Lawsuit settlement allows newborn screening program to move forward

MDH begins destroying archived blood spots, test results to comply with Supreme Court ruling

The Minnesota Department of Health (MDH) has settled the lawsuit over its storage and use of newborn screening residual dried blood spots and test results. As a result of the case being settled, the district court order to preserve these blood spots and test results has been lifted and the department has begun destroying approximately 1.1 million archived blood spots and test results as required by a Minnesota Supreme Court ruling. These blood spots and test results were all collected prior to the November 16, 2011 Supreme Court decision and have been held in storage under court order since that time.

MDH and its newborn screening partners will now operate the newborn screening program in accordance with the Minnesota Supreme Court ruling and the subsequent 2012 legislative changes to the Minnesota laws governing the program. Under the revised statute, MDH holds blood spots that have all negative test results for 71 days from the date the spots are received by MDH; blood spots that have a positive or abnormal test result are kept for two years from the date they were received by MDH to allow for follow-up testing and services; all blood spot test results are held for two years, to comply with federal requirements, and then destroyed, unless parental consent to retain them is obtained; blood spots may be retained for longer than the 71 days or two years if parental consent to retain them is received.

The department reached a settlement with 21 families who had filed suit alleging the program’s collection, use, storage, and dissemination of residual dried blood spots and test results without written, parental consent violated the Minnesota State Genetic Information Act of 2006. First begun in 2009, the lawsuit was initially dismissed in
district court and the dismissal was upheld on appeal. However, on Nov. 16, 2011, the Minnesota Supreme Court ruled that the use of the blood spots and/or test results for anything other than the initial screening was not explicitly authorized in statute. In 2012, the Minnesota Legislature changed the statutory language to explicitly authorize short-term storage and the use of blood spots and test results for program operations, but written, informed consent is required for long-term storage and use of blood spots or test results.

The Supreme Court sent part of the lawsuit back to district court to see if there should be any remedies for the plaintiffs. That part of the lawsuit was settled recently with an agreement between the parties. Under the terms of the agreement, MDH has returned the minor plaintiffs' blood spots and, within 120 days, will destroy the minor plaintiffs' test results. MDH also agreed to pay a portion of the plaintiffs' attorneys' fees. The court made no determinations or awards, and has dismissed the case.

“With the lawsuit behind us, we will now be able to devote our resources to operating and advancing the newborn screening program to ensure a healthy start in life for Minnesota babies,” said Minnesota Commissioner of Health Dr. Ed Ehlinger. “Newborn screening is an important public health program serving all Minnesotans.” Since 1965, more than 5,000 Minnesota infants were found to have rare medical disorders through newborn screening and were able to receive early treatment that prevented serious complications or death.

The Legislature has asked MDH to report on options for future retention periods for dried blood spots and test results. This report will address the current retention periods as well as options for future storage and use of the dried blood spots and test results.

-MDH-

*Media inquiries:*

Doug Schultz MDH Communications 651-201-4993