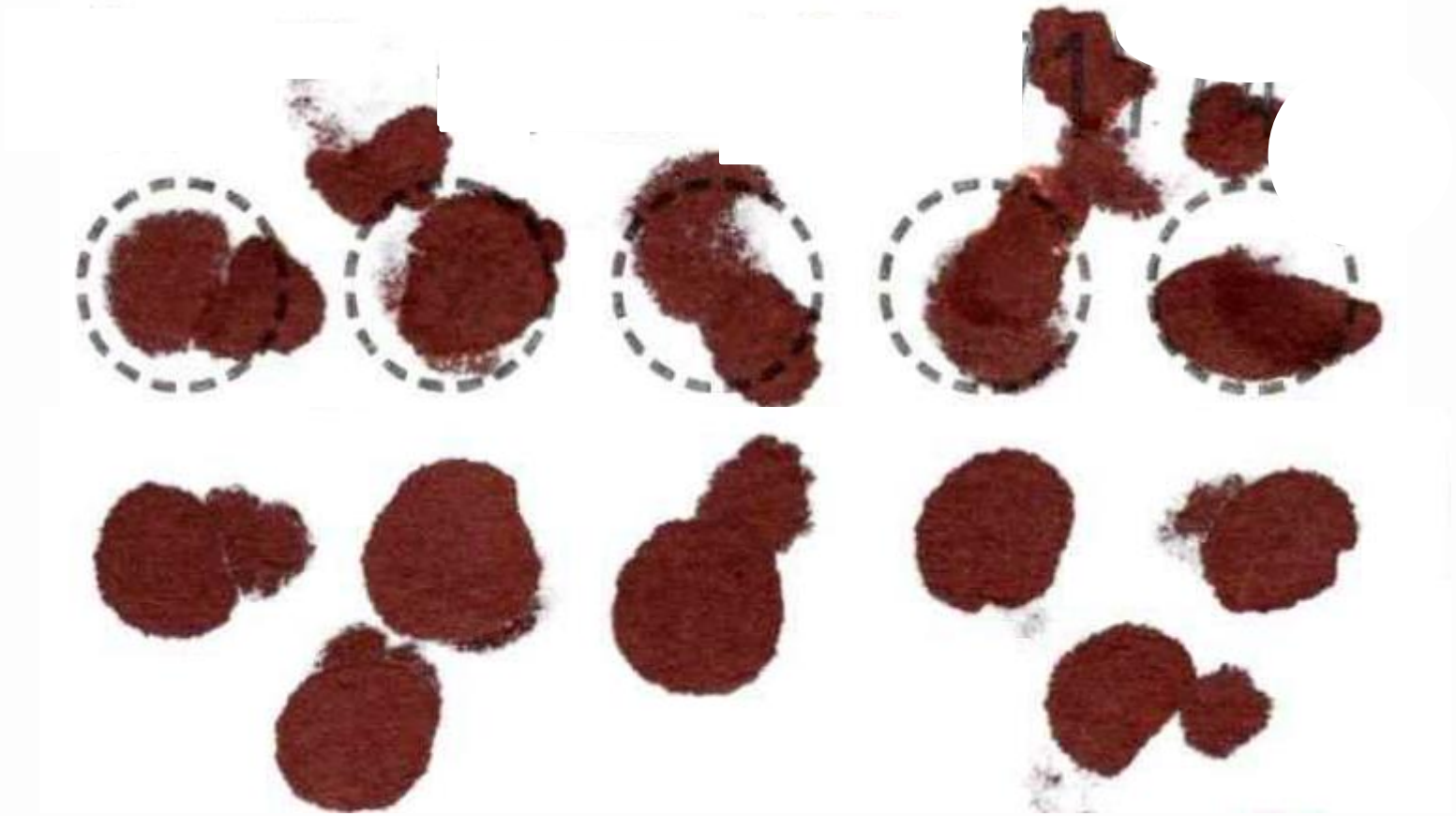
Unsatisfactory specimen: what is the concern here?

Front:

Back:



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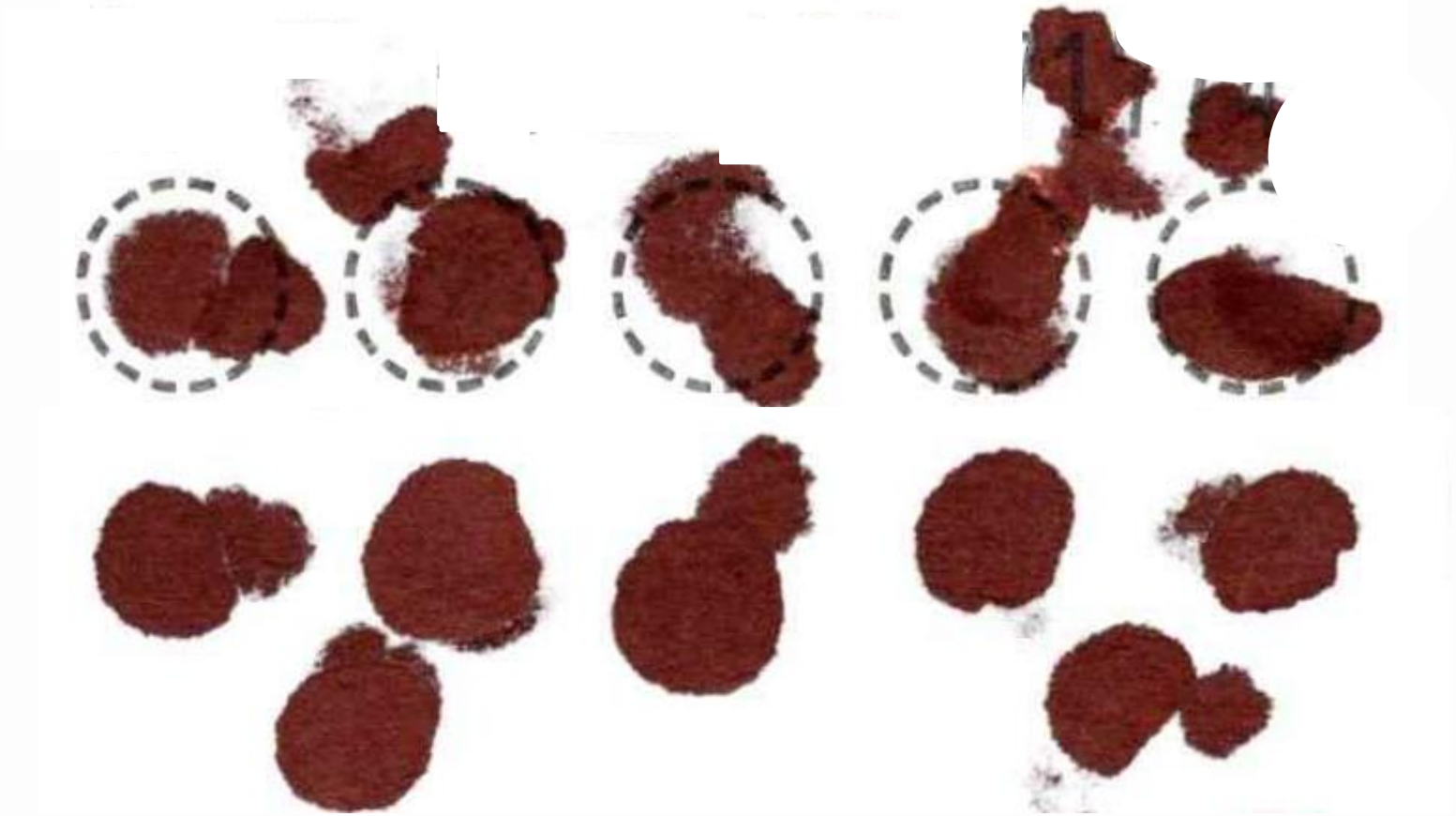
Unsatisfactory specimen: what is the concern here?

Front:

Back:



Answer: Uneven saturation: multiple blood drops were applied to each circle. Blood was applied to both sides of the card.

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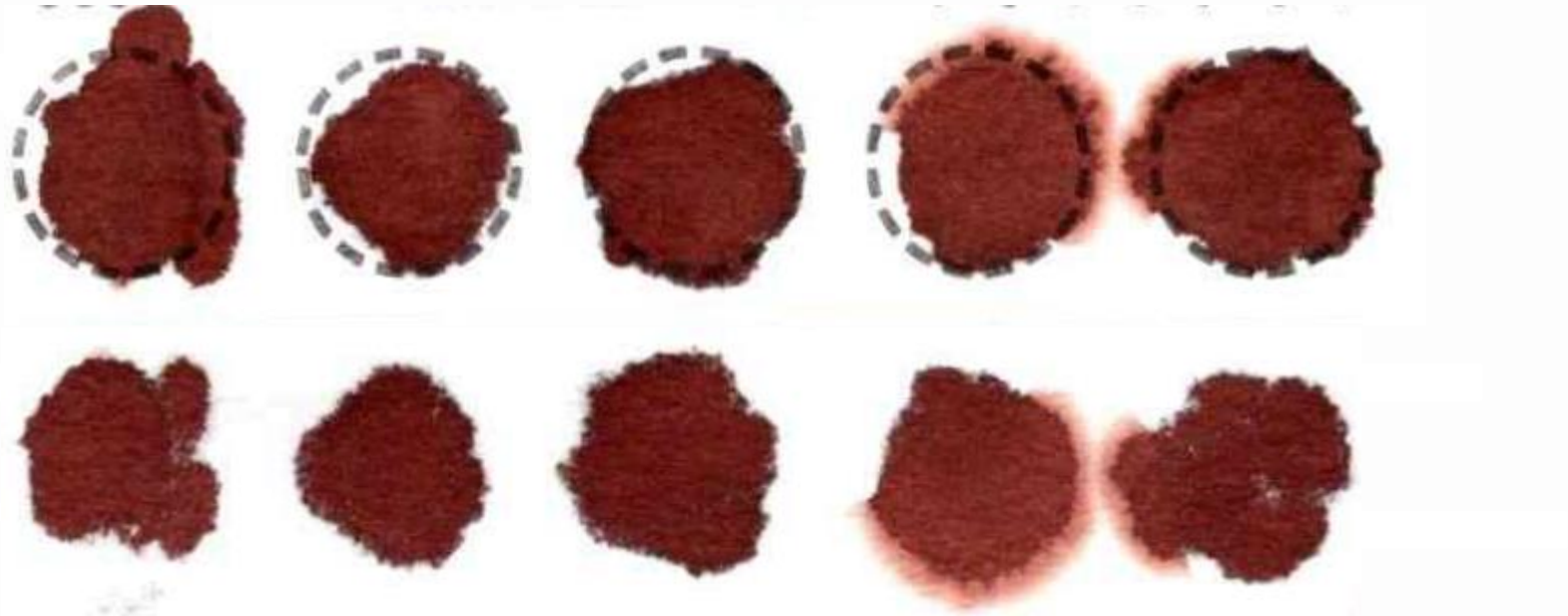
Unsatisfactory specimen: what is the concern here?

Front:

Back:



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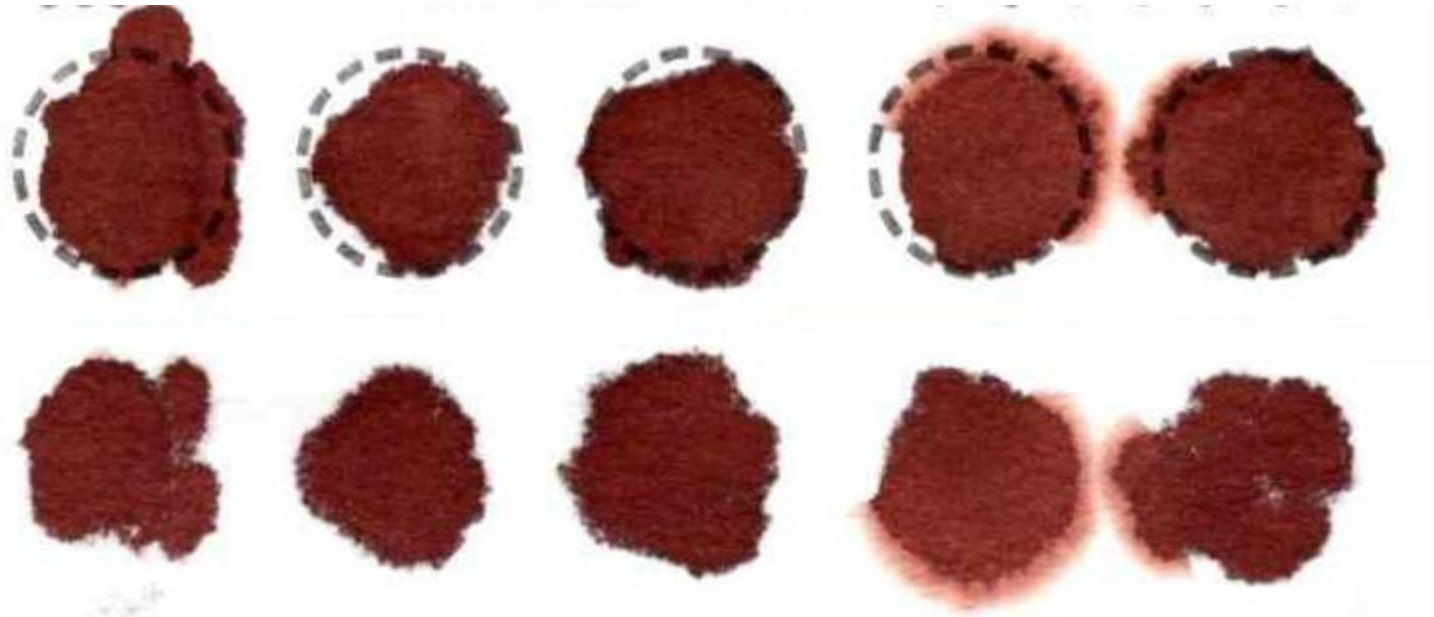
Unsatisfactory specimen: what is the concern here?

Front:

Back:



Answer: Uneven saturation: multiple blood drops were applied to each circle. Last 2 circles have serum rings.

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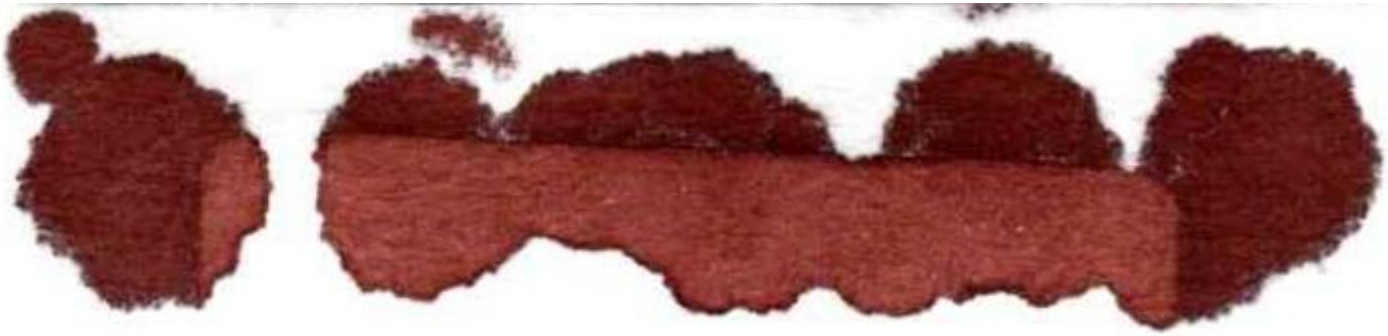
Unsatisfactory specimen: what is the concern here?

Front:

Back:



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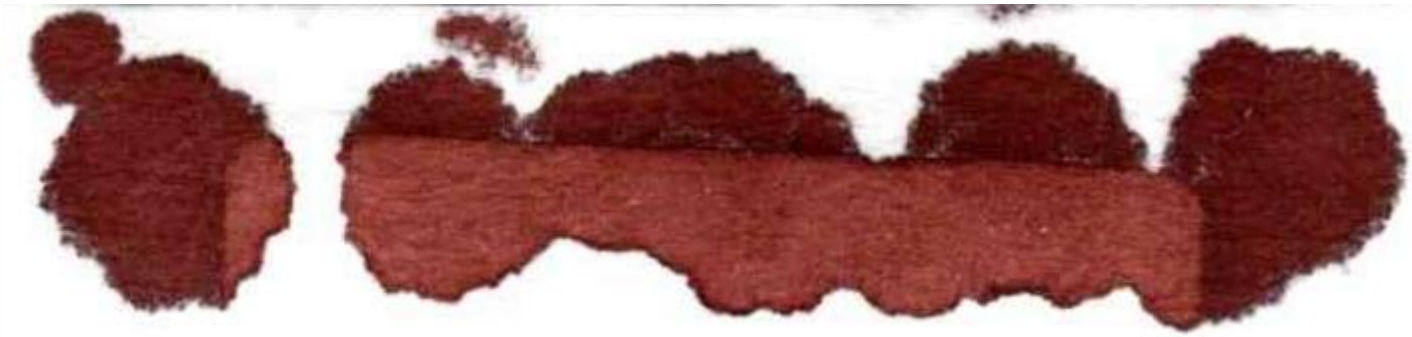
Unsatisfactory specimen: what is the concern here?

Front:

Back:



Answer: Uneven saturation: multiple blood drops were applied to each circle. Patient label was applied over the blood spots.

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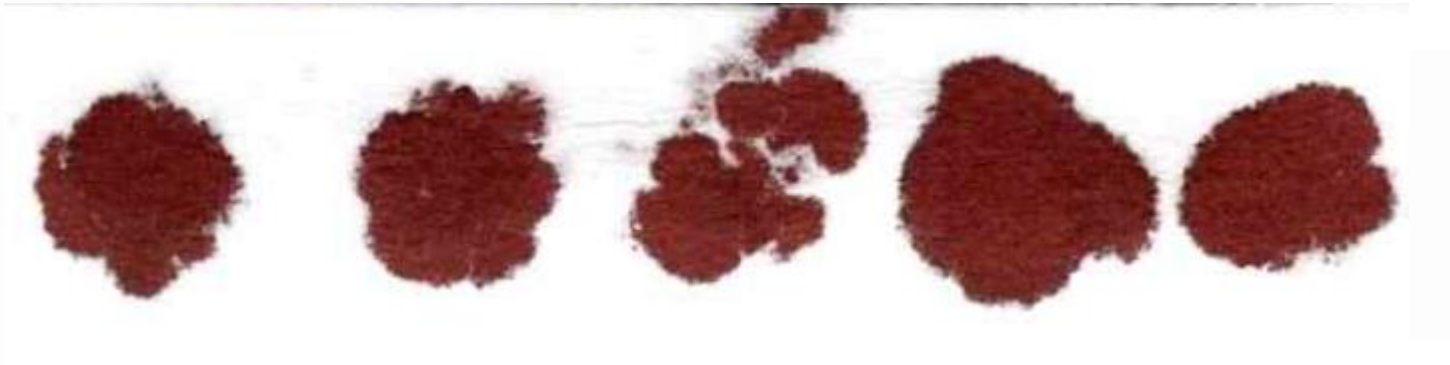
Unsatisfactory specimen: what is the concern here?

Front:

Back:



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Unsatisfactory specimen: what is the concern here?

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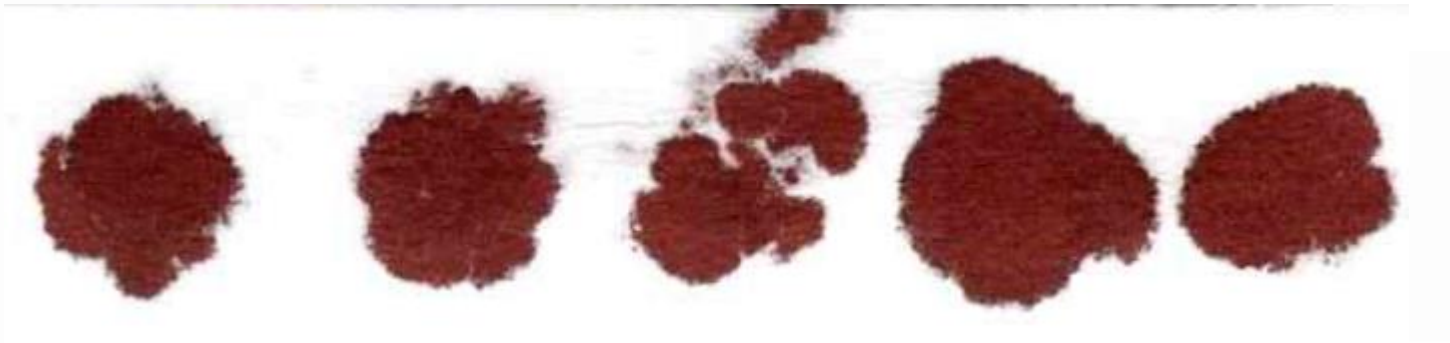

Answer: Uneven saturation: multiple blood drops were applied to each circle.

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Unsatisfactory specimen: what is the concern here?

Front:

Back:

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Unsatisfactory specimen: what is the concern here?

Front:

Back:

Answer: uneven saturation. Multiple blood drops were applied to each circle.

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Unsatisfactory specimen: what is the concern here?

Front:

Back:

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Unsatisfactory specimen: what is the concern here?

Front:

Back:

Answer: insufficient blood

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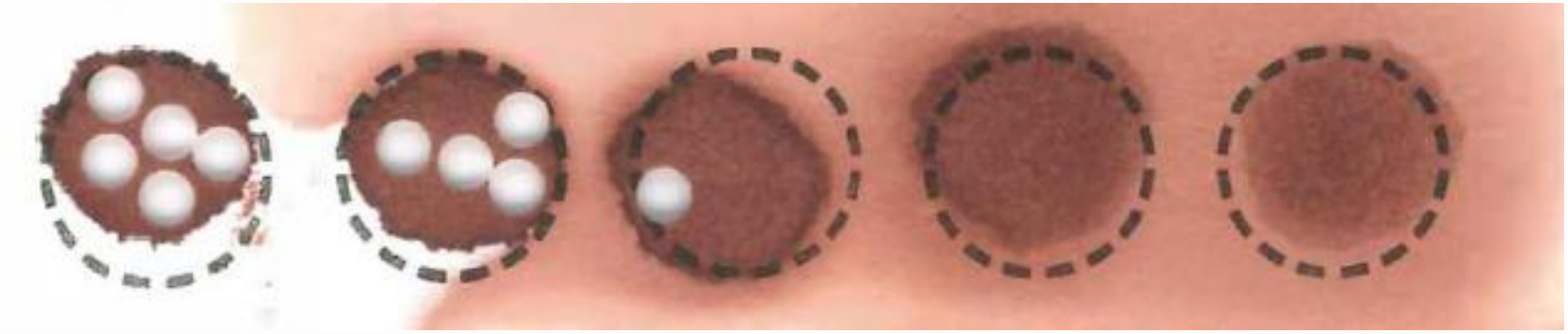
Unsatisfactory specimen: what is the concern here?

Front:



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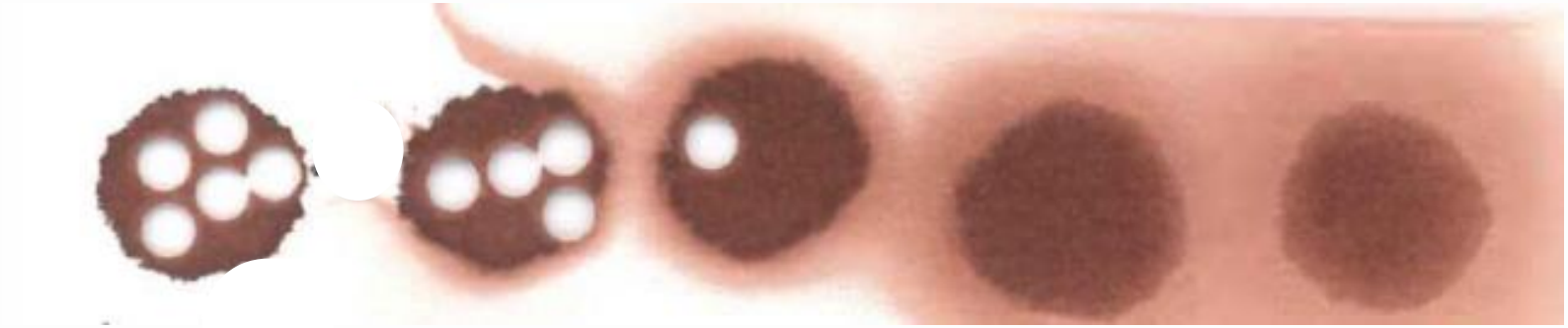

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Unsatisfactory specimen: what is the concern here?

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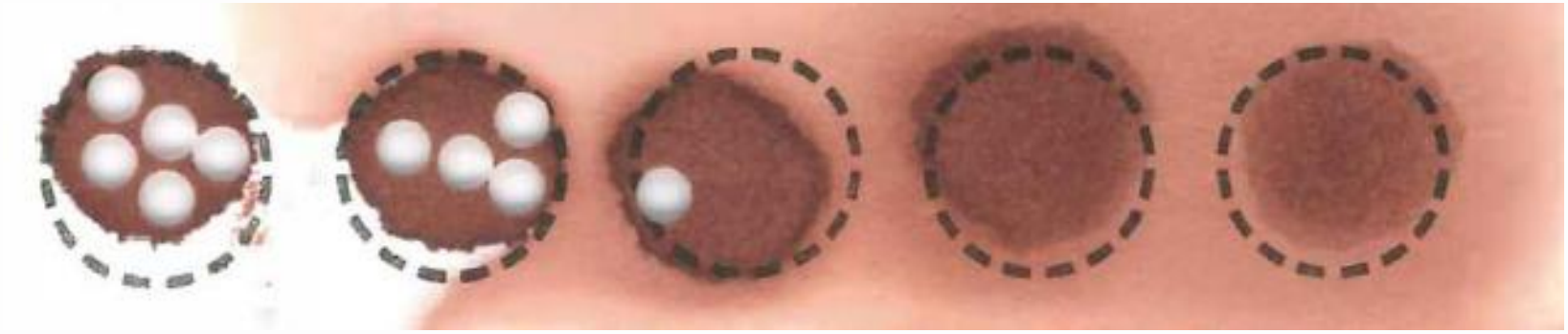
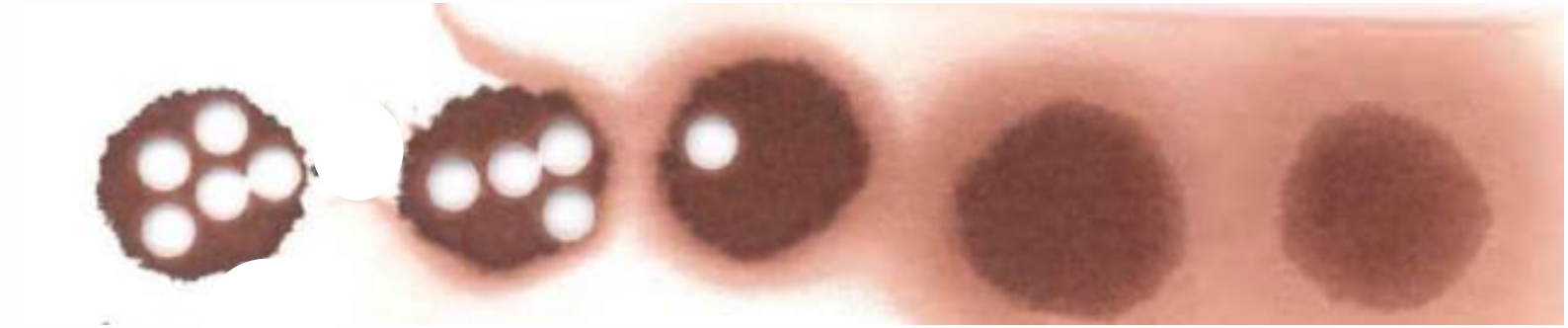


Back:



Answer: contamination with water

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Repeat: an acceptable specimen collection

Front:

Back:

- The circles are completely filled with one drop of blood in each circle
- Blood is evenly saturated
- Looks the same on both sides of filter paper
- No contamination evident

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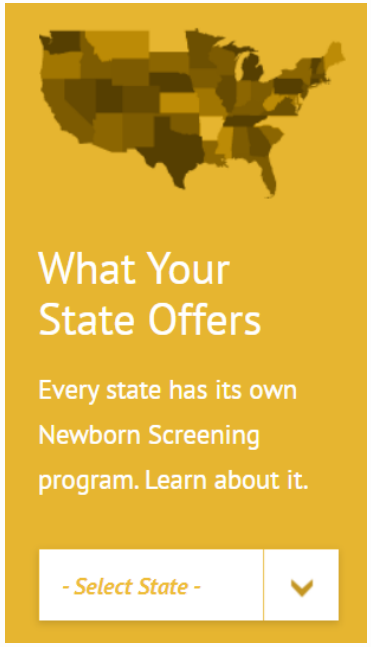
Retention of specimens

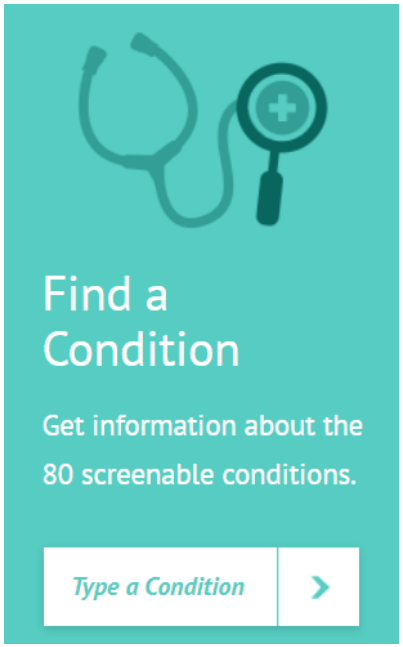
- Specimens are stored at the lab for 18 months and then securely destroyed.
- Specimens with unused bloodspots may be used for internal lab quality control purposes.
- Specimens will only be released by the lab:
  - When required by a court order
  - When requested by the parent or guardian
  - To perform routine newborn bloodspot screening if testing cannot be performed by OSPHL

Additional Information: Families

Babies First Test Website: www.babysfirsttest.org

- Information about what disorders are screened for in Oregon
- Information about each disorder
- Living with a disorder
- The newborn screening process





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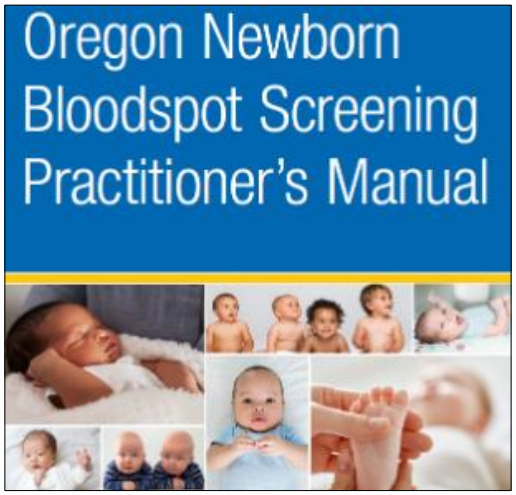
Additional information: Facilities

New Mexico NBS website:
https://www.nmhealth.org/about/phd/fhb/cms/nbgs

- Updated Practitioner's Manual
- Order form for NBS specimen kits/pamphlets
- Program updates
- SRV online results portal is available on the Oregon NBS website: www.healthoregon.org/nbs



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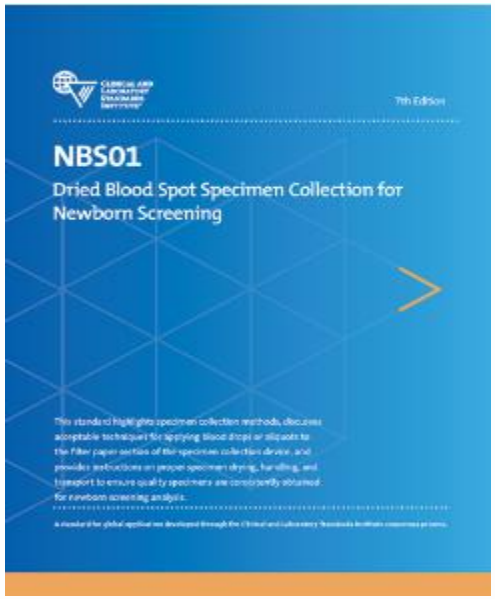
Additional information: Facilities

Clinical and Laboratory Standards Institute website: https://clsi.org

- Clinical standards for newborn bloodspot collection practices
- Newborn bloodspot collection video: https://clsi.org/nbs01ol (no cost to view after log-in created)



CLSI

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