

ENGLISH

Intended Use

The Axis-Shield HbA1c Calibrator Kit is intended to be used for the calibration of the Axis-Shield HbA1c Reagent Assay on Clinical Chemistry analysers.

Summary and Principle

The Axis-Shield HbA1c Calibrator Kit has been designed for calibration of a direct HbA1c Immunoturbidimetric assay. Refer to the Axis-Shield HbA1c reagent instructions for use for further information.

Contents:

1 vial (Calibrator 1) containing buffer and 4 vials (Calibrator 2 - 5) containing lyophilised human whole blood. The concentrations of HbA1c in each calibrator are lot-specific. **Refer to the calibrator vial labels for specific concentrations.**

Calibrator	CAL 1	CAL 2	CAL 3	CAL 4	CAL 5
Format	Liquid	Lyophilised	Lyophilised	Lyophilised	Lyophilised
Pre-treatment	1.0 mL Ready for Use	To be reconstituted	To be reconstituted	To be reconstituted	To be reconstituted

Standardization

The HbA1c assigned values are matched to internal reference standards. The internal reference standards are traceable to the International Federation of Clinical Chemistry (IFCC) reference standards.

The concentrations of HbA1c are lot-specific. **Refer to the calibrator vial labels for specific concentrations.**

Measuring Units

The default result unit for the assay is % HbA1c.

For alternative units, manual calculations can be used according to the following equations:

- NGSP %HbA1c to IFCC mmol/mol: [%HbA1c x 10.93] - 23.50
- IFCC mmol/mol to NGSP %HbA1c: [mmol/mol x 0.09148] + 2.152

Precautions

IVD For *In Vitro* Diagnostic Use.



The Calibrators contains 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. Material contains <0.10% sodium azide as preservative. Safety data sheets (MSDS/SDS) are available upon request.

Storage and Stability

The Axis-Shield HbA1c Calibrator Kit as supplied must be stored refrigerated (2-8°C) until use. The lyophilised Calibrators are stable until the expiration date when stored and handled as directed. Do not use after the expiration date. For further details on storage directions after reconstitution refer to the procedure and handling section.

Procedure and Handling

Calibrator level 1 is liquid ready for use buffer. Calibrator levels 2, 3, 4 and 5 are lyophilised whole blood.

Each Calibrator must be run in accordance with the instructions accompanying the instrument and Axis-Shield HbA1c Reagent Kit. Before reconstitution and sampling, allow the vials to warm to room temperature (18-25°C).

Reconstitute Calibrator levels 2, 3, 4 and 5 with 1.0 mL of distilled or RO water.

Replace the stopper and allow the vial to stand for ten minutes, and then rotate gently until completely dissolved.

After reconstitution, Calibrators are stable for up to:

- 4 hours at room temperature (18-25°C)
- 4 days at 2-8°C.
- 4 weeks at -20°C or colder (aliquoted). Calibrators may undergo one freeze/thaw cycle.

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 HbA1c Reagent Kit.

Limitations






This product must not be used after the expiration date or exceed the recommended storage directions.

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.

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

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
	CAUTION, consult accompanying documents
CALIBRATOR KIT	Calibrator Kit
CAL 1 - CAL 5	Calibrator 1 - 5

RPBL1089/R1
Ver 2014/06



Axis-Shield Diagnostics Ltd.
The Technology Park
Dundee DD2 1XA
United Kingdom
Tel: +44 (0) 1382 422000
Fax: +44 (0) 1382 422088