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HOMOCYSTEINE

This reagent is intended for the in vitro quantitative determination of Homocysteine (HCY) in human serum.

REF: BS.1/HM1.050.0050	50 tests	REF: BS.1/HM1.100.0100	100 tests

CLINICAL SIGNIFICANCE

Homocysteine as an independent cardiovascular risk index has been widely accepted, is another risk factor for high cholesterol, smoking, diabetes outside. 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 irritation 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 diseases.
Increased: seen in cardiovascular disease, neural tube defects, congenital malformations, pre-eclampsia, Parkinson's disease, slow fetal growth, chronic renal failure and other diseases.

METHOD PRINCIPLE

$$\text{HCY+ Ser} \xrightarrow{\text{CBS}} \text{LCY}$$

$$\text{LCY} \xrightarrow{\text{CBL}} \text{HCY+ NH3+ PA}$$

$$\text{PA +α-KG+NADH} \xrightarrow{\text{LDH}} \text{LAC+ NAD+}$$

REAGENT COMPOSITION

Reagents:	Composition
R1 Reagent	NADH (0.47 mM) LDH (38 KU/L) Serine (0.76 mM), Trizma Base 1-10% Trizma Hydrochloride 1-10%, Sodium Azide < 1%. Reductant (TCEP:2.9 mM)
R2 Reagent	Cycling Enzymes CBS (0.748 KU/L) CBL (16.4 KU/L) Sodium Azide < 1%
CALIBRATOR SET	Homocysteine concentration is stated on the vial label.

Both reagents contain Sodium azide as a preservative.

PRECAUTIONS AND WARNINGS

Reagent to be handled by entitled and professionally educated person. Do not ingest or inhale as reagent contains sodium azide which is classified as dangerous substance for environment.

Good Laboratories practices using appropriate precautions should be followed in:

- Wearing personnel protective equipment (overall, gloves, glasses,).
- Do not pipette by mouth.
- In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.
- Respect country requirement for waste disposal.

S56: dispose of this material and its container at hazardous or special waste collection point.
S57: use appropriate container to avoid environmental contamination.
S61: avoid release in environment.

For further information, refer to the HOMOCYSTEINE reagent material safety data sheet.

REAGENT PREPARATION, STORAGE AND STABILITY

Unopened, avoid light preservation in 2 ~ 8 ℃, valid for 12 months;
Opened, avoid light preservation in 2 ~ 8 ℃, valid for 1 month.
Reagent is not allowed frozen.

Working reagent: Prepare the necessary amount as follows :240 µl Buffer Reagent + 60 µl Latex Reagent.

Deterioration
The ***BioScien*** HOMOCYSTEINE reagent can be damaged due to Presence of particles and turbidity.

SPECIMEN COLLECTION AND PRESERVATION

It is best to fresh serum or heparin anticoagulant blood plasma, once take, blood immediately centrifugal separation of plasma.
Sample stability: 2～8℃ preservation stability in 2 weeks .
Don't use the blood sample collection bottle containing sodium fluoride. Before take blood, please try to avoid high protein diet, high protein diet may lead to increase Hcy.
In sample, blood ammonia ≤50µmol/L; glutathione ≤0.5mmol/L; The elf sulfide concentration ≤20µmol/; adenosine ≤100µmol/L; bilirubin ≤20 mg/dL 、hemoglobin ≤1200 mg/dL; triglyceride ≤2500mg/dL; ascorbic acid≤10mmol/L; S-adenosylmethionine （SAM）≤20µmol/L; Lcysteine≤1.0mmol/L, not observed clearly obvious interference.

SYSTEM PARAMETERS

Wavelength	340 nm
Optical path	1 cm
Assay type	Fixed Rate
Temperature	37 ˚C
Direction	Decreasing
Delay time	150 seconds
Reading time	150 seconds

EQUIPMENT REQUIRED NOT PROVIDED

- Sterile Syringe
- Analytical tubes
- Centrifuge
- Stop watch
- Variable Micropipettes
- Automatic analyzer

ASSAY PROCEDURE

	Calibrator	Sample
R1	240 µl	240 µl
Calibrator	15 µl	
Sample		15 µl
Mix, and incubate for 5 minutes, then add		
R2	60 µl	60 µl

Mix and read the absorbance after 150 sec. (A1) and after anther 150 sec. (A2) of the sample addition.

CALCULATION

Calculate the absorbance difference (A2-A1) of each point of the calibration curve and plot the values obtained against the HOMOCYSTEINE concentration of each calibrator concentration. HOMOCYSTEINE concentration in the sample is calculated by interpolation of its (A2-A1) in the calibration curve.

QUALITY CONTROL

Control sera are recommended to monitor the performance of manual and automated assay procedures.
Each laboratory should establish its own quality control scheme and corrective actions if controls do not meet the acceptable tolerances.
For more information please contact ***BioScien*** technical support.

PERFORMANCE CHARACTERISTICS

1. Reagent blank absorbance≥1.0,(340nm,lcm optical path).
2. **Precision:** repeatability CV≤10%;batch variations R≤10%.
3. **Accuracy:** relative deviation ≤10%.
4. **Linearity range:** 0～40 µmol/L, r≥0.990.
 If testing results is upper limit, dilute with 0.9% sodium chloride solution before test, results multiplied by the dilution ratio.

INTERFERING SUBSTANCES

Human error, the processing of specimen, analysis instrument deviation, etc. all can affect the measurement result; When one sample deviates from the expected value too far, need to be tested again.

LIMITATIONS OF PROCEDURE

HCY testing is just one of the standard that clinicist diagnose the patient.
Clinical physicians should according to patients' bodies, history and other diagnostic program, to get comprehensive judgment.

EXPECTED VALUES

In plasma, Hcy age-related in the normal reference range,
adult≤15µmol/L,
Above 60 years 15~20µmol/L,
Above 100 years 25~27µmol/L.

REFERENCES

1. Wick M, Pinnggera W, Lehmann P. Ferritin in iron metabolism. Diagnosis of anemias. 2nd ed. Springer-Verlag. Wien 1994.
2. Rodriguez Perez J et al. Revista Clinica Española 1980: 156 (1): 39-43
3. Milman N et al. Eur J Haematol 1994: 53: 16-20.

SYMBOLS IN PRODUCT LABELLING			
IVD	For in-vitro diagnostic use	Σ	Number of <n> test in the pack
LOT	Batch Code/Lot number	⚠	Caution
REF	Catalogue Number		Do not use if package is damaged
	Temperature Limitation		Consult Instruction for use
	Expiration Date		
	Manufactured by		