TEXAS

Newborn Screening Program NEWS

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Unsatisfactory Specimens

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Newborn screening involves the analysis of blood samples, taken in early infancy, to detect diseases for which early intervention can avert serious health problems or death. Texas newborn screening services began in the early 1960's with the development of a test for the rare metabolic disease phenylketonuria (PKU). Over the years, the Texas Newborn Screening Program (NBS) has added screens for four additional disorders: galactosemia, congenital adrenal hyperplasia (CAH), congenital hypothyroidism (CH), and sickle cell disease.

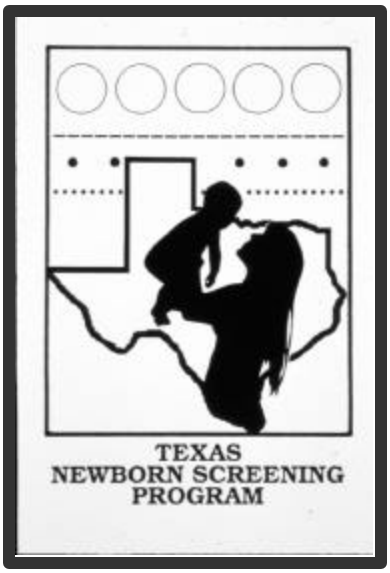
All babies born in Texas are mandated to have two screening tests. The first screen should be collected within the first 72 hours of life (preferably after 36 hours of age and 24 hours after the first milk feeding), or before hospital discharge. It is preferable to obtain the first specimen 24 hours after the first milk feeding in order to increase the likelihood of detecting PKU and galactosemia. However, if the baby is discharged from the hospital before 24 hours of age, the first screen should be collected before discharge. At one to two weeks of age, the baby receives the second screen.

The Texas Administrative Code states "The physician or non-physician attending the newborn has the primary responsibility for causing the screening tests to be performed and that a satisfactory blood specimen is submitted to the Texas Department of Health (TDH) Laboratory on a properly completed filter paper collection form obtained from the department."

Ideal NBS Specimen Characteristics

- All five circles should be completely filled and saturated with blood.
- Blood should be applied from only one side of the paper and appear as an even, uniform layer. (The recommended collection technique is to absorb the blood directly from the heel onto the back side of the paper while watching the circle to ensure that it completely fills).
- The specimen should be air dried for at least 3 hours on a flat, nonabsorbent surface in a horizontal position, protected from heat or direct sunlight. Universal precautions pertaining to blood and body fluids should be maintained.
- The specimen should be mailed directly after drying (accumulated or 'batched" specimens may result in specimens too old to test).

Unsatisfactory Specimen Rejection



The TDH Laboratory performs the newborn screening test series on specimens received from over 5,000 locations around the state. Approximately 3,000 specimens arrive in the mail each day. This is the highest workload of any single laboratory facility in the world performing newborn screening. These specimens are visually inspected to determine if they are suitable to test. A specimen will be deemed "**Unsatisfactory to Test**" for any of the following reasons:

- No blood samples received with request form
- Blood did not completely fill specimen rings
- Blood did not soak through paper-incomplete saturation
- Blood was caked, clotted, or layered on paper
- Specimen appeared contaminated or discolored

- Serum separation from improper drying or collection
- Improper capillary use, paper scratched/blood uneven
- Specimen too old upon receipt (received 14 or more days after collection date)
- Missing or invalid information-check name, date,
- Specimen submitted on improper collection form
- Specimen submitted on out-of-date collection form
- Specimen damaged during transport to TDH

Unsatisfactory Individual Test Results

Common Causes:

1. *Assay Interference*: Assay Interference is a code used only in the metabolic test for galactosemia. This test is a microbiological assay that relies on growth of bacteria to determine abnormal results. When newborns are treated for infection, the antibiotic in the blood stream may interfere with test results. The TDH Laboratory is researching new techniques to overcome this problem.

2. *Clotted or Caked Blood:* Clotted or caked blood is caused by excessive blood being applied to the circle. For example, in congenital hypothyroidism, a heavy application of blood could falsely elevate the T4 level resulting in a false negative result.

3. *Specimen Too Old On Receipt*: A screen is sometimes run on a specimen received without a collection date and then determined to be too old. T4 deteriorates with time, and delays in testing could possibly give false results.

Others causes include: Insufficient specimen, incomplete saturation, uneven saturation and incomplete elution.

Demographic Data

Missing demographic data is another concern of the TDH Laboratory. All the information requested on the collection form is essential. The date of birth, date of specimen, and infant's age at specimen collection (in hours or days) is critical. The correct birth weight (in grams) is needed because normal ranges are different for low weight and full weight babies for CAH and CH. In January 2000, the TDH Laboratory received 62,000 specimens, 2,400 (4%) with missing collection dates.

We hope this information helps to explain why we request repeat specimens. If you have any questions about the neonatal screening blood specimen collection and handling procedure, please call 1-800-422-2956 and ask for extension 3204 or order online at www.tdh.state.tx.us/newborn/pubs/htm.

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LAB REPORTING

For information regarding newborn screening results, please call

512/458-7578

BIRTH WEIGHT

It is important for the NBS follow-up staff to have the **correct birth weight** for babies in grams.

Call **1-800-422-2956** extension **3204**
for a free weight conversion chart

or order online at

www.tdh.state.tx.us/newborn/pubs.htm