

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: 17 α -Hydroxyprogesterone + Total Galactose

Product ID: 17OHP/TGAL QC-05

Expiration Date: September 2026

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: 17OHP: Revvity GSP 17OHP Kit
TGAL: Revvity Neonatal Total Galactose Kit


Material Storage: $-20^{\circ}\text{C} \pm 10^{\circ}\text{C}$

Units: 17OHP: ng/mL serum
TGAL: mg/dL blood

Lot	Analyte	Enrichment	Mean Value	95%LL	95%UL
A2405	17 α -Hydroxyprogesterone (17OHP)	25	24.9	20.0	29.8
A2405	Total Galactose (TGal)	5	6.1	5.3	6.9
B2405	17 α -Hydroxyprogesterone (17OHP)	50	48.1	41.0	55.1
B2405	Total Galactose (TGal)	10	11.3	9.3	13.3
C2405	17 α -Hydroxyprogesterone (17OHP)	100	94.5	76.7	112.4
C2405	Total Galactose (TGal)	30	28.0	24.5	31.5

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>.

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