

HbA1c CALIBRATOR SET

Lot xxxxxxxx



Cat. No.:	Pack name:	Packaging (Content):
XSYS0057	HBA1C CAL SET	4 x 0.25 ml

Intended use

HbA1c Calibrator Set is a set of four liquid-stable calibrators with different levels based on human blood material (erythrocytes).

Storage

The calibrators both unopened and opened must be stored at 2 – 8 °C, protected from light and heat.

Stability

Unopened and opened until the end of the indicated month of expiry if contamination and evaporation are avoided after having opened the bottles.

Proper storage and handling must be observed.

Warnings and Precautions

Reagents of the kit are not classified like dangerous but contain less than 0.1% sodium azide classified as very toxic and dangerous substance for the environment.

Each individual blood donation used for production of HbA1c Calb. was found to be non-reactive when tested with approved methods for HBsAg, anti-HIV 1+2 and anti-HCV. As there is no possibility to exclude definitely that products derived from human blood transmit infectious agents, it is recommended to handle the calibrator with the same precautions used for patient specimens.

Preparation

HbA1c Calibrator set is ready to use. Calibrators must be treated the same way as patient samples. Please refer to the package insert of the reagent HbA1c, Cat. No. XSYS0054.

Calibrator preparation:

Hemolyzing Solution (R3) 500 µl
Calibrator 10 µl

Mix and allow to stand for 5 minutes or until complete lysis is apparent.

Procedure

Please refer to the reagent package insert for instructions for use.

Assay Values

The calibrator values have been made traceable to the approved IFCC reference method. Values according to DCCT/NGSP in % have been derived from the values according to IFCC by calculation. Calibrator values listed below are specific for this lot number of calibrator only.

Waste management

Please refer to local legal requirements.

Literature

1. The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes in the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Engl J Med.1993; 329:977-86.
2. Little RR, Rohlfing CI, Wiedmeyer HM, Myers GL et al. The national Glycohemoglobin Standardization Program: A five-Year Progress Report. Clin Chem 2001; 47:1985-92.

QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485



- Little RR, Rohlfing CI, Wiedmeyer HM, Myers GL et al. The national Glycohemoglobin Standardization Program: A five-Year Progress Report. Clin Chem 2001; 47:1985-92.
- Jeppsson JO, Kobold U, Barr J, Finke A et al. Approved IFCC Reference method for the measurement of HbA1c in human blood. Clin Chem Lab Med 2002; 40:78-89.
- Hoelzel W, Weykamp C et al. IFCC Reference system for measurement of HbA1c in Human Blood and the national standardization Schemes in the United States, Japan and Sweden: A Method Comparison Study. Clin Chem 2004; 50:1:1666-74.
- Biosafety in Microbiological and Biomedical Laboratories. U.S. Department of Health and Human Services, Washington 1993 (HHS Publication No. [CDC] 93-8395).

Assigned values

Target values according to IFCC (mmol/mol)

	Lot No.	Expiry Date	Calibrator Value	
			3-component system	2-component system
HbA1c Level 1	1031310	01/2014	28.7 mmol/mol	27.7 mmol/mol
HbA1c Level 2	1031310	01/2014	58.6 mmol/mol	57.0 mmol/mol
HbA1c Level 3	1031310	01/2014	105 mmol/mol	110 mmol/mol
HbA1c Level 4	1031310	01/2014	146 mmol/mol	150 mmol/mol

Calibrator values according to DCCT/NGSP (%)


	Lot No.	Expiry Date	Calibrator Value	
			3-component system	2-component system
HbA1c Level 1	1031310	01/2014	4.78 %	4.68 %
HbA1c Level 2	1031310	01/2014	7.51 %	7.37 %
HbA1c Level 3	1031310	01/2014	11.8 %	12.2 %
HbA1c Level 4	1031310	01/2014	15.5 %	15.9 %


SYMBOLS:


The following symbols are used in the labelling of ERBA kits:


REF Catalogue No  CE Mark - Device comply with the Directive 98/79/EC

LOT Batch Code **IVD** In Vitro Diagnostics

 Expiry Date
(Last day of the month)

 Consult Instruction for Use

 Manufactured by

 Storage temperature

HbA1c CALIBRATOR SET Product Name **CONT** Content

Date of Revision: 27.6.2013



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