

AXIS-SHIELD Clinical Chemistry Heparin Binding Protein Control Kit



REF FHHBP200

IVD



ENGLISH

Intended Use

The Axis-Shield Clinical Chemistry Heparin Binding Protein (HBP) Control kit is intended to be used as an assayed quality control material when used in the Axis-Shield Clinical Chemistry HBP assay for the quantitative measurement of HBP levels in human plasma samples.

Summary and Principle

The use of quality control material is to monitor acceptable performance of the Axis-Shield Clinical Chemistry HBP Assay. Refer to the Axis-Shield Clinical Chemistry HBP Reagent instructions for use for further information.

Contents

2 vials containing human plasma in buffer:

Control	Format	Range (ng/mL)
CONTROL L	Liquid, ready to use (1.0 mL)	<26.8
CONTROL H	Liquid, ready to use (1.0 mL)	70.0 – 130.0

Measuring Units

The default result unit for the assay is ng/mL.

Warnings and Precautions

IVD For *In Vitro* Diagnostic Use.

Caution: 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, HIV-2 and HCV. 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. Safety data sheets (MSDS/SDS) are available upon request.

 WARNING CONTROL L CONTROL H	WARNING	H317 - May cause an allergic skin reaction.
	PREVENTION	P261 - Avoid breathing dust/fumes/gas/mist/vapours/spray. P272 - Contaminated work clothing should not be allowed out the workplace. P273 - Avoid release to the environment. P280 - Wear protective gloves/protective clothing/eye protection/face protection. P302+352 - IF ON SKIN: Wash with plenty of water. P333+313 - If skin irritation or rash occurs. Get medical attention P363 - Wash contaminated clothing before use.

Storage and Stability

The Axis-Shield Clinical Chemistry HBP Control Kit as supplied must be stored refrigerated (2-8°C) prior to use. The controls are stable (unopened) until the expiration date when stored and handled as directed. Do not use after the expiration date. DO NOT FREEZE.

Procedure and Handling

- Each control must be run in accordance with the instructions accompanying the instrument and the Axis-Shield Clinical Chemistry HBP Reagent Kit.
- Allow each control to warm to room temperature (18-25°C).
- Controls are stable at 2-8°C for up to:
 - Opened – 30 days
- Dispose of any used materials in accordance with local waste management regulations.

¹ US Department of Health and Human Services, *Biosafety in Microbiological and Biomedical Laboratories*, Fifth Edition. Washington, DC: US Government Printing Office December 2009.

Assignment of values











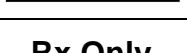
It is recommended that each laboratory establishes its own mean and acceptable ranges and use those provided only as a guide. Refer to the vial labels for specific concentration.

Limitations

- This product must not be used after the expiration date or exceed the recommended storage directions. Do not freeze.
- This product must be discarded and not used if there is evidence of microbial contamination or excessive turbidity.
- This product is not intended for use as a calibrator in the Axis-Shield Clinical Chemistry HBP assay.

Technical Support

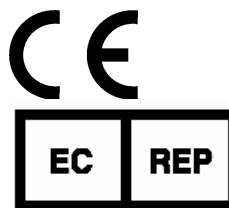
For Technical Support please contact your local distributor or representative.

	Product Code
	<i>In Vitro</i> Diagnostic Medical Device
	Lot number
	Consult Instructions For Use
	Manufacturer
	Use by
	Store at 2-8°C
	CAUTION, consult accompanying documents
	Control Kit
	Control Low, High (L, H)
	For Prescription Use Only

RPBL1198/R3
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