



LIQUID STABLE (LS) 2-PART HOMOCYSTEINE REAGENT

INTENDED USE:

Liquid Stable (LS) 2-Part Homocysteine Reagent is intended for *in vitro* quantitative determination of total homocysteine in serum and plasma.

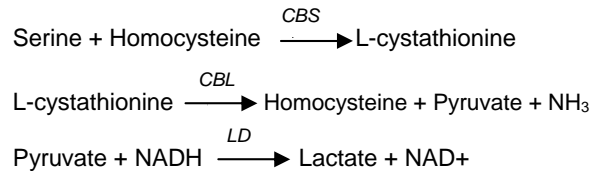
CLINICAL SIGNIFICANCE:

Homocysteine is a by-product of protein metabolism, specifically the breakdown of the essential amino acid, methionine. It is not itself incorporated into proteins but is further broken down by enzymes into cysteine, or is converted back to methionine. In small amounts, homocysteine is not harmful to the body or blood vessels, but when excess amounts accumulate in the blood stream, arterial vessels may be damaged and the resulting inflammation may eventually cause blockage of blood to the heart. Clinical studies began in 1969, when Dr. Kilmer S. McCully reported that children born with a genetic error of metabolism that causes their homocysteine levels to be significantly elevated (homocystinuria), died with advanced artery disease at a very young age⁽¹⁾. More recent studies are yielding evidence that elevated blood levels of homocysteine have a predictive value for risk of coronary artery disease similar to that of elevated cholesterol levels^(2,3).

METHOD SUMMARY:

Oxidized forms of homocysteine are reduced to free homocysteine which then reacts with serine catalyzed by cystathionine β -synthase (CBS) to form L-cystathionine. Cystathionine is cycled back to homocysteine by cystathionine β -lyase (CBL) forming in

the process pyruvate and ammonia. This cycling sequence increases the sensitivity of the method by about 10-fold. Pyruvate is detected using lactate dehydrogenase with NADH. The rate of conversion of NADH to NAD is directly proportional to the amount of homocysteine in the sample or calibrator.



REAGENT COMPOSITION

Active Ingredients	Concentration
Lactate Dehydrogenase (Porcine Heart)	> 35 KU/L
Serine	0.76 mmol/L
NADH	0.47 mmol/L
Cystathionine β -Synthase (Microbial)	> 20 KU/L
Cystathionine β -Lyase (Microbial)	> 10 KU/L
Buffers and Stabilizers	

REAGENT PREPARATION:

R1 and R2 are packaged ready to use. The reagents are stable until the expiration date specified on the label.

CALIBRATOR PREPARATION AND USE:

The calibrators are prepared gravimetrically and are traceable to Standard Reference Material NIST SRM 1955. The calibrators are supplied as a 2-level set and are provided ready to use. Values are printed on the labels.

WARNING:

Specimens from patients taking methotrexate, carbamazepine, phenytoin, nitrous oxide, 6-azauridine triacetate or S-Adenosyl methionine may have elevated levels of homocysteine due to their effect on the metabolic pathway.

This reagent is for *in vitro* diagnostic use only. **DO NOT INGEST.** Avoid contact with skin and eyes. Contains sodium azide which may react with lead or copper

plumbing to form explosive compounds. Flush drains with copious amounts of water when disposing of this reagent. Additional safety information concerning storage and handling of this product is provided in the Material Safety Data Sheet for this product. To obtain an MSDS, please call Catch Incorporated at
+ 1 (866) 719 6099

STABILITY AND STORAGE:

The Homocysteine Reagent Kit should be stored refrigerated at 2-8 °C. **DO NOT FREEZE.** The reagents are stable when stored as supplied until the expiration date on the label. The reagent is stable on board for 30 days. Do not mix different lots of reagent.

SPECIMEN COLLECTION AND HANDLING:

Fresh EDTA or heparinized plasma free of hemolysis or turbidity is the recommended specimen for measurement of homocysteine. Serum collected in serum separator tubes may also be used. However, it is not recommended to use individual patient results from serum, heparinized plasma and EDTA plasma interchangeably. All samples must be placed on ice immediately after collection and should be centrifuged and separated from cells as soon as possible (within one hour). Severely lipemic specimens (4+) are unsatisfactory. Samples should be stored tightly capped at 2-8 °C for up to 48 hours, or frozen at -20 °C if testing is delayed⁽⁵⁾.

PROCEDURE:

Materials provided:

Catalog Number. 4-501

R1:	1 x 50 mL
R2:	1 x 7 mL
Calibrator:	2 x 3 mL

*** The number of tests that can be obtained from this kit is dependent on the analyzer used.**

Materials Required but not provided:

An analyzer capable of dispensing two reagents and of measuring absorbance at 340 nm with temperature control (37 °C).
Saline (0.85%)

