HAEMOGLOBIN A_{1c} CONTROL SET (HbA_{1c} CONTROL)

CAT. NO: HA5072 **LOT NO:** 2568HA & 2569HA
SIZE: 2 x 2 x 0.5 ml **EXPIRY:** 2028-08-28
GTIN: 05055273208818

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°C to +8°C. This stability claim is based on data obtained using immunoturbidimetric methodology.

N.B. 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.

N.B. Once reconstituted, these controls should be treated in the same way as samples and in accordance with kit or reagent being used.

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

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

MATERIALS REQUIRED BUT NOT PROVIDED
Double deionised water
Volumetric pipette

ASSIGNED % HbA1c VALUES
Due to the variation caused by test equipment, test reagents and laboratory technique, the quoted ranges are provided for guidance. It is recommended that these ranges are used until each laboratory has established its own ranges, based on individual laboratory requirements.

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 Randox Laboratories - Technical Services, Northern Ireland, tel: +44 (0) 28 9445 1070 or email Technical.Services@randox.com.

The presence of a vertical bar in the margin indicates a technical update from the previous revision.

LEVEL 1

Method	Units	Target	Range
Abbott Architect c(Direct Turbidimetric) (DCCT/NGSP)	%HBA1C	5.95	4.76 - 7.14
Abbott Architect c(Direct Turbidimetric) (IFCC)	mmol/mol	41.5	33.2 - 49.8
Anbio HbA1c Rapid Test Kit (DCCT/NGSP)	%HBA1C	5.72	4.58 - 6.86
Anbio HbA1c Rapid Test Kit (IFCC)	mmol/mol	39	31.2 - 46.8
Arkray Pocket Chem A1c Advanced (DCCT / NGSP)	%HBA1C	6.62	5.30 – 7.94
Arkray Pocket Chem A1c Advanced (IFCC)	mmol/mol	48.9	39.1 – 58.7
Beckman HbA1c Advanced (DCCT/NGSP)	%HBA1C	5.84	4.67 - 7.01
Beckman HbA1c Advanced (IFCC)	mmol/mol	40.3	32.2 - 48.4
Biorad D-10 (DCCT/NGSP)	%HBA1C	5.87	4.7 - 7.04
Biorad D-10 (IFCC)	mmol/mol	40.7	32.6 - 48.8
Biorad Variant II (ion exchange) (DCCT/NGSP)	%HBA1C	5.90	4.72 - 7.08
Biorad Variant II (ion exchange) (IFCC)	mmol/mol	41.0	32.8 - 49.2
Boditech Med Inc AFIAS (DCCT/NGSP)	%HBA1C	5.38	4.30 - 6.46
Boditech Med Inc AFIAS (IFCC)	mmol/mol	35.3	28.2 - 42.4
Clover A1c (DCCT/NGSP)	%HBA1C	5.77	4.62 - 6.92
Clover A1c (IFCC)	mmol/mol	39.6	31.7 - 47.5
Cormay Accent (DCCT/NGSP)	%HBA1C	5.53	4.42 - 6.64
Cormay Accent (IFCC)	mmol/mol	36.9	29.5 - 44.3
DiaSys QDx Alc Advance (DCCT / NGSP)	%HBA1C	6.62	5.30 – 7.94
DiaSys QDx Alc Advance (IFCC)	mmol/mol	48.9	39.1 – 58.7
DiaSys respons A1c (DCCT / NGSP)	%HBA1C	6.62	5.30 – 7.94
DiaSys respons(IFCC)	mmol/mol	48.9	39.1 – 58.7
D&G Group SRL Performa A1c (DCCT / NGSP)	%HBA1C	6.62	5.30 – 7.94
D&G Group SRL Performa A1c (IFCC)	mmol/mol	48.9	39.1 – 58.7
EKF Quotient Quo-Lab A1c Test (DCCT/NGSP)	%HBA1C	6.44	5.15 - 7.73
EKF Quotient Quo-Lab A1c Test (IFCC)	mmol/mol	46.9	37.5 - 56.3
Erba XL Series (DCCT/NGSP)	%HBA1C	5.88	4.70 - 7.06
Erba XL Series (IFCC)	mmol/mol	40.8	32.6 - 49
GCMS Greencare A1c (DCCT / NGSP)	%HBA1C	6.62	5.30 – 7.94
GCMS Greencare A1c (IFCC)	mmol/mol	48.9	39.1 – 58.7
Medconn MQ-3000 (HPLC) (DCCT/NGSP)	%HBA1C	5.79	4.63 - 6.95
Medconn MQ-3000 (HPLC) (IFCC)	mmol/mol	39.8	31.8 - 47.8
Mindray BS Series (DCCT/NGSP)	%HBA1C	5.73	4.58 - 6.88
Mindray BS Series (IFCC)	mmol/mol	39.1	31.3 - 46.9
MTI Diagnostics HA-1500 (DCCT/NGSP)	%HBA1C	5.96	4.77 - 7.15
MTI Diagnostics HA-1500 (IFCC)	mmol/mol	41.6	33.3 - 49.9
Ortho Vitros A1C1 (Enzymatic) (DCCT/NGSP)	%HBA1C	6.35	5.08 - 7.62
Ortho Vitros A1C1 (Enzymatic) (IFCC)	mmol/mol	45.9	36.7 - 55.1
Randox Rx HbA1c II (DCCT/NGSP)	%HBA1C	5.91	4.73 - 7.09
Randox Rx HbA1c II (IFCC)	mmol/mol	41.1	32.9 - 49.3
Roche Cobas 6000/8000 (DCCT/NGSP)	%HBA1C	5.75	4.6 - 6.9
Roche Cobas 6000/8000 (IFCC)	mmol/mol	39.3	31.4 - 47.2
Roche Cobas c513 (DCCT/NGSP)	%HBA1C	5.82	4.66 - 6.98
Roche Cobas c513 (IFCC)	mmol/mol	40.1	32.1 - 48.1
Roche Modular P/Cobas c111 (DCCT/NGSP)	%HBA1C	5.83	4.66 – 7.00
Roche Modular P/Cobas c111 (IFCC)	mmol/mol	40.2	32.2 - 48.2
Siemens Atellica CH A1c_E (DCCT/NGSP)	%HBA1C	5.30	4.24 - 6.36
Siemens Atellica CH A1c_E (IFCC)	mmol/mol	34.4	27.5 - 41.3
Wondfo Finecare Meter (DCCT/NGSP)	%HBA1C	5.73	4.58 - 6.88
Wondfo Finecare Meter (IFCC)	mmol/mol	39.1	31.3 - 46.9

Total Haemoglobin		Target	Range
Beckman AU Instruments	g/dl	13.2	10.6-15.8

LEVEL 2

Method	Units	Target	Range
Abbott Architect c (DCCT/NGSP)	%HBAIC	10.6	8.48 - 12.7
Abbott Architect c (IFCC)	mmol/mol	92.4	73.9 - 111
Anbio HbA1c Rapid Test Kit (DCCT/NGSP)	%HBAIC	10.9	8.72 - 13.1
Anbio HbA1c Rapid Test Kit (IFCC)	mmol/mol	95.6	76.5 - 115
Arkray Pocket Chem A1c Advanced (DCCT / NGSP)	%HBAIC	11.6	9.28 – 13.9
Arkray Pocket Chem A1c Advanced (IFCC)	mmol/mol	103	82.4 - 124
Beckman HbA1c Advanced (DCCT/NGSP)	%HBAIC	11.4	9.12 - 13.7
Beckman HbA1c Advanced (IFCC)	mmol/mol	101	80.8 - 121
Biorad D-10 (DCCT/NGSP)	%HBAIC	11.3	9.04 - 13.6
Biorad D-10 (IFCC)	mmol/mol	100	80.0 - 120
Biorad Variant II (ion exchange) (DCCT/NGSP)	%HBAIC	11.0	8.8 - 13.2
Biorad Variant II (ion exchange) (IFCC)	mmol/mol	96.7	77.4 - 116
Boditech Med Inc i-CHROMA (DCCT/NGSP)	%HBAIC	9.80	7.81 - 11.7
Boditech Med Inc i-CHROMA (IFCC)	mmol/mol	83.2	66.6 - 100
Clover A1c (DCCT/NGSP)	%HBAIC	11.0	8.8 - 13.2
Clover A1c (IFCC)	mmol/mol	96.7	77.4 - 116
Cormay Accent (DCCT/NGSP)	%HBAIC	11.5	9.20 - 13.8
Cormay Accent (IFCC)	mmol/mol	102	81.6 - 122
DiaSys QDx Alc Advance (DCCT / NGSP)	%HBAIC	11.6	9.28 – 13.9
DiaSys QDx Alc Advance (IFCC)	mmol/mol	103	82.4 - 124
DiaSys respons A1c (DCCT / NGSP)	%HBAIC	11.6	9.28 – 13.9
DiaSys respons(IFCC)	mmol/mol	103	82.4 - 124
D&G Group SRL Performa A1c (DCCT / NGSP)	%HBAIC	11.6	9.28 – 13.9
D&G Group SRL Performa A1c (IFCC)	mmol/mol	103	82.4 - 124
EKF Quotient Quo-Lab A1c Test (DCCT/NGSP)	%HBAIC	12.1	9.68 - 14.5
EKF Quotient Quo-Lab A1c Test (IFCC)	mmol/mol	109	87.2 - 131
Erba XL Series (DCCT/NGSP)	%HBAIC	11.7	9.36 - 14
Erba XL Series (IFCC)	mmol/mol	104	83.2 - 125
GCMS Greencare A1c (DCCT / NGSP)	%HBAIC	11.6	9.28 – 13.9
GCMS Greencare A1c (IFCC)	mmol/mol	103	82.4 - 124
Medconn MQ2000PT HPLC (DCCT/NGSP)	%HBAIC	11.0	8.8 - 13.2
Medconn MQ2000PT HPLC (IFCC)	mmol/mol	96.7	77.4 - 116
Medconn MQ-8000 (HPLC) (DCCT/NGSP)	%HBAIC	11.1	8.88 - 13.3
Medconn MQ-8000 (HPLC) (IFCC)	mmol/mol	97.8	78.2 - 117
Mindray BS Series (DCCT/NGSP)	%HBAIC	11.2	8.96 - 13.4
Mindray BS Series (IFCC)	mmol/mol	98.9	79.1 - 119
MTI Diagnostics HA-1500 (DCCT/NGSP)	%HBAIC	10.8	8.64 - 13
MTI Diagnostics HA-1500 (IFCC)	mmol/mol	94.5	75.6 - 113
Ortho Vitros A1C1 (Enzymatic) (DCCT/NGSP)	%HBAIC	12.5	10.0 – 15.0
Ortho Vitros A1C1 (Enzymatic) (IFCC)	mmol/mol	113	90.4 - 136
Randox Rx HbA1c II (DCCT/NGSP)	%HBAIC	11.7	9.36 - 14.0
Randox Rx HbA1c II (IFCC)	mmol/mol	104	83.2 - 125
Roche Cobas 4000/c311 (DCCT/NGSP)	%HBAIC	11.4	9.12 - 13.7
Roche Cobas 4000/c311 (IFCC)	mmol/mol	101	80.8 - 121
Roche Cobas c303/c503/c703 (DCCT/NGSP)	%HBAIC	11.2	8.96 - 13.4
Roche Cobas c303/c503/c703 (IFCC)	mmol/mol	98.9	79.1 - 119
Roche Integra (DCCT/NGSP)	%HBAIC	11.3	9.04 - 13.6
Roche Integra (IFCC)	mmol/mol	100	80.0 - 120
Siemens Atellica CH A1c_3 (DCCT/NGSP)	%HBAIC	10.6	8.48 - 12.7
Siemens Atellica CH A1c_3 (IFCC)	mmol/mol	92.4	73.9 - 111
Wondfo Finecare Meter (DCCT/NGSP)	%HBAIC	11.6	9.28 - 13.9
Wondfo Finecare Meter (IFCC)	mmol/mol	103	82.4 - 124

Total Haemoglobin		Target	Range
Beckman AU Instruments	g/dl	12.2	9.76 – 14.6

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