CYSTATIN C
Multi Purpose (MPR)
Liquid Reagent

Glenbio
Diagnostics & Research Laboratory Solutions

KIT SPECIFICATIONS:

Cat. No.	*Quantity*	*Reagent*	*Storage*
GL1103CC	1 x 100 ml	Reagent 1	2 – 8 °C
	1 x 20 ml	Reagent 2	

INTENDED USE:

In Vitro Diagnostic reagent pack for the quantitative determination of Cystatin C in serum and plasma on automated and semi-automated analysers.

SUMMARY AND EXPLANATION:

Cystatin C is a basic proteinase inhibitor with a low molecular mass of 13Kda that is produced at a constant rate in all nucleated cells and appears in human plasma and serum. Cystatin C is freely filtered through the glomerulus, is not secreted by the tubule or eliminated via any extra-renal route, and is almost completely absorbed and catabolized by proximal tubular cells. Therefore, the plasma concentration of Cystatin C is almost exclusively determined by the glomerular filtration rate (GFR), making Cystatin C an excellent indicator of GFR. Cystatin C has advantages over routine clinical measures of renal function. It is more accurate than plasma creatinine and the Cockcroft-Gault estimation of creatinine clearance and is more reliable than the 24-h creatinine clearance. There is a growing body of evidence that suggests that Cystatin C can be used to detect kidney disease at earlier stages than serum creatinine which may help facilitate prevention efforts in the elderly and those with diabetes, hypertension or cardiovascular disease.

PRINCIPLE OF THE TEST:

Glenbio Cystatin C is based on the reactions between Cystatin C and latex covalently bound antibodies against human Cystatin C. Cystatin C values are determined turbidimetrically using fixed- time measurement with sample blank correction. The relationship between absorbance and concentration permits a multipoint calibration with a measuring range of between 0 to 10 mg/L. The measuring temperature is 37ºC. The assay can be performed on all instruments allowing turbidimetric measurements at 500 to 600nm.

WARNINGS AND PRECAUTION

Components Colour and Appearance:
Reagent 1: Slightly Yellow Liquid
Reagent 2: White Liquid

Any significant changes could indicate that the assay might be compromised. Refer to Laboratory's QC program for actions to be taken. In case of serious damage to the bottle and/or cap, resulting in product leakage and/or contamination, do not use the reagent pack and contact your distributor.

Safety precautions:
This product is not hazardous under EU specifications. Contains <1% Sodium Azide. Material Safety Data Sheet is available upon request.

Handling precautions:
- Take the necessary precautions required for handling all laboratory reagents.
- Reagents containing Sodium azide must be handled with precaution. Sodium azide can form explosive azides with lead and copper plumbing.
- Do not ingest
- Avoid contact with skin and eyes.
- Do not use components past the expiry date stated on the Bottles.
- Do not Freeze Reagents.
- Do not use components for any purpose other than described in the "Intended Use" section.
- Do not interchange caps among components as contamination may occur and compromise test results.
- Refer to local legal requirements for safe waste disposal.

INSTRUMENTS:

Instrument applications are available upon request.

COMPONENT COMPOSITION:

Component	*Ingredients*
Reagent 1- Buffer	30ml of Tris Buffer solution (pH7.2), containing detergents, polyethleneglycol and 0.09% sodium azide as perservative
Reagent 2- Latex Reagent	5.1ml of Polystyrene particles (0.5%) coated with antibodies anti-human Cystatin C serum in a glycine buffer (0.1M, pH8.2) containing NaCL (0.15M) and bovine serum albumin (0.5%), preservative : sodium azide 0.075%

REAGENT PREPARATION AND STABILITY:

Reagent 1: Is supplied ready to use
Reagent 2: Is supplied ready to use
R2 should be shaken gently before each use to ensure a homogenous suspension.
The assay range is established from 0 to 10mg/L. Manually dilute samples having higher concentration with 0.9% NaCL. Multiple the result by the appropriate factor.

Cystatin C assay reagents should be stored at 2-8°C.
DO NOT FREEZE.
If stored and handled properly, unopened component is stable up to the expiry date stated on the label.
Do not mix reagents of different lots.

TYPE OF SPECIMEN:

Fresh or deep frozen serum can be used. Cystatin C remain stable for 12 days at +2 to +8ºC. If the test should be performed later, it is recommended to freeze the serum. Avoid successive freezing and thawing. Discard haemolysed or contaminated samples.

It is recommended to follow CLSI procedures (or similar standardised conditions) regarding specimen handling. Specimen should be collected in an appropriate sampling container, with proper specimen identification. Serum/Plasma should be separated from cells within 2 hours after collection.

TEST PROCEDURE:

Materials required but not supplied:

Description	*Catlog No*	*Description*	*Catlog No*
Cystantin C Control Set	GL9103	Photometer	N/A
Cystatin C Calibrator (5 Levels)	GL9706	General Laboratory Equipment	N/A

Assay procedure:

Wavelength: 1 : 550nm
Temperature: 37°C
Optical path: 1 cm light path

	Blank	**Calibrator**	**Sample**
Reagent 1	1000 µl	1000 µl	1000 µl
Sample	----	----	12 µl
Calibrator	----	12 µl	----
Gently mix and Incubate at 37°C for 1 minute			
Reagent 2	200 µl	200 µl	200 µl
Gently mix and immediately measure the change of optical density per minute. Measure the Optical Density (ΔOD/min) over the next 5 minutes			

Calibration:
Cystatin C calibrators are provided separately and ready for use. For automated analysers, use the recommended calibrator and calibrate the assay. The calibration curve is stable for up to 14 days after which a new curve must be generated. Recalibrate when:
- When using a new reagent kit or changing lot number.
- Following preventive maintenance or replacement of a critical part of the photometer used.
- When Quality Control results are out of range.

Quality Control:
All clinical laboratories should establish an Internal Quality Control program. Verify instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program:
Controls should be assayed:
- Prior to reporting patient results.
- Following any maintenance procedure.
- At intervals established by the laboratory Q.C. programme.

CALCULATION:

The Turbidimetric analysers automatically calculate the Cystatin C concentration of each sample.
Conversion mg/L = µg/ml

EXPECTED VALUES:

The reference interval is 0.59 – 1.03 mg/L are considered within the normal range.
Each laboratory should establish its own reference range. Results should always be reviewed with the patient's medical examination and history.

PERFORMANCE CHARACTERISTICS:

Performance results can vary with the instrument used. Data obtained in each individual laboratory may differ from these values.

Linearity:
Linearity was evaluated using serial dilutions, prepared with saline solution, of three pooled samples, which contained values of Cystatin C in the range of analysis ranging from 0.05 to 8mg/L. Linear regression values of Cystatin C mg/L vs concentration yielded correlation coefficients , r>0.999, for all samples. Within the assays measuring range, the deviations of measurement from theoretical values did not exceed the 10% level. In addition, the system did not show prozone phenomenon at least up to 16mg/L.

Interfering substances:
Results of study are as follows:

Bilirubin: Less than 10% interference up to 18 mg/dL
Haemoglobin: Less than 10% interference up to 5g/L

Precision:
The precision of Glenbio Cystatin C Assay was determined as follows:

Within Run N = 80	Mean *(mg/l)*	*% CV*	*Between Run N = 80*	Mean *(mg/l)*	*% CV*
Level 1	0.86	0.70	Level 1	0.86	1.54
Level 2	5	1.22	Level 2	5	3.37

Accuracy:
Various concentrations of Cystatin C (0.5 – 8.0mg/L) were added to 43 different serum samples. The linear regression gives correlation of r^2 value of 0.98, slope of 0.97 and Y intercept of 0.05.

Method Comparison:
Analytical characteristics have been obtained in a single experiment in a Cobras-Mira plus analyser. As is well known the analytical characteristics of a clinical chemistry reagent depend on both the reagents and instrument used. Multicenter studies indicate important differences in analytical characteristics among similar instruments. Therefore, the data expressed in the present document should be interpreted as a guide example.

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SYMBOLS:

The following symbols are used in the labelling of Glenbio Ltd. systems:

IVD	In Vitro Diagnostics	REF	Catalogue No
LOT	Batch Code	CONT	Content
REAG	Reagent	Ab	Antibody
CAL	Calibrator	SUBS	Substrate
BUF	Buffer	STD	Aqueous Standard
	Storage temperature	CE	CE Mark - Device complies with the Directives 98/79/EC
→	Reconstitute with		
	Expiry Date (Last day of the month)		Manufactured By
	Biological risk		Consult Instruction for Use

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