Spectrum For Diagnostic Industries

CYSTATIN-C (4+1)

IVD

Immunoturbidimetry

REF.	Pack size
395 01 020	100 tests R1 Buffer Reagent 2 x 20 ml R2 Latex 1 X 7.8 ml

Intended Use

Cystatin-C reagent is intended for Quantitative turbidimetric determination of Cystatin-C in human serum.

Background

Cystatin C is a nonglycosilated 13-kDa basic protein belonging to the cystatin super-family of cysteine proteinase inhibitors. Cystatin C is produced by virtually all nucleated cells, and is present in all investigated body fluids. The production rate is constant and unaffected by inflammatory processes, sex, age, diet and nutritional status. In the normal kidney, cystatin C is freely filtrated through the glomerular membrane of the nephron and then nearly completely reabsorbed and degradated by the proximal tubular cells. Therefore, Cystatin C concentration in plasma is regulated by the glomerular filtration rate (GFR) and is thus considered an excellent measure of GFR. Research has shown that monitoring Cystatin C levels in blood may lead to diagnosis of acute renal failure 24 to 48 hours earlier than by measuring creatinine .

Assay Principle

This Cystatin C test is based upon 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 between 0 and 10 mg/L. The measuring temperature is 37ºC. The assay can be performed on all instruments allowing turbidimetric measurements at 500 to 600 nm.

Reagent

Buffer (R1)
TRIS buffer, pH: 9,2, containing detergents, polyethyleneglycol
Sodium azide 0.9 %

Latex Reagent (R2)
Latex particles (0.5%) coated with antibodies anti-human-Cystatin C serum in a glycine buffer (0.1 M, pH: 8.2), containing NaCL (0.15 M) and bovine serum albumin (0.5%).
Sodium azide 0.075 %

Cystatin -C Calibrator(A) : Calibrator 6

Calibrator Preparation

Prepare serial dilution of the Calibrator (A) With saline (B) as diuents as follows :
Cal 6 : Calibrator A
Cal 5 : 250 µl Calibrator 6 (A) + 250 µl Saline (B)
Cal 4 : 250 µl Cal 5 + 250 µl Saline (B)
Cal 3 : 250 µl Cal 4 + 250 µl Saline (B)
Cal 2 : 250 µl Cal 3 + 250 µl Saline (B)
Cal 1 : Saline (B) : Zero

Reagent Preparation, Storage and Stability

Cystatin C reagents are stable up to the expiry date labeled on the bottles when stored at 2 - 8ºC and contaminations are prevented during their use.

Immediately following the completion of an assay run, the reagent vials should be capped until next use in order to maximize curve stability.

Once opened the reagent can be used within 1 month if stored tightly closed at 2 - 8ºC after use.

Deterioration

Do not use the Cystatin C reagents if presence of particles and turbidity.
Do not freeze; frozen Antibody or diluent could change the functionality of the test.
The Cystatin C latex reagent should have a white, turbid appearance free of granular particulate. Visible agglutination or precipitation may be a sign of deterioration, and the reagent should be discarded.

Precautions

For in vitro diagnostic use only. Do not pipette by mouth. Reagents containing sodium azide must be handled with precaution. Sodium azide can form explosive azides with lead and copper plumbing. Since absence of infectious agents cannot be proven, all specimens and reagents obtained from human blood should always be handled with precaution using established good laboratory practices.

Specimen Collection and Preparation

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

Procedure

Wavelength	550 nm
Temperature	37ºC
Cuvette	1cm light path
Zero adjustment	distilled water

Bring the reagents at 37ºC and pipette:

	Calibrator	Sample
Reagent (R1)	400 µl	400 µl
Reagent (R2)	100 µl	100 µl
Mix and incubate for 1 minute.		
Calibrator	5 µl	-----
Sample	-----	5 µl

After addition of sample or calibrator record 1st reading (A1) immediately.
Incubate at 37ºC and after 2 minutes record 2nd reading (A2)

Calculation

(using calibration curve)

Determine Δ absorbance of the sample and each calibrator as following:
Δ absorbance of sample = (A2 - A1) sample
Δ absorbance of each calibrator = (A2 - A1) for each calibrator
Plot the calibration curve and obtain the result.

Note: Adaptation sheets for several auto-analyzers are available upon request.

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

Calibration and Quality Control

The calibration curve is stored in memory by the analyzer and recalled for later use.

Calibration curves are stable for up to 14 days, after which a new curve must be generated. Additionally, recalibration must be performed whenever reagent lots are changed.

For quality control use Control or other suitable control material. The control intervals and limits must be adapted to the individual laboratory requirements. Values obtained should fall within established limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits. Control must be assayed and evaluated as for patient samples.

Expected Values

Up to 50 years of age : 0.55 -1.15 mg/L.
>50 years of age : 0.63 -1.44 mg/L.
Each laboratory should establish its own reference range.

Sensitivity

When run as recommended, the minimum detection limit of the assay is 0.05 mg/L.

Linearity

Up to 7.5 mg/L.
specimens showing higher concentration should be diluted using physiological saline and repeat the assay. Multiply the result by the appropriate factor.

Interfering Substances

Haemoglobin	up to 5 g/L.
Bilirubin	up to 18 mg/dL.

Dynamic Range

0.05 - 7.5 mg/L.

Waste Disposal

This product is made to be used in professional laboratories.
Please consult local regulations for a correct waste disposal.
S56: dispose of this material and its container at hazardous or special waste collection point.
S57: use appropriate container to avoid environmental contamination.
S61: avoid release in environment. refer to special instructions/safety data sheets.

References

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4. Michael G. Shlipak and al. Cystatin C and the risk of Death and cardiovascular events among elderly persons. NEJM 2005 volume 352:2049-2060.

5. David J Newman. Cystatin C. Ann Clin Biochem 2002; 39: 89 – 104.

6. Li Hai Xia, Xu Guo Bing and Xia Tie An. Serum Cystatin C assay for the detection of early renal impairment in diabetic patients. JCLA 2004; 18:31-35.

7. Young DS. Effects of Drugs on Clinical Laboratory Test. 5th Edition, AACC Press, 2000.

SYMBOLS IN PRODUCT LABELLING

IVD	For in-vitro diagnostic use
LOT	Batch Code/Lot number
REF	Catalogue Number
	Consult instructions for use
	Temperature Limitation
	Use by/Expiration Date
	CAUTION. Consult instructions for use
	Manufactured by

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