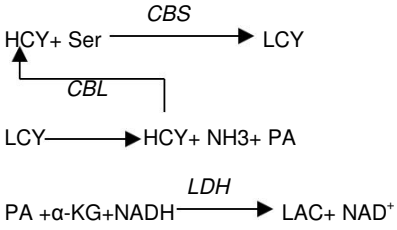
ACCUCARE™
HOMOCYSTEINE (Enzymatic)

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

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.

METHODOLOGY


STABILITY AND STORAGE
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.

SPECIMEN COLLECTION AND HANDLING
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; L-cysteine≤1.0mmol/L, not observed clearly obvious interference.

APPLICABLE INSTRUMENT
Biochemistry Analyzer.

SYSTEM PARAMETERS
The following system parameters are recommended. Individual instrument applications are available upon request from the Technical Support Group

Assay Type	Fixed Time
Temperature	37℃
Cuvette light path	1.0cm
Primary Wavelength	340 nm
Secondary Wavelength	405 nm
Direction	Decreasing
Sample Vol	13 μL
Reagent Vol	305 μL
Delay Time	90 seconds
Read Time	180 seconds
Linearity	0～50μmol/L

MULTI POINT CALIBRATION
Multi Point calibrator Available on request (Optional)
Prepare the following HCY calibrator dilutions in NaCl 9 g/dL, Multiply the concentration of the HCY calibrator by the corresponding factor stated in the table below to obtain the HCY concentration of each dilution.

Calibrator Dilution	1	2	3	4	5
Calibrator HCY (μl)	-	25	50	75	100
NaCl 9 g/dL (μl)	100	75	50	25	-
Factor	0	0.25	0.50	0.75	1.0

OPERATION STEPS

Addition Sequenc	Calibr (C)	Test (T)
Reagent 1	240 μL	240 μL
Calibrator	13 μL	-
Sample	-	13 μL
Mix well and incubate for 5 minutes at 37° C		
Reagent 2	65 μL	65 μL

Mix well, and read the absorbance after 90 sec A1 and after 180 sec minutes A2 of the sample/calibrator addition.

CALCULATION

Sample Concentration = $\frac{\text{Sample } \Delta\text{Abs/min}}{\text{Calibrator } \Delta\text{Abs/min}}$ ×Calibrator Concentration

REFERENCE RANGE
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.

Recommendation: The laboratory set up its own reference range!

THE LIMITATIONS OF TESTING RESULTS
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.

THE INTERPRETATION OF TEST RESULTS
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.

PERFORMANCE INDEX
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**: 0～50μmol/L, r≥0.990.

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

2. The maximum linearity is 50μmol/L. If testing results is upper limit, dilute with 0.9% sodium chloride solution before test, results multiplied by the dilution ratio.

3. Liquid waste disposal: Suggest follow local regulations

4. Different batches reagents cannot mix, when replacing reagents batch number, please calibration again

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