GCAL® NEPH

GCAL® NEPH Calprotectin on the Siemens Healthineers BN™ II and BN ProSpec® Systems

For Research Use Only (ROU). Not for use in diagnostic procedures. The RUO kits cannot be used to compare the quality of the Gentian assay to other assays without our approval.

Principle of the Procedure

The GCAL® NEPH Immunoassay is an immunonephelometric assay intended for the *in vitro* quantitative determination of calprotectin in human lithium heparin plasma and serum samples.

The GCAL® NEPH Immunoassay is a particle-enhanced nephelometric immunoassay (PENIA). The lithium heparin plasma or serum sample is mixed with GCAL® NEPH immunoparticles. Calprotectin from the sample and the anti-calprotectin antibodies from the immunoparticles solution bind to form aggregates that increase the turbidity of the solution. The degree of turbidity is proportional to the concentration of calprotectin, which can be quantified via an established standard calibration curve.

Hazards Identification

Hazard pictograms (CLP): GHS07

Signal word (CLP): Warning
Contains: 2-methylisothiazol-3(2H)-one
Hazard statements (CLP):
H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H319 - Causes serious eye irritation.
Precautionary statements (CLP):
P280 - Wear eye protection, protective gloves, protective clothing.
P302+P352 - IF ON SKIN: Wash with plenty of soap and water.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313 - If eye irritation persists: Get medical advice/attention.
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.

To obtain the SDS (safety data sheet), please contact local distributor.

Warnings and Precautions

1. Contains substances from human or animal origin and should be considered as potentially infectious material. Handle with caution and discard following local regulations.
2. Reagents containing MOPS/Tween (R1) and EDTA (R2) can be irritating to eyes, respiratory tract and skin. Handle with due caution and do not ingest.
3. R1 contains avian proteins. Handle with due caution to avoid allergic skin reaction.

Additional Handling Instructions

1. This test is for *in vitro* use only and must be handled by qualified personnel.
2. Use only validated and approved instrument applications.
3. Do not use products after the expiration date has passed.
4. Do not mix reagents of different lots or interchange caps of reagents, controls, calibrators, and lots.
5. Tighten caps carefully back on after use of reagents, calibrators, and controls to avoid evaporation.

Storage instructions

All products provided for the GCAL® NEPH Immunoassay must be stored at 2-8°C. The expiry date is printed on the labels.

Procedure

Reagent Preparation

The reagents are ready for use. Mix the reagents gently before placing them into the assigned reagent positions. The reagent bottles fit directly into the instrument rack.

Assay Kit Components

Products available	
GCAL® NEPH Calprotectin • R1 Supplement (2.0 mL) • 3 x R2 Reagent (1.9 mL)	SMN 10873788 (REF 1701-RUO)
GCAL® NEPH Calibrator (3 x 0.6 mL)	SMN 10873789 (REF 1712-RUO)
GCAL® NEPH Controls (2 levels, each 3 x 1.1 mL)	SMN 10873787 (REF 1719-RUO)
N Diluent (Siemens Healthineers)	REF OUMT65
BN II Evaporation Stoppers (optional) (Siemens Healthineers)	REF OVLE21
BN™ II System or BN ProSpec® System (Siemens Healthineers)	

All GCAL® NEPH products are ready for use.

Calibration Curve Establishment

The calibration curve is created from a dilution series that is automatically prepared by the instrument. Calibrator values are lot specific, and calibration must be performed whenever a new lot is used. The values assigned to the calibrators are provided in the analytical value sheet. A new calibration should be performed according to the calibration curve stability or when a new reagent lot is used.

QC Controls

The GCAL® NEPH Controls should be assayed every day that the test is in use to validate the calibration curve. The controls have lot specific concentration ranges that must be met before measuring samples. The assigned value ranges are given in the analytical value sheet. If the control values measured are not valid, repeat the control measurements. Recalibrate if necessary.

Control and Calibrator Value Assignment

The control and calibrator values are given in the analytical value sheet.

Measuring Samples

When a valid calibration curve has been established and the control values are within the valid range, the lithium heparin plasma or serum sample may be measured. Ensure that the minimum sample volume is present in the sample cups/tubes and assay the samples according to the instructions given in the instrument manual.

Application Notes

Contact marketing@gentian.com for application notes describing the procedures for installation and analysis on specific instruments. For instructions on how to install a new application, consult the instrument manual. Maintenance, operation, and precautions must be handled in accordance with the specific instrument manual.

Results

The results are calculated automatically by the instrument . The results are presented in mg/L.

Gentian AS

Bjornasveien 5
N-1596 Moss
Norway
TEL: +47 99 33 99 05
www.gentian.com
marketing@gentian.com

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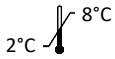
Modification from the Previous Version

First version.

Symbols Key

	Temperature Limit
	Use by Date
	Consult Instructions for Use
	Manufacturer
RUO	Research Use Only
LOT	Lot Number
REF	Catalogue Number
CONTENTS	Contents
R1	R1 Assay Buffer
R2	R2 Immunoparticles
CONTROL L	Control Low
CONTROL H	Control High
CAL	Calibrator
	Warning