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.