

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

**CAT. NO.** HA5072                      **LOT NO.** 2020HA & 2023HA  
**SIZE:** 2 x 2 x 0.5 ml              **EXPIRY:** 2021-03-28  
**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 pre-treatment 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 / Alinity c (DCCT/NGSP)	%HbA1c	5.30	4.24 - 6.36
Abbott Architect c / Alinity c (IFCC)	mmol/mol	34.4	27.5 - 41.3
Abbott Architect c(Direct Turbidimetric) (DCCT/NGSP)	%HbA1c	6.16	4.93 - 7.39
Abbott Architect c(Direct Turbidimetric) (IFCC)	mmol/mol	43.8	35.0 - 52.6
Agappe Mispa i3 (DCCT/NGSP)	%HbA1c	6.34	5.07 - 7.61
Agappe Mispa i3 (IFCC)	mmol/mol	45.8	36.6 - 55.0
Arkray/Adams/Menarini A1c HA-8000 Series (DCCT/NGSP)	%HbA1c	5.59	4.47 - 6.71
Arkray/Adams/Menarini A1c HA-8000 Series (IFCC)	mmol/mol	37.6	30.1 - 45.1
Beckman AU Instruments (DCCT/NGSP)	%HbA1c	5.78	4.62 - 6.94
Beckman AU Instruments (IFCC)	mmol/mol	39.7	31.8 - 47.6
Beckman DxC600/DxC800 (DCCT/NGSP)	%HbA1c	5.84	4.67 - 7.01
Beckman DxC600/DxC800 (IFCC)	mmol/mol	40.3	32.2 - 48.4
Bioanalytic Diagnostic HbA1c (DCCT/NGSP)	%HbA1c	5.58	4.46 - 6.70
Bioanalytic Diagnostic HbA1c (IFCC)	mmol/mol	37.5	30.0 - 45.0
Biorad D-10 (DCCT/NGSP)	%HbA1c	5.65	4.52 - 6.78
Biorad D-10 (IFCC)	mmol/mol	38.3	30.6 - 46.0
Biorad D-100 (DCCT/NGSP)	%HbA1c	5.72	4.58 - 6.86
Biorad D-100 (IFCC)	mmol/mol	39.0	31.2 - 46.8
Biorad Variant II (ion exchange) (DCCT/NGSP)	%HbA1c	5.70	4.56 - 6.84
Biorad Variant II (ion exchange) (IFCC)	mmol/mol	38.8	31.0 - 46.6
Ceragem Labona Check (DCCT/NGSP)	%HbA1c	5.90	4.72 - 7.08
Ceragem Labona Check (IFCC)	mmol/mol	41.0	32.8 - 49.2
EKF Quotient Quo-Lab A1c Test (DCCT/NGSP)	%HbA1c	6.50	5.20 - 7.80
EKF Quotient Quo-Lab A1c Test (IFCC)	mmol/mol	47.5	38.0 - 57.0
Erba XL Series (DCCT/NGSP)	%HbA1c	5.76	4.61 - 6.91
Erba XL Series (IFCC)	mmol/mol	39.5	31.6 - 47.4
Konelab 20/30/60 / Thermo Indiko (DCCT/NGSP)	%HbA1c	6.00	4.80 - 7.20
Konelab 20/30/60 / Thermo Indiko (IFCC)	mmol/mol	42.1	33.7 - 50.5
Mindray BS200/300/400 (DCCT/NGSP)	%HbA1c	5.84	4.67 - 7.01
Mindray BS200/300/400 (IFCC)	mmol/mol	40.3	32.2 - 48.4
Nycocard Reader (DCCT/NGSP)	%HbA1c	7.54	6.03 - 9.05
Nycocard Reader (IFCC)	mmol/mol	58.9	47.1 - 70.7
Ortho Vitros 4600 / 5600 / 5.1 FS (DCCT/NGSP)	%HbA1c	5.63	4.50 - 6.76
Ortho Vitros 4600 / 5600 / 5.1 FS (IFCC)	mmol/mol	38.0	30.4 - 45.6
Randox Rx HbA1c (DCCT/NGSP)	%HbA1c	6.13	4.90 - 7.36
Randox Rx HbA1c (IFCC)	mmol/mol	43.5	34.8 - 52.2
Roche Cobas 4000/c311 (DCCT/NGSP)	%HbA1c	5.47	4.38 - 6.56
Roche Cobas 4000/c311 (IFCC)	mmol/mol	36.3	29.0 - 43.6
Roche Cobas 6000/8000 (DCCT/NGSP)	%HbA1c	5.57	4.46 - 6.68
Roche Cobas 6000/8000 (IFCC)	mmol/mol	37.4	29.9 - 44.9
Roche Cobas c513 (DCCT/NGSP)	%HbA1c	5.67	4.54 - 6.80
Roche Cobas c513 (IFCC)	mmol/mol	38.5	30.8 - 46.2
Roche Integra (DCCT/NGSP)	%HbA1c	5.64	4.51 - 6.77
Roche Integra (IFCC)	mmol/mol	38.1	30.5 - 45.7
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
SD A1c Care (DCCT/NGSP)	%HbA1c	5.54	4.43 - 6.65
SD A1c Care (IFCC)	mmol/mol	37.0	29.6 - 44.4

**LEVEL I (continued)**

Method	Units	Target	Range
Sebia Capillarys / Minicap (DCCT/NGSP)	%HbA1c	5.45	4.36 - 6.54
Sebia Capillarys / Minicap (IFCC)	mmol/mol	36.1	28.9 - 43.3
Siemens ADVIA 1200/1650/1800/2400 (DCCT/NGSP)	%HbA1c	5.84	4.67 - 7.01
Siemens ADVIA 1200/1650/1800/2400 (IFCC)	mmol/mol	40.3	32.2 - 48.4
Siemens DCA2000/Vantage (DCCT/NGSP)	%HbA1c	6.05	4.84 - 7.26
Siemens DCA2000/Vantage (IFCC)	mmol/mol	42.6	34.1 - 51.1
Siemens/Dade Dimension (DCCT/NGSP)	%HbA1c	5.87	4.70 - 7.04
Siemens/Dade Dimension (IFCC)	mmol/mol	40.7	32.6 - 48.8
TOSOH HLC723/G7/G8/GX (DCCT/NGSP)	%HbA1c	5.67	4.54 - 6.80
TOSOH HLC723/G7/G8/GX (IFCC)	mmol/mol	38.5	30.8 - 46.2
Trin Bio CLC385/PDQ/Ultra 2 (DCCT/NGSP)	%HbA1c	6.10	4.88 - 7.32
Trin Bio CLC385/PDQ/Ultra 2 (IFCC)	mmol/mol	43.2	34.6 - 51.8
Trinity Biotech Tri-stat (DCCT/NGSP)	%HbA1c	6.94	5.55 - 8.33
Trinity Biotech Tri-stat (IFCC)	mmol/mol	52.3	41.8 - 62.8
Trinity/Menarini Premier Hb9210 (DCCT/NGSP)	%HbA1c	6.25	5.00 - 7.50
Trinity/Menarini Premier Hb9210 (IFCC)	mmol/mol	44.8	35.8 - 53.8

Total Haemoglobin	Units	Target	Range
Beckman AU Instruments	g/dl	12.0	9.60 - 14.4
Randox Rx Series	g/dl	12.9	10.3 - 15.5
Roche Cobas 4000/c311	g/dl	13.0	10.4 - 15.6
Roche Cobas 6000/8000	g/dl	13.7	11.0 - 16.4
Siemens ADVIA 1200/1650/1800/2400	g/dl	12.8	10.2 - 15.4

### LEVEL 2

Method	Units	Target	Range
Abbott Architect c / Alinity c (DCCT/NGSP)	%HbA1c	10.2	8.16 - 12.2
Abbott Architect c / Alinity c (IFCC)	mmol/mol	88.0	70.4 - 106
Abbott Architect c(Direct Turbidimetric) (DCCT/NGSP)	%HbA1c	11.8	9.44 - 14.2
Abbott Architect c(Direct Turbidimetric) (IFCC)	mmol/mol	105	84.0 - 126
Abbott Architect i/ Alinity i (DCCT/NGSP)	%HbA1c	13.9	11.1 - 16.7
Abbott Architect i/ Alinity i (IFCC)	mmol/mol	128	102 - 154
Agappe Mispa i3 (DCCT/NGSP)	%HbA1c	13.0	10.4 - 15.6
Agappe Mispa i3 (IFCC)	mmol/mol	119	95.2 - 143
Arkray PocketChem A1c (DCCT/NGSP)	%HbA1c	11.2	8.96 - 13.4
Arkray PocketChem A1c (IFCC)	mmol/mol	98.9	79.1 - 119
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
Beckman DxC600/DxC800 (DCCT/NGSP)	%HbA1c	11.4	9.12 - 13.7
Beckman DxC600/DxC800 (IFCC)	mmol/mol	101	80.8 - 121
Bioanalytic Diagnostic HbA1c (DCCT/NGSP)	%HbA1c	12.7	10.2 - 15.2
Bioanalytic Diagnostic HbA1c (IFCC)	mmol/mol	115	92.0 - 138
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	8.80 - 13.2
Biorad D-100 (IFCC)	mmol/mol	96.7	77.4 - 116
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	9.28	7.42 - 11.1
Ceragem Labona Check (IFCC)	mmol/mol	77.9	62.3 - 93.5
EKF Quotient Quo-Lab A1c Test (DCCT/NGSP)	%HbA1c	11.7	9.36 - 14.0
EKF Quotient Quo-Lab A1c Test (IFCC)	mmol/mol	104	83.2 - 125
Erba XL Series (DCCT/NGSP)	%HbA1c	10.4	8.32 - 12.5
Erba XL Series (IFCC)	mmol/mol	90.2	72.2 - 108
Human HumaMeter A1c (DCCT/NGSP)	%HbA1c	11.4	9.12 - 13.7
Human HumaMeter A1c (IFCC)	mmol/mol	101	80.8 - 121
Konelab 20/30/60 / Thermo Indiko (DCCT/NGSP)	%HbA1c	11.6	9.28 - 13.9
Konelab 20/30/60 / Thermo Indiko (IFCC)	mmol/mol	103	82.4 - 124
Mindray BS200/300/400 (DCCT/NGSP)	%HbA1c	11.6	9.28 - 13.9
Mindray BS200/300/400 (IFCC)	mmol/mol	103	82.4 - 124
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 (DCCT/NGSP)	%HbA1c	10.9	8.72 - 13.1
Ortho Vitros 4600 / 5600 / 5.1 FS (IFCC)	mmol/mol	95.6	76.5 - 115
Randox Rx HbA1c (DCCT/NGSP)	%HbA1c	11.8	9.44 - 14.2
Randox Rx HbA1c (IFCC)	mmol/mol	105	84.0 - 126
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	11.6	9.28 - 13.9
Roche Cobas c513 (IFCC)	mmol/mol	103	82.4 - 124

**LEVEL 2 (continued)**

Method	Units	Target	Range
Roche Integra (DCCT/NGSP)	%HbA1c	11.1	8.88 - 13.3
Roche Integra (IFCC)	mmol/mol	97.8	78.2 - 117
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	9.53	7.62 - 11.4
SD A1c Care (IFCC)	mmol/mol	80.7	64.6 - 97.0
Sebia Capillarys / Minicap (DCCT/NGSP)	%HbA1c	10.8	8.64 - 13.0
Sebia Capillarys / Minicap (IFCC)	mmol/mol	94.5	75.6 - 113
Siemens ADVIA 1200/1650/1800/2400 (DCCT/NGSP)	%HbA1c	10.8	8.64 - 13.0
Siemens ADVIA 1200/1650/1800/2400 (IFCC)	mmol/mol	94.5	75.6 - 113
Siemens DCA2000/Vantage (DCCT/NGSP)	%HbA1c	11.5	9.20 - 13.8
Siemens DCA2000/Vantage (IFCC)	mmol/mol	102	81.6 - 122
Siemens/Dade Dimension (DCCT/NGSP)	%HbA1c	11.1	8.88 - 13.3
Siemens/Dade Dimension (IFCC)	mmol/mol	97.8	78.2 - 117
TOSOH HLC723/G7/G8/GX (DCCT/NGSP)	%HbA1c	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)	%HbA1c	11.4	9.12 - 13.7
Trin Bio CLC385/PDQ/Ultra 2 (IFCC)	mmol/mol	101	80.8 - 121
Trinity/Menarini Premier Hb9210 (DCCT/NGSP)	%HbA1c	11.0	8.8 - 13.2
Trinity/Menarini Premier Hb9210 (IFCC)	mmol/mol	96.7	77.4 - 116

Total Haemoglobin	Units	Target	Range
Beckman AU Instruments	g/dl	11.2	8.96 - 13.4
Randox Rx Series	g/dl	13.7	11 - 16.4
Roche Cobas 4000/c311	g/dl	12.0	9.6 - 14.4
Roche Cobas 6000/8000	g/dl	13.7	11 - 16.4
Siemens ADVIA 1200/1650/1800/2400	g/dl	12.9	10.3 - 15.5

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