GCAL® NEPH

GCAL® NEPH Calibrator on the Siemens Healthineers BN™ II, Atellica® NEPH 630 and BN ProSpec® Systems

SMN 10873735

For *in vitro* diagnostic use by laboratory professionals.

This document describes the general use of the product above. For instrument specific settings, please refer to the application notes available upon request to marketing@gentian.com.

Intended purpose

The GCAL® NEPH Immunoassay is an immunonephelometric assay intended for the *in vitro* quantitative determination of calprotectin, a neutrophilic protein that is a marker of inflammation, in human lithium heparin plasma and serum samples. The GCAL® NEPH Immunoassay is intended for use on automated clinical analysers by laboratory professional users. Used in conjunction with other laboratory findings and clinical assessments, GCAL® NEPH is intended to be used as an aid in detection and assessment of inflammation and inflammatory response to infections.

Calibrator kit indication for use

The GCAL® NEPH Calibrator is intended to be used to establish a calibration curve for measuring calprotectin concentration in human lithium heparin plasma and serum samples with the GCAL® NEPH Immunoassay.

Calibrator value assignment

The calibrator value, given in the analytical value sheet, is assigned according to Gentian's value transfer protocol based on published methods [1]. For lot specific concentrations, please consult the analytical value sheet available on www.gentian.com.

Calibrator standardisation

No international standard is available for calprotectin. Therefore, traceability is established according to section 5.6 in ISO 17511 [2] where the highest metrological entry level is the manufacturer's selected measurement procedure. The calibrator is traceable to a highly pure recombinant Calprotectin solution, value assigned by total protein determination by UV_{280} and known extinction coefficient. A working calibrator of the pure recombinant material in calibrator matrix is used with the manufacturer's standing measurement procedures to assign value to the product calibrators via a published value transfer protocol [1].

Assay kit components

Products provided	
GCAL® NEPH Calibrator (3 x 0.6 mL)	SMN 10873735 (REF 1712)
Other available products (not included)	
GCAL® NEPH Controls (2 levels, each 3 x 1.1 mL)	SMN 10873736 (REF 1719)
GCAL® NEPH Calprotectin • R1 Supplement (2.0 mL) • 3 x R2 Reagent (1.9 mL)	SMN 10873737 (REF 1701)

All products are ready for use.

Composition

The GCAL® NEPH Calibrator consists of protein enriched HEPES buffer spiked with human calprotectin of native origin. ProClin® 950 is used as preservation. For lot specific concentrations, please consult the analytical value sheet.

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 or Gentian at marketing@gentian.com.

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. Exposure may result in irritation of skin and eyes.
3. Avoid contact with incompatible materials.
4. Avoid exposure to heat and direct sunlight.

Additional handling instructions

1. This test is for *in vitro* use only and must be handled by laboratory professionals.
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.

Reagent storage and stability

All products provided for the GCAL® NEPH Immunoassay must be stored at 2-8 °C. The expiry date is printed on the labels. Using an BN™ II, the in-use stability of the GCAL® NEPH Calibrator was found to be at least 12 weeks performed as an open vial study (at 2-8 °C), and the calibration curve stability 4 weeks in a study based on the CLSI guideline EP25 [3].

Procedure

Establishment of the calibration curve

The GCAL® NEPH Calibrator is used to establish standard curve as defined in the instrument manual. The calibrator is ready to use. Calibrator values are lot specific, and calibration must be performed whenever a new lot is used. The values assigned to the calibrator is provided in the analytical value sheet available on www.gentian.com. 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 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 available on www.gentian.com. If the control values measured are not valid, repeat the control measurements. Recalibrate if necessary. If the calibration cannot be performed without error, or valid control values cannot be reproduced, contact the local distributor for support.

Symbols key

2°C 8°C	Temperature limit
	Use by date
	Consult instructions for use
	Manufacturer
CE 0123	CE mark with Notified Body number
UK CA	UKCA mark for UK
CH REP	Swiss authorised representative
IVD	*In Vitro* Diagnostic medical device
LOT	Lot number
REF	Catalogue number
UDI	Unique Device Identifier
CONTENTS	Contents
CAL	Calibrator
	Warning

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References

1. Blirup Jensen et al., Clin Chem Lab Med 2008;46(10):1470–1479
2. EN ISO 17511:2021 In vitro diagnostic medical devices — Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples. (ISO 17511:2020)
3. CLSI. Evaluation of stability of in vitro Diagnostic Reagents; Approved Guideline. CSLI document EP25-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2009

Serious incidents

Please notify the manufacturer and your competent authority if any serious incidents have occurred in relation to the device.

Modification from previous version

- Added number of the Notified Body to CE mark.
- Added UKCA mark.
- Added chapter “Representatives.
- Added reference 2 and 3.
- Added point 2-4 in Warning and Precautions
- Minor editorial changes and corrections throughout the document.

Date of issue

2023-03-01