

# HbA1c CONTROL

Lot xxxxxxx



Cat. No.:	Pack name:	Packaging (Content):
XSYS0055	HBA1C CON L	1 x 0.25 ml

## Intended use

HbA1c liquid control is a human-based control. The HbA1c concentration in HbA1c Control Low is normal.

## 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

12000121  
12000150



Erba Lachema s.r.o., Karásek 1d, 621 00 Brno, CZ  
e-mail: [diagnostics@erbalachema.com](mailto:diagnostics@erbalachema.com), [www.erbamannheim.com](http://www.erbamannheim.com)

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