Pariksha Biotech
A game changer in IVD

Cystatin-C Estimation Kit

High-Q Cystatin-C

Latex Enhanced Turbidimetric Immuno Assay (LETIA)

HIGH Q
Command on Quality

Intended use :
Cystatin C (CysC) diagnostic reagent is used for quantitative in vitro determination of Cystatin C in human serum on photometric systems.

Clinical significance:
Cystatin C is a low molecular weight (13 kDa) cytoplasmic protein, functioning as an inhibitor of various cystein proteases in the bloodstream. Cystatin C has a stable production rate and is removed from the blood circulation by glomerular filtration. In healthy individuals Cystatin C is completely reabsorbed and degraded in the tubules but in subjects with renal disorders its level in blood may be raised as high as 2 to 5 times normal values. Unlike creatinine, Cystatin C is unaffected by inflammatory processes, sex, age, diet, and nutritional status. Numerous studies have shown that serum Cystatin C is superior to serum creatinine as a marker of GFR.

Principle:
Cystatin C in the test sample binds to the specific polyclonal rabbit anti- Cystatin C antibody, which has been adsorbed to Colloidal Gold particles and agglutinates. The agglutination is detected as absorbance change when read on an automated clinical chemistry analyzer. The magnitude of the change is proportional to the quantity of Cystatin C in the test sample. Cystatin C concentration is then determined by interpolation from a calibration curve prepared from calibrators of known concentrations.

Kit components:

Composition

R1Tris buffer (pH =7.2)

R2Turbi Latex particles coated with polyclonal anti- Cystatin C antibodies (rabbit)

Cystatin C Reagents and Stability:
Reagents are stable up to the expiry date mentioned on the labels. Onboard stability of the reagents is 30 days.

Cystatin C Calibrators:

High Q Cystatin C Calibrators are available as ready to use liquid stable 6 Level Calibrators and are stable till the expiry date mentioned on the labels

Specimen preparation

1. Unhemolyzed Fresh Human serum is the specimen
2. After sampling, the test should be performed without delay. If the test cannot be performed immediately, the sample should be placed in a tightly sealed container and stored at -20C or below. Once the sample has been thawed it should not be refrozen.
3. For serum samples, after the blood has clotted thoroughly, the sample should be centrifuged to allow the serum to be separated from blood cells and fibrin.

Assay Procedure:

System Parameters:

Calibration Method	**Multi Point -Linear- Spline**
Reaction Type (Mode)	Fixed Time /Two Point
Reaction Direction	Increasing
Wave Length	546 nm
Flow Cell Temp.	37°C
Delay Time	5 Seconds
Measuring Time	120 Seconds
Blank	Distilled Water Blank
Reagent Volume	320 µl (R1) + 80 µl (R2)
Sample Volume)	5 µl
Calibrator Concentrations	(On the Vials Lot Specific)
Linearity	10 mg/L

Procedure

Reagent	**Calibrator**	**Sample/Control**
Cystatin-C R1	**320 µl**	**320 µl**
Calibrator(1,2,3,4,5,6)	**5 µl**	**----**
Sample	**—**	**5 µl**
Cystatin-C R2	**80 µl**	**80 µl**

1) Read absorbance A1 after 5 Seconds. (Delay)
2) Incubate and Read the absorbance A2 after 120 Seconds (Measuring)
3) Calculate the absorbance differences ΔA=A2–A1 for each point of the calibration curve, controls and all unknown samples.
4) The concentration of Cystatin-C in the unknown sample can be calculated from ΔA=A2–A1
5) Using a 3rd order polynomial mathematical model where abscissa (X) is the ΔA=A2–A1 and ordinate (Y) is the concentration of Cystatin-C or plotting the values of ΔA=A2–A1 obtained for every concentration level of the calibrator against the Cystatin-C concentration and interpolating the individual ΔA=A2–A1 of every sample in the calibration curve.

Calculations with Calibrators/ Calibration Curve/ Result Interpretation:

Calculation:
The concentration of Cystatin-C in unknown samples is derived from a calibration curve using an appropriate mathematical models such as Multi Point / Linear/Spline. The calibration curve is obtained with 6 calibrators at different levels. Stability of calibration: 4 weeks

Reference Range:
0.56-1.25 mg/L
It is recommended that each laboratory should establish its own reference interval.

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Quality control:
High-Q Cys-C Controls are recommended for daily quality control. The control intervals and limits should be adapted to each laboratory's individual requirements.Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits

Calibration:
The assay requires the use of a Cystatin C calibrator. Recalibration is recommended at anytime if one of the following events occurs:
- The Lot number of reagents changes.
- Preventative maintenance is performed or a critical component is replaced.
- Control values have shifted or are out of range and a new vial of control does not rectify the problem.

Performance characteristics :
Measuring range:
0.2 mg/L – 10.0 mg/L
Samples above this concentration should be diluted 1+1 with 0.9% NaCl solution and the result multiplied by 2.

Automation:
Special adaptations for automatic analyzers can be made on request.

References:

1. Filler G, Bökenkamp A, Hofmann W, Le Bricon T, Martinéz-Brú C, Grubb A. Cystatin C as a marker of GFR - history, indications, and future research. Clin. Biochem. 38: 1, 2005.

2. Dharnidharka VR, Kwon C, Stevens G. Serum cystatin C is superior to serum creatinine as a marker of kidney function: a meta-analysis. Am J Kidney Dis. 40, 221, 2002.

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Ordering Information

Ref./Cat. No.	Pack Size	Presentation
P-CYC-25	25 ml	Two Liquid Reagents with Calibrator

Product Features

- Latex Enhanced Turbidimetric Immuno Assay (LETIA)
- Liquid Stable Two Reagents
- 6 level Calibrators provided
- 2 Level Controls provided (Optional)
- Measuring wavelength 546 nms
- 2 Minutes test procedure (5 Sec + 120 Sec)
- Linearity: 0.2 mg/L – 10.0 mg/L
- Adaptable to Semi and Fully auto analyzers

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Symbols used with IVD devices

	Date of manufacture		Manufactured by
IVD	In vitro diagnostic medical device		Keep away from sunlight
	Do not freeze		This way up
	Use-by date		Do not use if package is damaged
	Keep dry	LOT	Batch Code
	Consult instructions for use	R	Reagent
eIFU Indicator	Consult electronic instructions for use	CAL	Calibrator Material
REF	Catalogue number		
	Caution		

eIFU Indicator

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SCAN TO EXPLORE MORE

Manufactured in India by :
Pariksha Biotech Pvt Ltd,
Plot no.1/B-14, SVICE,
Balanagar,
Hyderabad-500037
Telangana State

+91 7075706709
info@parikshabio.com
www.parikshabio.com

AN ISO 13485 Certified Company

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