HbA1c CONTROL

Lot xxxxxxx

EN

CE IVD

Cat. No.:	Pack name:	Packaging (Content):
XSYS0056	HBA1C CON H	1 x 0.25 ml

Intended use

HbA1c liquid control is a human–based control. The HbA1c concentration in HbA1c Control High is pathological.

Storage and Stability

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

Unopened and opened: Maximum 15 months within indicated period of shelf life if contamination and evaporation are avoided after having opened the bottles.

Proper storage and handling of this product must be observed.

Precautions and Warnings

Reagent of the kit is not classified like dangerous but contains 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 control 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 control with the same precautions used for patient specimens.

Preparation

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

Control preparation:

Hemolyzing Solution (R3)	500 µl
Control	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

HbA1c control values according to DCCT/NGSP in % and according to IFCC in mmol/mol have been derived from percentage values according to IFCC by calculation.

Waste management

Please refer to local legal requirements.

QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485

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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 Cl, Wiedmeyer HM,Myers GL et al. The national Glycohemoglobin Standardization Program: A five-Year Progress Report. Clin Chem 2001; 47:1985-92.
3. Jeppsson JO, Kobold U, Barr J, Finke A at al. Approved IFCC Reference method for the measurement of HbA1c in human blood. Clin Cem Lab Med 2002; 40:78-89.
4. 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.
5. Röhle G, Siekmann L. Quality assurance of quantitative determination. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 1393-1401.
6. 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		Target value	Range
HbA1c Control High	1031309	01/2014	3-component system	104 mmol/mol	83.2 – 125 mmol/mol
			2-component system	110 mmol/mol	88.0 – 132 mmol/mol

Target values according to DCCT/NGSP (%)

	Lot No.	Expiry Date		Target value	Range
HbA1c Control High	1031309	01/2014	3-component system	11.7 %	9.76 – 13.6 %
			2-component system	12.2 %	10.2 – 14.2 %

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 CON H Product Name

CONT Content

Date of Revision: 27.6.2013

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