

TruCal HbA1c

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

Order Information

1 3350 99 10 044 2 x 0.3 mL

Description

TruCal HbA1c net is a lyophilized calibrator based on human blood material (erythrocytes). The calibrator is used for calibration of DiaSys HbA1c net FS (Prod. code 1 3348...). Using the TWIN test application, the concentrations of HbA1c and total hemoglobin are determined successively. Therefore, calibrations for HbA1c as well as for total hemoglobin have to be done simultaneously. After entering the calculation formula into the instrument calculation of the HbA1c ratio from total hemoglobin is automatically conducted.

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 calibrator from light. Avoid contamination and evaporation.

Warnings and Precautions

- Each individual blood donation used for production of TruCal 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 calibrator with the same precautions used for patient specimens.
- Hemoglobin and HbA1c values determined with DiaSys HbA1c net FS are used to calculate the HbA1c ratio from total hemoglobin exclusively. Individual results for total hemoglobin [g/dL] and HbA1c [g/dL] must not be used for diagnostic purposes.
- Please refer to the safety data sheets and take necessary precautions for use of calibrators and controls.
- 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 0.3 mL of distilled water. Close the vial carefully and allow the calibrator to stand for 10 minutes at room temperature. Then, for further 20 minutes homogenize the calibrator by swirling occasionally. Avoid foaming! Do not shake! Two different calibrator levels must be prepared. Please, refer to the section "sample preparation" in the package insert of the reagent. The use of DiaSys HbA1c net Hemolyzing Solution product code 1 4590... is required.

Procedure

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

Calibrator Values

The calibrator values have been made traceable to the approved IFCC reference method [3]. Calculation according to DCCT/NGSP is possible [1, 2].

Calibrator values listed below are specific for this lot number of calibrator only.

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-Years 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.
- 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

Calibrator Values for use with manual hemolysis

	Lot No.	Expiry Date	Calibrator Value	
			Hemoglobin	HbA1c
TruCal HbA1c net Level 1	38304	2027-02-28	6.23 g/dL	0.370 g/dL
TruCal HbA1c net Level 2			13.8 g/dL	1.06 g/dL

Calibrator Values for use with onboard hemolysis

	Lot No.	Expiry Date	Calibrator Value	
			Hemoglobin	HbA1c
TruCal HbA1c net Level 1	38304	2027-02-28	7.20 g/dL	0.412 g/dL
TruCal HbA1c net Level 2			15.2 g/dL	1.08 g/dL