



STATE OF MICHIGAN
DEPARTMENT OF COMMUNITY HEALTH
LANSING

RICK SNYDER
GOVERNOR

OLGA DAZZO
DIRECTOR

September 28, 2011

SUBJECT: Important change in the Newborn Screening Panel

Dear Laboratory Director:

Beginning October 1, 2011, the conditions screened for in the Newborn Screening panel will include severe combined immunodeficiency (SCID) and other primary immunodeficiency disorders.

SCID represents a group of more than a dozen inherited disorders that lack functional T-cells and B-cells responsible for cellular and humoral immunity, respectively. The usual treatment for SCID is hematopoietic stem cell transplantation.

This testing will be performed by real time quantitative PCR for T-cell receptor excision circles (TREC). T-cell receptor excision circles assay was developed and its performance characteristics determined by MDCH. The assay is based on previous work by Dr. Jennifer Puck and on pilot studies in Wisconsin and Massachusetts (1-3). It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary if performance characteristics are verified at the testing laboratory.

Newborn Screening Laboratory reports will provide SCID screening results as normal or very low level of TREC copy numbers. Those infants that screen positive for SCID will be referred to a primary immunodeficiency referral center.

For questions or comments on this important change, please contact the Newborn Screening program at (517) 335-9205.

Sincerely,

Kevin Cavanagh, PhD
Division Director, Chemistry & Toxicology
Bureau of Laboratories

References:

- 1) Chan K and Puck JM. "Development of population-based newborn screening for severe combined immunodeficiency." *J Allergy Clin Immunol.* 2005; 115 (2): 391-8.
- 2) Baker MW, Grossman WJ, Laessig RH, Hoffman GL, Brokopp CD, Kurtycz DF, Cogley, MF, Litsheim TJ, Katcher, ML, Routes, JM. "Development of a routine newborn screening protocol for severe combined immunodeficiency." *J. Allergy Clin Immunol.* 2009; 124(3): 522-527.
- 3) Gerstel-Thompson JL, Wilkey JF, Baptiste JC, Navas JS, Pai SY, Pass KA, Eaton RB, Comeau AM. "High-throughput multiplexed T-cell-receptor excision circle quantitative PCR assay with internal controls for detection of severe combined immunodeficiency in population-based newborn screening." *Clin Chem.* 2010; 56 (9): 1466-7.