

ENGLISH

Intended Use

The Axis-Shield HbA1c Control Kit is intended to be used as an assayed quality control material when used in the Axis-Shield HbA1c assay for the quantitative measurement of percent HbA1c in human blood samples.

Summary and Principle

The use of quality control material is to monitor acceptable performance of the Axis-Shield HbA1c Assay. Refer to the Axis-Shield HbA1c Reagent instructions for use for further information.


Contents

2 vials containing lyophilised human whole blood. **The concentrations of HbA1c in each Control are lot-specific.** Refer to the vial labels for specific concentration and ranges.

Control	Format	Pre-Treatment
CONTROL L	Lyophilised	To be reconstituted
CONTROL H	Lyophilised	To be reconstituted

Precautions

IVD For *In Vitro* Diagnostic Use.

 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 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. Safety data sheets (MSDS/SDS) are available upon request.

Storage and Stability

The Axis-Shield HbA1c Control Kit as supplied must be stored refrigerated (2-8°C) prior to use. The lyophilised controls are stable until the expiration date when stored and handled as directed. Do not use after the expiration date. Further details on storage directions for reconstituted controls are detailed in the procedure and handling section.

Procedure and Handling

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

Reconstitute each level of control material 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, Controls 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). Controls may undergo one freeze/thaw cycle.

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

Assignment of values

It is recommended that each laboratory establishes its own mean and acceptable ranges and use those provided only as a guide. The concentrations of HbA1c in each Control are lot-specific. **Refer to the vial labels for specific concentration and ranges.**

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

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.

This product is not intended for use as a calibrator in the Axis-Shield HbA1c assay.

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
CONTROL KIT	Control Kit
CONTROL L	Control Low, High (L, H)

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