

TurbiMAX Cystatin-C

Latex Enhanced Turbidimetric Immuno Assay (LETIA)

ORDERING INFORMATION

Ref. No.	Pack Size	Presentation
AVCYCT-25	25 ml	Two Liquid Reagents with Calibrator

INTENDED USE :

TurbiMAX Cystatin-C is an in-vitro diagnostic kit for the Quantative determination of Cystatin C (CysC) in human serum.

PRODUCT FEATURES

1. Latex Enhanced Turbidimetric Immuno Assay (LETIA)
2. Liquid Stable Two Reagents
3. 6 level Calibrators provided
4. 2 Level Controls provided (Optional)
5. Measuring wavelength 546 nms
6. 2 Minutes test procedure (5 Sec + 120 Sec)
7. Linearity: 0.2 mg/L – 10.0 mg/L
8. Adaptable to Semi and Fully auto analyzers

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 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.

PRINCIPLE:

Cystatin C in the test sample binds to the specific polyclonal rabbit anti-Cystatin C antibody, which has been adsorbed to Colloidal Gold particles and agglutinates. The agglutination is detected as absorbance change when read on an automated clinical chemistry analyzer. The magnitude of the change is proportional to the quantity of Cystatin C in the test sample. Cystatin C concentration is then determined by interpolation from a calibration curve prepared from calibrators of known concentrations.

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the labels when stored at 2-8°C and the contaminations is prevented during their use. Do not freeze the latex and diluent.

KIT COMPONENTS

1. Buffer Reagent R1
2. Cystatin-C Latex Reagent R2
3. Cystatin-C Calibrators (6) : Concentration as stated on the label

COMPOSITION

Reagent R1 : Tris buffer (pH =7.2)

Reagent R2 :Turbi Latex particles coated with polyclonal anti - Cystatin C antibodies (rabbit)

REAGENT RECONSTITUTION & STABILITY

Reagent are liquid stable no need for reconstitution.

When the reagent is stored properly at 2-8°C & the contamination avoided, it is stable up to the expiry date mention on the label & kit box.

TurbiMAX Cystatin-C Calibrators are available as ready to use liquid stable 6 Level Calibrators and are stable till the expiry date mentioned on the labels

MATERIAL REQUIRED BUT NOT PROVIDED

Laboratory Instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi auto, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath controls, saline.

REAGENT DETERIORATION

Discard reagent if blank reagent absorbance exceeds 1.3 at 546 nm against distilled water.

WARNING & PRECAUTIONS

- Reagent may contain some non reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
- Specimen should be considered infectious and handled appropriately.
- Contamination by soap or glycerol will affect this assay.
- Perform the test according to the general " Good Laboratory Practice" GLP

SPECIMEN COLLECTION & STORAGE

1. Unhemolyzed Fresh Human serum is the specimen
2. 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 -20C or below. Once the sample has been thawed it should not be refrozen.
3. 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.

SYSTEM PARAMETERS:

Calibration Method	Multi Point -Linear- Spline
Reaction Type (Mode)	Fixed Time /Two Point
Reaction Direction	Increasing
Wave Length	546 nm
Flow Cell Temp.	37°C
Delay Time	5 Seconds
Measuring Time	120 Seconds
Blank	Distilled Water Blank
Reagent Volume	320 µl (R1) + 80 µl (R2)
Sample Volume)	5 µl
Calibrator Concentrations	(On the Vials Lot Specific)
Linearity	10 mg/L

TEST PROCEDURE

Reagent	Calibrator	Sample/Control
Reagent R1	320 µl	320 µl
Calibrator(1,2,3,4,5,6)	5 µl	----
Sample	—	5 µl
Reagent R2	80 µl	80 µl

- 1) Read absorbance A1 after 5 Seconds. (Delay)
- 2) Incubate and Read the absorbance A2 after 120 Seconds (Measuring)
- 3) Calculate the absorbance differences $\Delta A = A2 - A1$ for each point of the calibration curve, controls and all unknown samples.
- 4) The concentration of Cystatin-C in the unknown sample can be calculated from $\Delta A = A2 - A1$
- 5) Using a 3rd order polynomial mathematical model where abscissa (X) is the $\Delta A = A2 - A1$ and ordinate (Y) is the concentration of Cystatin-C or plotting the values of $\Delta A = A2 - A1$ obtained for every concentration level of the calibrator against the Cystatin-C concentration and interpolating the individual $\Delta A = A2 - A1$ of every sample in the calibration curve.

Calculations with Calibrators/ Calibration Curve/ Result Interpretation:

CALCULATION:

The concentration of Cystatin-C in unknown samples is derived from a calibration curve using an appropriate mathematical models such as Multi Point / Linear/Spline. The calibration curve is obtained with 6 calibrators at different levels. Stability of calibration: 4 weeks

EXPECTED VALUE

0.56-1.25 mg/L

It is recommended that each laboratory should establish its own reference interval.

QUALITY CONTROL & CALIBRATION

TurbiMAX Cystatin-C Controls are recommended for daily quality control. The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits

Calibration:

- The assay requires the use of a Cystatin-C calibrator. Recalibration is recommended at anytime if one of the following events occurs
- The Lot number of reagents changes.
- Preventative maintenance is performed or a critical component is Replaced
- Control values have shifted or are out of range and a new vial of control Does not rectify the problem.

PERFORMANCE CHARACTERISTICS:

1. Linearity

Linearity : 10.0 mg/L

2. Sensitivity/ Limit of Detection (LOD)

The lower limit of detection is 0.2 mg/L

3. Interferences:

Hemoglobin (10 g/l), bilirubin (20 mg/dl) and lipemia (10 g/l) do not interfere.

4. Precision: The reagent has been tested for 20 days, using two levels of serum in a EP5-based study (NCCLS).

Intra-Assay

N=10	Mean (mg/L)	SD (mg/L)	CV%
Control serum 1	1.3	0.02	1.53
Control serum 2	6.2	0.2	3.2

Inter-Assay

N=10	Mean (mg/L)	SD (mg/L)	CV%
Control serum 1	1.32	0.023	1.74
Control serum 2	6.25	0.26	4.16

5. Method Comparison:

Results obtained using this reagent (y) were compared to those obtained using a commercial reagent (x) with similar characteristics. 86 samples ranging from 0.2 to 10 mg/L of Cystatin-C were assayed. The correlation coefficient (r) was 0.95 and the regression equation $y = 0.797x - 1.075$.

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

LIMITATIONS (calibration curve): 0.2 to 10 mg/L, under the described assay conditions. Samples with higher concentrations should be diluted 1/5 in saline (10 parts serum sample + 40 parts normal saline ex: 10µl serum sample+40 µl saline) and retested again and the results should be multiplied by 5. 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.














WASTE DISPOSAL

Reagents must be disposed off in accordance with local regulations.

REFERENCES:

1. Filler G, Bökenkamp A, Hofmann W, Le Bricon T, Martínéz-Brú C, Grubb A. Cystatin C as a marker of GFR - history, indications, and future research. Clin. Biochem. 38: 1, 2005.
2. Dharmidharka 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.

Symbols Used on Pack

	Catalogue Number		Warning/Caution
	Batch No.		In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Contains sufficient no. of test		

Ver. : 05/12-25