

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

CAT. NO: HA5072

LOT NO: 1898HA & 1901HA

SIZE: 2 x 2 x 0.5 ml

EXPIRY: 2020-04-28

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. Controls are treated the same as samples and in accordance with kit or reagent being used. Use with Randox 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 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 systems (DCCT / NGSP)	%HbA _{1c}	5.25	4.20 – 6.30
Abbott Architect c systems (IFCC)	mmol/mol	33.9	27.1 – 40.7
Abbott Architect c (Direct Turbidimetric) (DCCT / NGSP)	%HbA _{1c}	6.05	4.84 – 7.26
Abbott Architect c (Direct Turbidimetric) (IFCC)	mmol/mol	42.6	34.1 – 51.1
Abbott Architect i systems (DCCT / NGSP)	%HbA _{1c}	6.43	5.14 – 7.72
Abbott Architect i systems (IFCC)	mmol/mol	46.8	37.4 – 56.2
Arkray Menarini HA8121/40/60/80 (DCCT / NGSP)	%HbA _{1c}	5.68	4.54 – 6.82
Arkray Menarini HA8121/40/60/80 (IFCC)	mmol/mol	38.6	30.9 – 46.3
Beckman AU400/480/600/640/2700/5400 (DCCT / NGSP)	%HbA _{1c}	5.85	4.68 – 7.02
Beckman AU400/480/600/640/2700/5400 (IFCC)	mmol/mol	40.4	32.3 – 48.5
Beckman DxC600/DxC800 (DCCT / NGSP)	%HbA _{1c}	5.75	4.60 – 6.90
Beckman DxC600/DxC800 (IFCC)	mmol/mol	39.3	31.4 – 47.2
Bioanalytic Diagnostic HbA _{1c} (DCCT / NGSP)	%HbA _{1c}	6.00	4.80 – 7.20
Bioanalytic Diagnostic HbA _{1c} (IFCC)	mmol/mol	42.1	33.7 – 50.5
Biorad D-10 (DCCT / NGSP)	%HbA _{1c}	5.68	4.54 – 6.82
Biorad D-10 (IFCC)	mmol/mol	38.6	30.9 – 46.3
Biorad Variant II (ion exchange) (DCCT / NGSP)	%HbA _{1c}	5.72	4.58 – 6.86
Biorad Variant II (ion exchange) (IFCC)	mmol/mol	39.0	31.2 – 46.8
EKF Quo-Lab A1c (DCCT / NGSP)	%HbA _{1c}	6.60	5.28 – 7.92
EKF Quo-Lab A1c (IFCC)	mmol/mol	48.6	38.9 – 58.3
Erba XL Series (DCCT / NGSP)	%HbA _{1c}	5.77	4.62 – 6.92
Erba XL Series (IFCC)	mmol/mol	39.6	31.7 – 47.5
Konelab 20/30/60 / Thermo Indiko (DCCT / NGSP)	%HbA _{1c}	6.16	4.93 – 7.39
Konelab 20/30/60 / Thermo Indiko (IFCC)	mmol/mol	43.8	35.0 – 52.6
Mindray BS200/300/400 (DCCT / NGSP)	%HbA _{1c}	5.60	4.48 – 6.72
Mindray BS200/300/400 (IFCC)	mmol/mol	37.7	30.2 – 45.2
Ortho Vitros 4600 / 5600 / 5.1 FS (DCCT / NGSP)	%HbA _{1c}	5.78	4.62 – 6.94
Ortho Vitros 4600 / 5600 / 5.1 FS (IFCC)	mmol/mol	39.7	31.8 – 47.6
Randox Rx Series (DCCT / NGSP)	%HbA _{1c}	5.96	4.77 – 7.15
Randox Rx Series (IFCC)	mmol/mol	41.6	33.3 – 49.9
Roche Cobas 4000/c311 (DCCT / NGSP)	%HbA _{1c}	5.63	4.50 – 6.76
Roche Cobas 4000/c311 (IFCC)	mmol/mol	38.0	30.4 – 45.6
Roche Cobas 6000/8000 (DCCT / NGSP)	%HbA _{1c}	5.62	4.50 – 6.74
Roche Cobas 6000/8000 (IFCC)	mmol/mol	37.9	30.3 – 45.5
Roche Cobas c513 (DCCT / NGSP)	%HbA _{1c}	5.67	4.54 – 6.80
Roche Cobas c513 (IFCC)	mmol/mol	38.5	30.8 – 46.2
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}	6.11	4.89 – 7.33
Roche Modular P/Cobas c111 (IFCC)	mmol/mol	43.3	34.6 – 52.0
Sebia Capillars / Minicap (DCCT / NGSP)	%HbA _{1c}	5.52	4.42 – 6.62
Sebia Capillars / Minicap (IFCC)	mmol/mol	36.8	29.4 – 44.2
Siemens ADVIA 1200/1650/1800/2400 (DCCT / NGSP)	%HbA _{1c}	5.83	4.66 – 7.00
Siemens ADVIA 1200/1650/1800/2400 (IFCC)	mmol/mol	40.2	32.2 – 48.2
Siemens DCA2000/Vantage (DCCT / NGSP)	%HbA _{1c}	6.21	4.97 – 7.45
Siemens DCA2000/Vantage (IFCC)	mmol/mol	44.4	35.5 – 53.3

LEVEL 1 (continued)

Method	Units	Target	Range
Siemens/Dade Dimension (DCCT / NGSP)	%HbA _{1c}	6.06	4.85 – 7.27
Siemens/Dade Dimension (IFCC)	mmol/mol	42.7	34.2 – 51.2
Tokyo Boeki/Prestige 24i (DCCT / NGSP)	%HbA _{1c}	5.75	4.60 – 6.90
Tokyo Boeki/Prestige 24i (IFCC)	mmol/mol	39.3	31.4 – 47.2
TOSOH HLC723/G7/G8/GX (DCCT / NGSP)	%HbA _{1c}	5.66	4.53 – 6.79
TOSOH HLC723/G7/G8/GX (IFCC)	mmol/mol	38.4	30.7 – 46.1
Trin Bio CLC385/PDQ/Ultra 2 (DCCT / NGSP)	%HbA _{1c}	6.13	4.90 – 7.36
Trin Bio CLC385/PDQ/Ultra 2 (IFCC)	mmol/mol	43.5	34.8 – 52.2
Trinity Biotech Tri-stat (DCCT / NGSP)	%HbA _{1c}	6.91	5.53 – 8.29
Trinity Biotech Tri-stat (IFCC)	mmol/mol	52.0	41.6 – 62.4
Trinity/Menarini Premier Hb9210 (DCCT / NGSP)	%HbA _{1c}	6.05	4.84 – 7.26
Trinity/Menarini Premier Hb9210 (IFCC)	mmol/mol	42.6	34.1 – 51.1

Total Haemoglobin		Target	Range
Randox Rx Series	g/dl	12.8	10.2 – 15.4

LEVEL 2

Method	Units	Target	Range
Abbott Architect c systems (DCCT / NGSP)	%HbA _{1c}	10.6	8.48 – 12.7
Abbott Architect c systems (IFCC)	mmol/mol	92.4	73.9 – 111
Abbott Architect c (Direct Turbidimetric) (DCCT / NGSP)	%HbA _{1c}	11.1	8.88 – 13.3
Abbott Architect c (Direct Turbidimetric) (IFCC)	mmol/mol	97.8	78.2 – 117
Abbott Architect i systems (DCCT / NGSP)	%HbA _{1c}	13.2	10.6 – 15.8
Abbott Architect i systems (IFCC)	mmol/mol	121	96.8 – 145
Arkray Menarini HA8121/40/60/80 (DCCT / NGSP)	%HbA _{1c}	10.9	8.72 – 13.1
Arkray Menarini HA8121/40/60/80 (IFCC)	mmol/mol	95.6	76.5 – 115
Beckman AU400/480/600/640/2700/5400 (DCCT / NGSP)	%HbA _{1c}	11.4	9.12 – 13.7
Beckman AU400/480/600/640/2700/5400 (IFCC)	mmol/mol	101	80.8 – 121
Beckman DxC600/DxC800 (DCCT / NGSP)	%HbA _{1c}	11.7	9.36 – 14.0
Beckman DxC600/DxC800 (IFCC)	mmol/mol	104	83.2 – 125
Bioanalytic Diagnostic HbA _{1c} (DCCT / NGSP)	%HbA _{1c}	11.9	9.52 – 14.3
Bioanalytic Diagnostic HbA _{1c} (IFCC)	mmol/mol	107	85.6 – 128
Biorad D-10 (DCCT / NGSP)	%HbA _{1c}	10.9	8.72 – 13.1
Biorad D-10 (IFCC)	mmol/mol	95.6	76.5 – 115
Biorad Variant II (ion exchange) (DCCT / NGSP)	%HbA _{1c}	11.0	8.80 – 13.2
Biorad Variant II (ion exchange) (IFCC)	mmol/mol	96.7	77.4 – 116
EKF Quo-Lab A1c (DCCT / NGSP)	%HbA _{1c}	11.6	9.28 – 13.9
EKF Quo-Lab A1c (IFCC)	mmol/mol	103	82.4 – 124
Erba XL Series (DCCT / NGSP)	%HbA _{1c}	11.6	9.28 – 13.9
Erba XL Series (IFCC)	mmol/mol	103	82.4 – 124
Konelab 20/30/60 / Thermo Indiko (DCCT / NGSP)	%HbA _{1c}	11.4	9.12 – 13.7
Konelab 20/30/60 / Thermo Indiko (IFCC)	mmol/mol	101	80.8 – 121
Mindray BS200/300/400 (DCCT / NGSP)	%HbA _{1c}	11.3	9.04 – 13.6
Mindray BS200/300/400 (IFCC)	mmol/mol	100	80.0 – 120

LEVEL 2 (continued)

Method	Units	Target	Range
Ortho Vitros 4600 / 5600 / 5.1 FS (DCCT / NGSP)	%HbA _{1c}	11.4	9.12 – 13.7
Ortho Vitros 4600 / 5600 / 5.1 FS (IFCC)	mmol/mol	101	80.8 – 121
Randox Rx Series (DCCT / NGSP)	%HbA _{1c}	12.2	9.76 – 14.6
Randox Rx Series (IFCC)	mmol/mol	110	88.0 – 132
Roche Cobas 4000/c311 (DCCT / NGSP)	%HbA _{1c}	11.3	9.04 – 13.6
Roche Cobas 4000/c311 (IFCC)	mmol/mol	100	80.0 – 120
Roche Cobas 6000/8000 (DCCT / NGSP)	%HbA _{1c}	11.2	8.96 – 13.4
Roche Cobas 6000/8000 (IFCC)	mmol/mol	98.9	79.1 – 119
Roche Cobas c513 (DCCT / NGSP)	%HbA _{1c}	11.4	9.12 – 13.7
Roche Cobas c513 (IFCC)	mmol/mol	101	80.8 – 121
Roche Integra (DCCT / NGSP)	%HbA _{1c}	11.3	9.04 – 13.6
Roche Integra (IFCC)	mmol/mol	100	80.0 – 120
Roche Modular P/Cobas c111 (DCCT / NGSP)	%HbA _{1c}	11.6	9.28 – 13.9
Roche Modular P/Cobas c111 (IFCC)	mmol/mol	103	82.4 – 124
Sebia Capillarys / Minicap (DCCT / NGSP)	%HbA _{1c}	10.7	8.56 – 12.8
Sebia Capillarys / Minicap (IFCC)	mmol/mol	93.4	74.7 – 112
Siemens ADVIA 1200/1650/1800/2400 (DCCT / NGSP)	%HbA _{1c}	11.1	8.88 – 13.3
Siemens ADVIA 1200/1650/1800/2400 (IFCC)	mmol/mol	97.8	78.2 – 117
Siemens DCA2000/Vantage (DCCT / NGSP)	%HbA _{1c}	12.0	9.60 – 14.4
Siemens DCA2000/Vantage (IFCC)	mmol/mol	108	86.4 – 130
Siemens/Dade Dimension (DCCT / NGSP)	%HbA _{1c}	11.3	9.04 – 13.6
Siemens/Dade Dimension (IFCC)	mmol/mol	100	80.0 – 120
Tokyo Boeki/Prestige 24i (DCCT / NGSP)	%HbA _{1c}	11.0	8.80 – 13.2
Tokyo Boeki/Prestige 24i (IFCC)	mmol/mol	96.7	77.4 – 116
TOSOH HLC723/G7/G8/GX (DCCT / NGSP)	%HbA _{1c}	10.8	8.64 – 13.0
TOSOH HLC723/G7/G8/GX (IFCC)	mmol/mol	94.5	75.6 – 113
Trin Bio CLC385/PDQ/Ultra 2 (DCCT / NGSP)	%HbA _{1c}	11.0	8.80 – 13.2
Trin Bio CLC385/PDQ/Ultra 2 (IFCC)	mmol/mol	96.7	77.4 – 116
Trinity Biotech Tri-stat (DCCT / NGSP)	%HbA _{1c}	12.3	9.84 – 14.8
Trinity Biotech Tri-stat (IFCC)	mmol/mol	111	88.8 – 133
Trinity/Menarini Premier Hb9210 (DCCT / NGSP)	%HbA _{1c}	11.1	8.88 – 13.3
Trinity/Menarini Premier Hb9210 (IFCC)	mmol/mol	97.8	78.2 – 117

Total Haemoglobin		Target	Range
Randox Rx Series	g/dl	12.9	10.3 – 15.5

08 Sep '17 ne