



# OHIO DEPARTMENT OF HEALTH

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John R. Kasich/Governor

Richard Hodges/Director of Health

April 11, 2016

From: Ohio Department of Health Laboratory  
To: Primary Care Providers

RE: Ohio Department of Health Laboratory Temporary Suspension of CFTR Testing

The Ohio Department of Health was notified on April 1, 2016 that the kit used for mutation analysis of the CFTR gene that causes cystic fibrosis (CF) was recalled by the manufacturer. The manufacturer will no longer produce CFTR kits, and no other company has a similar product that can be immediately used in its place. The Ohio Newborn Screening (NBS) Program has suspended CFTR mutation analysis until a solution can be found. All other analytes in the newborn screen are unaffected by this recall and will be reported out as usual.

According to the recall notice, false positive CFTR results are possible when using the recalled kits. We are in the process of identifying newborn screening specimens that had CFTR testing performed using the lot of recalled kits. The CFTR results for these babies may be inaccurate. Primary care physicians will be notified of babies in their care who may need further assessment. We are working with the Ohio Cystic Fibrosis Treatment Centers to determine the best course of action for follow-up of identified babies.

Ohio has been screening for CF since 2006. The screening for CF has consisted of two separate tests. The first test measures the level of immunoreactive trypsinogen (IRT) in the blood. IRT is a pancreatic enzyme precursor. An elevation in IRT can be the first sign of the pancreatic insufficiency associated with CF. IRT can also be benignly elevated in healthy babies who do not have CF. In order to better determine babies at risk of CF, Ohio performs CFTR mutation analysis on the newborn screens that have an IRT results above the 96th percentile. Only babies that have CFTR mutations identified or significantly elevated IRT levels are considered to be at risk for having cystic fibrosis.

For the time being, CFTR mutation testing will not be performed by the NBS laboratory. The lab will continue to perform IRT screening and identify babies that have elevated IRT values. ***A repeat newborn screen will be requested for babies with elevated IRT levels.*** If the IRT is still elevated on the repeat screen, a consultation with a CF Treatment Center will be recommended. The NBS laboratory is exploring options for providing CFTR analysis in the near future either at the state lab or through another laboratory. All newborn screens reported with elevated IRT will have CFTR mutation testing as soon as it is available and the newborn screening report will be reissued with updated results.

To put this in perspective, each week the NBS laboratory receives approximately 3,000 newborn screening specimens. The majority of newborn screens will have normal IRT values and will be reported as usual. Around 120 screens each week will have an elevated IRT value. For the time being, CFTR mutation analysis will not be performed on these 120 specimens. The newborn screening results will report as "Inconclusive" for IRT, and a repeat screen will be requested. If the IRT on the repeat screen is also elevated, then consultation with a CF Center will be recommended.

Please contact the Newborn Screening Program if you have any questions.

Regards,

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