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.