HOMOCYSTEINE

Enzymatic method

ATLAS
Bion Chemistry

INTENDED USE

Reagent for in vitro quantitative determination of HOMOCYSTEINE in serum or plasma on Photometers or Clinical Biochemistry Analysers.

SUMMARY AND BACKGROUND OF THE CLINICAL UTILITY

Homocysteine (HCY) is a thiol-containing amino acid with a molecular weight of 135.2 Dalton. HCY is not contained in the protein or DNA, but is a metabolic intermediary derived from the essential Sulphur containing amino acid, methionine. Total homocysteine 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 HCT in the bloodstream may cause injuries 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.

TEST PRINCIPAL

First, oxidized HCY is reduced to free HCY. Free HCY then reacts with a co-substrate, catalysed by cycling enzymes, and was significantly amplified. Then through dehydrogenation, NADH converts to NAD^+. The concentration of HCY in the sample is indirectly proportional to the amount of NADH converted to NAD^+.

KIT COMPOSITION

Reagents are ready for use.

R1:

- TCEP 0.5 mmol/L
- NADH 0.4 mmol/L

R2:

- Co-substrate 0.1 mmol/L
- Cycling enzymes 3 kU/L

EAGENT STABILITY

The reagents are stable until the expiry date stated on the labels when stored at 2-8° C and protected from light. Avoid contamination by using clean laboratory material.

SPECIMEN COLLECTION AND PREPARATION

Serum or plasma collected by standards procedures. HCY specimen is stable in serum or plasma;

- For 2 days at 2-8 °C
- For 1 month at -20 °C

TEST MANUAL PROCEDURE

Wavelength:	340 nm (334-365)
Temperature:	37°C
Cuvette:	1 cm light path
Direction:	Increase
Zero adjustment:	Reagent blank

	Sample	Standard
Sample	50 µL	-
Standard	-	50 µL
Reagent R1	750 µL	750 µL
Mix well separately R1 and sample and, incubate for 3-5 minutes at 37°C.		
Reagent R2	250 µL	250 µL
Then add R2. Mix well separately, incubate for 1 minutes at 37°C, read the absorbance A1, then incubate for 2 minutes, read the absorbance A2, calculate the change of absorbance per minute △A/min.		

CALCULATION

The concentration of HCY in patient must be calculated from the two-point calibration chart.

REQUIRED MATERIALS

Materials provided: HCY reagent
Materials required but not provided:
General laboratory equipment

Procal Homocysteine calibrator
Procon Homocysteine control material for a level of an appropriate quality control testing.
Spectrophotometer with thermostatic cuvette holder or biochemistry autoanalyzer in the list below.
The frequency of routine calibration is 5 days. If there is a change in reagent lot number or major maintenance performed on the analyzer or if control results fall outside acceptable range recalibration is required. A level of an appropriate quality control should be run every 24 hours.

QUALITY CONTROL

For quality control use adequate control materials, available from ABC (ProCon).

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REFERENCE VALUES

Serum or plasma;

Women:

≤30 years	6-14 µmol/L
30-59 years	5-13 µmol/L
≥60 years	7-14 µmol/L

Men:

≤30 years	6-14 µmol/L
30-59 years	6-16 µmol/L
≥60 years	6-17 µmol/L

This range is given for orientation only; each laboratory should establish its own reference range.

MEASURING RANGE

Linearity: The method is linear up to 50 µmol/L. At Higher concentrations, dilute the sample 1+1 with %0.9 NaCl or distilled water. And multiply by 2.

The limit of detection: 3 µmol/L.

SYMBOLS USED

IVD **For in vitro diagnostic medical use**

LOT **Batch Code**

Use by

Temperature limitation

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