



MEMORANDUM

DATE: November 12, 2025

TO: South Carolina Newborn Screening (SC NBS) Community

FROM: Jenny Meredith, Ph.D., HCLD(ABB) *JM*
SC DPH Public Health Laboratory (PHL) Director

SUBJECT: SC NBS Program's Updated Immunoreactive Trypsinogen (IRT) Expected Range

Effective November 19, 2025, the SC NBS Laboratory is updating the IRT expected range. IRT is the 1st tier marker used to screen newborns for Cystic Fibrosis (CF); when a specimen has an IRT result that exceeds the expected range, it is reflexed to a targeted CF DNA mutation panel.

The current IRT expected range is based on a daily floating cut-off, representative of the top 4% of the daily batch of patient IRT results. The new IRT expected range will keep the daily floating cut-off but will also include a fixed low cut-off of 50 ng/mL, which will be applied when the daily floating cut-off is above 50 ng/mL. See **Table 1** for a summary of the current and new IRT expected ranges.

Table 1. Current and New IRT Expected Ranges

Current IRT Expected Range	New IRT Expected Range
< 96 th percentile of the daily IRT patient values	< 96 th percentile or < 50 ng/mL [†]
	[†] The IRT Expected Range is a daily floating cutoff of less than the 96 th percentile of daily patient IRT concentrations or less than 50 ng/mL, whichever is the lowest concentration.

This change is part of the SC NBS Program's commitment to continuous improvement.

Please direct any questions to Beth Bair, M.S., Ph.D., Newborn Screening Section Director at bairea@dph.sc.gov; 803-896-0991.