



## DEPARTMENT OF HEALTH

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Laboratories Administration  
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### MEMORANDUM

Date: June 22, 2026

To: All providers of Newborn Screening specimens

From: M. Christine Dorley Ph.D., Newborn Screening Chief, Laboratories Administration

Through: Robert A. Myers, Ph.D., Director, Laboratories Administration *R.A.M.*

Subject: **Newborn Screening for Cystic Fibrosis**

We are pleased to announce that starting with specimens received on Monday, June 15, 2026, we transitioned testing for Cystic Fibrosis using immunoreactive trypsinogen (IRT) to the automated Genetic Screening Processor (GSP) platform. We will continue to report on IRT by category (Within Normal Limits, Borderline, or Abnormal) based on our cutoffs in combination with CFDNA results and/or an expanded CFTR variant panel. Newborn specimens will be evaluated against a percentile cutoff (**95<sup>th</sup> percentile**) while subsequent specimens will be evaluated against a fixed cutoff (**50 ng/mL**).

#### Additional information:

1. False negatives can be caused by exposure to heat and humidity plus long transport times, therefore please expedite transport to the newborn screening laboratory.
2. Meconium ileus can cause a false negative on this assay; therefore, it is imperative that infants with meconium ileus have a sweat test in light of an IRT result that is WNL.
3. Non-CF neonatal hypertrypsinemia, low APGAR scores, significant hypoxia and acute illness can cause an elevated IRT for some infants. False positives are also seen in some African American infants and some CF carriers.

We are excited about this change and appreciate your patience as we continue to make improvements. We anticipate our migration of congenital adrenal hyperplasia to the GSP shortly. For questions or inquiries, please contact the MDH NBS Laboratory at 443-681-3900 or by email at [mdphl.nbs@maryland.gov](mailto:mdphl.nbs@maryland.gov). For inquiries about the interpretation of results please contact the MDH NBS Follow-up Unit at 443-681-3916 or by email at: [mdh.newbornscreeningfollowup@maryland.gov](mailto:mdh.newbornscreeningfollowup@maryland.gov).