



MLS: Laboratory Update Outdated Newborn Screening Cards

March 8, 2011

Purpose of this Message:

To make the laboratory community aware that many of the newborn screening cards still in circulation expired at the end of February, 2011 and to provide a mechanism to exchange the old cards for new.

Background

The FDA has designated newborn screening cards as Type II medical devices. As such, they require expiration dates. Many of the newborn screening cards still in circulation expired on the last day of February 2011. Blood collected on those cards on or after March 1st will not be accepted for analysis.

How to Exchange the Cards

All laboratories are encouraged to review their stock of cards on hand. Please pay special attention to cards that may be in outpatient labs, satellite sites, and those “hidden” away for emergencies. Any expired cards can be exchanged by returning them to MDH-PHL. Along with the cards please send a completed version of the Purchase/Replacement Request form; you will find the address on the form. Form is available on the Newborn Screening website at:

<http://www.health.state.mn.us/newbornscreening/cardordering.html>

The potential for expired cards may require some changes in your policies. Staff members who enter demographic information on cards and those who collect newborn screening specimens will need to verify the expiration date before using the card. The expiration date is printed on the upper right hand corner of the cards with an hourglass symbol next to it.

Questions?

Any questions about expired cards can be directed to the Newborn Screening Program at 1-800-664-7772 or 651-201-5466 or health.newbornscreening@state.mn.us

Thanks to all the laboratory staff statewide who have already completed this switchover.

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****Please forward this to all appropriate personnel within your institution and Health System****

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