

HOMOCYSTEINE

(Enzymatic)

INTENDED USE:

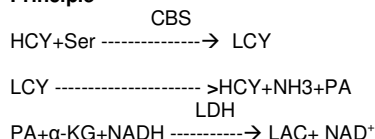
The Homocysteine Reagent is intended for in vitro quantitative determination of total homocysteine in human serum,

CLINICAL SIGNIFICANCE:

Homocysteine as an independent cardiovascular risk index has been widely accepted is another risk factor for high cholesterol, smoking, diabetes. Homocysteine is a sulfur containing amino acid produced by the metabolism of methionine. HCY levels and cardiovascular disease are closely related .HCY increased blood vessel wall because of limitation caused by damage to the arteries, eventually causing heart blood flow is blocked. High homocystinuria patients because of severe genetic defects affect HCY metabolism, resulting in high HCY hyperlipidemia slight genetic defects or nutritional deficiencies of B vitamins will be accompanied by moderate or mild elevated HCY also increase the risk of heart disease. HCY increased distortion and can cause neural tube birth defects such as congenital malformation disease.

INCREASED: seen in cardiovascular disease, neural tube defects, congenital malformation, pre-eciampsia Parkinson's disease, slow fetal growth chronic renal failure and other disease.

Principle



STORAGE AND STABILITY

- All the kit components are stable until the expiration date on the label, when stored tightly closed at 2-8°C, protected from light and contaminations prevented during their use.
- Do not Freeze.

APPLICABLE INSTRUMENTS

Biochemistry Analyzer.

SPECIMEN COLLECTION AND HANDLING

- Fresh serum (collected in serum or serum separator tubes) or plasma (collected in potassium EDTA or lithium heparin tubes). It is important to centrifuge blood samples immediately after collection to separate the plasma from the blood cells. If immediate centrifugation is not possible, collected blood specimens should be kept on ice and centrifuged within an hour.
- Hemolysed, turbid or lipemic specimens are not recommended.
- If the assay will be performed within 2 weeks after collection, the specimen should be stored at 2-8°C. If the testing will be delayed more than 2 weeks, the specimen should be stored frozen at -20°C or colder. Specimens have been shown to be stable at -20°C for 8 months.

ASSAY GUIDELINE FOR ANALYZERS

Reaction type	Fixed Time
Reaction Slope	Decreasing
Primary Wavelength	340 nm
Flow cell Temperature	37°C
Delay Time	180 sec.
Reading Time	120 Sec.
Sample volume	10 µl
Reagent 1 volume	240 µl
Reagent 2 volume	60 µl
Linearity	47.3 µmol/L

MULTIPOINT CALIBRATION

Prepare the following HCY Calibrator dilutions in NaCl 9g/L. Multiply the concentration of the HCY Calibrator by the corresponding factor stated in table below obtain the HCY concentration of each Dilution.

Calibrator Dilution	1	2	3	4
Calibrator HCY(µl)	0	25	50	100
NaCl 9 g/L(µl)	0	75	50	-
Factor	0	0.25	0.50	1.0

ASSAY GUIDELINES FOR MANUAL PROCEDURE

Pre warm the required amount of working reagent at Room Temperature before use. Perform the assay as given below:

Reagents	Calibrator	Test
Reagent 1	240 µl	240 µl
Calibrator	10 µl	-
Serum/Plasma	-	10 µl
Mix well and incubate for 5 minutes at 37°C Then add.		
Reagent 2	60 µl	60 µl

Mix and aspirate the assay procedure. The first reading should be recorded at 180 sec (A1) followed by second reading at 120 sec (A2) at 37°C, 340 nm ($\Delta A = A2 - A1$)

CALCULATIONS

$$\text{HCY } (\mu\text{mol/L}) = \frac{\Delta A \text{ of sample}}{\Delta A \text{ Calibrator}} \times \text{calibrator concentration}$$

Reference Values

Newborns		3-9 $\mu\text{mol/L}$
Adolescents		5-11 $\mu\text{mol/L}$
Adults	Male	6-22 $\mu\text{mol/L}$
	Female	3-18 $\mu\text{mol/L}$
	Elderly (>60)	Up to 25 $\mu\text{mol/L}$
	Centenarians	Up to 29 $\mu\text{mol/L}$

Recommended: The laboratory set up its reference range.

PERFORMANCE INDEX:

- Measuring Range:** The test has been developed to determine HCY within a measuring range from 0.1-47.3 µmol/L.
- Linearity:** The higher limit of detection is up to 47.3 µmol/L. If the concentration exceeds this value, the sample should be diluted 1:1 with 0.9% w/v NaCl solution and re-assayed. Multiply the result by dilution factor.
- Sensitivity:** The analytical sensitivity of HCY assay is 0.1 µmol/L.
- Specificity/Interference:** The effect of the following substances can be neglected if the concentrations of the following substances are at or below the given values:

Substances	Concentrations
Triglycerides	1000 mg/dL
Hemoglobin	1200 mg/dL
Ascorbic Acid	10 mg/dL
Bilirubin Conjugate	20 mg/dL
Bilirubin	20 mg/dL

ATTENTION:

Reagent contains sodium azide (toxic) preservative, avoid contact with skin and mucous membrane. If necessary preventive measures should be taken use of reagent, reagent contact with skin and mucous membrane, please rinse with water, please go to doctor if necessary.

References

1. Mc Cully KS. Vascular Pathology of Homocysteinemia: implications for the Pathogenesis of Arteriosclerosis. Am J Pathol 1969; 56: 111-122
2. Malinow MR. Plasma Homocyst(e)ine and Atrial Occlusive Diseases: A Mini-Review. ClinChem 1995; 41:173-176

Symbols

IVD

In Vitro Diagnostics

LOT

Batch No.

CONT

Content

 **i**

Read Instructions



Storage Temperature

REF

Catalogue No.



Caution



Product Expiry Date



Manufactured By



Date of Manufacture



Keep Dry



Fragile



Keep away from sun light



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