Cystatin C

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

REF A52763

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 or upon request to 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.

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 serum or plasma 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 NaN3 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.

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

All materials are ready for use.

Calibrator value assignment

The calibrator 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.

Calibrator standardization

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

Calibration curve establishment

Use the standards 1 to 6 to establish a 6-point standard curve as defined in the Beckman Coulter® AU, Immage, Synchron and UniCel Systems Instrument Manuals. Calibrator values are lot dependent, and a new calibration must be performed whenever a new calibration lot is used. The calibrator's assigned values are given in the Analytical Value Sheet (AVS) 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 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. 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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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 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

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
IVD	*In Vitro* Diagnostic medical device
LOT	Lot number
REF	Catalogue number
UDI	Unique Device Identifier
CONTENTS	Contents
CAL	Calibrator
CAL 1	Calibrator level 1
CAL 2	Calibrator level 2
CAL 3	Calibrator level 3
CAL 4	Calibrator level 4
CAL 5	Calibrator level 5
CAL 6	Calibrator level 6
RxOnly	Caution: Federal law restricts this device to sale by or on the order of a physician.