APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES®

APHL Position Statement

Quality Assurance and Quality Control in the Newborn Screening Laboratory

A. Statement of Position

The Association of Public Health Laboratories (APHL) supports efforts to assure and sustain the highest quality of testing by Public Health Newborn Screening (NBS) programs. As part of its support, APHL endorses the role of the CDC Newborn Screening Quality Assurance Program (NSQAP) and urges expansion of its services for disorders screened by state NBS programs.

B. Implementation

1. APHL will serve as a liaison to organizations, programs and activities that address issues concerning quality assurance for newborn screening systems.
2. APHL will provide feedback to the CDC on issues related to QA and QC and proficiency testing, including making recommendations on expansion of current programs.
3. APHL will provide resources to state NBS programs to support their QA and QC efforts including training and education, distributing federal funds, developing guidance on relevant issues, and adapting resources based on their needs.
4. APHL will review information regarding quality indicators and provide information from the state perspective.
5. APHL will monitor and provide input regarding new conditions added to the Recommended Uniform Screening Panel[3], guidelines for the FDA's regulation of laboratory developed tests and other issues that affect quality assurance in newborn screening systems.

C. Background/Data Supporting Position

NBS for certain congenital and heritable disorders is a major public health responsibility. NBS involves collecting and testing dried blood spots to identify at-risk infants and ensure timely follow-up in order to save or improve their lives. Quality assurance (QA) is the monitoring and evaluation of the various aspects of a system to ensure that standards of quality are being met. NBS QA is a dynamic process of defining and measuring the quality of performance of the screening process.[1] APHL strongly supports continuous quality improvement through internal and external QA activities.

The NSQAP, which is co-sponsored by APHL, provides critical support to NBS laboratories by offering proficiency testing (PT), external quality control (QC) materials for analytes measured in dried blood spots by NBS laboratories, and technical assistance. For most analytes, this is the only source of these materials using a filter paper matrix. Successful participation in the NSQAP satisfies regulatory requirements for PT[2].

An overall plan for defining the QA elements and QC actions to monitor and detect quality issues in pre-analytical, analytical and post-analytical activities

should be developed by each NBS program.

The pre- analytical category may include monitoring: (1) the quality of specimens received against set criteria; (2) the time from specimen collection to receipt in the laboratory; (3) kit and reagent lot; and (4) instrument performance and preventive maintenance.

The analytical category may include: (1) monitoring results from calibrators, standards, and controls; (2) monitoring results from patient samples (particularly the population mean and/or median); and (3) establishing and periodically refining cutoff values that trigger follow-up action.

The post-analytical category may include: monitoring (1) result reporting activities; (2) presumptive positive results; (3) unsatisfactory results; (4) confirmed positive results; and (5) ensuring accurate diagnoses have been reported where possible. The post-analytical category also includes overall QA management, such as monitoring the time from specimen receipt by the laboratory to the start of treatment, and the training and competency assessment of laboratory staff.

Written policies should be established for processes and procedures for specimen collection, transport, and retention, data retention storage, and uses that comply with applicable laws and ethical standards. All policies should be reviewed periodically, and updated as necessary.

D. References

1. Hannon WH, Henderson LO, Bell CJ. Newborn Screening Quality Assurance. In: Khoury, Muin J., Wylie Burke, and Elizabeth Jean Thomson, eds. *Genetics and public health in the 21st century: using genetic information to improve health and prevent disease*. Vol. 40. Oxford University Press, 2000:243-258.
2. Chen, Bin, Joanne Mei, Lisa Kalman, Shahram Shahangian, Irene Williams, MariBeth Gagnon, Diane Bosse, Angela Ragin, Carla Cuthbert Barbara Zehnbauer. "Good laboratory practices for biochemical genetic testing newborn screening for inherited metabolic disorders." *MMWR* 61 (2012): 1-45
3. Recommended Uniform Screening Panel. Advisory Committee on Heritable Disorders in Newborns and Children, Health Resources and Services Administration, U.S. Department of Health and Human Services. http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/recommendedpanel/ Accessed September 21, 2015.

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