

CYSTATIN C

REF: L-9590T
B-9490T

For the quantitative determination of Cystatin C in human serum by immunoturbidimetry.

Diagnostic Relevance

Cystatin C is a nonglycosylated 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 degraded by the proximal tubular cells. Therefore, the plasma concentration of cystatin C is almost exclusively determined by the GFR (glomerular filtration rate), making cystatin C an excellent indicator of GFR. At the same time cystatin C is becoming acknowledged as a marker of elevated risk of death from cardiovascular complications – myocardial infarction and stroke.

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 37°C. The assay can be performed on all instruments allowing turbidimetric measurements at 500 to 600 nm.

Reagents

Buffer - TRIS buffer, pH: 7,2, containing PEG and < 0,1 % sodium azide as preservative..

Latex reagent - Polystyrene 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%). Preservative: Sodium azide < 0.1%.

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.

Disposal of all waste material should be in accordance with local guidelines.

As with other diagnostic tests, results should be interpreted considering all other test results and the clinical situation of the patient.

Materials required

Automatic analyzer. Saline solution. Calibrator. Controls.

Storage and Stability

Reagents are ready to use. Shake the latex reagent gently before dispensing its content into the appropriate plastic vials. Reagents in the original bottle are stable to the expiration date indicated on the label when capped and stored at +2...+8°C. Do not freeze.

The Cystatin C buffer reagent should be clear and colourless. Any turbidity may be sign of deterioration and reagent should be discarded.

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.

Specimens

Fresh or deep frozen serum. Cystatin C remain stable for 12 days at +2 to +8°C. 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

The reagents are ready to use as supplied. Latex reagent should be gently shaken (invert the recipient 3-4 times) before each use. Follow the instructions of the operator's manual to load the cartridge, technique programation, calibration, sample measurement and control

Volume R1/working reagent:	Volume R2/start reagent:	Volume sample:
250 µl	50 µl	3 µl
Step 1: mix R1 and R2, add sample and read 1st reading immediately after mixing.		
Step 2: 5 min after read 2nd reading.		
Wavelength: 550 nm	Incubation Time at 37° C: 5 min	

* Volume, time and wavelength are recommended. Adjust them depending of analyser features.

This reagent is intended to be used in clinical chemistry analysers. Adaptations for some of them are available.

Calibration. Quality Control

Standardization: use Biolatex Calibrator or other suitable calibrator material.

For quality control use Biolatex 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.

Calculation

The turbidimetric analysers automatically calculate the Cystatin C concentration of each sample. Conversion: mg/l = µg/ml.

Reference Values

Each laboratory should establish an expected range for the geographical area in which it is located.

Values 0.59 – 1.03 mg/L are considered within the normal range.

Automatic Analyzer

This product is performed for use it in turbidimetric automatic analysers.

Specific Performance Characteristics*

As is well known, the analytical characteristics of a clinical chemistry reagent depend on both the reagents and the instrument used. Multicenter studies indicate important differences in analytical characteristics among similar instruments. Therefore, this data must be calculated by each instrument.

(* Analytical characteristics obtained in a single experiment in a Cobas-Mira plus analyser could be provided under demand.

Literature

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