Cystatin C

Gentian Cystatin C Calibrator Kit on Beckman Coulter® AU, IMMAGE , Synchron and UniCel Systems

REF A52763

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 instructions for use available on www.gentian.com or 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 kit indication for use

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

Assay kit components

Products provided:	BCI REF	Gentian REF
Gentian Cystatin C Calibrator Kit (6 levels x 1 mL)	A52763	1051
Products required, but not provided for use on Synchron and UniCel:		
Gentian Cystatin C Reagent Kit	A52761	1100
Gentian Cystatin C Control Kit (2 levels x 1 mL)	A52765	1019
Items required, but not provided for use on Synchron and UniCel:		
User-Defined Reagent Cartridge (pkg. of 12)	442835	Not applicable
Products required, but not provided for use on AU system:		
Gentian Cystatin C Reagent Kit	B08179	1103
Gentian Cystatin C Control Kit (2 levels x 1 mL)	A52765	1019
Products required, but not provided for use on IMMAGE system:		
Gentian Cystatin C Reagent Kit	A52761	1100
Gentian Cystatin C Control Kit (2 levels x 1 mL)	A52765	1019
Items required, but not provided for use on IMMAGE system:		
User-Defined Reagent Cartridge (pkg. of 10)	447250	Not applicable
Evaporation Caps (pkg. of 20)	447170	Not applicable

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

For additional safety information, please refer to the SDS (Safety Data Sheet) available on www.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 Kit was found to be at least 26 weeks performed as an open vial study (at 2-8 °C) based on CLSI guideline EP25 [2].

Procedure

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 calibrator levels 1 to 6 are used to establish a 6-point standard curve as defined in the instrument manual. The calibrators are ready to use, do not program dilution. Calibrator values are lot specific, and calibration must be performed whenever a new lot is used. The values assigned to the calibrator kit are provided in the analytical value sheet available on www.gentian.com. The calibration curve stability was found to be at least 4 weeks on DxC 700 AU instrument in a study based on the CLSI guideline EP25 [2]. Synchron and UniCel systems requires calibration every 2 weeks.

QC controls

The Gentian Cystatin C Control Kit 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.

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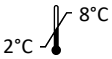
Additional information

For more detailed information on AU, IMMAGE, Synchron and UniCel Systems, refer to the appropriate system manual. As Beckman Coulter® does not manufacture the reagent or perform quality control or other tests on individual lots, Beckman Coulter® cannot be responsible for the quality of the data obtained which is caused by performance of the reagent, any variation between lots of reagent, or protocol changes by the manufacturer.

Shipping damage

Please notify your distributor if this product is received damaged. For technical assistance please contact your local distributor.

Symbols key

	Temperature limit
	Use by date
	Consult instructions for use
	Manufacturer
	CE mark with Notified Body number
	UKCA mark
	Swiss authorized representative
	*In Vitro* Diagnostic medical device
	Lot number
	Catalogue number
	Unique Device Identifier
	Contents
	Calibrator
	Calibrator level 1
	Calibrator level 2
	Calibrator level 3
	Calibrator level 4
	Calibrator level 5
	Calibrator level 6

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

Modifications from previous version

- Included information about the SDS available on the Gentian website.

Date of issue

2023-12-07

For other languages visit:
https://www.gentian.com/clinical-diagnostic-products/beckman-coulter-customers-cystatin-c