

AXIS-SHIELD Homocysteine Control Kit



REF FHCY200
REF B08177

ENGLISH

Intended Use

The Axis-Shield 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. **For professional use 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 practises. Three levels of control are available to allow performance monitoring within the clinical range.

Contents

3 vials (1.5 mL each) contain L-homocysteine in processed human serum in the following concentration ranges:

HOMOCYSTEINE ASSAY	PRODUCT CODE	CONTROL L	CONTROL M	CONTROL H
		RANGE (µmol/L)	RANGE (µmol/L)	RANGE (µmol/L)
Axis-Shield Liquid Stable (LS) 2-Part Homocysteine Reagent Assay	FHRWR100 / 200	3.6-9.4	8.7-15.7	19.1-32.0
	B08176*			

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Assignment of values


The Axis-Shield Homocysteine controls are composed of charcoal stripped human serum spiked with L-Homocysteine. The target concentrations / ranges of each control level are measured using Homocysteine assay calibrators gravimetrically manufactured with S-adenosyl-L-homocysteine (SAH) in phosphate buffer. The assay calibrators are tested for acceptance using internal reference standards, that are traceable to NIST SRM 1955¹⁻⁶.

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.

Precautions

IVD For *In Vitro* Diagnostic Use.

Caution: **For US applicable product**, Federal law restricts this device to sale by or on the order of a physician

 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 2⁷ or local/national guidelines on laboratory safety procedures. Controls contain <0.10% sodium azide as preservative. **Safety data sheets for the 3 vials of controls are available to users on request from Axis-Shield Diagnostics Ltd.**

Storage and Stability

The Axis-Shield 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.

For analysers with on-board storage capabilities the Axis-Shield Homocysteine Controls can be stored on-board for up to 3 hours.

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.

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.

References

1. Ueland PM, Refsum H, Stabler SP, Malinow R, Andersson A, Allen RH. Total homocysteine in plasma or serum: Methods and clinical applications. Clin Chem 1993;39:1764-1779.
2. Nehler MR, Taylor LM Jr, Porter JM. Homocysteine as a risk factor for atherosclerosis: A review. Cardiovasc Pathol 1997;6:1-9.
3. Lussier-Cacan S, Xhignesse M, Piolot A, Selhub J, Davignon J, Genest J Jr. Plasma total homocysteine in healthy subjects: sex-specific relation with biological traits. Am J Clin Nutr 1996; 64:587-593.
4. Clarke R, Woodhouse P, Ulvik A, Frost C, Sherliker P, Refsum H, Ueland PM, Khaw K- T. Variability and determinants of total homocysteine concentrations in plasma in an elderly population. Clin Chem 1998;44:102-107.
5. Jacques PF, Selhub J, Bostom AG, Wilson PWF, Rosenberg IH. The effect of folic acid fortification on plasma folate and total homocysteine concentrations. N Engl J Med 1999;340:1449-1454.
6. Lawrence JM, Pettit DB, Watkins M, Umekubo MA. Trends in serum folate after food fortification. Lancet 1999;354:915-916.
7. US Department of Health and Human Services, *Biosafety in Microbiological and Biomedical Laboratories*, Sixth Edition. Washington, DC: US Government Printing Office June 2020.

Key to Symbols:

	Product Code
	<i>In Vitro</i> Diagnostic Medical Device
	Lot number
	EC Importer
	EC Authorised Representative
	Consult Instructions For Use https://globalpointofcare.eifu.abbott/
Rx Only	For Prescription Use Only
	Manufacturer
	Use by
	Store at 2-8°C
	CAUTION, consult accompanying documents
	Contains biological material of human origin
	Control Kit
	Control Low, Medium, High (L, M, H)

Serious Incident / Adverse Event Notice

Contact Axis-Shield Diagnostics Ltd, EC Authorized Representative and the Competent Authority of the Member State the incident occurred in.

Product Support

Contact one of the following Product Support Care Centres if you have any questions regarding the use of your product. You may also contact us at www.globalpointofcare.abbott.

Region	Phone	Email
Europe & Middle East	+44 161 483 9032	EME.TechSupport@abbott.com
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