TruCal HbA1c liquid

Calibrator set for use in tests for quantitative in vitro determination of hemoglobin A1c (HbA1c) on photometric systems

Order Information

1 3320 99 10 043 4 x 0.25 mL

Description

TruCal HbA1c liquid is a set of four liquid-stable calibrators with different levels based on human blood material (erythrocytes). The calibrator set is to be used for calibration of the DiaSys test **oneHbA1c FS** (Cat. No. 1 3329).

Storage

The calibrators 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

1. Each individual blood donation used for production of TruCal 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 calibrator with the same precautions used for patient specimens.
2. Please refer to the safety data sheets and take the necessary precautions for the use of calibrators and controls.
3. For professional use only!

Preparation

The TruCal HbA1c liquid 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.

Waste Management

Please refer to local legal requirements.

Calibrator 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 [1–4].
Calibrator values listed below are specific for this lot number of calibrator only.

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-Years 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. Biosafety in Microbiological and Biomedical Laboratories. U.S. Department of Health and Human Services, Washington 1993 (HHS Publication No. [CDC] 93-8395).

Manufacturer

IVD CE

DiaSys Diagnostic Systems GmbH
Alte Strasse 9
65558 Holzheim Germany

Calibrator values according to IFCC

	Lot No.	Expiry Date	Calibrator Value
			2-component system
TruCal HbA1c liquid Level 1	34200	2024-04-30	33.1 mmol/mol
TruCal HbA1c liquid Level 2	34201	2024-04-30	70.8 mmol/mol
TruCal HbA1c liquid Level 3	34202	2024-04-30	116 mmol/mol
TruCal HbA1c liquid Level 4	34203	2024-04-30	145 mmol/mol