Inspector Instructions:

	• Specimen collection instructions, including handling, transport, and submission • Sampling of procedures and records for follow up of positive or invalid results • Records for the monitoring of the quality of specimens, completeness of collection records, and transportation time • Sampling of patient reports
	• How is follow-up tracked for patients requiring additional testing?

CBG.20110 Specimen Collection Instructions — Phase II

Instructions for the proper collection, handling, transport, and submission of newborn screening specimens are provided to locations submitting specimens for analysis.

NOTE: It is acceptable for this information to be electronically available to users rather than in paper format. Instructions must describe the proper application and drying of blood spots and submission of patient information needed for interpretation of the data. The collection instructions must be in compliance with the current edition of the CLSI Standard NBS01, Blood Collection on Filter Paper for Newborn Screening Programs, and state or local regulations for collection of specimens.

REFERENCES

1) Clinical and Laboratory Standards Institute. *Blood Collection on Filter Paper for Newborn Screening Programs.* 7th ed. CLSI standard NBS01. Clinical and Laboratory Standards Institute. Wayne, PA; 2021.

CBG.20120 Specimen Quality Monitoring — Phase II

The laboratory monitors specimen quality, completeness of patient records, and transportation time for specimens submitted for newborn screening.

NOTE: The patient records submitted with newborn screening specimens must include information for patient identification and proper interpretation of the data including all required elements defined in the most recent edition of CLSI Standard NBS01. If problems with specimen quality or missing collection information are identified, the laboratory must record appropriate corrective actions that lead to continuous quality improvement.

Specimens should be transported after they are dry and no later than 24 hours after collection or following the instructions provided by the designated newborn screening laboratory. Delays in specimen transportation from the collection facility to the testing laboratory may compromise the integrity of the specimen and results. Ultimately, the delay could critically impact the newborn.

Evidence of Compliance:

- ✓ Records of monitoring for poor quality specimens, incomplete collection information submitted, and specimen transport problems **AND**
- ✓ Records of communications with clients that submit specimens with quality issues

CBG.20130 Consent Procedure — Phase II

In cases where an indication of consent is required on the newborn screening collection device, either for collection or for later use (research), there is a process for review and action to ensure appropriate use of the specimen.

NOTE: Records must demonstrate that this procedure is followed.

CBG.20140 Out-of-Range/Invalid Results **Phase II**

The laboratory reports positive (out of range) or invalid results to the submitting location and other appropriate entities to allow for patient follow-up within a timeframe appropriate to ensure maximum health benefit.

NOTE: Positive results include those results that are outside of the expected range of testing results established for a particular condition. Invalid results include situations where the laboratory is unable to complete the screening process due to an unsuitable specimen, test, or incomplete information. The findings must be communicated in a manner consistent with the urgency of the intervention needed. For situations requiring repeat screening or confirmatory testing, the laboratory must clearly communicate the timing of the actions to be taken.

Results must be reported to the submitting location within seven days of specimen receipt and within three days for specimens received for tests requiring additional action (eg, invalid or positive). The records must indicate when results were reported and who received the results. In cases where the testing laboratory is responsible for ensuring that a replacement specimen has been received and analyzed, appropriate records must attest to specimen receipt, testing and result reporting.

CBG.20150 Results Reporting **Phase II**

Newborn screening results are reported to the submitting location and include all required result reporting elements from the Laboratory General Checklist.

CBG.20160 Follow-up Procedures **Phase I**

In cases where the testing laboratory is responsible for testing and follow-up (including patient tracking), all follow-up procedures are "closed loops" consistent with the CLSI Guideline NBS02, Newborn Screening Follow-up, or appropriate local policy.

NOTE: The laboratory's written procedures should include:

1. *Cases requiring notification*
2. *Roles and responsibilities of all individuals in the follow up system, as appropriate (laboratory staff, physicians, and birthing centers)*
3. *Method and timing of notifications (eg, phone call, fax or letter)*
4. *Monitoring of follow-up to track the actions taken until resolution - specimen monitoring, follow-up calls/letters, nurse visits, etc.*
5. *Case Resolution - follow-up actions, including the extent of actions required before closing a case without resolution or lost to follow up*

The procedures must follow local laws and regulations. "Lost to follow up" occurs when a notification cannot be made.

REFERENCES

1) Clinical and Laboratory Standards Institute. *Newborn Screening Follow-up;* 3rd ed. CLSI Guideline NBS02. Clinical and Laboratory Standards Institute, Wayne, PA; 2023.

HEMOGLOBIN SEPARATION

This section is intended for laboratories that are performing screening tests on newborns from whole blood heel stick specimens collected on filter paper for the routine screening for abnormal hemoglobin variants.