Lyophilized HbA1c Controls

HbA1c Controls

REF	Product Size
HS201-020-01 HS201-020-02	1x1 mL

Intended Use:

JTC HbA1c controls are lyophilized human blood-based control materials that are used during the performance evaluation of HbA1c kits for Internal/External Quality Assessment purposes.

Summary

JTC HbA1c Controls are freeze-dried substances manufactured from human serum. Each control lot provides target values relevant to that specific batch. The concentrations of the Hemoglobin and HbA1c are typically set within the normal range and pathological range for Level 1 and Level 2, respectively.

Handling

Carefully remove the screw cap and stopper to prevent any loss of lyophilized material, then pipette 1.0 mL of distilled/deionized water into the vial. Allow the vial to rest undisturbed in a light-protected area for at least 30 minutes, gently swirling it until the lyophilized material completely dissolves. While swirling, be careful to prevent foam formation and avoid shaking the vial. When not in use, store the controls tightly capped and protected from light at a temperature between +2°C to +8°C. Remember to mix before using them again.

Assay Procedure

Transfer the required volume of control into a sample cup and perform the test in the same way as patient samples.
Controls should be run each day in parallel with patient samples and after every calibration.

Storage and Stability

JTC HbA1c Controls remain stable until the expiration date when kept unopened at +2/+8°C. After reconstitution, the stability of components is as follows:
- 1 day at +15/+25°C
- 1 week at +2/+8°C
- 21 days in -20°C.

Target Values and Ranges

The determined target values are given in value sheet provided with the product. Value assignment has been performed on HPLC based HbA1c methods under fully standardized conditions.

The specified target value is the average of all obtained values. The corresponding control range is calculated as the target value ± 3 standard deviations (standard deviation is calculated considering values obtained from several target value determinations). Results should fall within the defined ranges. If values are outside the range, corrective actions should be determined by each laboratory.

Warnings and Precautions for Use

The used H. Blood units of European origin have been tested by CE-marked test kits and found to be non-reactive for HBsAg, anti-HIV 1+2, anti-HCV, and Syphilis. In addition, HAV, HBV, HCV, HIV-1, and Parvo B19 have been tested by PCR.

However, all human material should be considered potentially infectious. Since no testing method can rule out the potential risk of infection with absolute certainty, the material should be handled with the same level of care as a patient specimen.

Disposal

Reagents must be disposed of in accordance with all Federal, Provincial, State, and local regulations.

	Manufacturer
IVD	In vitro diagnostic medical device
REF	Catalog Number
	Exclamation Mark

JTC Diagnosemittel GmbH	
Address:	Schulweg 7, (34516) Vöhl, Germany
Tel:	+49 563 59 92 93 46 +49 163 27 58 499
Website:	https://jtc-diagnostics.de/
E-mail:	info@jtc-diagnostics.de

Doc. Number: JTC-OTH-10-06
Revision No: 00
Revision Date: 02/04/2024