APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES®

APHL Position Statement

Newborn Screening Residual Dried Blood Spot Specimens

A. Statement of Position

APHL supports policies on the retention and use of residual dried blood spot (DBS) specimens that are transparent, protect privacy, address parental concerns, and promote education and informed public participation.[1]

B. Implementation

1. APHL will share this position statement with key state and federal policy makers.
2. APHL will evaluate state public health programs' current practices and policies regarding residual DBS specimen collection, handling and storage and identify strengths and challenges.
3. APHL will collaborate with newborn screening programs to collect and share best practices, model policies and parent/provider educational materials for residual DBS specimen collection, safe handling, and secure storage.
4. APHL will collaborate with CDC, state public health programs, and partners in order to develop educational materials for public health laboratories concerning the use and secure storage of residual DBS specimens.

C. Background/Data Supporting Position

The Association of Public Health Laboratories (APHL) endorses the Committee Report: Considerations and Recommendations for National Guidance Regarding the Retention and Use of Residual Dried Blood Spot Specimens after Newborn Screening, 2011, put forth by the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC).[1] This report states that every state newborn screening program should have a policy in place that has been reviewed by a state attorney general or other legal authority. This policy should specify who is responsible for storage, access, use, and secure destruction of residual DBS specimens after testing is completed.[1]

Once newborn screening is complete, state programs retain residual DBS specimens for various lengths of time, from several weeks to greater than 18 years.[1] State programs store residual DBS specimens for a variety of reasons. Residual DBS specimens are primarily used to support essential program functions such as program evaluation, quality assurance, result verification, test refinement, and quality improvement initiatives.[1,2,3,4] Specifically, residual DBS specimens are used to document that specimens were properly collected, transported, received, and analyzed for the benefit of the newborn. Residual DBS specimens are used in quality assurance efforts to ensure continual accuracy and integrity of testing. Particularly, they allow programs to demonstrate that instruments

and reagents operate correctly and that results reported to the healthcare provider are consistently accurate.[4] Residual DBS specimens provide a source of short-term validation of screening results should questions arise. Use and analysis of residual DBS specimens are also essential to program improvement initiatives such as new test development (particularly when a new test is to be added to the newborn screening panel), validation, establishment of cutoffs for new methods, and development of quality control materials.[4] Beyond these primary uses, residual DBS specimens are a valuable resource for public health and medical research, such as studying diseases in children, and for possible development of related tests.[2,3,4] Use of residual DBS specimens for these purposes is governed by policies that provide for informed consent or means to ensure that findings cannot be linked back to any individual.

State programs currently without policies on retaining, storing and using residual DBS specimens should make it a priority to develop one. States that already have a policy should ensure that their policy has been reviewed by the appropriate legal authority and is comprehensive, easy to understand, accessible, and transparent to the public. Policies should include a process for final destruction of specimens where appropriate, including after research has been completed. If at all possible, state programs should strive to keep residual specimens under the recommended CLSI storage conditions for as long as they are able within their designated storage lifetime. It is important that newborn screening laboratories storing specimens include provisions in their policies which accentuate their compliance with federal and state research and privacy rules and regulations. Additionally, once states have obtained their desired, optimal and legally approved policy, they may consider making the policy a rule, regulation, or statute.

State newborn screening programs should develop and execute strategies to educate health care professionals and families about their state's residual NBS specimen polices, focusing on education during the prenatal and postnatal periods. Prenatal education materials should include sufficient information to inform the public about any additional uses of specimens beyond screening including information about possible research in cases where such uses are allowed and the security in place to maintain the confidentiality of identifiable health information. State newborn screening programs have a responsibility to improve public health, while also ensuring privacy and maintaining the public's trust.

D. References

1. Therrell BL, Hannon WH, Bailey DB, Goldman EB, Monaco J, Norgaard-Pedersen B, Terry SF, Harris A, Vasquez LM, Johnson A, Lloyd-Puryear MA, Howell RR. Committee report: Considerations and recommendations for national guidance regarding the retention and use of residual dried blood spot specimens after newborn screening. Genet Med. 2011 Jul;13. Available at: http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/reportsrecom mendations/reports/residualdriedbloodspots.pdf. Accessed July 2, 2013.
2. American College of Medical Genetics. Position statement on the importance of residual newborn screening dried blood spots. Available at: http://www.acmg.net/StaticContent/NewsReleases/Blood_Spot_Position_Statement2009. pdf. Accessed July 2, 2013.
3. Therrell BL, Hannon WH, Pass KA, et al. Guidelines for the retention, storage, and use of residual dried blood spot specimen after newborn screening analysis: statement of the Council of Regional Networks for Genetic Services, Biochem Molec Med 57: 116-124, 1996.
4. 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.

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