Cystatin C-turbilatex

Latex turbidimetry

Quantitative determination of Cystatin C (C-CYS)

CE

IVD

PACKAGING

Ref.: 101-0754	Cont.: 1 x 20 / 1 x 4 mL

Store 2 - 8º C.

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 tubular 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 [1, 2].

PRINCIPLE OF THE METHOD

The C-CYS is a quantitative turbidimetric test for the measurement of Cystatin C in serum or plasma.

Latex particles coated with polyclonal rabbit anti-Cystatin C antibodies are agglutinated when mixed with samples containing Cystatin C. The agglutination causes an absorbance change, dependent upon the C-CYS contents of the patient sample. Cystatin C concentration is then determined by interpolation from a calibration curve prepared from calibrators of known concentrations.

REAGENTS

Diluent (R1)	Tris buffer 20 mmol/L, pH 8.6.
Latex (R2)	Synthesized polystyrene latex particles coated with polyclonal anti- Cystatin C antibodies (rabbit)
Optional	C-CYS Calibrator Set C-CYS Control Set

PRECAUTIONS

Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2). However handle cautiously as potentially infectious.

CALIBRATION

Cys-C Calibrators sold separately from Spinreact should be used for calibration and 0.9 % NaCl shall be used for the zero calibrator (blank solution). It is recommended that each laboratory determine calibration frequency, as this would depend on the analyzer in use as well as the types and number of other assays being run. A new calibration curve should be drawn at least once a month or when a new lot of reagent is used.

PREPARATION

Reagents are ready for use. Do NOT shake the reagent bottles when set on analyzers.

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8º C and contaminations prevented during their use. Do not use reagents over the expiration date.

Once opened, reagents are stable on the analyzers for 30 days when refrigerated.

ADDITIONAL EQUIPMENT

- Thermostatic bath at 37º C.
- Spectrophotometer or photometer thermostatable at 37º C with a 546 nm filter.

SAMPLES

Human serum, EDTA-plasma and heparinized-plasma can be used for the assay. 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 -20° C or below. Once the sample has been thawed it should not be refrozen. 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.

PROCEDURE

Notes: CHRONOLAB SYSTEMS has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.

The assay should be conducted according to the specific application parameters for the automated chemistry analyzer in use.

Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

1. Incubate 3 µL sample with 230 µL R1 at 37° C for 5 minutes.
2. Add 50 µL R2.
3. Read absorbance change at 546 nm for 4 minutes, 30 seconds after the addition of R2.
4. Calculate Cystatin concentration with the read absorbance change by interpolation from a calibration curve prepared with calibrators of known concentrations.

QUALITY CONTROL

For quality control, use Cystatin Control set sold separately from Chronolab. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES

0.59 – 1.03 mg/L

It is recommended each laboratory establish its own reference intervals based on its patient population.

PERFORMANCE CHARACTERISTICS

1. **Detection limit:** Values less than 0.1 mg/L give non-reproducible results.
2. **Measurement range**: Up to 10 mg/L, under the described assay conditions. Samples with higher concentrations should be diluted 1/5 in NaCl (9 g/L) and retested again. The linearity limit and measurement range depends on the sample to reagent/ratio, as well as the analyzer used. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.
3. **Prozone effect:** No prozone effect was detected up to 60 mg/L.
4. **Precision:**

	Intra-assay (n=10)	
Mean (mg/L)	0.545	1.058
SD	0.010	0.009
CV	1.82	0.85

5. **Accuracy:** Results obtained using this reagent (y) was compared to those obtained using a commercial reagent (x) with similar characteristics. 100 samples ranging from 0.58 to 6.42 mg/L of C-CYS were assayed. The correlation coefficient (r) was 0.999 and the regression equation y=1.047x - 0.080.

The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

Hemoglobin (up to 500 mg/dL), conjugated and unconjugated bilirubin (up to 30 mg/dL), and Intralipid (up to 5%) do not interfere with Cystatin C determination of this test. Other substances may interfere.

BIBLIOGRAPHY

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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