

# Cystatin C

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

REF A52765

This document describes the general use of the product above and is applicable for USA only. For instrument specific settings, please refer to the package inserts available on [www.gentian.com](http://www.gentian.com) or upon request to [marketing@gentian.com](mailto:marketing@gentian.com).

### Intended use

The Gentian Cystatin C Immunoassay is an *in-vitro* diagnostic test for quantitative determination of cystatin C in human serum and plasma. The measurement of cystatin C is used in the diagnosis and treatment of renal diseases.

### Control kit indication for use

The Gentian Cystatin C Controls are intended to be used to evaluate the quality of the calibration curve established from Gentian Cystatin C Calibrator with the Gentian Cystatin C Immunoassay.

### Principles of the procedure

Human serum or plasma sample is mixed with cystatin C immunoparticles. Cystatin C from the sample aggregates with anti-cystatin C antibodies from the immunoparticles solution. The complex particles created absorb light, and by turbidimetry the absorption is related to cystatin C concentration via interpolation on an established standard calibration curve

### Composition

The Gentian Cystatin C Calibrator is a delipidated human serum pool spiked with human cystatin C. Antibiotics are used as preservation.

### Warnings and precautions

For *in vitro* diagnostic use by laboratory professionals.

Caution: Federal law restricts this device to sale by or on the order of a physician.

1. Contains substances from human or animal origin and should be considered as potentially infectious material. Serum used in Gentian Cystatin C Controls and calibrators is tested for hepatitis HBsAG, anti-HCV, anti-HIV1 and anti-HIV2 and found to be negative. Handle with caution and discard following local regulations.
2. Contains antibiotics and must be handled with due caution.
3. The sodium azide concentration of the assay is not characterized as hazardous. Although, accumulated NaN<sub>3</sub> in lead and copper pipes may cause generation of explosive metal azides. To prevent this, rinse thoroughly if discarded into the drain.
4. Exposure may result in irritation of skin and eyes.
5. Avoid contact with incompatible materials.
6. Avoid exposure to heat and direct sunlight.

To obtain the SDS (Safety Data Sheet), please refer to the SDS (Safety Data Sheet) available on [www.gentian.com](http://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.

### Directions for reconstitution/dilution

The product is ready to use.

### Storage instructions

Store at 2-8 °C. Do not use past the expiration date stated on the label.

### 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.

### Reagent preparation

For instrument setup information, consult the Gentian Cystatin C Immunoassay Package Insert specific to the instrument as well as the instrument manual. Reagents are supplied ready to use, mix gently before loading into instrument. The reagent bottles may fit directly into the instrument unless otherwise stated on the package insert.

### Assay kit components

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

All products are ready for use.

### Control value assignment

The control values, given in the analytical value sheet, are assigned according to Gentian's value transfer protocol as recommended in ISO 17511 [1] for calibrators and controls. For lot specific concentrations, please refer to the Analytical Value Sheet (AVS) available on [www.gentian.com](http://www.gentian.com).

### Calibrator standardization

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

### QC controls

The Gentian Cystatin C controls low and high must be assayed each day before any samples are assayed in order to validate the calibration curve. The controls have an assigned value range that must be met before measuring samples. The assigned values are given in the Analytical Value Sheet (AVS) available on [www.gentian.com](http://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 local distributor.

### Bibliography

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.



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### Date of issue

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### Additional information

For more detailed information on AU, IMAGE, 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.

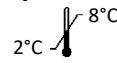













### Shipping damage

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

### Serious incidents

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

### Symbols key

	Temperature limit
	Use by date
	Consult instructions for use
	Manufacturer
	CE mark with Notified Body number
	UKCA mark
	<i>In Vitro</i> Diagnostic medical device
	Lot number
	Catalogue number
	Unique Device Identifier
	Contents
	Control Low
	Control High
	Caution: Federal law restricts this device to sale by or on the order of a physician.