Cystatin C

Latex turbidimetry

CE

In Vitro Diagnostic reagent for the quantitative determination of Cystatin C in serum and plasma. Store at 2-8ºC .

REF: CYC-037B

Summary:

Cystatin C is a low molecular weight protein of 13Kda which is produced at a constant rate and is filtered through the glomerular filtration.
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 is more accurate than plasma creatinine and is more reliable than the 24-h creatinine clearance.
More and more studies suggest 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:

This test is based on the reaction 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.

Composition:

R1: Tris Buffer pH7.2 with protein stabilisers - 0.1M, Preservative
R2: Glycine Buffer pH8.2 - 0.1M, NaCl - 0.15M, BSA - 0.5%, anti-human Cystatin C antibody, Preservative

Precautions:

Components Colour and Appearance:
Reagent 1: Clear 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:

This assay is designed to run on clinical chemistry analysers. Refer to relevant user's manual or Laboratory internal practice for routine maintenance procedures. Instrument applications are available upon request.
All information is encoded in the barcode, where applicable. If analyser fails to read or if the barcode is damaged, enter the series of numbers beneath the barcode.

Preparation:

Reagent is ready to use.
Before use, mix reagent by gently inverting each bottle.
If stored and handled properly, component is stable until expiry date stated on the label.

Samples:

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 NCCLS 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.

Equipment:

- Cystatin C Control and Calibrator
- General Laboratory Equipment

Procedure:

1. Assay conditions:
Wavelength: . . . . . .550 nm
Cuvette: . . . . . .1 cm. light path
Temperature . . . . . .37°C

	Blank	Calibrator	Sample
R1 (µL)	1000	1000	1000
Sample (µL)	-	-	12
Calibrator (µL)	-	12	-
Gently mix and incubate at 37°C for 5 minutes			
R2 (µL)	250	250	250

2. Gently mix and Incubate at 37°C, measure the Optical Density (OD1) after 30 sec. Measure the Optical Density (OD2) after further 5 minutes.
3. 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 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.

Calculations:

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

Quality control:

All clinical laboratories should establish an Internal Quality Control program. Check 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 reporting patient results.
- Following any maintenance procedure on the photometer used.
- At pre-established intervals following the Q.C. Laboratory recommandations.

Reference 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:

	Intra-assay		Inter-assay	
N=80	Mean (mg/L)	%CV	Mean (mg/L)	%CV
level 1	0.86	0.70	0.86	1.54
level 2	5	1.22	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 r2 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.

References:

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