Cat. No 4-500

DIAGNOSTIC KIT FOR DETERMINATION OF CYSTATIN C CONCENTRATION

HC – CYSTATIN C

INTRODUCTION
Cystatin C is a low molecular weight protein (13kD), one of the cysteine proteinases inhibitors. Cystatin C is produced in all nucleated cells and secreted into extracellular space at constant rate. Cystatin C molecule stability and dependence of its concentration solely on GFR (Glomerular Filtration Rate) decide about high diagnostic efficiency of cystatin C determination. Cystatin C level is not affected by muscle mass or diet and its increase is observed even at slight GFR reduction. Clinical applications of cystatin C are for monitoring GFR in children, elderly patients, patients with potentially nephrotoxic drug therapy, for assessment of renal transplantation status, for kidney function monitoring in acute and chronic kidney diseases including diabetic nephropathy.

METHOD PRINCIPLE
Turbidimetric method. An antigen-antibody reaction occurs between cystatin C and antibodies coated on polystyrene particles and immuno-complexes are formed. The change of turbidity is related to the quantity of cystatin C in the sample.The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of known concentration.

REAGENTS
Package

1-Reagent	1 x 47.7 ml
2-Reagent	1 x 8.7 ml

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. The reagents are stable for 9 weeks on board the analyser at 2-10°C. Protect from light and avoid contamination!

Concentrations in the test

suspension of polystyrene particles coated with anti-cystatin C antibodies	8.5 g/l
MOPS buffer [3-(N-morpholino)-propanesulfonic acid]	8 g/l
gentamycin	12.5 mg/l
amphotericin B	1.25 mg/l

Warnings and notes
- Product for in vitro diagnostic use only.
- The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.
- The reagents contain antibiotics and must be handled with due cautions.
- The reagents contain sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.

SPECIMEN
Serum or EDTA/heparinised plasma.
Sample stability testing showed that cystatin C in serum and plasma samples are stable for 14 days at room temperature (8-25ºC) and for 21 days if stored at 2-8ºC, otherwise store frozen at below -20ºC. Mix samples well before analysing. The samples can be shipped without special cooling and must then be analysed within 14 days after shipment.
Nevertheless it is recommended to perform the assay with freshly collected samples.

PROCEDURE
The reagents are ready to use.
These reagents may be used in automatic analyser Hitachi 911/912.
Application should be entered using handheld barcode scanner and attached barcodes sheet, according to procedure described below:
1. Delete previous version of application and calibrators assigned to it and restart the analyser.
2. Enter codes of calibrators according to the attached list.
3. Enter barcoded application and assign proper values to calibrators.
4. To activate entered application go to the tab UTILITY | APPLICATION | RANGE and change value of field DATA MODE from INACTIVE to ON BOARD. Confirm the change using UPDATE button.
5. Put reagents on board the analyser – they will be assigned to relevant tests automatically. Perform also measurement of level of reagents inside the bottles.
6. After calibration analyser is ready to use.

REFERENCE VALUES [8]

serum, plasma	mg/l
adults	0.5 – 1.2
children (0.2 – 18 yr)	0.7 – 1.4

It is recommended for each laboratory to establish its own reference ranges for local population. Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.

QUALITY CONTROL
For internal quality control it is recommended to use the CORMAY CYSTATIN C CONTROLS (Cat. No 4-460) with each batch of samples.
For the calibration of automatic analysers the CORMAY CYSTATIN C CALIBRATORS (Cat. No 5-185) is recommended. **Calibrators and 0.9% NaCl** should be used for calibration.
The calibration curve should be prepared every 9 weeks, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS
These metrological characteristics have been obtained using the automatic analysers Hitachi 912 and Modular P. Results may vary if a different instrument is used.

- **Sensitivity:** 0.37 mg/l.
- **Linearity:** up to 8.39 mg/l.
- **Specificity / Interferences**
  Haemoglobin up to 0.7 g/dl, bilirubin up to 800 mg/l, triglycerides up to 14 g/l and ascorbate up to 300 mg/l do not interfere with the test.
- **Precision**

Repeatability (run to run) n = 10	Mean [mg/l]	SD [mg/l]	CV [%]
level 1	1.13	0.01	1.05
level 2	3.56	0.02	0.54

Reproducibility (day to day) n = 20	Mean [mg/l]	SD [mg/l]	CV [%]
level 1	0.878	0.024	2.727
level 2	5.245	0.230	4.384

- **Method comparison**

A comparison between cystatin C values determined at Hitachi 912 (y) and at BN ProSpec (x) using 23 samples gave following results:
y = 0.9368 x + 0.1354 mg/l
R = 0.9985 (R – correlation coefficient)

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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