Cystatin C

Gentian Cystatin C Control Kit

REF 1019

This document describes the general use of the product above and is applicable for USA only. For instrument specific settings, please refer to the application notes available upon request from 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 and Immunoparticles.

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 Controls are manufactured from 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

Methods for the Gentian Cystatin C Immunoassay are established on multiple clinical chemistry analyzers. Detailed, validated Application Notes describing the procedures for installation and analyzing on specific instruments are available upon request from marketing@gentian.com.

Reagent preparation

For instrument setup information, consult the Gentian Cystatin C Immunoassay Application Note 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 application notes.

Assay kit components

Materials provided	
Cystatin C Control Low, 1 mL	REF 1020
Cystatin C Control High, 1 mL	REF 1021
Materials required, but not provided	
Gentian Cystatin C Reagent kit (58 mL + 10 mL)	REF 1101
Gentian Cystatin C Calibrator, 1 mL	REF 1012

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.

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. 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.

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)

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

Symbols key

2°C 8°C	Temperature limit
	Use by date
	Consult instructions for use
	Manufacturer
CE 0123	CE mark with Notified Body number
UKCA	UKCA mark
IVD	*In Vitro* Diagnostic medical device
LOT	Lot number
REF	Catalogue number
UDI	Unique Device Identifier
CONTENTS	Contents
CONTROL L	Control Low
CONTROL H	Control High
RxOnly	Caution: Federal law restricts this device to sale by or on the order of a physician.