



RICK SNYDER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF HEALTH AND HUMAN SERVICES
LANSING

NICK LYON
DIRECTOR

**IMPORTANT ADVISORY
FOR NEWBORN SCREENING SPECIMEN SUBMITTERS and COORDINATORS
Regarding Cystic Fibrosis Newborn Screening**

This letter is official notification of a voluntary recall by Hologic, the manufacturer of the InPlex® ASR card- a component of the molecular test used by our laboratory as a 2nd tier test for cystic fibrosis (CF) on newborn dried blood spot specimens.

Hologic's recall, issued March 31, 2016, was initiated in response to nine complaints of false positive HET mutations (heterozygous, 1 mutation, cases) and two technical performance complaints (leaking). The company believes the issues are related to a manufacturing defect at a key component supplier.

As a reminder, the initial CF newborn screen uses an immunoreactive trypsinogen (IRT) assay. In our laboratory, specimens with elevated IRT are then screened for 40 CF gene mutations. The recall involves only this 2nd tier of testing; and is being conducted to verify the positive result.

In response to this recall, the 2nd tier of CF screening has been temporarily suspended in our laboratory. Until we can resume 2nd tier testing with a new assay, we have made arrangements to send all specimens received since March 28, 2016 that have elevated IRT results to another laboratory for confirmation using a different method that analyzes **60** CF gene mutations. This may result in a minor delay in the reporting of results for the DNA portion of the CF newborn screening test.

Our laboratory is taking steps to identify all specimens screened using the recalled Hologic kits since July, 2015. All specimens with a positive CF screen (one or two mutations identified) will be retested using the original stored blood spot card. The retesting process may take 3-6 months until a final report is issued. **For infants originally reported with a positive CF screen**, Michigan CF Center directors are being instructed to ensure their patients have received appropriate confirmatory testing while we prepare to retest the samples. Primary care providers are being instructed to inform parents of infants identified as carriers that their stored specimen will be retested to confirm the presence of one mutation. A revised report of the results for all patients receiving confirmatory testing will be posted on the Michigan Care Improvement Registry (MCIR) in approximately 4 weeks indicating DNA validation is pending. At this time there is no evidence to suggest an increased risk of a false negative result using the recalled product.

We are working to resolve these issues as quickly as possible and are in the process of acquiring an appropriate replacement for the Hologic test in order to resume 2nd tier CF screening in our laboratory. We will follow all regulations and perform our validation testing as quickly as possible, but anticipate it will take at least three months to fully validate the new system.

We will keep all relevant partners informed, and notify you in the event any additional information becomes available about this recall that alters our response. Please contact the Newborn Screening Program with any questions at newbornscreening@michigan.gov or 1-866-673-9939.