TruLab HbA1c net

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

Order Information

5 9930 99 10 076 Level 1 6 x 1 mL

Description

TruLab HbA1c net is a lyophilized control based on human blood material (erythrocytes). The HbA1c concentration in TruLab HbA1c net Level 1 is normal.

Stability

Unopened: Until the end of the indicated month of expiry, stored at 2 – 8°C

Reconstituted:

Storage temperature	– 20°C *	+ 2 – 8°C	+ 15 – 25°C
Stability	3 months	28 days	2 days

* Freeze only once!

Proper storage and handling of this product must be observed. Protect the control from light. Avoid contamination and evaporation.

Warnings and Precautions

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

Preparation

The lyophilisate is vacuum sealed; therefore, the vial should be opened very carefully to avoid loss of dried material. For reconstitution add exactly 1 mL of distilled water. Close the vial carefully and allow the control to stand for 10 minutes at room temperature. Then, for further 20 minutes homogenize the control by swirling occasionally. Avoid foaming! Do not shake! Controls must be treated the same way as patient samples. Please refer to section “sample preparation” in the package insert of the reagent. The use of DiaSys HbA1c net Hemolyzing Solution product code 1 4590… is required.

Target Values

The assay values were determined using DiaSys reagent HbA1c net FS, calibrated by DiaSys TruCal HbA1c net. Control values according to DCCT/NGSP and according to IFCC have been calculated from IFCC values [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

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 et al. Approved IFCC reference method for the measurement of HbA1c in human blood. Clin Chem Lab Med 2002;40:78-89.
4. 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.
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).

Waste Management

Please refer to local legal requirements.

Manufacturer

IVD CE

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

Target for use with manual hemolysis

Target values according to IFCC [mmol/mol]					
	Lot No.	**Expiry date**	**Test**	**Target value**	**Range**
TruLab HbA1c net Level 1	38957	2027-07-31	**HbA1c net FS**	36.7 mmol/mol	29.4 – 44.0 mmol/mol
Target values according to DCCT/NGSP [%]					
TruLab HbA1c net Level 1	38957	2027-07-31	**HbA1c net FS**	5.51 %	4.84 – 6.18 %

Target Values for use with onboard hemolysis

Target values according to IFCC [mmol/mol]					
	Lot No.	**Expiry date**	**Test**	**Target value**	**Range**
TruLab HbA1c net Level 1	38957	2027-07-31	**HbA1c net FS**	34.7 mmol/mol	27.8 – 41.6 mmol/mol
Target values according to DCCT/NGSP [%]					
TruLab HbA1c net Level 1	38957	2027-07-31	**HbA1c net FS**	5.33 %	4.69 – 5.96 %