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Newborn Screening and Birth Defects Surveillance

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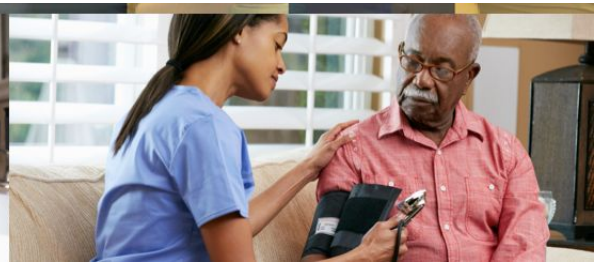

Prevention and Health Promotion Administration

MISSION AND VISION

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MISSION

- The mission of the Prevention and Health Promotion Administration is to protect, promote and improve the health and well-being of all Marylanders and their families through provision of public health leadership and through community-based public health efforts in partnership with local health departments, providers, community based organizations, and public and private sector agencies, giving special attention to at-risk and vulnerable populations.

VISION

- The Prevention and Health Promotion Administration envisions a future in which all Marylanders and their families enjoy optimal health and well-being.

Statutes and Regulations

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Establishment of Newborn Screening Programs

Health Article-General Section §13-109, §13-107 and §13-111

Birth Defects Reporting Information Systems (BDRIS)

Health Article-General Section §18-206

Annotated Code of Maryland (COMAR) 10.52.12.04

Critical Congenital Heart Disease (CCHD)

Health-General Article, §13-109, §13-111, and §18-107(a)

Annotated Code of Maryland (COMAR)10.52.15

Infant Hearing

HEALTH-GENERAL Code Ann. § 13-601

Annotated Code of Maryland (COMAR) 10.11.02

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COMAR 10.11.02.07

http://www.dsd.state.md.us/comar/SubtitleSearch.aspx?search=10.11.02.

.07 Procedures for Birthing Hospitals and Alternative Birthing Sites.

For each infant delivered at the facility or site, birthing hospital staff and, in the cases of alternative birthing sites,

the licensed professional attending the birth shall:

A. Within 48 hours of delivery, enter demographic and birth event data into the Department database;

B. Within 48 hours of discharge from care in the Department database:

(1) Document:

(a) The hearing screening test results; and

(b) Any known risk factors; and

(2) Identify and document:

(a) The infant's primary care provider; and

(b) Any referrals made; and

C. Provide to the family:

(1) Written documentation of the birth hearing screening results;

(2) Any identified risk factors; and

(3) Instructions for any recommended follow-up..

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Types of Screening

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Public Health Basis

Conditions screened for must:

- Be serious and be detectable prior to the onset of symptoms
- Have an available test that is widely available, sensitive and specific
- Have an effective treatment
- Benefits of screening must also outweigh risks of screening

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Public Health Basis

- Federal guideline is the Recommended Uniform Screening Panel (RUSP).
- Formal process with rigorous review to have conditions added to the RUSP.
- Typically once a condition is added to the RUSP, states gradually add to testing panel when they are able.

Newborn Screening

Blood Spot Screening

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Consent for Screening

Newborn screening is based on implied consent

- Birth facility is responsible for educating family about newborn screening and notifying State Health Department if parent declines

Blood Spot Screening

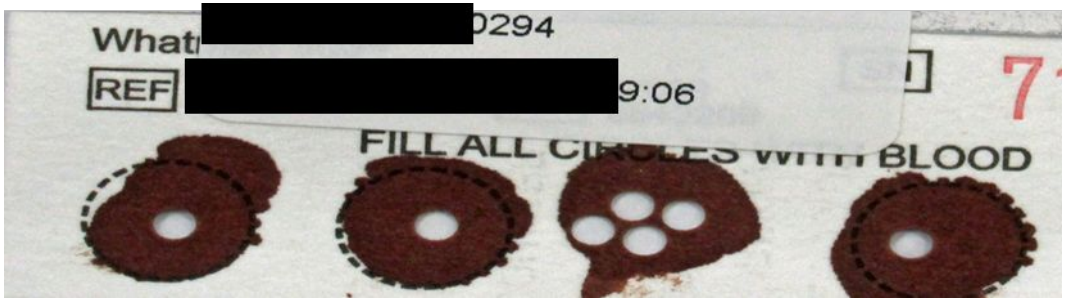
- Collected at 24-48 hours of age & after 24 hours of feeding
- All samples sent to MD State Lab
- MD routinely does 2 screens - 2nd at 7-14 days of age
- Results and follow up occurs after discharge and continues until diagnosis

Point of Care Screening

Results of screening are known prior to discharge

- Hearing screening – follow up after discharge for "missed" or "not passed"
- CCHD screening – ALL follow up should be completed prior to discharge

Blood Spot Screening



What happens to those little spots?
What is included in this screening?
Why are some specimens unsatisfactory?
Why do babies get a second screen?
What happens if a screen is abnormal?

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Blood Spot Screening

- Blood Spot Screening is a screening test.
- It only identifies babies who may have a disorder from those babies who most likely do not have a disorder.
- Diagnostic testing is needed to determine if the baby has a disorder.

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Blood Spot Screening

- NBS is a life saving practice so timing is crucial
- Delays for any reason can cause infants with certain disorders to die before parents realize something is wrong
- The sooner a disorder is identified, the earlier treatment can be started
- Infant outcome depends on newborn screening practices

Blood Spot Screening

What do we need from you?

- Accurate, complete information on lab slip
- Good quality specimens collected at the right time
- Assistance with locating information for mother or PCP if needed

Blood Spot Screening Specimen Quality

- The Maryland State Newborn Screening Laboratory receives hundreds of specimens each day - both from birth hospitals and provider offices.
- Unsatisfactory specimens slow down the testing.
- The specimen may be unsatisfactory secondary to missing vital information on the lab slip or blood spots which are not acceptable for testing.

Blood Spot Screening Frequently Missing Information

Birth Date and Collection Date

- Used to determine age of infant at the time of collection
- Date of collection also determines age of blood at the time of analysis

Baby's current weight

This information is very important for proper laboratory analysis of the results*

TRAB (Test Request Authorized By)

- The name of the provider ordering the test must be on the form in order for the lab to release the result

Blood Spot Screening "Unsatisfactory Specimen"

- If the blood specimen does not give reliable results, it will have to be repeated
- Getting a repeat specimen can take weeks, putting the newborn baby at risk
- Always check the specimen before sending to make sure it appears acceptable

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Blood Spot Screening

Collecting a Specimen

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Collecting a Specimen

Completing Collection Form

- Specimen cards are legal documents.
- Accurate information is crucial for valid and reliable testing, as well as linking of initial and repeat specimens.
- Use block letters in the spaces provided. Use of BLOCK LETTERS allows for faster and more accurate data entry into the State Lab computer system.
- Stickers should not be applied to the front of the collection form. Identification stickers, if used, should be placed on the back side of the top white slip.
- **Do not place any stickers either on the front or the back of the actual filter paper.**

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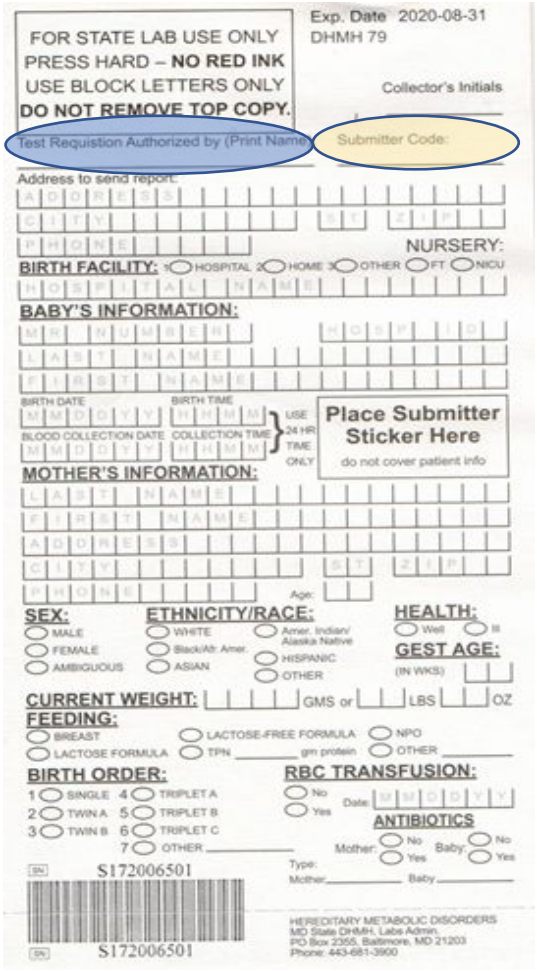
Collecting a Specimen



Completing Collection Form

- Write in your Submitter Code. If you do not know your code or do not have a code, please call 443-681-3900.
- Test Request Authorized By (TRAB) – this line must contain the name of the provider who is ordering the test. Results cannot be released if the TRAB is not completed
- Using BLOCK LETTERS fill in all demographic information for provider's office and for mother.
- *The purpose of this information is to provide a way to link the baby's first and second specimens and to find the infant with a positive result quickly*

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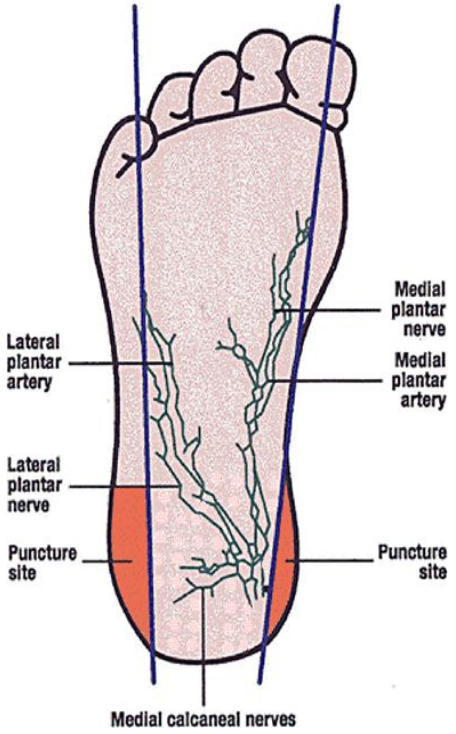
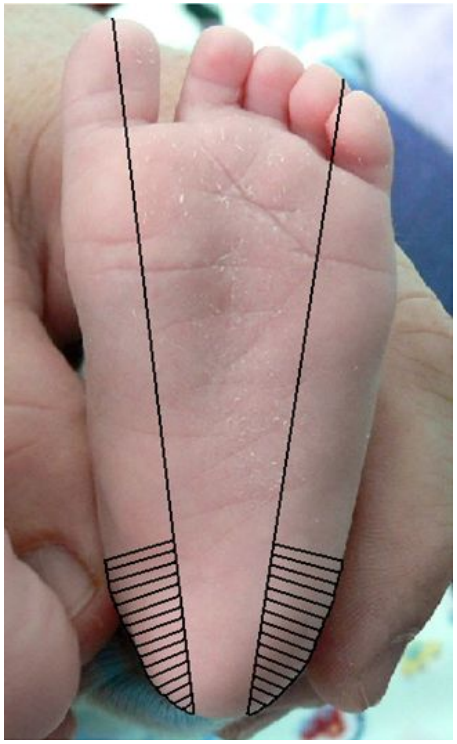
Recommended Sites



Puncture site should be on the medial or lateral portion of the plantar surface of the heel. (The plantar surface is the part of the foot that touches the floor if standing or walking)

The shaded areas show the best sites for puncture. Use of these areas will help prevent possible damage to the heel bone and the nerves and arteries noted on the diagram.



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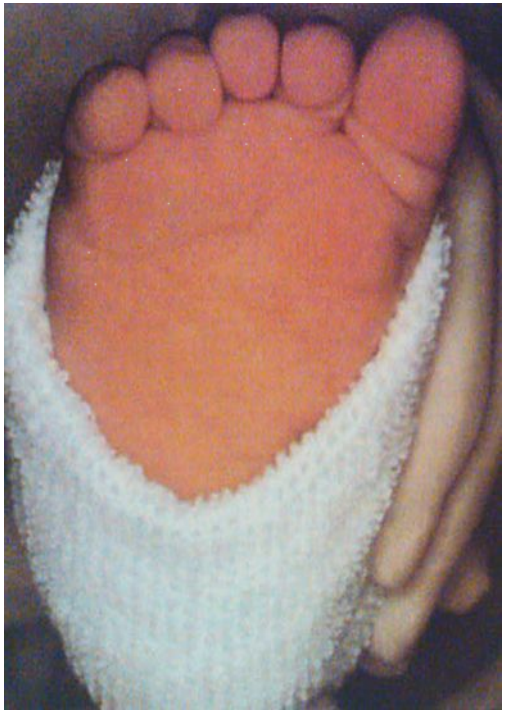
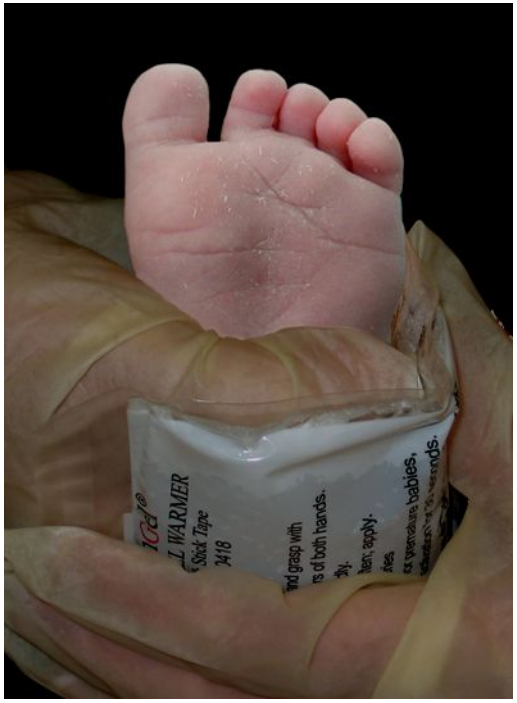
Preparation for neonatal capillary blood sampling



Warm infant's heel with soft cloth or diaper, moistened with warm water for 3 to 5 minutes.

You can also used a commercially prepared disposable heat pack. (make sure to follow your facilities guidelines for using heat packs)

Place infant's heel in a dependent position, such as Mom cradling infant with head higher than feet.



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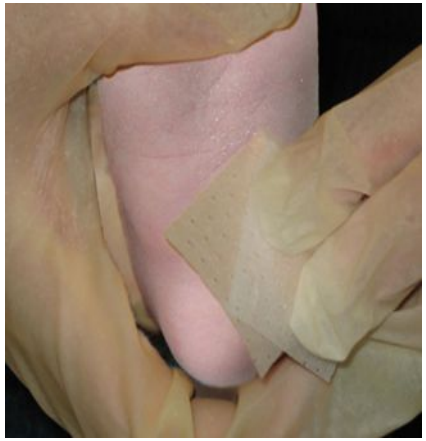
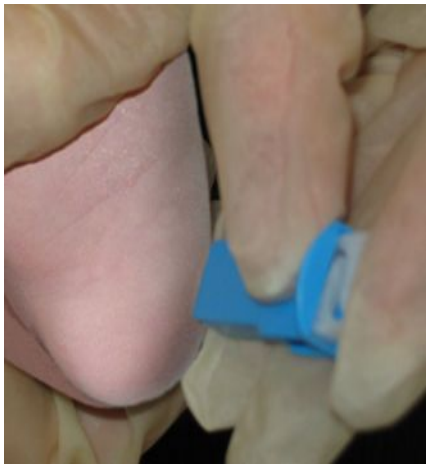
Neonatal capillary blood sampling





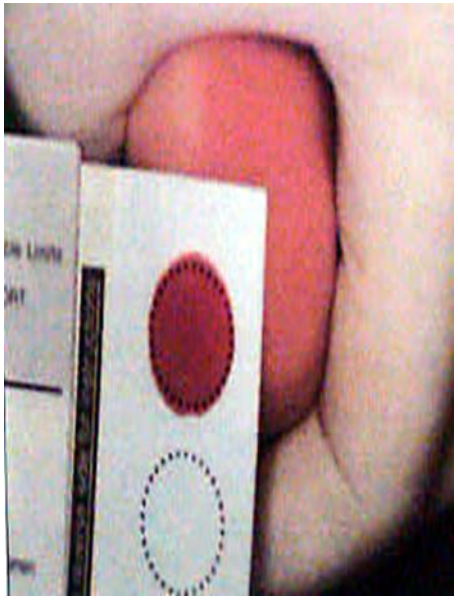
Cleanse site with alcohol prep and allow to dry.

Puncture heel with sterile lancet which has a puncture depth of less than 2.0 mm. The lancet should be labeled for use in newborn capillary specimen collection.

Wipe away first blood drop with sterile gauze pad.

Allow another LARGE blood drop to form

Neonatal capillary blood sampling



Direct application of blood onto the filter paper is recommended. Capillector tubes should not be used as they may scratch the top of the filter paper.

Lightly touch filter paper to LARGE blood drop.

Filter paper acts like a capillary tube, drawing blood into itself

Allow blood to soak through and completely fill circle with SINGLE application. (To enhance blood flow, VERY GENTLE intermittent pressure may be applied to the heel. Do not milk or squeeze tissue next to the puncture site because this may cause serum to separate.)

Apply blood to only one side of the filter paper

Fill remaining circles by lightly touching one LARGE blood drop to each circle.
If blood flow diminishes, clean a new site and repeat the process with a new sterile lancet.

Important Points to Remember

- Do not touch the actual filter paper portion of the lab slip either before, during or after blood collection. Contamination of the filter paper with water, formula or powder from gloves will affect the results.

- Check the specimen to make sure the blood saturated through the card and there is no overlapping of blood in the circles. If there is a problem with the specimen, test should be repeated.

- Allow specimen to dry in on a clean flat non-absorbent surface for a minimum of 3 hours.

- Completed specimen should arrive at the Maryland State Laboratory within 72 hours of collection. Do not hold or "batch" specimens while waiting for several specimens to be mailed together.

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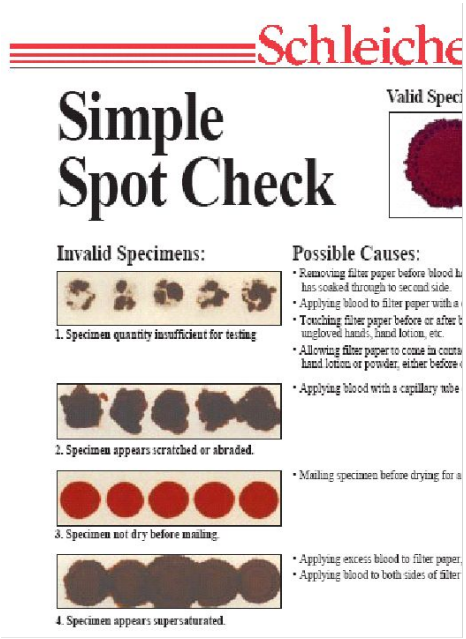
Common Problems with Specimen Collection



The most common problem with newborn bloodspot screening specimens is layering of blood on the circles.

Another common problem is not getting enough blood on the circles or letting the blood soak through the filter paper.

Scratching of the filter paper occurs frequently when capillector tubes are used and the blood is “colored” on the spots.

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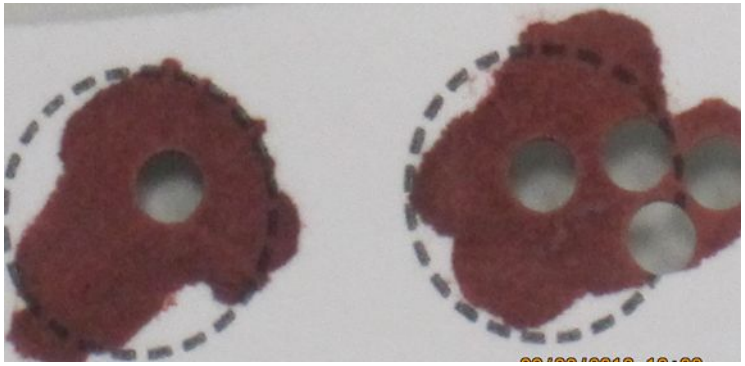
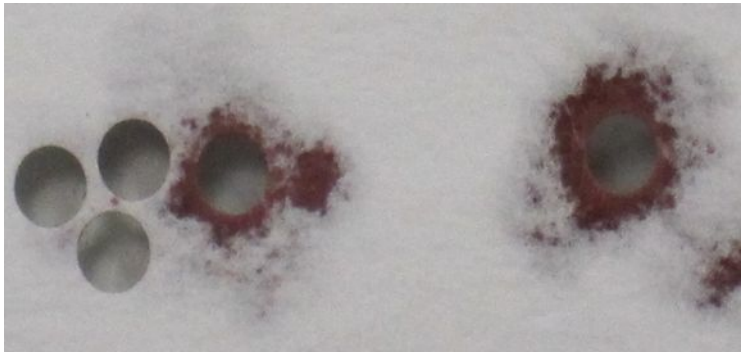
UNS 1- Insufficient Blood to Run All Tests





From the front of the card, this specimen appears to be satisfactory.
Turning over the same specimen card shows that the blood did not saturate through the filter paper to the back of the card.

If a specimen looks like this, start over with a new card. Never apply blood to both sides of the card.

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Newborn Screening

Critical Congenital Heart Disease (CCHD) Screening

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Critical Congenital Heart Disease (CCHD) Screening

- CCHD Screening was implemented in MD as a part of newborn screening on September 1, 2012

- Purpose of screening is to identify babies who may have a critical congenital heart defect prior to discharge from the hospital

Critical Congenital Heart Disease (CCHD) Screening

Background

- About 25% of congenital heart disease is considered “critical”
- Diagnosis previously relied on prenatal diagnosis or neonatal signs/symptoms
- Delayed diagnosis of CCHD causes increased morbidity and mortality
- Pulse ox screening of newborns helps improve detection of CCHD when combined with a thorough exam

Critical Congenital Heart Disease (CCHD) Screening

When should screening be performed:

- 24-48 hours of age is ideal
- Avoid performing pulse oximetry on a crying or cold infant

How is screening performed:

- Pulse ox reading obtained from R hand (preductal) and either foot (postductal)
- Readings are compared

Critical Congenital Heart Disease (CCHD) Screening

- Any infant with sats < 90% in either reading has failed and must be evaluated by the attending clinician.
- If sats are between 90 - 94% in both RH and foot, or if there is more than 3% difference between RH and foot, repeat in 1 hour.
- If still abnormal screen after repeat X 2, screen is failed and baby must be evaluated.

Critical Congenital Heart Disease (CCHD) Screening

Mueller CCHD Screening Table

Green = Negative screen (PASS) Red = Rescreen in 1 hour
Red for 3 consecutive screens = Positive screen (FAIL) *Red* = Automatic Positive screen (FAIL)

RIGHT HAND	FOOT											<90
100	100	99	98	97	96	95	94	93	92	91	90	*
99	100	99	98	97	96	95	94	93	92	91	90	*
98	100	99	98	97	96	95	94	93	92	91	90	*
97	100	99	98	97	96	95	94	93	92	91	90	*
96	100	99	98	97	96	95	94	93	92	91	90	*
95	100	99	98	97	96	95	94	93	92	91	90	*
94	100	99	98	97	96	95	94	93	92	91	90	*
93	100	99	98	97	96	95	94	93	92	91	90	*
92	100	99	98	97	96	95	94	93	92	91	90	*
91	100	99	98	97	96	95	94	93	92	91	90	*
90	100	99	98	97	96	95	94	93	92	91	90	*
<90	*	*	*	*	*	*	*	*	*	*	*	<90

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Critical Congenital Heart Disease (CCHD) Screening

Documentation of CCHD screening must be completed in the OZ database

- Although not required, it is helpful to enter sat results in database
- results turn red if failed
- helps determine if documentation of result is correct.

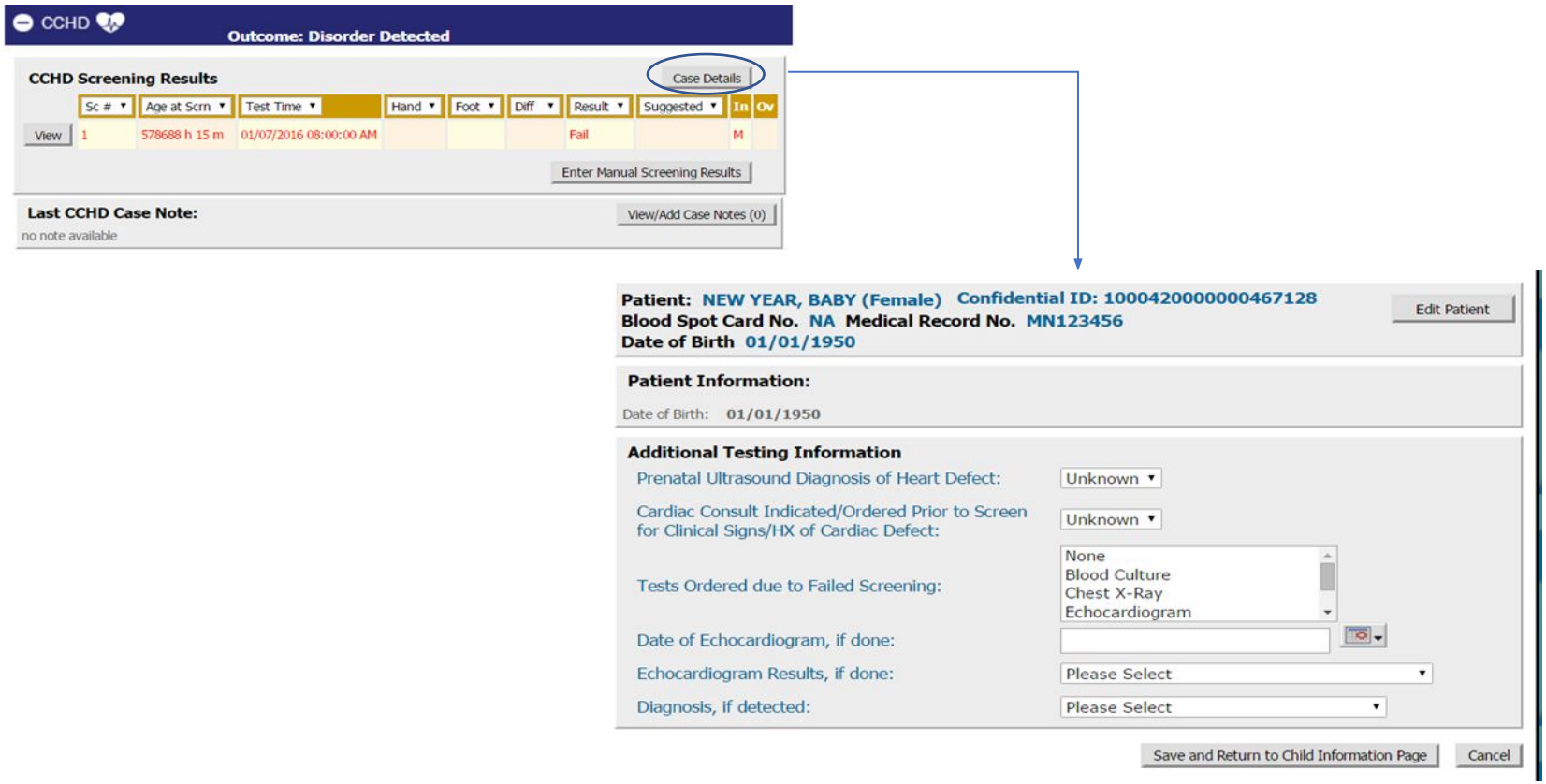
Critical Congenital Heart Disease (CCHD) Screening

Both result of screen and result of evaluation need to be documented in OZ.

- Result of evaluation should be entered in “Case Details”
- Can also use “CCHD case notes”

Outcomes of all failed screens are needed to evaluate effectiveness of screening program

Critical Congenital Heart Disease (CCHD) Screening



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Birth Defects Reporting and Information Systems

BDRIS

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Surveillance

- Want to identify potential causes/ protective factors based on incidence in different regions, racial/ethnic groups, age groups.
- Using birth defects data is how folic acid was correlated to decreased neural tube defects
- Other diagnosis of public interest

Birth Defects Surveillance (BDRIS)

Birth Defects Reporting and Information System (BDRIS) designed to:

- Gather data on incidence of birth defects to provide to CDC for national surveillance and research on prevention.
- Gather data for surveillance within the state by region to identify changes in rates and areas where resources may be needed.
- Provide information on resources to families.
- Data available to each facility for internal quality measures

Birth Defects Surveillance (BDRIS)

Examples of the necessity of timely data reporting;

- NB with multiple congenital anomalies not reported in appropriately in OZ, follow up missed.
- NB with complete microtia/atresia not reported appropriately in OZ, not referred to Infant and Toddler; follow up delayed; lifelong language (and all associated) outcomes impacted
- NB who fails pulse ox screening and has no outcome in database can require reaching out to family by health department causing unnecessary stress and anxiety

Reporting

What's needed in OZ?

- Completed within 48 hours of discharge
- Complete demographics (both parents if possible)
- Lifestyle factors
- Birth Conditions
- ICD10
- Case notes
- Prenatal tests
- Prenatal Health History
- Pregnancy History

Reporting Birth Condition/Disorder

Suspected vs. Detected

- If “suspected” should have PCP and/or lab information in case note.
- Zika Virus/ Congenital Zika Syndrome reporting
- Must document travel history of mother and partner prior to and during pregnancy
  - New guidelines issued on 02/28/2019

Newborn Screening

Hearing Screening

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Hearing Screening

- Maryland follows the 1-3-6 Joint Committee on Infant Hearing timeline recommendation:

- SCREEN by age 1 month
- DETERMINE HEARING STATUS by age 3 months
- BEGIN EARLY INTERVENTION SERVICES by age 6 months for babies who have been diagnosed with a hearing loss

- Studies show that infants born with a hearing loss who are identified and given appropriate intervention before 6 months of age demonstrated significantly better speech and reading comprehension than children identified after 6 months of age

Hearing Screening

Notify each infant's PCP of the screen results

- Update OZ file within 48 hours of discharge with results, risk factors, and the PCP/Medical Home the baby will see after discharge
- Document in OZ Case Notes section, any known Zika Virus exposure and any known travel by the mother or partner to any Zika affected area prior to and/or during pregnancy
- If microcephaly exists, indicate in OZ Case Notes section and select cranio-facial anomalies from the risk factors drop down menu

Reporting Hearing Screens

What's needed in OZ?

- Completed within 48 hours of testing
- Date of screen
- Results of screen
- Recommendations given to family if baby does not pass screen

OZ Systems

How are patients added to the system

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Licensed Professional Registration

Online Access Registration Form

Prevention and Health Promotion Administration Link

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Questions?

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