

Intended Use

The Pointe Homocysteine Control Kit is intended to be used as an assayed quality control serum when used for the quantitative measurement of total L-homocysteine in human serum or plasma. **Rx Only**

Summary and Principle

The use of quality control material is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practices. Three levels of control are available to allow performance monitoring within the clinical range.

Precautions

The controls contain human sourced and potentially infectious components. Components sourced from human blood have been tested and found to be non-reactive for Hepatitis B Surface Antigen (HBsAg), HIV-1 Antigen (HIVAg) or HIV-1 RNA, HCV antibody, HIV-1/2 antibody, HTLV-1/2 antibody and Hepatitis B core Antibody (HBc). No known test method can offer complete assurance that products derived from human sources will not transmit infection. Therefore all human sourced materials should be considered potentially infectious. It is recommended that these materials be handled in accordance with Biosafety Level 2¹ or local/national guidelines on laboratory safety procedures. Controls contain <0.10% sodium azide as preservative.

Storage and Stability

The Pointe Homocysteine Control Kit must be stored refrigerated (2-8°C). The controls are stable until the expiration date when stored and handled as directed. Do not use past expiration date.

Materials Provided

The Pointe Homocysteine Tri-Level Controls are provided in kits of 2 x 1.5 mL of each of three levels.

Procedure and Handling

Each control should be treated as a patient sample and run in accordance with the instructions accompanying the instrument, kit or reagent being used. Before sampling, allow the control to reach room temperature (18-25°C) and swirl gently before use to ensure homogeneity. Return the control to storage at 2-8°C immediately after use.

Dispose of any discarded materials in accordance with local waste management regulations.

Assignment of values

Individual laboratory means should fall within the corresponding acceptable range. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by test method modifications. It is recommended that each laboratory establishes its own mean and acceptable ranges and use those provided only as a guide.

Level	Homocysteine (µmol/L)
1	3.6 – 9.4
2	8.7 – 15.7
3	19.1 – 32.0

Limitations

This product must not be used past the expiration date.










If there is evidence of microbial contamination or excessive turbidity in the product discard the vial.





This product is not intended for use as a calibrator.

Reference

1. US Department of Health and Human Services, *Biosafety in Microbiological and Biomedical Laboratories*, Fifth Edition. Washington, DC: US Government Printing Office January 2007.

Symbol Key

 Use by (YYYY-MM-DD)	 Lot and batch code
 Catalog number	 Manufacturer
 <i>In vitro</i> diagnostic medical device	 Temperature limitation
 Consult instructions for use	Rx Only: Prescription Use Only
 CE mark	 Authorized representative in the European Community

 H7575-CTL  Manufactured for HORIBA Instruments Incorporated
5449 Research Drive Canton, MI 48188  2°C-8°C 

Manufactured for HORIBA Instruments Incorporated – Pointe Brand
5449 Research Drive, Canton, MI 48188

European Authorized Representative:

Obelis s.a.

Boulevard Général Wahis 53

1030 Brussels, BELGIUM

Tel: (32)2.732.59.54 Fax:(32)2.732.60.03 email: mail@obelis.net



Certified to Perform Reagents

The Pointe reagents are certified to be manufactured according to specified parameters. Any Pointe reagent product not meeting specifications through its listed expiration date will be remedied immediately without charge.

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