



## Department of Health

ANDREW M. CUOMO  
Governor

HOWARD A. ZUCKER, M.D., J.D.  
Commissioner

SALLY DRESLIN, M.S., R.N.  
Executive Deputy Commissioner

July 1, 2019

Re: Changes to the New York State Newborn Screening Program's Cystic Fibrosis Algorithm

Dear Health Care Provider,

Please be advised that beginning on July 1, 2019, specimens with elevated immunoreactive trypsinogen (IRT; top 5%), will be tested for Cystic Fibrosis (CF) variants using a new second-tier panel. The new custom NYS VariantPlex *CFTR* panel manufactured by ArcherDx uses next generation sequencing (NGS) technology to detect 338 clinically-relevant *CFTR* gene variants, compared to the current Luminex xTAG CF39v2 panel, which detects 39 *CFTR* variants. All variants on the Luminex panel are also targeted by the Archer panel. The custom Archer panel has the capability to interrogate the entire *CFTR* gene using a bioinformatics approach, and therefore the current Illumina MiSeqDx Cystic Fibrosis Clinical Sequencing Assay will also be discontinued.

Overall, the CF algorithm has not changed. Infants with two clinically-relevant *CFTR* variants will continue to be referred to CF Specialty Care Centers for diagnostic sweat testing, and those with a single variant will be reported as CF carriers. Infants with no variants detected will be released as screen negative. The protocol for management of newborns with CF has not changed.

Due to space limitations, newborn screening reports will no longer list all variants screened, but these can be found online at the following link under **Cystic Fibrosis, Newborn Screening, Second-tier Screening**:

<https://www.wadsworth.org/programs/newborn/screening/screened-disorders>

Thank you for your cooperation in making New York State's Newborn Screening Program the best it can be. Questions can be directed to our main telephone number (518) 473-7552.

Sincerely,

Michele Caggana, Sc.D., FACMG  
Director, Newborn Screening Program