Newborn Screening and Molecular Biology Branch

Centers for Disease Control and Prevention (CDC)
Newborn Screening Quality Assurance Program
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Reference Material Product Information Sheet

Reference Material: Immunoreactive Trypsinogen

Product ID: IRTQC-09

Expiration Date: September 2025

Product Description and Intended Use: Dried blood spot (DBS) materials prepared to mimic newborn DBS specimens. Materials are provided at three or more levels and are intended to be used as secondary quality control (QC) materials for newborn screening tests. These specimens are not intended to replace primary QC materials including kit QC. The reference values listed below do not represent the target values for the respective analytes. They are based on control limit calculations from a minimum of 20 runs. Minimum sample size is to be determined by the user based on assay specifications.

Analysis Method: Revvity GSP Neonatal

Material Storage: -20°C ± 10°C

Units: ng/mL blood

Lot	Analyte	Assayed Value	95% LL	95% UL
A2309	Immunoreactive Trypsinogen (IRT)	16.4	13.8	19.0
B2309	Immunoreactive Trypsinogen (IRT)	64.8	58.0	71.5
C2309	Immunoreactive Trypsinogen (IRT)	134.6	121.8	147.5
D2309	Immunoreactive Trypsinogen (IRT)	229.1	196.3	261.8

Period of Validity: This material is valid until the expiration date indicated above, within the uncertainty specified, provided the material is handled and stored in accordance with the instructions stated on this product information sheet. The validity of the material is nullified if the material is damaged, contaminated, otherwise modified, or used in a manner for which it was not intended.

Health and Safety: See Quality Control Assaying and Reporting Instructions provided at https://www.cdc.gov/newborn-screening/media/pdfs/2024/05/QC-Analysis-Instructions-Q1.pdf.

Authorized by: Joanne Mei, PhD, Lab Chief

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Version 2