

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

CAT. NO: HA5072 **LOT NO:** 2341HA & 2343HA
SIZE: 2 x 2 x 0.5 ml **EXPIRY:** 2025-04-28
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. 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

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.

LEVEL I

Method	Units	Target	Range
Abbott Architect c Systems (DCCT/NGSP)	%HbA1c	4.63	3.7 -5.56
Abbott Architect c Systems (IFCC)	mmol/mol	27.1	21.7 - 32.5
Abbott Architect I Systems (DCCT/NGSP)	%HbA1c	5.03	4.02 -6.04
Abbott Architect I Systems (IFCC)	mmol/mol	31.5	25.2 - 37.8
Agappe Mispa i3 (DCCT/NGSP)	%HbA1c	5.49	4.39 -6.59
Agappe Mispa i3 IFCC	mmol/mol	36.5	29.2 - 43.8
Arkray Menarini HA8121/40/60/80 (DCCT/NGSP)	%HbA1c	4.97	3.98 -5.96
Arkray Menarini HA8121/40/60/80 (IFCC)	mmol/mol	30.8	24.6 - 37
Arkray Pocket Chem A1c Advanced (DCCT/NGSP)	%HbA1c	6.15	4.92 – 7.38
Arkray Pocket Chem A1c Advanced (IFCC)	mmol/mol	43.7	35.0 – 52.4
Beckman AU400/600/640/2700/5400 (DCCT/NGSP)	%HbA1c	5.06	4.05 -6.07
Beckman AU400/600/640/2700/5400 (IFCC)	mmol/mol	31.8	25.4 - 38.2
Beckman DxC 600/DxC 800 (DCCT/NGSP)	%HbA1c	5.20	4.16 -6.24
Beckman DxC 600/DxC 800 (IFCC)	mmol/mol	33.3	26.6 - 40
Bioanalytic Diagnostic HbA1c (DCCT/NGSP)	%HbA1c	4.85	3.88 -5.82
Bioanalytic Diagnostic HbA1c IFCC	mmol/mol	29.5	23.6 - 35.4
Biorad D-10 (DCCT/NGSP)	%HbA1c	5.07	4.06 -6.08
Biorad D-10 (IFCC)	mmol/mol	31.9	25.5 - 38.3
Biorad D-100 (DCCT/NGSP)	%HbA1c	5.05	4.04 -6.06
Biorad D-100 (IFCC)	mmol/mol	31.7	25.4 - 38
Biorad Variant II (ion exchange) (DCCT/NGSP)	%HbA1c	5.05	4.04 -6.06
Biorad Variant II (ion exchange) (IFCC)	mmol/mol	31.7	25.4 - 38
Boditech Med Inc i-CHROMA (DCCT/NGSP)	%HbA1c	5.06	4.05 -6.07
Boditech Med Inc i-CHROMA IFCC	mmol/mol	31.8	25.4 - 38.2
Centronic HbA1c (DCCT/NGSP)	%HbA1c	5.27	4.22 -6.32
Centronic HbA1c IFCC	mmol/mol	34.1	27.3 - 40.9
Clover A1c (DCCT/NGSP)	%HbA1c	5.22	4.18 -6.26
Clover A1c IFCC	mmol/mol	33.6	26.9 - 40.3
DiaSys India QDx A1c Advance	%HbA1c	6.19	4.95 – 7.43
DiaSys India QDx A1c Advance (IFCC)	mmol/mol	44.2	35.4 – 53.0
EKF Quotient Quo-Lab A1c Test (DCCT/NGSP)	%HbA1c	5.87	4.7 -7.04
EKF Quotient Quo-Lab A1c Test IFCC	mmol/mol	40.7	32.6 - 48.8
GCMS GREENCARE A1c	%HbA1c	6.16	4.93 – 7.39
GCMS GREENCARE A1c IFCC	mmol/mol	43.8	35.0 – 52.6
Konelab 20/30/60 (DCCT/NGSP)	%HbA1c	5.17	4.14 -6.2
Konelab 20/30/60 (IFCC)	mmol/mol	33.0	26.4 - 39.6
Labnovation LD-500 (DCCT/NGSP)	%HbA1c	5.01	4.01 -6.01
Labnovation LD-500 IFCC	mmol/mol	31.3	25 - 37.6
MediSys Hemo G Smart	%HbA1c	6.19	4.95 – 7.43
MediSys Hemo G Smart IFCC	mmol/mol	44.2	35.4 – 53.0
Mindray BS200/300/400/800 (DCCT/NGSP)	%HbA1c	4.96	3.97 -5.95
Mindray BS200/300/400/800 IFCC	mmol/mol	30.7	24.6 - 36.8
Mindray H50/ H50P (DCCT/NGSP)	%HbA1c	5.00	4.00 – 6.00
Mindray H50/ H50P IFCC	mmol/mol	31.1	24.9 - 37.3
Ortho Vitros 4600/5600/5.1 FS (DCCT/NGSP)	%HbA1c	5.06	4.05 -6.07
Ortho Vitros 4600/5600/5.1 FS (IFCC)	mmol/mol	31.8	25.4 - 38.2
Randox Rx Series HbA1c (DCCT / NGSP)	%HbA1c	5.82	4.65 – 6.98
Randox Rx Series HbA1c (IFCC)	mmol/mol	40.1	32.1 – 48.1
Roche Cobas 4000/C311 (DCCT/NGSP)	%HbA1c	4.91	3.93 -5.89
Roche Cobas 4000/C311 (IFCC)	mmol/mol	30.2	24.2 - 36.2
Roche Cobas 6000/8000 (DCCT/NGSP)	%HbA1c	4.97	3.98 -5.96
Roche Cobas 6000/8000 (IFCC)	mmol/mol	30.8	24.6 - 37
Roche Cobas c303/c503 (DCCT/NGSP)	%HbA1c	5.14	4.11 -6.17
Roche Cobas c303/c503 IFCC	mmol/mol	32.7	26.2 - 39.2
Roche Cobas c513 (DCCT/NGSP)	%HbA1c	5.07	4.06 -6.08
Roche Cobas c513 IFCC	mmol/mol	31.9	25.5 - 38.3
Roche Integra (DCCT/NGSP)	%HbA1c	5.16	4.13 -6.19
Roche Integra (IFCC)	mmol/mol	32.9	26.3 - 39.5
Roche Modular P/ Cobas c111 (DCCT/NGSP)	%HbA1c	5.08	4.06 -6.1
Roche Modular P/ Cobas c111 (IFCC)	mmol/mol	32.0	25.6 - 38.4
Sebia Capillars / Minicap (DCCT/NGSP)	%HbA1c	4.95	3.96 -5.94
Sebia Capillars / Minicap IFCC	mmol/mol	30.6	24.5 - 36.7
Shenzhen Lifotronic HbA1c (DCCT/NGSP)	%HbA1c	4.91	3.93 -5.89
Shenzhen Lifotronic HbA1c IFCC	mmol/mol	30.2	24.2 - 36.2
Siemens Atellica CH A1c_E (DCCT/NGSP)	%HbA1c	4.67	3.74 -5.6
Siemens Atellica CH A1c_E IFCC	mmol/mol	27.5	22.0 – 33.0

LEVEL I (continued)

Method	Units	Target	Range
Siemens DCA2000/Vantage (DCCT/NGSP)	%HbA1c	5.32	4.26 - 6.38
Siemens DCA2000/Vantage IFCC	mmol/mol	34.6	27.7 - 41.5
Siemens/Dade Dimension (DCCT/NGSP)	%HbA1c	5.21	4.17 - 6.25
Siemens/Dade Dimension (IFCC)	mmol/mol	33.4	26.7 - 40.1
Tokyo Boeki/Prestige 24i (DCCT/NGSP)	%HbA1c	5.53	4.42 - 6.64
Tokyo Boeki/Prestige 24i IFCC	mmol/mol	36.9	29.5 - 44.3
TOSOH G8 Automated HPLC Analyser (DCCT / NGSP)	%HbA1c	5.72	5.26 - 6.12
TOSOH G8 Automated HPLC Analyser (IFCC)	mmol/mol	39.0	35.9 - 42.1
TOSOH GX Automated HPLC Analyser (DCCT / NGSP)	%HbA1c	5.67	5.22 - 6.07
TOSOH GX Automated HPLC Analyser (IFCC)	mmol/mol	38.5	35.4 - 41.6
TOSOH G11 Automated HPLC Analyser (DCCT / NGSP)	%HbA1c	5.70	5.24 - 6.10
TOSOH G11 Automated HPLC Analyser (IFCC)	mmol/mol	38.8	35.7 - 41.9
Trinity Biotech Premier Hb9210 (DCCT / NGSP)	%HbA1c	6.26	5.88 - 6.64
Trinity Biotech Premier Hb9210 (IFCC)	mmol/mol	44.9	40.8 - 49.0
Wonfo Finecare Meter (DCCT/NGSP)	%HbA1c	5.28	4.22 - 6.34
Wonfo Finecare Meter IFCC	mmol/mol	34.2	27.4 - 41

Total Haemoglobin	Units	Target	Range
Roche Cobas 6000/8000	g/dl	15.1	12.1 - 18.1
Roche Integra	g/dl	14.3	11.4 - 17.2
Randox RX Series	g/dl	14.5	11.6 - 17.4

LEVEL 2

Method	Units	Target	Range
Abbott Architect c Systems (DCCT/NGSP)	%HbA _{1c}	13.2	10.6 - 15.8
Abbott Architect c Systems (IFCC)	mmol/mol	121	96.8 - 145
Abbott Architect I Systems (DCCT/NGSP)	%HbA _{1c}	13.5	10.8 - 16.2
Abbott Architect I Systems (IFCC)	mmol/mol	124	99.2 - 149
Agappe Mispal i3 (DCCT/NGSP)	%HbA _{1c}	14.9	11.9 - 17.9
Agappe Mispal i3 IFCC	mmol/mol	139	111 - 167
Arkay Menarini HA8121/40/60/80 (DCCT/NGSP)	%HbA _{1c}	13.0	10.4 - 15.6
Arkay Menarini HA8121/40/60/80 (IFCC)	mmol/mol	119	95.2 - 143
Arkay Pocket Chem A1c Advanced (DCCT/NGSP)	%HbA _{1c}	10.2	8.16 - 12.2
Arkay Pocket Chem A1c Advanced (IFCC)	mmol/mol	88.0	70.4 - 106
Beckman AU400/600/640/2700/5400 (DCCT/NGSP)	%HbA _{1c}	13.5	10.8 - 16.2
Beckman AU400/600/640/2700/5400 (IFCC)	mmol/mol	124	99.2 - 149
Beckman DxC 600/DxC 800 (DCCT/NGSP)	%HbA _{1c}	13.3	10.6 - 16
Beckman DxC 600/DxC 800 (IFCC)	mmol/mol	122	97.6 - 146
Bioanalytic Diagnostic HbA _{1c} (DCCT/NGSP)	%HbA _{1c}	11.9	9.5 - 14.3
Bioanalytic Diagnostic HbA _{1c} IFCC	mmol/mol	107	85.6 - 128
Biorad D-10 (DCCT/NGSP)	%HbA _{1c}	13.5	10.8 - 16.2
Biorad D-10 (IFCC)	mmol/mol	124	99 - 149
Biorad D-100 (DCCT/NGSP)	%HbA _{1c}	13.2	10.6 - 15.8
Biorad D-100 (IFCC)	mmol/mol	121	96.8 - 145
Biorad Variant II (ion exchange) (DCCT/NGSP)	%HbA _{1c}	13.2	10.6 - 15.8
Biorad Variant II (ion exchange) (IFCC)	mmol/mol	121	96.8 - 145
Boditech Med Inc i-CHROMA (DCCT/NGSP)	%HbA _{1c}	11.2	8.96 - 13.4
Boditech Med Inc i-CHROMA IFCC	mmol/mol	98.9	79.1 - 119
Centronic HbA _{1c} (DCCT/NGSP)	%HbA _{1c}	13.1	10.5 - 15.7
Centronic HbA _{1c} IFCC	mmol/mol	120	96 - 144
Clover A1c (DCCT/NGSP)	%HbA _{1c}	12.2	9.76 - 14.6
Clover A1c IFCC	mmol/mol	110	88 - 132
DiaSys India QDx A1c Advance	%HbA _{1c}	10.9	8.72 - 13.1
DiaSys India QDx A1c Advance (IFCC)	mmol/mol	95.6	76.5 - 115
EKF Quotient Quo-Lab A1c Test (DCCT/NGSP)	%HbA _{1c}	13.6	10.9 - 16.3
EKF Quotient Quo-Lab A1c Test IFCC	mmol/mol	125	100 - 150
GCMS GREENCARE A1c (DCCT/NGSP)	%HbA _{1c}	10.9	8.72 - 13.1
GCMS GREENCARE A1c (IFCC)	mmol/mol	95.6	76.5 - 115
Konelab 20/30/60 (DCCT/NGSP)	%HbA _{1c}	12.9	10.3 - 15.5
Konelab 20/30/60 (IFCC)	mmol/mol	117	93.6 - 140
Labnovation LD-500 (DCCT/NGSP)	%HbA _{1c}	11.4	9.12 - 13.7
Labnovation LD-500 IFCC	mmol/mol	101.1	80.9 - 121
MediSys Hemo G Smart (DCCT/NGSP)	%HbA _{1c}	10.9	8.72 - 13.1
MediSys Hemo G Smart (IFCC)	mmol/mol	95.6	76.5 - 115
Mindray BS200/300/400/800 (DCCT/NGSP)	%HbA _{1c}	13.6	10.9 - 16.3
Mindray BS200/300/400/800 IFCC	mmol/mol	125	100 - 150
Mindray H50/ H50P (DCCT/NGSP)	%HbA _{1c}	13.3	10.6 - 16
Mindray H50/ H50P IFCC	mmol/mol	122	97.6 - 146
Ortho Vitros 4600/5600/5.1 FS (DCCT/NGSP)	%HbA _{1c}	13.6	10.9 - 16.3
Ortho Vitros 4600/5600/5.1 FS (IFCC)	mmol/mol	125	100 - 150
Randox Rx Series HbA _{1c} (DCCT / NGSP)	%HbA _{1c}	13.9	11.08 - 16.6
Randox Rx Series HbA _{1c} (IFCC)	mmol/mol	128	103 - 154
Roche Cobas 4000/C311 (DCCT/NGSP)	%HbA _{1c}	13.2	10.6 - 15.8
Roche Cobas 4000/C311 (IFCC)	mmol/mol	121	96.8 - 145
Roche Cobas 6000/8000 (DCCT/NGSP)	%HbA _{1c}	13.1	10.5 - 15.7
Roche Cobas 6000/8000 (IFCC)	mmol/mol	120	96 - 144
Roche Cobas c303/c503 (DCCT/NGSP)	%HbA _{1c}	13.6	10.9 - 16.3
Roche Cobas c303/c503 IFCC	mmol/mol	125	100 - 150
Roche Cobas c513 (DCCT/NGSP)	%HbA _{1c}	13.5	10.8 - 16.2
Roche Cobas c513 IFCC	mmol/mol	124	99.2 - 149
Roche Integra (DCCT/NGSP)	%HbA _{1c}	13.6	10.9 - 16.3
Roche Integra (IFCC)	mmol/mol	125	100 - 150
Roche Modular P/ Cobas c111 (DCCT/NGSP)	%HbA _{1c}	13.6	10.9 - 16.3
Roche Modular P/ Cobas c111 (IFCC)	mmol/mol	125	100 - 150
Sebia Capillarys / Minicap (DCCT/NGSP)	%HbA _{1c}	12.8	10.2 - 15.4
Sebia Capillarys / Minicap IFCC	mmol/mol	116	92.8 - 139
Shenzhen Lifotronic HbA _{1c} (DCCT/NGSP)	%HbA _{1c}	12.6	10.1 - 15.1
Shenzhen Lifotronic HbA _{1c} IFCC	mmol/mol	114	91.2 - 137
Siemens Atellica CH A1c_E (DCCT/NGSP)	%HbA _{1c}	13.1	10.5 - 15.7
Siemens Atellica CH A1c_E IFCC	mmol/mol	120	96 - 144

LEVEL 2 (continued)

Method	Units	Target	Range
Siemens DCA2000/Vantage (DCCT/NGSP)	%HbA1c	13.8	11 - 16.6
Siemens DCA2000/Vantage IFCC	mmol/mol	127	101.6 - 152
Siemens/Dade Dimension (DCCT/NGSP)	%HbA1c	12.9	10.3 - 15.5
Siemens/Dade Dimension (IFCC)	mmol/mol	117	93.6 - 140
Tokyo Boeki/Prestige 24i (DCCT/NGSP)	%HbA1c	13.6	10.9 - 16.3
Tokyo Boeki/Prestige 24i IFCC	mmol/mol	125	100 - 150
TOSOH G8 Automated HPLC Analyser (DCCT / NGSP)	%HbA1c	11.5	10.5 - 12.3
TOSOH G8 Automated HPLC Analyser (IFCC)	mmol/mol	102	93.5 - 110
TOSOH GX Automated HPLC Analyser (DCCT / NGSP)	%HbA1c	11.4	10.5 - 12.2
TOSOH GX Automated HPLC Analyser (IFCC)	mmol/mol	101	93.0 - 109
TOSOH G11 Automated HPLC Analyser (DCCT / NGSP)	%HbA1c	11.3	10.4 - 12.1
TOSOH G11 Automated HPLC Analyser (IFCC)	mmol/mol	100	92.0 - 108
Trinity Biotech Premier Hb9210 (DCCT / NGSP)	%HbA1c	11.5	10.8 - 12.2
Trinity Biotech Premier Hb9210 (IFCC)	mmol/mol	102	94.9 - 110
Wonfo Finecare Meter (DCCT/NGSP)	%HbA1c	13.2	10.6 - 15.8
Wonfo Finecare Meter IFCC	mmol/mol	121	96.8 - 145

Total Haemoglobin	Units	Target	Range
Roche Cobas 6000/8000	g/dl	14.9	11.9 - 17.9
Roche Integra	g/dl	14.1	11.3 - 16.9
Randox RX Series	g/dl	13.4	10.7 - 16.1

EC REP

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

Rev. 19 Jan '23 me

THIS PAGE IS INTENTIONALLY BLANK