Cystatin C

Gentian Cystatin C Control High

REF 1021

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 High 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.

Calibrator Value and Standardisation

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

Assay Reagents

Materials provided:	
Cystatin C Control High, 1ml	REF 1021
Materials required but not provided	
Gentian Cystatin C Control kit (2 levels), 1 ml	REF 1019
Gentian Cystatin C Reagent kit , 58 ml + 10 ml	REF 1101
Gentian Cystatin C Calibrator kit, 6 levels x 1 ml	REF 1051
Gentian Cystatin C Calibrator, 1 ml	REF 1012

All materials are ready for use

Composition

The Gentian Cystatin C controls are delipidated human serum pools spiked with human cystatin C. Antibiotics are used as preservation. The controls are ready to use.

Warnings and Precautions

1. This test is for *in vitro* use only and must be handled by qualified personnel.
2. Reagents contain antibiotics and must be handled with due caution.
3. The immunoparticles, calibrators and controls contain potentially infectious substances of animal and human origin and should be handled with due caution. Disposal of any discarded materials should be in accordance to local requirements.
4. Use only instrument applications approved by Gentian AS.
5. Reagents containing sodium azide must be handled with due caution: Do not ingest or allow contact to skin or mucous membranes. The sodium azide concentration of this product is not characterised as dangerous. 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.
6. Reagents containing MOPS can be irritating to eye and skin. Handle with due caution.
7. Do not mix reagents of different reagent lots or switch caps between reagents.
8. Avoid evaporation of controls and calibrators.
9. Do not use reagents after expiry date.

Reagent Storage and Stability

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

Procedure

Application Notes

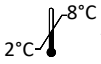
Methods for the Gentian Cystatin C Immunoassay are established on multiple clinical chemistry analysers. Detailed, validated Application Notes describing the procedures for installation and analysing on specific instruments are available at: www.gentian.com.

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 included with the Gentian Cystatin C Control Kit. 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 Gentian for support.

Symbols Key

Lot number



Temperature limit


Use by date


Consult instructions for use


Manufacturer

Catalogue number

In vitro diagnostic medical device


Gentian AS

CE

Bjornasveien 5, N-1596 Moss, Norway
TEL: +47 99 33 99 05
http://www.gentian.com

Shipping Damage

Please notify your local distributor if the product received is damaged.

References

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