

## HAEMOGLOBIN A<sub>1c</sub> CONTROL SET (HbA<sub>1c</sub> CONTROL)

**CAT. NO.** HA5072

**LOT NO.** 1978HA & 1981HA

**SIZE:** 2 x 2 x 0.5 ml

**EXPIRY:** 2020-11-28

**GTIN:** 05055273208818

### INTENDED USE

This product is intended for *in vitro* diagnostic use, in the quality control of HbA<sub>1c</sub> 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<sub>1c</sub> & 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<sub>1c</sub> CONTROL 1)

**Level 2 Control:** 2 x 0.5 ml  
(HbA<sub>1c</sub> CONTROL 2)

### MATERIALS REQUIRED BUT NOT PROVIDED

Double deionised water  
Volumetric pipette

### ASSIGNED % HbA<sub>1c</sub> VALUES

Each batch of HbA<sub>1c</sub> 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](mailto:Technical.Services@randox.com).

**LEVEL I**

Method	Units	Target	Range
Abbott Architect c systems (DCCT / NGSP)	%HbA <sub>1c</sub>	5.41	4.33 – 6.49
Abbott Architect c systems (IFCC)	mmol/mol	35.6	28.5 – 42.7
Abbott Architect c (Direct Turbidimetric) (DCCT / NGSP)	%HbA <sub>1c</sub>	6.47	5.18 – 7.76
Abbott Architect c (Direct Turbidimetric) (IFCC)	mmol/mol	47.2	37.8 – 56.6
Abbott Architect i systems (DCCT / NGSP)	%HbA <sub>1c</sub>	6.95	5.56 – 8.34
Abbott Architect i systems (IFCC)	mmol/mol	52.5	42.0 – 63.0
Arkray Menarini HA8121/40/60/80 (DCCT / NGSP)	%HbA <sub>1c</sub>	5.69	4.55 – 6.83
Arkray Menarini HA8121/40/60/80 (IFCC)	mmol/mol	38.7	31.0 – 46.4
Beckman AU400/480/600/640/2700/5400 (DCCT / NGSP)	%HbA <sub>1c</sub>	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 <sub>1c</sub>	6.07	4.86 – 7.28
Beckman DxC600/DxC800 (IFCC)	mmol/mol	42.8	34.2 – 51.4
Bioanalytic Diagnostic HbA <sub>1c</sub> (DCCT / NGSP)	%HbA <sub>1c</sub>	5.83	4.66 – 7.00
Bioanalytic Diagnostic HbA <sub>1c</sub> (IFCC)	mmol/mol	40.2	32.2 – 48.2
Biorad D-10 (DCCT / NGSP)	%HbA <sub>1c</sub>	5.70	4.56 – 6.84
Biorad D-10 (IFCC)	mmol/mol	38.8	31.0 – 46.6
Biorad Variant II (ion exchange) (DCCT / NGSP)	%HbA <sub>1c</sub>	5.81	4.65 – 6.97
Biorad Variant II (ion exchange) (IFCC)	mmol/mol	40.0	32.0 – 48.0
EKF Quotient Quo-Lab A <sub>1c</sub> Test (DCCT / NGSP)	%HbA <sub>1c</sub>	6.72	5.38 – 8.06
EKF Quotient Quo-Lab A <sub>1c</sub> Test (IFCC)	mmol/mol	49.9	39.9 – 59.9
Konelab 20/30/60 / Thermo Indiko (DCCT / NGSP)	%HbA <sub>1c</sub>	6.20	4.96 – 7.44
Konelab 20/30/60 / Thermo Indiko (IFCC)	mmol/mol	44.3	35.4 – 53.2
Mindray BS200/300/400 (DCCT / NGSP)	%HbA <sub>1c</sub>	5.80	4.64 – 6.96
Mindray BS200/300/400 (IFCC)	mmol/mol	39.9	31.9 – 47.9
Ortho Vitros 4600 / 5600 / 5.1 FS (DCCT / NGSP)	%HbA <sub>1c</sub>	5.72	4.58 – 6.86
Ortho Vitros 4600 / 5600 / 5.1 FS (IFCC)	mmol/mol	39.0	31.2 – 46.8
Randox Rx Series (DCCT / NGSP)	%HbA <sub>1c</sub>	5.95	4.76 – 7.14
Randox Rx Series (IFCC)	mmol/mol	41.5	33.2 – 49.8
Roche Cobas 4000/c311 (DCCT / NGSP)	%HbA <sub>1c</sub>	5.59	4.47 – 6.71
Roche Cobas 4000/c311 (IFCC)	mmol/mol	37.6	30.1 – 45.1
Roche Cobas 6000/8000 (DCCT / NGSP)	%HbA <sub>1c</sub>	5.62	4.50 – 6.74
Roche Cobas 6000/8000 (IFCC)	mmol/mol	37.9	30.3 – 45.5
Roche Integra (DCCT / NGSP)	%HbA <sub>1c</sub>	5.73	4.58 – 6.88
Roche Integra (IFCC)	mmol/mol	39.1	31.3 – 46.9
Roche Modular P/Cobas c111 (DCCT / NGSP)	%HbA <sub>1c</sub>	5.80	4.64 – 6.96
Roche Modular P/Cobas c111 (IFCC)	mmol/mol	39.9	31.9 – 47.9
Sebia Capillarys / Minicap (DCCT / NGSP)	%HbA <sub>1c</sub>	5.56	4.45 – 6.67
Sebia Capillarys / Minicap (IFCC)	mmol/mol	37.3	29.8 – 44.8
Siemens ADVIA 1200/1650/1800/2400 (DCCT / NGSP)	%HbA <sub>1c</sub>	5.93	4.74 – 7.12
Siemens ADVIA 1200/1650/1800/2400 (IFCC)	mmol/mol	41.3	33.0 – 49.6
Siemens DCA2000/Vantage (DCCT / NGSP)	%HbA <sub>1c</sub>	6.35	5.08 – 7.62
Siemens DCA2000/Vantage (IFCC)	mmol/mol	45.9	36.7 – 55.1
Siemens/Dade Dimension (DCCT / NGSP)	%HbA <sub>1c</sub>	5.93	4.74 – 7.12
Siemens/Dade Dimension (IFCC)	mmol/mol	41.3	33.0 – 49.6
TOSOH HLC723/G7/G8/GX (DCCT / NGSP)	%HbA <sub>1c</sub>	5.74	4.59 – 6.89
TOSOH HLC723/G7/G8/GX (IFCC)	mmol/mol	39.2	31.4 – 47.0

**LEVEL 1** (continued)

Method	Units	Target	Range
Trin Bio CLC385/PDQ/Ultra 2 (DCCT / NGSP)	%HbA <sub>1c</sub>	6.32	5.06 – 7.58
Trin Bio CLC385/PDQ/Ultra 2 (IFCC)	mmol/mol	45.6	36.5 – 54.7
Trinity Biotech Tri-stat (DCCT / NGSP)	%HbA <sub>1c</sub>	7.73	6.18 – 9.28
Trinity Biotech Tri-stat (IFCC)	mmol/mol	61.0	48.8 – 73.2
Trinity/Menarini Premier Hb9210 (DCCT / NGSP)	%HbA <sub>1c</sub>	6.35	5.08 – 7.62
Trinity/Menarini Premier Hb9210 (IFCC)	mmol/mol	45.9	36.7 – 55.1

Total Haemoglobin		Target	Range
Randox Rx Series	g/dl	13.1	10.5 – 15.7

**LEVEL 2**

Method	Units	Target	Range
Abbott Architect c systems (DCCT / NGSP)	%HbA <sub>1c</sub>	10.8	8.64 – 13.0
Abbott Architect c systems (IFCC)	mmol/mol	94.5	75.6 – 113
Abbott Architect c (Direct Turbidimetric) (DCCT / NGSP)	%HbA <sub>1c</sub>	12.5	10.0 – 15.0
Abbott Architect c (Direct Turbidimetric) (IFCC)	mmol/mol	113	90.4 – 136
Abbott Architect i systems (DCCT / NGSP)	%HbA <sub>1c</sub>	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 <sub>1c</sub>	11.1	8.88 – 13.3
Arkray Menarini HA8121/40/60/80 (IFCC)	mmol/mol	97.8	78.2 – 117
Beckman AU400/480/600/640/2700/5400 (DCCT / NGSP)	%HbA <sub>1c</sub>	11.3	9.04 – 13.6
Beckman AU400/480/600/640/2700/5400 (IFCC)	mmol/mol	100	80.0 – 120
Beckman DxC600/DxC800 (DCCT / NGSP)	%HbA <sub>1c</sub>	11.5	9.20 – 13.8
Beckman DxC600/DxC800 (IFCC)	mmol/mol	102	81.6 – 122
Bioanalytic Diagnostic HbA <sub>1c</sub> (DCCT / NGSP)	%HbA <sub>1c</sub>	12.8	10.2 – 15.4
Bioanalytic Diagnostic HbA <sub>1c</sub> (IFCC)	mmol/mol	116	92.8 – 139
Biorad D-10 (DCCT / NGSP)	%HbA <sub>1c</sub>	11.2	8.96 – 13.4
Biorad D-10 (IFCC)	mmol/mol	98.9	79.1 – 119
Biorad Variant II (ion exchange) (DCCT / NGSP)	%HbA <sub>1c</sub>	11.2	8.96 – 13.4
Biorad Variant II (ion exchange) (IFCC)	mmol/mol	98.9	79.1 – 119
EKF Quotient Quo-Lab A1c Test (DCCT / NGSP)	%HbA <sub>1c</sub>	11.8	9.44 – 14.2
EKF Quotient Quo-Lab A1c Test (IFCC)	mmol/mol	105	84.0 – 126
Konelab 20/30/60 / Thermo Indiko (DCCT / NGSP)	%HbA <sub>1c</sub>	11.3	9.04 – 13.6
Konelab 20/30/60 / Thermo Indiko (IFCC)	mmol/mol	100	80 – 120
Mindray BS200/300/400 (DCCT / NGSP)	%HbA <sub>1c</sub>	11.4	9.12 – 13.7
Mindray BS200/300/400 (IFCC)	mmol/mol	101	80.8 – 121
Ortho Vitros 4600 / 5600 / 5.1 FS (DCCT / NGSP)	%HbA <sub>1c</sub>	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 <sub>1c</sub>	12.5	10.0 – 15.0
Randox Rx Series (IFCC)	mmol/mol	113	90.4 – 136
Roche Cobas 4000/c311 (DCCT / NGSP)	%HbA <sub>1c</sub>	11.5	9.20 – 13.8
Roche Cobas 4000/c311 (IFCC)	mmol/mol	102	81.6 – 122

**LEVEL 2** (continued)

Method	Units	Target	Range
Roche Cobas 6000/8000 (DCCT / NGSP)	%HbA <sub>1c</sub>	11.4	9.12 – 13.7
Roche Cobas 6000/8000 (IFCC)	mmol/mol	101	80.8 – 121
Roche Integra (DCCT / NGSP)	%HbA <sub>1c</sub>	11.4	9.12 – 13.7
Roche Integra (IFCC)	mmol/mol	101	80.8 – 121
Roche Modular P/Cobas c111 (DCCT / NGSP)	%HbA <sub>1c</sub>	11.3	9.04 – 13.6
Roche Modular P/Cobas c111 (IFCC)	mmol/mol	100	80.0 – 120
Sebia Capillarys / Minicap (DCCT / NGSP)	%HbA <sub>1c</sub>	10.9	8.72 – 13.1
Sebia Capillarys / Minicap (IFCC)	mmol/mol	95.6	76.5 – 115
Siemens ADVIA 1200/1650/1800/2400 (DCCT / NGSP)	%HbA <sub>1c</sub>	11.0	8.80 – 13.2
Siemens ADVIA 1200/1650/1800/2400 (IFCC)	mmol/mol	96.7	77.4 – 116
Siemens DCA2000/Vantage (DCCT / NGSP)	%HbA <sub>1c</sub>	12.2	9.76 – 14.6
Siemens DCA2000/Vantage (IFCC)	mmol/mol	110	88.0 – 132
Siemens/Dade Dimension (DCCT / NGSP)	%HbA <sub>1c</sub>	11.5	9.20 – 13.8
Siemens/Dade Dimension (IFCC)	mmol/mol	102	81.6 – 122
TOSOH HLC723/G7/G8/GX (DCCT / NGSP)	%HbA <sub>1c</sub>	11.0	8.80 – 13.2
TOSOH HLC723/G7/G8/GX (IFCC)	mmol/mol	96.7	77.4 – 116
Trin Bio CLC385/PDQ/Ultra 2 (DCCT / NGSP)	%HbA <sub>1c</sub>	11.1	8.88 – 13.3
Trin Bio CLC385/PDQ/Ultra 2 (IFCC)	mmol/mol	97.8	78.2 – 117
Trinity Biotech Tri-stat (DCCT / NGSP)	%HbA <sub>1c</sub>	12.1	9.68 – 14.5
Trinity Biotech Tri-stat (IFCC)	mmol/mol	109	87.2 – 131
Trinity/Menarini Premier Hb9210 (DCCT / NGSP)	%HbA <sub>1c</sub>	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	12.6	10.1 – 15.1

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