Cystatin C

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.

<table>
<thead>
<tr>
<th>Items provided:</th>
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<tbody>
<tr>
<td>Gentian Cystatin C Control Kit, 2 vials of 1 mL</td>
<td>REF A52765</td>
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<table>
<thead>
<tr>
<th>Additional items required for use on DxC system:</th>
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<tbody>
<tr>
<td>Gentian Cystatin C Reagent Kit</td>
</tr>
<tr>
<td>Gentian Cystatin C Calibrator Kit, 6 vials of 1 mL</td>
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<tr>
<td>User-Defined Reagent Cartridge (pkg. of 12)</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Additional items required for use on AU system:</th>
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<tbody>
<tr>
<td>Gentian Cystatin C Reagent Kit for AU systems</td>
</tr>
<tr>
<td>Gentian Cystatin C Calibrator Kit, 6 vials of 1 mL</td>
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</tbody>
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<tr>
<th>Additional items required for use on IMMAGE system:</th>
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<tr>
<td>Gentian Cystatin C Reagent Kit</td>
</tr>
<tr>
<td>Gentian Cystatin C Calibrator Kit, 6 vials of 1 mL</td>
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<tr>
<td>User-Defined Reagent Cartridge (pkg. of 10)</td>
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<tr>
<td>Evaporation Caps (pkg. of 20)</td>
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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-custmers-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