

Chargen-B.: 1183HA/ 1184HA Artikel-Nr.: KG5072

Inhalt: 2 x 2 x 0.5 ml Verwendbar bis: 2012-08

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

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 1 month 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. Add 0.5 ml of double deionised water to the control.
3. Replace control bottle cap. Swirl the bottle several times and leave to stand at room temperature for 15 minutes.
4. 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: 2 x 0.5 ml
(HbA_{1c} CONTROL 1)

Level 2 Control: 2 x 0.5 ml
(HbA_{1c} CONTROL 2)

MATERIALS REQUIRED BUT NOT PROVIDED

Double Deionised Water
Volumetric pipette

ASSIGNED % HbA_{1c} VALUES

Each batch of HbA_{1c} control is submitted to a number of external laboratories and values are assigned from a consensus of results obtained by these laboratories.

If a method is unavailable, contact BGT BioGenTechnologies GmbH, Tel: 02551/4090 or email info@biogentechnologies.de.

LEVEL 1

Methode	Einheit	Zielwert	Bereich
Abbott Architect c/ci Systems (DCCT/NGSP)	%HbA _{1c}	5.55	4.44-6.66
Abbott Architect c/ci Systems (IFCC)	mmol/mol	37.1	29.7-44.5
Abbott Axsym (DCCT/NGSP)	%HbA _{1c}	5.60	4.48-6.72
Abbott Axsym (IFCC)	mmol/mol	37.7	30.1-45.2
Arkray Menarini HA8121/10/60 (DCCT/NGSP)	%HbA _{1c}	5.48	4.38-6.58
Arkray Menarini HA8121/10/60 (IFCC)	mmol/mol	36.4	29.1-43.7
Beckman AU400/600/640/2700/5400 (DCCT/NGSP)	%HbA _{1c}	5.45	4.36-6.54
Beckman AU400/600/640/2700/5400 (IFCC)	mmol/mol	36.0	28.8-43.2
Beckman Synchron CX 4/5/7/9 (DCCT/NGSP)	%HbA _{1c}	5.55	4.44-6.66
Beckman Synchron CX 4/5/7/9 (IFCC)	mmol/mol	37.2	29.8-44.6
Beckman Synchron LX20/PRO (DCCT/NGSP)	%HbA _{1c}	5.40	4.32-6.48
Beckman Synchron LX20/PRO (IFCC)	mmol/mol	35.5	28.4-42.6
Biorad D-10 (DCCT/NGSP)	%HbA _{1c}	5.60	4.48-6.72
Biorad D-10 (IFCC)	mmol/mol	37.7	30.1-45.2
Biorad Variant II (Boronate Affinity) (DCCT/NGSP)	%HbA _{1c}	5.70	4.56-6.84
Biorad Variant II (Boronate Affinity) (IFCC)	mmol/mol	38.8	31.0-46.6
Biorad Variant II (ion exchange) (DCCT/NGSP)	%HbA _{1c}	6.10	4.88-7.32
Biorad Variant II (ion exchange) (IFCC)	mmol/mol	43.2	34.6-51.8
Drew DS5/G15 (DCCT/NGSP)	%HbA _{1c}	5.93	4.74-7.12
Drew DS5/G15 (IFCC)	mmol/mol	41.3	33.0-49.6
Hitachi 9 Series (DCCT/NGSP)	%HbA _{1c}	5.65	4.52-6.78
Konelab 20/30/60 (DCCT/NGSP)	%HbA _{1c}	6.03	4.82-7.24
Konelab 20/30/60 (IFCC)	mmol/mol	42.4	33.9-50.9
Nycocard Reader (DCCT/NGSP)	%HbA _{1c}	6.63	5.30-7.96
Nycocard Reader (IFCC)	mmol/mol	49.0	39.2-58.8
Primus CLC385 /PDQ /Ultra 2 (DCCT/NGSP)	%HbA _{1c}	5.79	4.63-6.95
Primus CLC385 /PDQ /Ultra 2 (IFCC)	mmol/mol	39.8	31.8-47.8
Randox Rx Daytona/ Imola (DCCT/NGSP)	%HbA _{1c}	5.76	4.61-6.91
Randox Rx Daytona/ Imola (IFCC)	mmol/mol	39.4	31.5-47.3
Roche Cobas 6000 (DCCT/NGSP)	%HbA _{1c}	5.73	4.58-6.88
Roche Cobas 6000 (IFCC)	mmol/mol	39.1	31.3-46.9
Roche Integra (DCCT/NGSP)	%HbA _{1c}	5.70	4.56-6.84
Roche Integra (IFCC)	mmol/mol	38.8	31.0-46.6
Roche Modular P/ Cobas c111 (DCCT/NGSP)	%HbA _{1c}	5.92	4.74-7.10
Roche Modular P/ Cobas c111 (IFCC)	mmol/mol	41.2	33.0-49.4
Siemens/ Bayer ADVIA 1200/1650/2400 (DCCT/NGSP)	%HbA _{1c}	5.44	4.35-6.53
Siemens/ Bayer ADVIA 1200/1650/2400 (IFCC)	mmol/mol	35.9	28.7-43.1
Siemens/ Bayer DCA2000 (DCCT/NGSP)	%HbA _{1c}	5.64	4.51-6.77
Siemens/ Bayer DCA2000 (IFCC)	mmol/mol	38.1	30.5-45.7
Siemens/ Dade Dimension (DCCT/NGSP)	%HbA _{1c}	5.70	4.56-6.84
Siemens/ Dade Dimension (IFCC)	mmol/mol	38.8	31.0-46.6
TOSOH HLC723/G7/G8 (DCCT/NGSP)	%HbA _{1c}	5.65	4.52-6.78
TOSOH HLC723/G7/G8 (IFCC)	mmol/mol	38.2	30.6-45.8

LEVEL 2

Methode	Einheit	Zielwert	Bereich
Abbott Architect c/ci Systems (DCCT/NGSP)	%HbA _{1c}	10.7	8.56-12.8
Abbott Architect c/ci Systems (IFCC)	mmol/mol	93.4	74.7-112.1
Abbott Axsym (DCCT/NGSP)	%HbA _{1c}	12.6	10.1-15.1
Abbott Axsym (IFCC)	mmol/mol	114.2	91.4-137.0
Arkray Menarini HA8121/10/60 (DCCT/NGSP)	%HbA _{1c}	10.6	8.48-12.7
Arkray Menarini HA8121/10/60 (IFCC)	mmol/mol	92.3	73.8-110.8
Beckman AU400/600/640/2700/5400 (DCCT/NGSP)	%HbA _{1c}	10.4	8.32-12.5
Beckman AU400/600/640/2700/5400 (IFCC)	mmol/mol	90.2	72.2-108.2
Beckman Synchron CX 4/5/7/9 (DCCT/NGSP)	%HbA _{1c}	11.4	9.12-13.7
Beckman Synchron CX 4/5/7/9 (IFCC)	mmol/mol	101.1	80.9-121.3
Beckman Synchron LX20/PRO (DCCT/NGSP)	%HbA _{1c}	11.1	8.88-13.3
Beckman Synchron LX20/PRO (IFCC)	mmol/mol	97.8	78.2-117.4
Biorad D-10 (DCCT/NGSP)	%HbA _{1c}	10.8	8.64-12.96
Biorad D-10 (IFCC)	mmol/mol	94.5	75.6-113.4
Biorad Variant II (Boronate Affinity) (DCCT/NGSP)	%HbA _{1c}	10.4	8.64-13.0
Biorad Variant II (Boronate Affinity) (IFCC)	mmol/mol	90.2	72.2-108.2
Biorad Variant II (ion exchange) (DCCT/NGSP)	%HbA _{1c}	10.3	8.32-12.5
Biorad Variant II (ion exchange) (IFCC)	mmol/mol	89.1	71.3-106.9
Drew DS5/G15 (DCCT/NGSP)	%HbA _{1c}	10.2	8.24-12.4
Drew DS5/G15 (IFCC)	mmol/mol	88.0	70.4-105.6
Hitachi 9 Series (DCCT/NGSP)	%HbA _{1c}	11.7	9.36-14.04
Konelab 20/30/60 (DCCT/NGSP)	%HbA _{1c}	11.7	9.36-14.04
Konelab 20/30/60 (IFCC)	mmol/mol	104.4	83.5-125.3
Nycocard Reader (DCCT/NGSP)	%HbA _{1c}	14.7	11.8-17.6
Nycocard Reader (IFCC)	mmol/mol	137.2	109.8-164.6
Primus CLC385 /PDQ /Ultra 2 (DCCT/NGSP)	%HbA _{1c}	15.5	12.4-18.6
Primus CLC385 /PDQ /Ultra 2 (IFCC)	mmol/mol	145.9	116.7-175.1
Randox Rx Daytona/ Imola (DCCT/NGSP)	%HbA _{1c}	11.5	9.20-13.8
Randox Rx Daytona/ Imola (IFCC)	mmol/mol	102.2	81.8-122.6
Roche Cobas 6000 (DCCT/NGSP)	%HbA _{1c}	10.8	8.64-13.0
Roche Cobas 6000 (IFCC)	mmol/mol	94.5	75.6-113.4
Roche Integra (DCCT/NGSP)	%HbA _{1c}	11.1	8.88-13.3
Roche Integra (IFCC)	mmol/mol	97.8	78.2-117.4
Roche Modular P/ Cobas c111 (DCCT/NGSP)	%HbA _{1c}	11.2	8.96-13.4
Roche Modular P/ Cobas c111 (IFCC)	mmol/mol	98.9	79.1-118.7
Siemens/ Bayer ADVIA 1200/1650/2400 (DCCT/NGSP)	%HbA _{1c}	10.8	8.64-13.0
Siemens/ Bayer ADVIA 1200/1650/2400 (IFCC)	mmol/mol	94.5	75.6-113.4
Siemens/ Bayer DCA2000 (DCCT/NGSP)	%HbA _{1c}	11.4	9.12-13.7
Siemens/ Bayer DCA2000 (IFCC)	mmol/mol	101.1	80.9-121.3
Siemens/ Dade Dimension (DCCT/NGSP)	%HbA _{1c}	10.9	8.72-13.1
Siemens/ Dade Dimension (IFCC)	mmol/mol	95.6	76.5-114.7
TOSOH HLC723/G7/G8 (DCCT/NGSP)	%HbA _{1c}	10.6	8.48-12.7
TOSOH HLC723/G7/G8 (IFCC)	mmol/mol	92.3	73.8-110.8