

LABORATORY TESTING AND REPORTING

Designated Laboratory

In order to conduct effective, timely follow-up for newborns affected by any of the disorders, the South Dakota Department of Health uses a centralized system to coordinate analyzing, reporting, and follow-up of newborn metabolic screens.

The State Hygienic Laboratory at the University of Iowa (SHL) in Ankeny, IA was designated as the contract laboratory for the South Dakota Newborn Screening Program beginning June 1, 2007. SHL is authorized to conduct newborn screening services for the State of South Dakota. **All newborn screening specimens for infants born in South Dakota must be submitted to UHL.** The SHL newborn screening laboratory operates every day including nights, weekends and holidays, 365 days/year and is responsible for testing, record keeping, quality control of laboratory testing, and the notification of test results.

Notification of Newborn Screening Test Results

All providers are to ascertain the results of newborn screening on any infant in their care. Do not presume that a newborn screening test was obtained, or that the results of the newborn screen were normal. Laboratory reports will be sent to the submitter of the specimen. These results are to be used as a record for the child's medical chart.

Normal Test Results

Normal results in hard copy format will be sent to the submitter by USPS to be placed in the child's medical record.

Unacceptable Specimens - Poor Quality - Recollect

The designated laboratory, SHL may consider a specimen to be of *poor quality* due to any of the following reasons: insufficient quality, layering, blood applied to both sides of the filter paper, blood not allowed to dry, contamination, serum separation, received more than 14 days after collection, etc. Before any specimen is rejected as "Poor Quality" two staff members examine it and agree to reject it (based on CLSI document LA4-A5).

Since a poor quality specimen may compromise test results, submitters are notified immediately (within 24 hours) by fax notification by UHL. UHL will identify these specimens by a "PQ" for Poor Quality. This notification indicates the need for a recollected specimen as soon as possible.

Invalid specimens, those with missing information, specimens collected after transfusion, and specimens collected from infants prior to 24 hours of age are tracked each workday and the submitting health care provider (and SDNSP) will be notified by fax to collect another specimen as soon as possible.

Repeat Testing

As part of the contract with the designated newborn screening laboratory, follow-up staff are required to notify the submitter, physician and the SDNSP of any specimen needing a repeat specimen collected on filter paper: early collection, unsatisfactory specimen, transfused specimen, and some abnormal or inconclusive results requiring only repeat filter paper specimen testing. The SDNSP also communicates with the infant's physician to assure they have received notification of abnormal results and will monitor for repeat testing results.

Abnormal Test Results (Presumptive Positive)

As part of the contract with the designated newborn screening laboratory, follow-up staff are required to notify the submitter, physician and SDNSP of any abnormal screening result. Some of these will fall in a "borderline" range requiring only a repeat filter paper specimen at that point in time. Others will require a different type of specimen to be tested by a different methodology.

Confirmatory Testing

Confirmatory testing information and instructions will be included with the notification process of presumptive positive results. Pay particular attention to the testing that is needed and the correct specimen type.

Link to the Laboratory Web Site

State Hygienic Laboratory at the University of Iowa (SHL) in Ankeny, IA

Phone: 1-515-725-1631

Website: <http://www.shl.uiowa.edu/screening/>