

NEWBORN SCREENING NEWSLETTER APRIL 4, 2016



CFTR Screening Temporarily Suspended

The Ohio Department of Health was notified on Friday (April 1) that Hologic was recalling the CF InPlex ASR Card and the InPlex CF Molecular Test Kit (IVD) effective immediately. The company is no longer going to produce the InPlex cards and kits. This is the kit currently validated and used by the Ohio Newborn Screening (NBS) Laboratory to identify CFTR mutations.

According to the recall notice, false positive CFTR results are possible when using the cards and kits of the recalled lots. We are currently reviewing data of previously reported newborn screening specimens that reported out CFTR positive results. If any of these specimens were tested using the recalled lots, CFTR results may be invalid and should be retested. Primary care physician will be notified of babies in their care who may need further assessment.

As of Friday, April 1, 2016 the Ohio Newborn Screening program suspended CFTR analysis. The state laboratory continues to perform IRT screening and identification of samples for which confirmatory testing is required. The laboratory is exploring other options for providing CFTR analysis. Our goal is to bring a new CFTR assay on-line within two months.

We would like the input of the Cystic Fibrosis Centers on what would be the best option for CF screening until a new CFTR assay is in place. Below are the options that we are considering.

- The NBS laboratory may be able to send specimens with elevated IRT to an outside lab for CFTR analysis. This would delay the reporting of screening results for all specimens with an elevated IRT by a week or more. We are currently exploring laboratories that could do Ohio's CFTR mutational analysis. It is not clear how quickly this option can be made available; it may take several weeks.
- The NBS laboratory can report out specimens with elevated IRT as "pending CFTR" and complete the mutation analysis once the new assay is in place. This would delay reporting of the CF screening results by up to two months, but would not delay other screening results.
- The NBS laboratory can adopt an IRT/IRT screening model where only IRT is measured on specimens and a repeat screen at 7 to 10 days is requested if the IRT is elevated on the initial sample. Babies with elevated IRTs on two consecutive screens would be considered to be at risk for CF.

We respect that all of you are very busy and do not have time for another meeting. We are hoping that a discussion of these issues will be possible using a listserv format. Please respond by email to all recipients with any questions or comments. Feel free to forward this to anyone you feel should be included. Our goal is to have a plan in place by Wednesday. We appreciate your input in choosing the best plan for Ohio's babies.

Bureau of Public Health Laboratory
8995 East Main St, Bldg 22, Reynoldsburg, OH 43068
Phone: 1-888-ODH-LABS; 614-466-2278
Email: odhlabs@odh.ohio.gov
<http://www.odh.ohio.gov/odhPrograms/phl/newbrn/nbrn1.aspx>