

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

REF A52765

### 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 Kit with the Gentian Cystatin C Immunoassay.

### Reagent Information

#### Composition

The Gentian Cystatin C Control Kit is made from a delipidated human serum pool spiked with human cystatin C. Antibiotics are used as preservative. The controls are ready to use.

#### Control Value Assignment

The control values, given in the enclosed analytical value sheet, are assigned according to Gentian's value transfer protocol as recommended in ISO 17511 [1] for calibrators and controls. The controls comprise of human cystatin C.

#### Calibrator Standardisation

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

Items provided:	
Gentian Cystatin C Control Kit, 2 vials of 1 mL	REF A52765
Additional items required for use on DxC system:	
Gentian Cystatin C Reagent Kit	REF A52761
Gentian Cystatin C Calibrator Kit, 6 vials of 1 mL	REF A52763
User-Defined Reagent Cartridge (pkg. of 12)	REF 442835
Additional items required for use on AU system:	
Gentian Cystatin C Reagent Kit for AU systems	REF B08179
Gentian Cystatin C Calibrator Kit, 6 vials of 1 mL	REF A52763
Additional items required for use on IMMAGE system:	
Gentian Cystatin C Reagent Kit	REF A52761
Gentian Cystatin C Calibrator Kit, 6 vials of 1 mL	REF A52763
User-Defined Reagent Cartridge (pkg. of 10)	REF 447250
Evaporation Caps (pkg. of 20)	REF 447170

### Storage

Shelf life of unopened reagents at 2 - 8°C: See expiry date on the label.  
Stability after opening: 6 months at 2 - 8°C.

### QC Controls

The low and high controls must be assayed each day before any sample is assayed in order to validate the calibration curve. If the control values are not valid, repeat the control measurements. If the calibration cannot be performed without error, or valid control values cannot be reproduced, contact Beckman Coulter® for support.

### Warnings and Precautions

1. The Gentian Cystatin C Control Kit is for *in vitro* use only, and must be handled by qualified personnel.
2. The Gentian Cystatin C Control Kit contains antibiotics and must be handled with due cautions.

3. Serum used in the manufacturing of the Gentian Cystatin C Control Kit is tested for hepatitis HBsAG, anti-HCV, anti-HIV1 and anti-HIV2 and found to be negative. Nevertheless, the materials contain substances of human origin and must be handled with due care. Disposal of any discarded materials should be in accordance to local requirements.

### Additional Information

For more detailed information on AU, IMMAGE, Synchron and UniCel Systems, refer to the appropriate system manual. Since 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.

For other languages visit:

<https://www.gentian.com/clinical-diagnostic-products/beckman-coulter-customers-cystatin-c>

### Symbols Key

	Lot number
	Temperature limit
	Use by date
	Consult instructions for use
	Manufacturer
	Catalogue number
	In vitro diagnostic medical device
	Caution
	Biological risks

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### Bibliography

[1] ISO 17511; In Vitro Diagnostic Medical Devices - Measurement of Quantities in Biological Samples - Metrological Traceability of Values Assigned to Calibrators and Control Materials. First edition 2003-08-15