



APHL Position Statement

Quality Assurance in the Newborn Screening Laboratory

A. Statement of Position

The Association of Public Health Laboratories (APHL) recognizes the intense efforts to assure and sustain the highest quality of testing possible for newborn screening (NBS) for public health programs. APHL strongly supports the tenets of continuous quality improvement through internal and external quality assurance activities. APHL endorses a sustained role for the APHL/CDC NBS Quality Assurance Program (NSQAP) and expansion of its services to include coverage for disorders that are screened for by state screening systems. The organization endorsed the Clinical Laboratory Standards Institute (CLSI) approved standard for collection of dried blood spots and supports its recommendation for collection of quality specimens.¹ Additionally, APHL encourages the use of Performance Evaluation Assessment Scheme (PEAS) for program self improvement.²

B. Background/Data Supporting Position

NBS for the detection of treatable, congenital or heritable diseases is a major public health responsibility. NBS is a system that involves the collection and testing of dried blood spots to identify and follow-up at-risk infants in order to prevent disabilities and premature death. Quality assurance (QA) for NBS is a dynamic process of defining the quality of performance required for each step in the testing process.³ QA is widely recognized as much more than quality control (QC)

of laboratory testing, and indeed QA encompasses all parameters of the NBS system. Quality control (QC) is the mechanism of monitoring the degree of adherence to defined criteria, taking corrective action when the system fails and documenting all of these events to convey the total quality of performance.³ Laboratory testing works in harmony with other system components including specimen collection, birthing centers, follow-up, counseling, diagnosis, and treatment. Consequently, the information obtained by all these areas needs to be available to each participant in the system.

The Clinical Laboratory Improvement Amendments of 1988 (CLIA'88) provides strong guidance and requirements for laboratories; in regard to laboratory facilities, personnel qualifications and competency, standard operating procedures, specimen collection, result reporting and review, quality control of tests, result turnaround times, assurance that clients are notified of all results especially in the case of abnormal values, and general effectiveness of the laboratory program.⁴ NBS laboratories must achieve and maintain CLIA certification. The NSQAP operated at CDC and sponsored by the APHL provides proficiency testing (PT) and external QC services for analytes measured in dried-blood spots by NBS laboratories. Successful participation in the NSQAP satisfies the CLIA requirements for PT.⁵ For tests not covered by NSQAP; the laboratory must either implement a

self-administered performance evaluation system and maintain appropriate records or participate in another PT service, if available.

Laboratories should monitor all core elements for their QA operations, including those elements that are shared and have overlapping responsibilities in the screening system. For each element, written criteria should be established for acceptable performance. Corrective actions and periodic audits should be performed and fully documented for all these activities. An overall plan for defining QA elements and QC actions should be developed based on: pre-analytical, analytical, and post-analytical activities. In the pre-analytical category, the laboratory activities include, but are not limited to monitoring the quality of specimens received against set criteria, time from specimen collection to receipt by laboratory, assay kit lots, reagent lots, and instruments and their preventive maintenance. The analytical category includes, but is not limited to, monitoring results from calibrators, standards, and controls, comparing results from overlapping analysis of different reagent lots, monitoring results from the actual samples analyzed (particularly the population median), and establishing and periodically refining cutoff values for triggering follow-up action. For post-analytical category, the laboratory should monitor result reporting activities, presumptive positive results, unsatisfactory results, and confirmed positive results. Also, post-analytical includes overall QA management, such as monitoring the time from receipt of specimen to start of treatment and the proportion of unsatisfactory specimens. Data systems including outcome data should be audited and documented. Policies for specimen retention and storage that comply with applicable laws and ethical standards should be documented and reviewed periodically. The identified elements are the minimal activities; other enhancements to the overall quality assurance effort should be considered and

monitored for their effectiveness in contributions to a continuous quality improvement system.

C. References

1. Hannon WH, Whitley RJ, Davin B, Fernhoff P, Halonen T, Lavochkin m, Miller J, Ojodu J, and Therrell BL Jr. Clinical Laboratory Standards Institute. Blood Collection on Filter Paper for Newborn Screening Programs – Fifth Edition; Approved Standard. CLSI document LA4-A5. Wayne, PA: CLSI, 2007.
2. Therrell BL, Schwartz M, Southard C, Williams D, Hannon WH, Mann My, et al. Newborn Screening Performance Evaluation Assessment Scheme (PEAS). *Sem Perinatol.* 2010; 34(2):105-20.
3. Hannon WH, Henderson LO, Bell CJ. NBS Quality Assurance. In: Khoury M, Burke W, Thomson E, editors. *Genetics and Public Health: Translating Advances in Human Genetics into Public Health Action.* Oxford (UK): Oxford University Press. 2000:243-258.
4. Code of Federal Regulations, “Medicare, Medicaid, and CLIA Programs; Laboratory requirements relating to quality systems and certain personnel qualifications; Final Rule,” *Federal Register (42CFR.493)*, January 2003.
5. Bell CJ, Hannon WH, Adams BW. Is the CLIA proficiency testing format appropriate for Newborn Screening? In Therrell BL Jr, Aldis BG, editors. *Proceedings of the 11th National Neonatal Screening Symposium; 1995 Sept 12-16; Corpus Christi (TX).* Washington (DC): ASTPHLD, 1996:1-2.

Recommended by: The Newborn Screening and Genetic Testing Committee, Approved by Board of Directors for Interim Use: May 2011, Approved by Membership: December 2011, Sunset Date: December 2016

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