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|  | **LABORATORY DEPARTMENT****POLICY AND PROCEDURES** | **Department:** **PHLEBOTOMY** |
| **Number:** **150.0-Phlb-gu-rev05/2014** |

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| **NEWBORN SCREENING** |

**POLICY**

Newborn screening is used to test newborns for inborn errors of metabolism. It is encouraged to use the term “Newborn Screen” or “Metabolic Screen” rather than “PKU” because tests for other conditions are now included in a newborn screening panel. As with any Laboratory test, both false negatives and false positive results are possible.

**SPECIMEN COLLECTION**

Specimens should be collected from newborn infants between 24 and 36 hours of age, or before discharge, whichever comes first, but no later than 72 hours of age. Newborn screens must be collected prior to transfusion. Hospitalized premature or sick infants should have the screen performed by 7 days of age. The optimum timing in full-term, healthy infants is as close to 24 hours old as possible. Arizona requires testing before discharge even if practitioners are confident that specific families would return when requested. A second screen is mandated by the state. The second screen specimens should be collected between 5-10 days. Early collection (before 24 hours of age) is not optimal, but is necessary if the patient is being discharged, the patient will be getting a transfusion, or the patient will be going on TPN.

**PROCEDURE**

1. The required information pertaining to the baby and mother must be filled out on the filter paper card by the nursing staff in ink. (See Reference #4 “Collection Kit Demographics”)
2. The time, date, and initials of the person collecting the specimen must also be filled out on the card.
3. Avoid touching the area within the circles on the filter paper card.
4. If parents refuse to have the infant tested, the designated area in the lower right hand corner of the filter paper card should be marked. **A refusal of examination and/or treatment form needs to be obtained from the nursery and included with the marked card when it is sent to the state**.
5. Only personnel working in the nursery may remove babies from the room or from the mother.
6. Check the ID bracelet of the infant – normally found on infant’s ankle. (Refer to Hand Held Specimen Collection policy #169.0-Phlb-gu)
7. Wash hands and put on fresh gloves; hold limb in a position lower than the heart to increase venous pressure.
8. Use a heel warmer on the infants heel to help blood flow.
9. Disinfect heel with **alcohol** (not Betadine) - allow to air dry.
10. Puncture the skin in one continuous motion using a sterile lancet with a tip no longer than 2.0mm. Wipe away and discard first drop of blood, since it may be contaminated with alcohol or tissue fluid. The appropriate area of the heel to be punctured is illustrated on the back of the filter card in the shaded areas.
11. Allow second drop to form by spontaneous free flow of blood.
12. Touch the drop of blood to the center of the filter paper circle. **Fill the circle with a single application of the filter paper to the heel**. Do not apply blood to both sides. Make sure each circle is saturated. Do not apply multiple drops to a single circle.
13. Saturation is enough when the blood soaks through to the backside of the filter paper in an area that is larger than a hole puncher. Do not apply blood to both sides.
14. Apply pressure to baby’s heel and then cover with gauze affixed with paper tape.
15. Air dry at room temperature in a horizontal position for at least 3-4 hours. Do not stack.
16. Specimen should be moved around as little as possible while wet to avoid contamination, so it is advised to let the Newborn Screen dry on the floor it was collected if possible.
17. Do not send in the tube system. They must be walked down to the lab. Do not stack cards while wet. For multiple Newborn Screens, alternate which side the blood spots are on to avoid cross contamination.
18. Do not place Newborn Screen in any plastic bag, whether or not it is dry.
19. Specimen will be sent down to the lab immediately once dry; approximately 3-4 hours.
20. The floor performing the Newborn Screen will tear out and keep the yellow copy for their records.
21. Newborn Screens will then be ordered in Cerner as a “Met Screen” and specimen will be sent to the lab.

**NURSERY PROCEDURES**

1. Check with Nursery staff if you have been exposed to any contagious disease prior to entering the Nursery.
2. Leave the phlebotomy tray in the scrub room. Take only the equipment you will need into the Nursery.
3. Washing of hands with soap and water is of major importance prior to handling the infants.
4. Put on clean gloves at the bedside.
5. Touch only the infant and necessary equipment.
6. Hand washing and changing of gloves is mandatory between each infant.

**POTENTIAL FOR INVALID RESULTS**

1. Specimens collected prior to 24 hours after protein intake.
2. Infants of low birth weight, receiving antibiotics or having transfusions before collection.
3. Specimens accompanied by improper or incomplete paperwork.
4. Infants on TPN or soy formula.

**POTENTIAL FOR UNSATISFACTORY SPECIMENS**

1. All circles are not thoroughly saturated to other side.
2. Filter paper is scratched or unevenly saturated from improper use.
3. Specimen appears contaminated.
4. Clotted or caked blood present on filter paper.
5. Interference with assay possibly due to antibiotics or other inhibitory substances.
6. **Incomplete saturation of blood from filter paper**.
7. **Paperwork incomplete or improperly completed**.
8. Filter paper is separated from form.
9. Specimen appears to have separated into cells and serum.
10. Lotion or hand oil on filter paper.

**HANDLING OF COLLECTED SPECIMENS**

1. Each filter card will be inspected upon receipt for a satisfactory specimen. If a specimen is found to be unsatisfactory, contact the Nursery as soon as possible and request a new specimen.
2. Specimen will be logged in to the lab; place Met Screen label in tracking book and Newborn Screen in designated area.
3. Dry blood spots thoroughly at room temperature for at least 3-4 hours in a horizontal position away from direct heat or sunlight or direct ventilation, in a designated area, separate from desks and papers, preferably in a designated drying rack.
4. There will be a designated person on the unit to check this location throughout their shift, or at designated times to ensure timely processing of dry specimens. This person will not be an individual but a person on each shift, each day - that will be responsible for ensuring timely processing.
5. Do not allow blood to come into contact with any other surface while drying.
6. Do not place specimen in refrigerator or envelope until completely dry.

**SHIPPING OF COLLECTED SPECIMENS**

Specimens will need to be transferred and prepared for shipment by the following process:

* Open “Transfer Specimens” button in Cerner.
* Select “New” to create a new packing list.
* Select the “from” location to be “Cntrl Proc VVMC” and the “To” location to be “Misc SO VVMC” and hit “Retrieve”.
* Check available orders in list against actual specimens that are being sent, highlight each and move them from the list on the left side to the right.
* Click “Save” once all specimens are accounted for.
* Put specimens on that list in Newborn Screen shipping envelope. When putting multiple specimens in one envelope, alternate which sides the blood spots face to reduce cross contamination.
* Click “Transfer” and then Confirm. Print out 2 packing lists.
* Check packing list against specimens in the envelope, initial one packing list and put it in the envelope with the specimens.
* Write the tracking number on the envelope on the other packing list and save it in the Newborn Screen Binder.
* Seal envelope and place in green bucket for pickup.
* Envelopes will be picked up by EZ Messenger Courier Service between 0900 and 1100 Monday Through Saturday

**REPORTING OF RESULTS**

1. Results are mailed to submitters and the ordering Physician by the state.
2. All results are reviewed by the Technologist and placed with other send out results to be scanned.
3. Each Newborn Screen Report will be scrutinized against Newborn Screens sent to ensure that every screen that was sent has results.
4. Abnormal results are reported to the submitting hospital and practitioner by the state with recommendations for further testing.
5. **The Laboratory will notify the ordering Physician as soon as possible**. This will be documented in the LIS using the RBV procedure.
6. Unsatisfactory results are reported to the submitting institution and the practitioner by the State with the request that another specimen be sent. The Laboratory will notify the ordering Physician. This will be documented in the LIS using the RBV procedure.
7. The provider’s office will then contact the parents for the return screening. A hard copy of the unsatisfactory results should also be sent to the provider’s office as a reminder- as well as for their record purposes.
8. After review, the results are scanned and become part of the patient’s permanent health record. The original copy from the Arizona Department of Health Services (ADHS) is shredded.

**REFERENCES**

1. College of American Pathologists (CAP) Laboratory General Checklist (Sept. 25, 2012), GEN. 40490.
2. Clinical Laboratory Improvement Act of 1988 (CLIA ’88) Standards.
3. [www.AZnewborn.com](http://www.AZnewborn.com)
4. Arizona Newborn Screening Program – Collection kit demographics.doc 12/09

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| **Prepared by/Title/Date:**DDanielson,MT(ASCP) 11/05**Approved by/Title/Date:**Signature on File in Lab   | **Committee Approval/Date:**Policy & Procedure \_\_\_\_\_\_ | **Dates Reviewed/Revised:**8/2006, 10/09, 8/2011,10/2013, 5/2014 |