

AXIS-SHIELD Clinical Chemistry Heparin Binding Protein Calibrator Kit



REF

FHHBP300

IVD



ENGLISH

Intended Use

The Axis-Shield Clinical Chemistry Heparin Binding Protein (HBP) Calibrator Kit is intended to be used for the calibration of the Axis-Shield Clinical Chemistry HBP Reagent Assay on Clinical Chemistry analysers.

Summary and Principle

The Axis-Shield Clinical Chemistry HBP Calibrator Kit has been designed for calibration of the Axis-Shield Clinical Chemistry HBP assay.

Refer to the Axis-Shield Clinical Chemistry HBP Reagent instructions for use for further information.

Contents:

6 vials (Calibrator 1 - 6) containing various levels of recombinant HBP in buffer.

Calibrator	CAL 1	CAL 2	CAL 3	CAL 4	CAL 5	CAL 6
Format	1.0 mL Ready for Use	1.0 mL Ready for Use	1.0 mL Ready for Use	1.0 mL Ready for Use	1.0 mL Ready for Use	1.0 mL Ready for Use

Standardization

Currently there is no international reference standard for this assay. The Axis-Shield Clinical Chemistry HBP assay is traceable to this standard. The concentrations of HBP antibodies in each calibrator are lot-specific. **Refer to the calibrator vial labels for specific concentrations.**

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

 WARNING CAL 1 - CAL 6	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 Calibrator Kit as supplied must be stored refrigerated (2-8°C) until use. The Calibrators 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 Calibrator must be run in accordance with the instructions accompanying the instrument and Axis-Shield Clinical Chemistry HBP Reagent Kit.
- Allow each calibrator to warm up to room temperature (18-25°C).
- Calibrators are stable at 2-8°C for up to:
 - Opened – 30 days
- Dispose of any used materials in accordance with local waste management regulations.

Calibration Procedure





For information about entering calibrator values, refer to the system operating instructions. For information on the calibration procedure, refer to the Axis-Shield Clinical Chemistry HBP Reagent Kit.

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.

Technical Support

For Technical Support please contact your local distributor or representative.

REF	Product Code
IVD	<i>In Vitro</i> Diagnostic Medical Device
LOT	Lot number
	Consult Instructions For Use
	Manufacturer
	Use by
	Store at 2-8°C
CALIBRATOR KIT	Calibrator Kit
CAL 1 - CAL 6	Calibrator 1 - 6
Rx Only	For Prescription Use Only

RPBL1199/R2

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