

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

CAT. NO: HA5072

LOT NOS: 2195HA & 2198HA

SIZE: 2 x 2 x 0.5 ml

EXPIRY: 2023-03-28

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. 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 HbA_{1c} & 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: 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 Randox Laboratories - Technical Services, Northern Ireland, tel: +44 (0) 28 9445 1070 or email Technical.Services@randox.com.

LEVEL I

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	5.70	4.56 - 6.84
Abbott Architect c(Direct Turbidimetric) (IFCC)	mmol/mol	38.8	31.0 - 46.6
Arkray PocketChem A1c (DCCT/NGSP)	%HbA1c	6.58	5.26 - 7.90
Arkray PocketChem A1c (IFCC)	mmol/mol	48.4	38.7 - 58.1
Arkray/Adams/Menarini A1c HA-8000 Series (DCCT/NGSP)	%HbA1c	5.51	4.41 - 6.61
Arkray/Adams/Menarini A1c HA-8000 Series (IFCC)	mmol/mol	36.7	29.4 - 44.0
Beckman AU Instruments (DCCT/NGSP)	%HbA1c	5.76	4.61 - 6.91
Beckman AU Instruments (IFCC)	mmol/mol	39.5	31.6 - 47.4
Bioanalytic Diagnostic HbA1c (DCCT/NGSP)	%HbA1c	5.76	4.61 - 6.91
Bioanalytic Diagnostic HbA1c (IFCC)	mmol/mol	39.5	31.6 - 47.4
Biorad D-10 (DCCT/NGSP)	%HbA1c	5.62	4.50 - 6.74
Biorad D-10 (IFCC)	mmol/mol	37.9	30.3 - 45.5
Biorad D-100 (DCCT/NGSP)	%HbA1c	5.60	4.48 - 6.72
Biorad D-100 (IFCC)	mmol/mol	37.7	30.2 - 45.2
Biorad Variant II (ion exchange) (DCCT/NGSP)	%HbA1c	5.68	4.54 - 6.82
Biorad Variant II (ion exchange) (IFCC)	mmol/mol	38.6	30.9 - 46.3
Ceragem Labona Check (DCCT/NGSP)	%HbA1c	5.81	4.65 - 6.97
Ceragem Labona Check (IFCC)	mmol/mol	40.0	32.0 - 48.0
EKF Quotient Quo-Lab A1c Test (DCCT/NGSP)	%HbA1c	6.64	5.31 - 7.97
EKF Quotient Quo-Lab A1c Test (IFCC)	mmol/mol	49.1	39.3 - 58.9
Erba XL Series (DCCT/NGSP)	%HbA1c	5.83	4.66 - 7.00
Erba XL Series (IFCC)	mmol/mol	40.2	32.2 - 48.2
Human HumaMeter A1c (DCCT/NGSP)	%HbA1c	6.75	5.40 - 8.10
Human HumaMeter A1c (IFCC)	mmol/mol	50.3	40.2 - 60.4
Konelab 20/30/60 / Thermo Indiko (DCCT/NGSP)	%HbA1c	5.72	4.58 - 6.86
Konelab 20/30/60 / Thermo Indiko (IFCC)	mmol/mol	39.0	31.2 - 46.8
Mindray BS200/300/400/800 (DCCT/NGSP)	%HbA1c	5.55	4.44 - 6.66
Mindray BS200/300/400/800 (IFCC)	mmol/mol	37.2	29.8 - 44.6
Nycocard Reader (DCCT/NGSP)	%HbA1c	7.88	6.30 - 9.46
Nycocard Reader (IFCC)	mmol/mol	62.6	50.1 - 75.1
Ortho Vitros 4600/5600/5.1 FS/XT 7600 (DCCT/NGSP)	%HbA1c	5.59	4.47 - 6.71
Ortho Vitros 4600/5600/5.1 FS/XT 7600 (IFCC)	mmol/mol	37.6	30.1 - 45.1
Randox Rx HbA1c (DCCT/NGSP)	%HbA1c	5.96	4.77 - 7.15
Randox Rx HbA1c (IFCC)	mmol/mol	41.6	33.3 - 49.9
Roche Cobas 4000/c311 (DCCT/NGSP)	%HbA1c	5.41	4.33 - 6.49
Roche Cobas 4000/c311 (IFCC)	mmol/mol	35.6	28.5 - 42.7

LEVEL I

Method	Units	Target	Range
Roche Cobas 6000/8000 (DCCT/NGSP)	%HbA1c	5.60	4.48 - 6.72
Roche Cobas 6000/8000 (IFCC)	mmol/mol	37.7	30.2 - 45.2
Roche Cobas c513 (DCCT/NGSP)	%HbA1c	5.63	4.50 - 6.76
Roche Cobas c513 (IFCC)	mmol/mol	38.0	30.4 - 45.6
Roche Integra (DCCT/NGSP)	%HbA1c	5.66	4.53 - 6.79
Roche Integra (IFCC)	mmol/mol	38.4	30.7 - 46.1
Roche Modular P/Cobas c111 (DCCT/NGSP)	%HbA1c	5.54	4.43 - 6.65
Roche Modular P/Cobas c111 (IFCC)	mmol/mol	37.0	29.6 - 44.4
SD A1c Care (DCCT/NGSP)	%HbA1c	5.76	4.61 - 6.91
SD A1c Care (IFCC)	mmol/mol	39.5	31.6 - 47.4
Sebia Capillars / Minicap (DCCT/NGSP)	%HbA1c	5.42	4.34 - 6.50
Sebia Capillars / Minicap (IFCC)	mmol/mol	35.7	28.6 - 42.8
Siemens ADVIA 1200/1650/1800/2400 (DCCT/NGSP)	%HbA1c	5.51	4.41 - 6.61
Siemens ADVIA 1200/1650/1800/2400 (IFCC)	mmol/mol	36.7	29.4 - 44.0
Siemens Atellica CH A1c_3 (DCCT/NGSP)	%HbA1c	5.59	4.47 - 6.71
Siemens Atellica CH A1c_3 (IFCC)	mmol/mol	37.6	30.1 - 45.1
Siemens DCA2000/Vantage (DCCT/NGSP)	%HbA1c	5.82	4.66 - 6.98
Siemens DCA2000/Vantage (IFCC)	mmol/mol	40.1	32.1 - 48.1
Siemens/Dade Dimension (DCCT/NGSP)	%HbA1c	5.88	4.70 - 7.06
Siemens/Dade Dimension (IFCC)	mmol/mol	40.8	32.6 - 49.0
TOSOH G7 Automated HPLC Analyser (DCCT/NGSP)	%HbA1c	5.70	5.20 - 6.10
TOSOH G7 Automated HPLC Analyser (IFCC)	mmol/mol	39.0	36.0 - 42.0
TOSOH G8 Automated HPLC Analyser (DCCT/NGSP)	%HbA1c	5.56	5.11 - 5.94
TOSOH G8 Automated HPLC Analyser (IFCC)	mmol/mol	37.2	34.2 - 40.2
TOSOH GX Automated HPLC Analyser (DCCT/NGSP)	%HbA1c	5.76	5.30 - 6.17
TOSOH GX Automated HPLC Analyser (IFCC)	mmol/mol	39.5	36.3 - 42.6
TOSOH G11 Automated HPLC Analyser (DCCT/NGSP)	%HbA1c	5.58	5.14 - 5.97
TOSOH G11 Automated HPLC Analyser (IFCC)	mmol/mol	37.5	34.5 - 40.5

Total Haemoglobin	Units	Target	Range
Beckman AU Instruments	g/dl	11.5	9.20 - 13.8
Randox RX Series	g/dl	12.4	9.92 - 14.9
Roche Cobas 6000/8000	g/dl	13.6	10.9 - 16.3
Roche Integra	g/dl	13.0	10.4 - 15.6

LEVEL 2

Method	Units	Target	Range
Abbott Architect c / Alinity c (DCCT/NGSP)	%HbA1c	10.7	8.56 - 12.8
Abbott Architect c / Alinity c (IFCC)	mmol/mol	93.4	74.7 - 112
Abbott Architect c(Direct Turbidimetric) (DCCT/NGSP)	%HbA1c	11.3	9.04 - 13.6
Abbott Architect c(Direct Turbidimetric) (IFCC)	mmol/mol	100	80.0 - 120
Arkray PocketChem A1c (DCCT/NGSP)	%HbA1c	11.4	9.12 - 13.7
Arkray PocketChem A1c (IFCC)	mmol/mol	101	80.8 - 121
Arkray/Adams/Menarini A1c HA-8000 Series (DCCT/NGSP)	%HbA1c	10.7	8.56 - 12.8
Arkray/Adams/Menarini A1c HA-8000 Series (IFCC)	mmol/mol	93.4	74.7 - 112
Beckman AU Instruments (DCCT/NGSP)	%HbA1c	11.1	8.88 - 13.3
Beckman AU Instruments (IFCC)	mmol/mol	97.8	78.2 - 117
Bioanalytic Diagnostic HbA1c (DCCT/NGSP)	%HbA1c	11.6	9.28 - 13.9
Bioanalytic Diagnostic HbA1c (IFCC)	mmol/mol	103	82.4 - 124
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	10.7	8.56 - 12.8
Biorad D-100 (IFCC)	mmol/mol	93.4	74.7 - 112
Biorad Variant II (ion exchange) (DCCT/NGSP)	%HbA1c	11.1	8.88 - 13.3
Biorad Variant II (ion exchange) (IFCC)	mmol/mol	97.8	78.2 - 117
Ceragem Labona Check (DCCT/NGSP)	%HbA1c	7.83	6.26 - 9.40
Ceragem Labona Check (IFCC)	mmol/mol	62.1	49.7 - 74.5
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	80.8 - 121
Erba XL Series (DCCT/NGSP)	%HbA1c	11.1	8.88 - 13.3
Erba XL Series (IFCC)	mmol/mol	97.8	78.2 - 117
Human HumaMeter A1c (DCCT/NGSP)	%HbA1c	11.6	9.28 - 13.9
Human HumaMeter A1c (IFCC)	mmol/mol	103	82.4 - 124
Konelab 20/30/60 / Thermo Indiko (DCCT/NGSP)	%HbA1c	11.3	9.04 - 13.6
Konelab 20/30/60 / Thermo Indiko (IFCC)	mmol/mol	100	80.0 - 120
Mindray BS200/300/400/800 (DCCT/NGSP)	%HbA1c	11.0	8.80 - 13.2
Mindray BS200/300/400/800 (IFCC)	mmol/mol	96.7	77.4 - 116
Nycocard Reader (DCCT/NGSP)	%HbA1c	11.3	9.04 - 13.6
Nycocard Reader (IFCC)	mmol/mol	100	80.0 - 120
Ortho Vitros 4600/5600/5.1 FS/XT 7600 (DCCT/NGSP)	%HbA1c	10.8	8.64 - 13.0
Ortho Vitros 4600/5600/5.1 FS/XT 7600 (IFCC)	mmol/mol	94.5	75.6 - 113
Randox Rx HbA1c (DCCT/NGSP)	%HbA1c	12.7	10.2 - 15.2

LEVEL 2

Method	Units	Target	Range
Randox Rx HbA1c (IFCC)	mmol/mol	115	92.0 - 138
Roche Cobas 4000/c311 (DCCT/NGSP)	%HbA1c	11.2	8.96 - 13.4
Roche Cobas 4000/c311 (IFCC)	mmol/mol	98.9	79.1 - 119
Roche Cobas 6000/8000 (DCCT/NGSP)	%HbA1c	11.1	8.88 - 13.3
Roche Cobas 6000/8000 (IFCC)	mmol/mol	97.8	78.2 - 117
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	11.0	8.80 - 13.2
Roche Modular P/Cobas c111 (IFCC)	mmol/mol	96.7	77.4 - 116
SD A1c Care (DCCT/NGSP)	%HbA1c	9.26	7.41 - 11.1
SD A1c Care (IFCC)	mmol/mol	77.7	62.2 - 93.2
Sebia Capillars / Minicap (DCCT/NGSP)	%HbA1c	10.6	8.48 - 12.7
Sebia Capillars / Minicap (IFCC)	mmol/mol	92.4	73.9 - 111
Siemens ADVIA 1200/1650/1800/2400 (DCCT/NGSP)	%HbA1c	10.3	8.24 - 12.4
Siemens ADVIA 1200/1650/1800/2400 (IFCC)	mmol/mol	89.1	71.3 - 107
Siemens Atellica CH A1c_3 (DCCT/NGSP)	%HbA1c	10.6	8.48 - 12.7
Siemens Atellica CH A1c_3 (IFCC)	mmol/mol	92.4	73.9 - 111
Siemens DCA2000/Vantage (DCCT/NGSP)	%HbA1c	11.4	9.12 - 13.7
Siemens DCA2000/Vantage (IFCC)	mmol/mol	101	80.8 - 121
Siemens/Dade Dimension (DCCT/NGSP)	%HbA1c	10.9	8.72 - 13.1
Siemens/Dade Dimension (IFCC)	mmol/mol	95.6	76.5 - 115
TOSOH G7 Automated HPLC Analyser (DCCT/NGSP)	%HbA1c	10.9	10.1 - 11.7
TOSOH G7 Automated HPLC Analyser (IFCC)	mmol/mol	96.0	88.0 - 104
TOSOH G8 Automated HPLC Analyser (DCCT/NGSP)	%HbA1c	10.8	9.93 - 11.6
TOSOH G8 Automated HPLC Analyser (IFCC)	mmol/mol	94.5	86.9 - 102
TOSOH GX Automated HPLC Analyser (DCCT/NGSP)	%HbA1c	11.1	10.2 - 11.9
TOSOH GX Automated HPLC Analyser (IFCC)	mmol/mol	98.2	90.3 - 106
TOSOH G11 Automated HPLC Analyser (DCCT/NGSP)	%HbA1c	10.8	9.92 - 11.5
TOSOH G11 Automated HPLC Analyser (IFCC)	mmol/mol	94.3	86.8 - 102

LEVEL 2

Total Haemoglobin	Units	Target	Range
Beckman AU Instruments	g/dl	11.5	9.20 - 13.8
Randox RX Series	g/dl	12.8	10.2 - 15.4
Roche Cobas 6000/8000	g/dl	13.4	10.7 - 16.1
Roche Integra	g/dl	12.7	10.2 - 15.2

EC REP

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