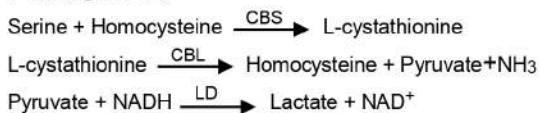


**Reagent kit for quantitative estimation of Homocysteine in Serum or Plasma.**

**DIAGNOSTIC SIGNIFICANCE:**

In-vitro test for the quantitative determination of HCY concentration in serum or plasma on photometric systems. Homocysteine (Hcy) is a thiol-containing amino acid produced by the intracellular demethylation of methionine. Total homocysteine (tHcy) represents the sum of all forms of Hcy including forms of oxidized, protein bound and free. Elevated level of tHcy has emerged as an important risk factor in the assessment of cardiovascular disease. Excess Hcy in the blood stream may cause injures to arterial vessels due to its irritant nature, and result in inflammation and plaque formation, which may eventually cause blockage of blood flow to the heart.

**PRINCIPLE:**



**SPECIMEN COLLECTION:**

*A minimum of 8 hours fasting is required for specimen collection as the Amino acid Methionine rich food intake grossly elevate the real homocysteine level.*

1. Heparin or EDTA plasma suitable for samples.
2. Preferably Serum collected in serum separator (SST) Or serum collected in sample tubes.
3. It is important to centrifuge blood samples immediately after collection to separate the serum from the clotted blood. If immediate centrifugation is not possible, collected blood should be kept on ice and centrifuge within an hour. Hemolyzed or turbid specimens or severely lipemic specimen are not recommended for HCY assay.

**Stability:** Serum/plasma: 5 days at 2–8°C.

**KIT PRESENTATION:**

Pack Size	1 X 15 ml	1 X 25ml
R1-Homocysteine Reagent	1 X 12 ml	1 X 20 ml
R2-Homocysteine Reagent	1 X 03 ml	1 X 05 ml
Calibrator (See Vial Label for Conc.)	1 No.	1 No.
Control Level - 1 (Optional)	1 No.	1 No.
Control Level - 2 (Optional)	1 No.	1 No.

**REAGENT & CALIBRATOR PREPARATION:**

1. Reagent Preparation : Reagents are ready to use.
2. Calibrator and Controls are ready to use.

**REAGENT STORAGE & STABILITY:**

All reagents are stable at 2-8°C until the expiry date stated on the label. Keep protected from light. Once opened, the reagents are stable for 28 days when refrigerated on the analyzer or refrigerator. Contamination of the reagents must be avoided. Do not freeze the reagents.

**ASSAY PARAMETERS:**

Reaction	: Fix Time Kinetic	Sample Volume	: 20 µl
Wavelength	: 340 nm	R1 + R2 Volume	: (400 + 100) µl
Flow Cell Temp.	: 37°C	Calibrator Conc.	: As Per Vial
Zero Setting	: Dist. Water	Reaction Slope	: Decreasing
Initial Delay	: 60 Sec	Linearity	: 50 µmol/L
Read Time	: 180 Sec	Unit	: µmol/L

**PROCEDURE:**

Addition Sequence	Calibrator	Test
R1- Homocysteine	400 µl	400 µl
Calibrator	20 µl	--
Sample (Test)	--	20 µl
Mix and incubate for 300 second (5 Minutes) at 37°C and then add		
R2 - Homocysteine	100 µl	100 µl

Mix & aspirate immediately and read difference in absorbance between 60 second (AT<sub>1</sub>) and 180 second (AT<sub>2</sub>) for Calibrator and Test.

**CALCULATION:**

$$\text{Homocysteine } (\mu\text{mol/L}) = \frac{\Delta\text{Abs of Test X Conc. of Calibrator}}{\Delta\text{Abs of Calibrator}}$$

Where  $\Delta\text{Abs} = (\text{AT}_1) - (\text{AT}_2)$

**NORMAL VALUES:** (Serum / Plasma)

New Born	3 – 10 µmol/L
Adolescent	5 – 12 µmol/L
Adult Male	6 – 24 µmol/L
Adult Female	3 – 20 µmol/L
Elderly (> 60 Years)	Up to 27 µmol/L
Centenarians	Up to 31 µmol/L

Each laboratory should establish its own reference range.

**INTERFERENCE:**

No signification interference by Bilirubin, Hemoglobin or intralipid.

**LIMIT OF DETECTION:** Not less than 2.0 µmol /L

**LINEARITY:** 50 µmol/L

**REFERENCE:**

- [1] Eikelboom JW, et.al. HCY and cardiovascular Disease: a critical review of the epidemiologic evidence. Ann Intern Med; 1999, 131: 363-75.
- [2] Scott JM, Weir DG. Homocysteine and cardiovascular disease. QJ Med; 1996,89:561-3.

IFU No.: 028/00 Rev. No.: 00/120723



Expiry Date



In-Vitro Diagnostics Use



Storage



Mfg. Date



Batch Number



Catalogue Number



See Package Insert