



APHL Position Statement

The Role of the Private Sector Laboratory in Public Health Newborn Screening Programs

A. Statement of Position

The Association of Public Health Laboratories (APHL) supports the position that there is a role for private sector laboratories in the provision of state public health newborn screening (NBS) services. Services provided by these laboratories under contractual arrangements should be integrated in the public health system, but must be clearly identified as coming from a private laboratory. Private laboratory involvement in NBS that is independent of the program must be identified as distinct from any public health mandated program and outside of the states' responsibility for tracking and case management provisions. Private sector laboratories must work collaboratively with state public health programs to ensure compliance with state and national program requirements and to maximize the benefit of screening, diagnosis, and treatment of infants with inborn errors of metabolism.

B. Implementation

APHL, and specifically the Newborn Screening and Genetics in Public Health Committee, should continue to convey the position of the organization to other groups such as ASTHO, AMCHP, NNSGRC, ACHDNC, SACGHS, ACMG, MOD, Hastings Center, CDC, CLIAC, etc. This effort is intended to assure that state newborn screening programs will be able to continue to operate as public health agency programs to assure access to testing and

treatment. APHL should collect and maintain state program statutes, regulations and contracts for services related to performance of laboratory services for public health newborn screening programs.

C. Background/Data Supporting Position

State-mandated public health NBS is a quintessential public health program. The statutory or regulatory authority allowing states to mandate such screening programs requires that the laboratory services involved, be carefully controlled by the state public health agencies responsible for these programs. This control provides for the overall program quality and required participation.

Non-governmental laboratories flourish in much the same sphere as state public health laboratories. In general, private sector laboratories supplement but do not supplant public health laboratories. ¹ Where the resources of the state public health system are required to assure testing, case follow-up tracking, and the provision of appropriate health care management of all infants detected as presumptively at risk for one of the specific conditions in the mandated screening panel, it is imperative that the state agency control the content and claims regarding NBS programs.

When a private sector laboratory is utilized for routine NBS, confirmatory or diagnostic testing, it is

the obligation of a state public health NBS program to assure that the screening panel includes all state mandated disorders and that the laboratory procedures have been analytically and clinically validated to standards established by the program. Laboratory expertise should be involved to assure that the screening program includes mechanisms for parental education regarding the conditions to be screened, the assays to be used, the treatment options available, the state resources that can be accessed, and the outcomes anticipated. The laboratory should provide input on developing mechanisms for appropriate health care provider education to assure that they understand the testing process, the conditions screened for and their individual roles in infant tracking, referral, or management.

Activities of private sector laboratories targeted to clinical testing in newborns must be distinguished from public health testing performed by mandated state NBS programs. Participation of private sector laboratories in mandated NBS programs should be clearly defined to assure their full compliance with all program requirements including method validation, quality assurance and quality control documentation, reporting, tracking, follow-up, and provider education and compliance monitoring. Ongoing communication and feedback between the private sector laboratory and the state NBS program is essential to assuring compliance and program improvement.

2. Serving the Family from Birth to the Medical Home: Newborn Screening: A Blueprint for the Future, Report of the American Academy of Pediatrics Newborn Screening Task Force, 106 Pediatrics 389, 409-410, 2000.
3. Health News, 39 (10) pp12-19, 1962, Newsletter of the New York State Department of Health.

D. References

1. Task Force Report on The Public Health Laboratory – A Critical National Resource, 29 January 1993, Members of Task Force ASTPHLD Dr George Anderson (MI), Dr Arthur DiSalvo (NV), Dr William Hausler, Chair (IA) Consultants Dr John Little (NCEH, CDC, USPHS), Dr Joseph McDade (CID, CDC, USPHS), Dr Eric Sampson (NCEH, CDC, USPHS).

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

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