RANDOX CE

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

CAT. NO: HA5072
SIZE: 2 x 2 x 0.5 ml
GTIN: 05055273208818
LOT NO: 2300HA & 2302HA
EXPIRY: 2024-09-28

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. When used with **Randox Haemoglobin A1c** reagent, catalogue numbers **HA3830, HA8043 or HA8321,** the controls should be pre-treated by mixing 10 µl of the reconstituted control with 400 µl of Haemoglobin denaturant reagent (1:41 dilution), prior to analysis for HbA1c & Total Haemoglobin.
When used with **Randox Haemoglobin A1c II** reagent, catalogue numbers **HA4068, HA8123 or HA8379,** no pre-treatment is required prior to analysis.

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.

EC REP Randox Teoranta, Meenmore,
Dungloe, Donegal,
F94 TV06, Ireland

Rev. 12 Apr '22 me

LEVEL 1

Method	Units	Target	Range
Abbott Architect c / Alinity c (DCCT/NGSP)	%HbA1c	5.29	4.23 - 6.35
Abbott Architect c / Alinity c (IFCC)	mmol/mol	34.3	27.4 - 41.2
Abbott Architect c(Direct Turbidimetric) (DCCT/NGSP)	%HbA1c	5.86	4.69 - 7.03
Abbott Architect c(Direct Turbidimetric) (IFCC)	mmol/mol	40.5	32.4 - 48.6
Arkray PocketChem A1c (DCCT/NGSP)	%HbA1c	5.58	4.46 - 6.70
Arkray PocketChem A1c (IFCC)	mmol/mol	37.5	30.0 - 45.0
Arkray/Adams/Menarini A1c HA-8000 Series (DCCT/NGSP)	%HbA1c	5.58	4.46 - 6.70
Arkray/Adams/Menarini A1c HA-8000 Series (IFCC)	mmol/mol	37.5	30.0 - 45.0
Beckman AU Instruments (DCCT/NGSP)	%HbA1c	5.68	4.54 - 6.82
Beckman AU Instruments (IFCC)	mmol/mol	38.6	30.9 - 46.3
Beckman DxC600/DxC800 (DCCT/NGSP)	%HbA1c	5.69	4.55 - 6.83
Beckman DxC600/DxC800 (IFCC)	mmol/mol	38.7	31.0 - 46.4
Bioanalytic Diagnostic HbA1c (DCCT/NGSP)	%HbA1c	5.47	4.38 - 6.56
Bioanalytic Diagnostic HbA1c (IFCC)	mmol/mol	36.3	29.0 - 43.6
Biorad D-10 (DCCT/NGSP)	%HbA1c	5.69	4.55 - 6.83
Biorad D-10 (IFCC)	mmol/mol	38.7	31.0 - 46.4
Biorad D-100 (DCCT/NGSP)	%HbA1c	5.74	4.59 - 6.89
Biorad D-100 (IFCC)	mmol/mol	39.2	31.4 - 47.0
Biorad Variant II (ion exchange) (DCCT/NGSP)	%HbA1c	5.63	4.50 - 6.76
Biorad Variant II (ion exchange) (IFCC)	mmol/mol	38.0	30.4 - 45.6
Boditech Med Inc i-CHROMA (DCCT/NGSP)	%HbA1c	5.54	4.43 - 6.65
Boditech Med Inc i-CHROMA (IFCC)	mmol/mol	37.0	29.6 - 44.4
Clover A1c (DCCT/NGSP)	%HbA1c	6.18	4.94 - 7.42
Clover A1c (IFCC)	mmol/mol	44.0	35.2 - 52.8
EKF Quotient Quo-Lab A1c Test (DCCT/NGSP)	%HbA1c	6.84	5.47 - 8.21
EKF Quotient Quo-Lab A1c Test (IFCC)	mmol/mol	51.3	41.0 - 61.6
Erba XL Series (DCCT/NGSP)	%HbA1c	5.44	4.35 - 6.53
Erba XL Series (IFCC)	mmol/mol	36.0	28.8 - 43.2
Human HumaMeter A1c (DCCT/NGSP)	%HbA1c	7.26	5.81 - 8.71
Human HumaMeter A1c (IFCC)	mmol/mol	55.8	44.6 - 67.0
Mindray BS200/300/400/800 (DCCT/NGSP)	%HbA1c	5.65	4.52 - 6.78
Mindray BS200/300/400/800 (IFCC)	mmol/mol	38.3	30.6 - 46.0
Mindray H50/ H50P (DCCT/NGSP)	%HbA1c	5.58	4.46 - 6.70
Mindray H50/ H50P (IFCC)	mmol/mol	37.5	30.0 - 45.0
MTI Diagnostics HA-1500 (DCCT/NGSP)	%HbA1c	5.77	4.62 - 6.92
MTI Diagnostics HA-1500 (IFCC)	mmol/mol	39.6	31.7 - 47.5
Ortho Vitros 4600/5600/5.1 FS/XT 7600 (DCCT/NGSP)	%HbA1c	5.67	4.54 - 6.80
Ortho Vitros 4600/5600/5.1 FS/XT 7600 (IFCC)	mmol/mol	38.5	30.8 - 46.2
Randox Rx HbA1c (DCCT/NGSP)	%HbA1c	6.04	4.83 - 7.25
Randox Rx HbA1c (IFCC)	mmol/mol	42.5	34.0 - 51.0
Roche Cobas 4000/c311 (DCCT/NGSP)	%HbA1c	5.61	4.49 - 6.73
Roche Cobas 4000/c311 (IFCC)	mmol/mol	37.8	30.2 - 45.4
Roche Cobas 6000/8000 (DCCT/NGSP)	%HbA1c	5.70	4.56 - 6.84
Roche Cobas c303/c503 (DCCT/NGSP)	%HbA1c	5.85	4.68 - 7.02
Roche Cobas c303/c503 (IFCC)	mmol/mol	40.4	32.3 - 48.5
Roche Cobas c513 (DCCT/NGSP)	%HbA1c	5.79	4.63 - 6.95
Roche Cobas c513 (IFCC)	mmol/mol	39.8	31.8 - 47.8
Roche Integra (DCCT/NGSP)	%HbA1c	5.70	4.56 - 6.84
Roche Integra (IFCC)	mmol/mol	38.8	31.0 - 46.6
Roche Modular P/Cobas c111 (DCCT/NGSP)	%HbA1c	5.70	4.56 - 6.84
Roche Modular P/Cobas c111 (IFCC)	mmol/mol	38.8	31.0 - 46.6

LEVEL 1 (continued)

Method	Units	Target	Range
Sebia Capillarys / Minicap (DCCT/NGSP)	%HbA1c	5.51	4.41 - 6.61
Sebia Capillarys / Minicap (IFCC)	mmol/mol	36.7	29.4 - 44.0
Siemens DCA2000/Vantage (DCCT/NGSP)	%HbA1c	6.01	4.81 - 7.21
Siemens DCA2000/Vantage (IFCC)	mmol/mol	42.2	33.8 - 50.6
Siemens/Dade Dimension (DCCT/NGSP)	%HbA1c	5.82	4.66 - 6.98
Siemens/Dade Dimension (IFCC)	mmol/mol	40.1	32.1 - 48.1

Total Haemoglobin	Units	Target	Range
Beckman AU Instruments	g/dl	15.13	12.10 - 18.16
Randox RX Series	g/dl	14.91	11.93 – 17.89
Roche Cobas 4000/c311	g/dl	16.24	12.99 - 19.49
Roche Cobas 6000/8000	g/dl	15.67	12.54 - 18.80

LEVEL 2

Method	Units	Target	Range
Abbott Architect c / Alinity c (DCCT/NGSP)	%HbA1c	10.3	8.24 - 12.4
Abbott Architect c / Alinity c (IFCC)	mmol/mol	89.1	71.3 - 107
Abbott Architect c(Direct Turbidimetric) (DCCT/NGSP)	%HbA1c	11.8	9.44 - 14.2
Abbott Architect c(Direct Turbidimetric) (IFCC)	mmol/mol	106	84.4 - 127
Arkray PocketChem A1c (DCCT/NGSP)	%HbA1c	10.4	8.32 - 12.5
Arkray PocketChem A1c (IFCC)	mmol/mol	90.2	72.2 - 108
Arkray/Adams/Menarini A1c HA-8000 Series (DCCT/NGSP)	%HbA1c	10.5	8.40 - 12.6
Arkray/Adams/Menarini A1c HA-8000 Series (IFCC)	mmol/mol	91.3	73.0 - 110
Beckman AU Instruments (DCCT/NGSP)	%HbA1c	10.9	8.72 - 13.1
Beckman AU Instruments (IFCC)	mmol/mol	95.6	76.5 - 115
Beckman DxC600/DxC800 (DCCT/NGSP)	%HbA1c	11.0	8.80 - 13.2
Beckman DxC600/DxC800 (IFCC)	mmol/mol	96.7	77.4 - 116
Bioanalytic Diagnostic HbA1c (DCCT/NGSP)	%HbA1c	11.3	9.04 - 13.6
Bioanalytic Diagnostic HbA1c (IFCC)	mmol/mol	100	80.0 - 120
Biorad D-10 (DCCT/NGSP)	%HbA1c	11.0	8.80 - 13.2
Biorad D-10 (IFCC)	mmol/mol	96.7	77.4 - 116
Biorad D-100 (DCCT/NGSP)	%HbA1c	11.0	8.8 - 13.2
Biorad D-100 (IFCC)	mmol/mol	96.7	77.4 - 116
Biorad Variant II (ion exchange) (DCCT/NGSP)	%HbA1c	10.9	8.72 - 13.1
Biorad Variant II (ion exchange) (IFCC)	mmol/mol	95.6	76.5 - 115
Boditech Med Inc i-CHROMA (DCCT/NGSP)	%HbA1c	9.70	7.76 - 11.6
Boditech Med Inc i-CHROMA (IFCC)	mmol/mol	82.5	66.0 - 99.0
Clover A1c (DCCT/NGSP)	%HbA1c	10.3	8.24 - 12.4
Clover A1c (IFCC)	mmol/mol	89.1	71.3 - 107
EKF Quotient Quo-Lab A1c Test (DCCT/NGSP)	%HbA1c	11.4	9.12 - 13.7
EKF Quotient Quo-Lab A1c Test (IFCC)	mmol/mol	101	80.9 - 121
Erba XL Series (DCCT/NGSP)	%HbA1c	10.3	8.24 - 12.4
Erba XL Series (IFCC)	mmol/mol	89.1	71.3 - 107
Human HumaMeter A1c (DCCT/NGSP)	%HbA1c	11.1	8.88 - 13.3
Human HumaMeter A1c (IFCC)	mmol/mol	97.8	78.2 - 117
Mindray BS200/300/400/800 (DCCT/NGSP)	%HbA1c	10.7	8.56 - 12.8
Mindray BS200/300/400/800 (IFCC)	mmol/mol	93.4	74.7 - 112
Mindray H50/ H50P (DCCT/NGSP)	%HbA1c	10.7	8.56 - 12.8
Mindray H50/ H50P (IFCC)	mmol/mol	93.4	74.7 - 112
MTI Diagnostics HA-1500 (DCCT/NGSP)	%HbA1c	11.4	9.12 - 13.7
MTI Diagnostics HA-1500 (IFCC)	mmol/mol	101	80.9 - 121
Ortho Vitros 4600/5600/5.1 FS/XT 7600 (DCCT/NGSP)	%HbA1c	11.1	8.88 - 13.3
Ortho Vitros 4600/5600/5.1 FS/XT 7600 (IFCC)	mmol/mol	97.8	78.2 - 117
Randox Rx HbA1c (DCCT/NGSP)	%HbA1c	12.9	10.3 - 15.5
Randox Rx HbA1c (IFCC)	mmol/mol	118	94.0 - 141
Roche Cobas 4000/c311 (DCCT/NGSP)	%HbA1c	11.1	8.88 - 13.3
Roche Cobas 4000/c311 (IFCC)	mmol/mol	97.8	78.2 - 117
Roche Cobas c303/c503 (DCCT/NGSP)	%HbA1c	11.2	8.96 - 13.4
Roche Cobas c303/c503 (IFCC)	mmol/mol	98.9	79.1 - 119
Roche Cobas c513 (DCCT/NGSP)	%HbA1c	11.3	9.04 - 13.6
Roche Cobas c513 (IFCC)	mmol/mol	100	80.0 - 120
Roche Integra (DCCT/NGSP)	%HbA1c	11.2	8.96 - 13.4
Roche Integra (IFCC)	mmol/mol	98.9	79.1 - 119
Roche Modular P/Cobas c111 (DCCT/NGSP)	%HbA1c	11.4	9.12 - 13.7
Roche Modular P/Cobas c111 (IFCC)	mmol/mol	101	80.9 - 121

LEVEL 2 (continued)

Method	Units	Target	Range
Sebia Capillarys / Minicap (DCCT/NGSP)	%HbA1c	10.6	8.48 - 12.7
Sebia Capillarys / Minicap (IFCC)	mmol/mol	92.4	73.9 - 111
Siemens DCA2000/Vantage (DCCT/NGSP)	%HbA1c	11.3	9.04 - 13.6
Siemens DCA2000/Vantage (IFCC)	mmol/mol	100	80.0 - 120
Siemens/Dade Dimension (DCCT/NGSP)	%HbA1c	10.7	8.56 - 12.8
Siemens/Dade Dimension (IFCC)	mmol/mol	93.4	74.7 - 112

Total Haemoglobin	Units	Target	Range
Beckman AU Instruments	g/dl	13.9	11.12 - 16.68
Randox RX Series	g/dl	15.6	12.48 – 18.72
Roche Cobas 4000/c311	g/dl	14.9	11.92 - 17.88
Roche Cobas 6000/8000	g/dl	15.9	12.72 - 19.08

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