Cystatin C

Gentian Cystatin C Calibrator

REF 1012

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 Gentian Cystatin C Immunoassay is an immunoturbidimetric assay intended for the *in vitro* quantitative determination of cystatin C in human serum and plasma on automated clinical analysers by laboratory professional users. The measurement of cystatin C is used in the diagnosis and treatment of renal diseases.

Calibrator (single) indication for use

The Gentian Cystatin C Calibrator is intended to be used to establish a calibration curve for measuring cystatin C concentration in human plasma and serum samples with the Gentian Cystatin C Immunoassay.

Calibrator value assignment

The calibrator value, given in the analytical value sheet, is assigned according to Gentian's value transfer protocol as recommended in ISO 17511 [1] for calibrators and controls. For lot specific concentrations, please consult the analytical value sheet available on www.gentian.com.

Calibrator standardisation

The Gentian Cystatin C Calibrator is standardised against the international calibrator standard ERM-DA471/IFCC.

Assay kit components

Products provided	
Gentian Cystatin C Calibrator (1 x 1 mL)	REF 1012
Products required, but not provided	
Gentian Cystatin C Control Kit (2 levels x 1 mL), or Gentian Cystatin C Control Kit (2 levels x 5 mL)	REF 1019 REF 1026
Gentian Cystatin C Reagent Kit • R1 Assay Buffer (58 mL) • R2 Immunoparticles (10 mL)	REF 1101

All products are ready for use.

Composition

The Gentian Cystatin C Calibrator consists of delipidated human serum pools spiked with human cystatin C. Antibiotics are used as preservation. For lot specific concentrations, please consult the analytical value sheet available on www.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. The sodium azide concentration of the assay is not characterised as hazardous. Although, accumulated NaN_3 in lead and copper pipes may cause generation of explosive metal azides. To prevent this, rinse thoroughly if discarded into the drain.
3. Contains a sensitizing substance below concentration limit. May produce an allergic reaction in some people and may cause respiratory irritation if inhaled.
4. Contains antibiotics and must be handled with due caution.
5. Exposure may result in irritation of skin and eyes.
6. Avoid contact with incompatible materials.
7. Avoid exposure to heat and direct sunlight.

To obtain the SDS (Safety Data Sheet), please contact Gentian at marketing@gentian.com.

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 Gentian Cystatin C Immunoassay must be stored at 2-8 °C. The expiry date is printed on the labels. The in-use stability of the Gentian Cystatin C Calibrator was found to be at least 26 weeks performed as an open vial study (at 2-8 °C) based on CLSI guideline EP25 [2]. For calibration curve stability, please refer to the instrument specific application notes.

Procedure

Application notes

Applications of the Gentian Cystatin C Immunoassay have been established on several clinical chemistry analysers. Detailed, validated application notes describing the procedures for installation and analysis on specific instruments are available upon request from marketing@gentian.com. 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.

Establishment of the calibration curve

The calibration curve is established from a dilution series automatically prepared by the instrument, as defined in the Application Note and the instrument manual. A multi-point standard calibration curve is established over the points achieved from the dilution series. 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 instrument specific calibration curve stability or when a new reagent lot is used.

QC controls

Gentian Cystatin C Controls must be tested each day before any samples are measured in order 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.

Cystatin C

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
CH REP	Swiss authorized representative
IVD	*In Vitro* Diagnostic medical device
LOT	Lot number
REF	Catalogue number
UDI	Unique Device Identifier
CONTENTS	Contents
CAL	Calibrator

Gentian AS

CE 0123 UK CA

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

Representatives

UK Responsible Person	Emergo Consulting (UK) Limited c/o Cr360 – UL International Compass House, Vision Park Histon Cambridge CB24 9BZ United Kingdom
CH REP	MedEnvoy Switzerland Gotthardstrasse 28 6302 Zug Switzerland

References

1. 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).
2. 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.

Modifications from previous version

- Added number of the Notified Body to CE mark
- Added UKCA mark
- Added chapter “Representatives”
- Minor editorial changes and corrections throughout the document

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