

TruLab Homocysteine

Homocysteine Control



Intended Use

Homocysteine Control is used to check the precision and accuracy of Homocysteine test reagent on photometric analyzers Reagent Kits

Item Code

10300295010

Pack size

L1: 1 x 1 mL; L2: 1 x 1 mL

Summary

The Homocysteine Enzymatic Controls are sets 2 control levels. These levels are to be used for a multi-point calibration of the DiaSys Homocysteine Enzymatic Assay.
Reagents - Working Solutions

Reactive components

- Human serum base and additives

Non-reactive components

Sodium azide (NaN₃) <0.1%

The Homocysteine Enzymatic Controls are multiple level sets that are supplied in liquid form. The control is manufactured from a human serum base. The concentration of the control is lot specific and the homocysteine concentrations are expressed in pmol/L.

Control values

The exact control values are given on the available Certificate of Analysis.

Traceability

The assigned values of the Control are traceable to reference material.

Precautions and Warnings

1. For in vitro diagnostic use only.
2. Exercise the normal precautions for handling all laboratory reagents. Each donor unit of serum used in the preparation of this Control set was tested by FDA-approved methods and found negative for the Human Immunodeficiency Virus Antibody (HIV I/II Ab), Hepatitis B Surface Antigen (HBsAg), and Hepatitis C Virus Antibody (HCV). Because no method can offer complete assurance as to the absence of infectious agents, however, this material and all patient samples should be handled as though capable of transmitting infectious disease and disposed of accordingly.
3. Additional safety information concerning storage and handling of this product is provided within the Material Safety Data Sheet for this product. To obtain an MSDS, please contact our customer service department at 858-455-4768.

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.

Handling

The Homocysteine Control is supplied in liquid form. Before use, gently swirl the control vials several times to ensure homogeneity. After each use, promptly replace the cap and return to 2-8°C storage.

Storage and Stability

Store at 2-8°C. DO NOT FREEZE.

Note: Store control tightly capped when not in use.

Stability

Closed Vial: Stability is up to the expiration date on label when stored at 2- 8°C.

Open Vial: Stability is up to 60 days when stored at 2- 8°C.

Materials Provided

The Homocysteine Enzymatic Control consists of liquid vials.

Materials required (but not provided)

DiaSys Homocysteine reagents General laboratory equipment.

Assay

Prepare standards as stated in the Handling section. The use of a 1.0 mL pipette is recommended. Take care to avoid the formation of bubbles.

References

1. Eikelboom JW, et. al. Ann Intern Med 131:363-75, (1999)
2. Scott J, Weir D. Q J Med 89: 561- 3 (1996)
3. Nygard O, N Engl J Med. 337(4):230-6(1997)
4. Seshadri S. et al. N. Engl. J. Med. 346:477-483(2002)
5. McLean R. et al. N. Engl. J. Med. 350: 2042-2049 (2004)
6. Refsum H. Clinical Laboratory News May 2002, pp 2-14
7. Guttormsen AB et al. J Nutr. 124(10): 1934-41 (1994)
8. Vilaseca et al. Clin. Chem. 43: 690-692 (1997)
9. Faure-Delanef et al. Am. J. Hum. Genet. 60: 999-1001 (1997)

Notes on Symbols and Marks



Consult instructions for use



Use-by date



Batch code



Catalogue number



Caution



Manufacturer



In vitro diagnostic medical device



Temperature limit



Do not re-use



The pack contains



Recycle



Date of manufacture

ISO 9001, ISO 13485 and ICMED 13485 Certified Company

DiaSys Diagnostics India Private Limited

Plot No. A – 821, T.T.C. Industrial Area, MIDC,
Mahape, Navi Mumbai – 400710.
Maharashtra, India.

Customer Care

For feedback/queries contact customer care at :

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