BGT BioGenTechnologies GmbH
Von-Langen-Weg 10
D-48565 Steinfurt
Tel.: 02551/4090 Fax.: 02551/1298

Hb A1c Kontrollset

KG3445 CE

INTENDED USE
This product is intended for *in-vitro* diagnostic use in the quality control of HbA_{1c} on clinical chemistry systems.

SAFETY PRECAUTIONS AND WARNINGS
This reconstitution fluid contains 0.09% w/v Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
The level 1 & level 2 controls contain human blood.
Warning: Potentially Biohazardous Material.
Human source material from which this product has been derived has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests.
However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.
For *in-vitro* diagnostic use only, do not pipette by mouth, exercise the normal precautions required for handling laboratory reagents.

STORAGE AND STABILITY
The level 1 & level 2 controls are stable up to expiry as supplied.
The reconstituted control is stable for 3 months when stored refrigerated at 2 - 8°C.
NB. Do not freeze the reconstituted controls.

PREPARATION FOR USE/RECONSTITUTION
1. Remove the cap from the control bottle.
2. Decant the appropriate amount of reconstitution fluid into a suitable vessel.
3. Add 0.25 ml of the reconstitution fluid to the control.
4. Replace control bottle cap. Swirl the bottle several times and leave to stand at room temperature for 15 minutes.
5. After 15 minutes, coat all surfaces of the bottle by rotating and inverting the bottle.
   Continue mixing until the solution is homogeneous and all lyophilised material is reconstituted.

NB. Controls are treated the same as samples and in accordance with kit or reagent being used. Use with BGT Kit will require pretreatment in order to assay for HbA_{1c} & Total Haemoglobin. Mix 10 µl of the reconstituted control with 400 µl of haemoglobin denaturant reagent (1:41 dilution).

MATERIALS PROVIDED

Level 1 Control: (HbA1c CONTROL 1)	2 x 0.25 ml
Level 2 Control: (HbA1c CONTROL 2)	2 x 0.25 ml
Reconstitution Fluid: (REC FL)	1 x 2 ml

MATERIALS REQUIRED BUT NOT PROVIDED
Distilled Water
Volumetric pipette

ASSIGNED % HbA1c VALUES
A value (mean and range about the mean) has been assigned to this lot of control at BGT Laboratories Ltd.

LEVEL	Lot No.	EXPIRY	%HbA_{1c} TARGET	%HbA_{1c} Range
NORMAL	1120HA	2010-01	5.30	4.24 - 6.36
ABNORMAL	1121HA	2010-01	12.82	10.26 - 15.38

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Control Values have been assigned as a consequence of NGSP traceability on the Dimension analyzer .A value (mean and range about the mean) has been assigned to this lot of control at BGT Laboratories Ltd.

LEVEL	Lot No.	EXPIRY	%HbA_{1c} TARGET	%HbA_{1c} Range
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A

CORRESPONDING THB CONCENTRATION VALUES

LEVEL	Lot No.	EXPIRY	THB MEAN	THB Range
NORMAL	1120HA	2010-01	16.34	13.07 - 19.61
ABNORMAL	1121HA	2010-01	15.66	12.53 - 18.79

Dimension analyser

LEVEL	Lot No.	EXPIRY	THB MEAN	THB Range
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A

CORRESPONDING HbA_{1c} CONCENTRATION VALUES

LEVEL	Lot No.	EXPIRY	HbA_{1c} MEAN	HbA_{1c} Range
NORMAL	1120HA	2010-01	0.87	0.70 - 1.04
ABNORMAL	1121HA	2010-01	1.95	1.56 - 2.34

Dimension analyser

LEVEL	Lot No.	EXPIRY	HbA_{1c} MEAN	HbA_{1c} Range
N/A	N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A	N/A

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