

TruLab HbA1c liquid

Assayed quality control material for monitoring assay performance of quantitative in vitro determination of hemoglobin A1c (HbA1c)

Order Information

5 9800 99 10 074	Level 2	4 x 0.25 mL
5 9800 99 10 060	Level 2	1 x 0.25 mL

Description

TruLab HbA1c liquid is a control based on human blood material (erythrocytes). The HbA1c concentration in TruLab HbA1c liquid Level 2 is pathological.

Storage

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

Stability

Unopened and opened:

Maximum 15 months within the 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.

Warnings and Precautions

- Each individual blood donation used for production of TruLab HbA1c liquid 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.
- Please refer to the safety data sheets and take the necessary precautions for the use of calibrators and controls.
- For professional use only!

Preparation

TruLab HbA1c liquid controls are ready to use. Controls must be treated the same way as patient samples. Please refer to the package insert of the reagent.

Target Values

The assay values were determined using DiaSys reagents oneHbA1c FS respectively oneHbA1c IS, calibrated by DiaSys TruCal HbA1c liquid. Assay values may vary slightly with different reagents. Control values according to DCCT/NGSP in % and according to IFCC have been derived from values according to IFCC by calculation [1–4]. The assay values listed below are specific for this lot number of control only.

Procedure

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

Literature

- 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.
- 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.
- 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 Hemoglobin A1c in Human Blood and the National Standardization Schemes in the United States, Japan, and Sweden: A Method-Comparison Study. *Clin Chem* 2004; 50:1:166-74.
- 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.
- Biosafety in Microbiological and Biomedical Laboratories. U.S. Department of Health and Human Services, Washington 1993 (HHS Publication No. [CDC] 93-8395).

Waste management

Please refer to local legal requirements.

Manufacturer

 DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

Target values according to IFCC [mmol/mol]

	Lot No.	Expiry date		Target value	Range
TruLab HbA1c liquid Level 2	27142	2020-06	3-component system	83.7 mmol/mol	67.0 – 100 mmol/mol
			2-component system	84.1 mmol/mol	67.3 – 101 mmol/mol
			InnovaStar® (New Application)	80.5 mmol/mol	64.4 – 96.6 mmol/mol
			InnovaStar®	66.6 mmol/mol	53.3 – 79.9 mmol/mol

Target values according to DCCT/NGSP [%] have been derived from the values according to IFCC by calculation

	Lot No.	Expiry date		Target value	Range
TruLab HbA1c liquid Level 2	27142	2020-06	3-component system	9.81 %	8.28 – 11.3 %
			2-component system	9.85 %	8.31 – 11.4 %
			InnovaStar® (New Application)	9.52 %	8.04 – 11.0 %
			InnovaStar®	8.24 %	7.03 – 9.46 %

Calculation formula:

$$\text{HbA1c (NGSP}^b) = 0.0915 \times \text{HbA1c (IFCC}^a) + 2.15$$

a: IFCC values in mmol/mol

b: NGSP values in %