Homocysteine (HCY) Diagnostic Reagent Kit (Circulation Enzyme Rate Method)
Product Instruction

Product name
Homocysteine (HCY) Diagnostic Reagent Kit (Circulation enzyme rate method)
Abbreviation: HCY

Package Specifications

R1	R2
40ml×1	10ml×1
40ml×2	10ml×1
100ml×2	25ml×2

Calibrator (liquid):
Specification 1 (1.0mL×1; 1 level);
Quality control (liquid):
Specification 1 (1.0mL×3; 3 levels).

Intended use
Homocysteine (HCY) diagnostic reagent is used for quantitative in vitro determination of homocysteine in human serum on photometric systems.

Clinical significance
Homocysteine is a thiol-containing amino acid produced by the intracellular demethylation of methionine. Total homocysteine represents the sum of all forms of HCY (including forms of oxidized, protein bound and free).
Elevated level of homocysteine has emerged as an important risk factor in the assessment of cardiovascular disease. Excess HCY 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.
Elevated homocysteine levels are caused by four major factors, including:
1. Genetic deficiencies in enzymes involved in HCY metabolisms such as cystathionine beta-synthase (CBS), methionine synthase (MS), and methylenetetrahydrofolate reductase (MTHFR);
2. Nutritional deficiency in B vitamins (B6, B12 and folate);
3. Renal failure for effective amino acid clearance;
4. Drug interactions such as nitric oxide, methotrexate and phenytoin that interfere with HCY metabolisms. Elevated levels of tHCY are also linked with Alzheimer's disease and osteoporosis. Guidelines for tHCY determination in clinical laboratories have recently been established.

Principle
Oxidized HCY is converted into free HCY, and free HCY reacts with serine under the catalysis of cystathionine β-synthase (CBS) to generate L-cystathionine. L-cystathionine is catalyzed by cystathionine β-lyase (CBL) to generate HCY, pyruvate and NH3. Pyruvate generated by this cyclic reaction can be detected by lactate dehydrogenase and nicotinamide adenine dinucleotide (NADH), and the rate at which NADH is converted to oxidized nicotinamide adenine dinucleotide (NAD+) is is proportional to the HCY content in the sample.

Main ingredient

Name	Ingredient	Concentration
R1	Tris(hydroxymethylamino methane)	10.0g/L
	Serine	0.08g/L
	β-Nicotinamide Adenine Dinucleotide	0.36g/L
	Lactate dehydrogenase	36KU/L
R2	Tris(hydroxymethylamino methane)	10.0g/L
	Disodium ethylenediamine tetraacetic acid	0.2g/L
	Cystathionine β-synthase	22KU/L
	Cystathionine β-lyase	11KU/L

Storage and stability
This kit stays stable for 18 months when stored in a dark condition at 2-8°C (do not freeze). After being opened for the first time, the kit can be stored at 2-8°C in an anti-pollution environment and stays stable for 14 days.

Specimen preparation
Fresh serum.
2-8°C, stable for 3 days.
-70°C, stable for 3 months.

Assay procedure
1. Reagent preparation
This reagent is liquid and can be used directly.

Main wavelength	340nm	Sample	13μl
Subwavelength	700 nm	Reagent 1	240μl
Reation temperature	37°C	Reagent 2	65μl
Cuvette light path	1cm	Reaction type	Rate method
Reaction Direction	Decreasing		

2. Operation steps

Add to the cuvette:	
Sample (S)	13μl
R1	240μl
Mix well, incubate at 37°C for 5 minutes, then add	
R2	65μl
Mix well, incubate at 37°C for 1 minute, continuously monitor the absorbance change of each tube for 1-2 minutes and calculate ΔA/min.	

Calculations

$$\text{Conc. of HCY} = \frac{\text{Sample tube absorbance AU}}{\text{Standard tube absorbance AS}} \times \text{conc. of Cal.}$$

Reference interval

0umol/L -15umol/L

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

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.

Performance characteristics

Measuring range:

1.5umol/L -50umol/L

Samples above this concentration should be diluted 1+1 with 0.9% NaCl solution and the result multiplied by 2.

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

Automation

Special adaptations for automatic analyzers can be made on request.

General precautions

For in vitro diagnostic use only.

Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.

Exercise the normal precautions required for handling all laboratory reagents.

Disposal of all waste material should be in accordance with local guidelines.

Precautions for measurement

Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.

Reagents with different lot numbers should not be interchanged or mixed.

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Material safety data sheet available for professional user on request.

Parameters

HITACHI	
Model	7180
Assay Code	RATE-A
Reaction Time	10
Assay Point	22-28
Wave Length Sec	700
Wave Length Prim	340
ABS. Limit	32000
Sample Volume（uL）	13
R1 Volume（uL）	240
R2 Volume（uL）	0
R3 Volume（uL）	65
Calibration Type	LINER
Calibration Point	2
Span Point	2
SD Limit	999
Duplicate Limit	1000 or (0%-1000Abs)
Sensitivity Limit	0
Prozone Limit	32000

OLYMPUS 400	
Sample Volume（uL）	13
Sample DIL. VOL.	/
R1 Volume（uL）	240
R2 Volume（uL）	65
Reagent DIL. VOL.	/
Measure Wave 1	340
Measure Wave 2	700
METHOD	RATE

SLOPE	-
Method Point	15-25
Linear Limit	-
NO LAG TIME	Yes
OD L	-
OD H	-
Reagent OD Limit	
FIRST	-2.0-+2.5
LAST	-2.0-+2.5
Dynamic Range L	-9999999
Dynamic Range H	9999999
Correlation Factor A	1.0
Correlation Factor B	0.0
Calibration Type	AB
Formula	liner
STD(1) Conc.#	*
Unit	umol/L

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