

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 A_{1c}** reagent, catalogue numbers **HA3830 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 A_{1c} 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 / Alinity c (DCCT/NGSP)	%HbA1c	5.09	4.07 - 6.11
Abbott Architect c / Alinity c (IFCC)	mmol/mol	32.1	25.7 - 38.5
Abbott Architect c(Direct Turbidimetric) (DCCT/NGSP)	%HbA1c	5.67	4.54 - 6.80
Abbott Architect c(Direct Turbidimetric) (IFCC)	mmol/mol	38.5	30.8 - 46.2
Agappe Mispa i3 (DCCT/NGSP)	%HbA1c	6.27	5.02 - 7.52
Agappe Mispa i3 (IFCC)	mmol/mol	45.0	36.0 - 54.0
Arkay/Adams/Menarini A1c HA-8000 Series (DCCT/NGSP)	%HbA1c	5.54	4.43 - 6.65
Arkay/Adams/Menarini A1c HA-8000 Series (IFCC)	mmol/mol	37.0	29.6 - 44.4
Beckman AU Instruments (DCCT/NGSP)	%HbA1c	5.74	4.59 - 6.89
Beckman AU Instruments (IFCC)	mmol/mol	39.2	31.4 - 47.0
Beckman DxC600/DxC800 (DCCT/NGSP)	%HbA1c	5.70	4.56 - 6.84
Beckman DxC600/DxC800 (IFCC)	mmol/mol	38.8	31.0 - 46.6
BioHermes Hb A1c (DCCT/NGSP)	%HbA1c	5.68	4.54 - 6.82
BioHermes Hb A1c (IFCC)	mmol/mol	38.6	30.9 - 46.3
Biorad D-10 (DCCT/NGSP)	%HbA1c	5.74	4.59 - 6.89
Biorad D-10 (IFCC)	mmol/mol	39.2	31.4 - 47.0
Biorad D-100 (DCCT/NGSP)	%HbA1c	5.73	4.58 - 6.88
Biorad D-100 (IFCC)	mmol/mol	39.1	31.3 - 46.9
Biorad Variant II (ion exchange) (DCCT/NGSP)	%HbA1c	5.74	4.59 - 6.89
Biorad Variant II (ion exchange) (IFCC)	mmol/mol	39.2	31.4 - 47.0
Centronic HbA1c (DCCT/NGSP)	%HbA1c	6.02	4.82 - 7.22
Centronic HbA1c (IFCC)	mmol/mol	42.3	33.8 - 50.8
Clover A1c (DCCT/NGSP)	%HbA1c	6.11	4.89 - 7.33
Clover A1c (IFCC)	mmol/mol	43.3	34.6 - 52.0
EKF Quotient Quo-Lab A1c Test (DCCT/NGSP)	%HbA1c	6.76	5.41 - 8.11
EKF Quotient Quo-Lab A1c Test (IFCC)	mmol/mol	50.4	40.3 - 60.5
Erba XL Series (DCCT/NGSP)	%HbA1c	5.97	4.78 - 7.16
Erba XL Series (IFCC)	mmol/mol	41.7	33.4 - 50.0
Labnovation LD-500 (DCCT/NGSP)	%HbA1c	6.02	4.82 - 7.22
Labnovation LD-500 (IFCC)	mmol/mol	42.3	33.8 - 50.8
Menarini HB Next (DCCT/NGSP)	%HbA1c	5.54	4.43 - 6.65
Menarini HB Next (IFCC)	mmol/mol	37.0	29.6 - 44.4
Mindray BS200/300/400/800 (DCCT/NGSP)	%HbA1c	5.50	4.40 - 6.60
Mindray BS200/300/400/800 (IFCC)	mmol/mol	36.6	29.3 - 43.9
Mindray H50/ H50P (DCCT/NGSP)	%HbA1c	5.67	4.54 - 6.80
Mindray H50/ H50P (IFCC)	mmol/mol	38.5	30.8 - 46.2
Nycocard Reader (DCCT/NGSP)	%HbA1c	6.96	5.57 - 8.35
Nycocard Reader (IFCC)	mmol/mol	52.6	42.1 - 63.1
Ortho Vitros A1C1 (Enzymatic) (DCCT/NGSP)	%HbA1c	6.40	5.12 - 7.68
Ortho Vitros A1C1 (Enzymatic) (IFCC)	mmol/mol	46.4	37.1 - 55.7
Ortho Vitros d%A1c (DCCT/NGSP)	%HbA1c	5.67	4.54 - 6.80
Ortho Vitros d%A1c (IFCC)	mmol/mol	38.5	30.8 - 46.2
Randox Rx HbA1c (DCCT/NGSP)	%HbA1c	5.14	4.11 - 6.17
Randox Rx HbA1c (IFCC)	mmol/mol	32.7	26.2 - 39.2
Randox Rx HbA1c II (DCCT/NGSP)	%HbA1c	5.43	4.34 - 6.52
Randox Rx HbA1c II (IFCC)	mmol/mol	35.8	28.6 - 43.0
Roche Cobas 4000/c311 (DCCT/NGSP)	%HbA1c	5.68	4.54 - 6.82
Roche Cobas 4000/c311 (IFCC)	mmol/mol	38.6	30.9 - 46.3
Roche Cobas 6000/8000 (DCCT/NGSP)	%HbA1c	5.71	4.57 - 6.85
Roche Cobas 6000/8000 (IFCC)	mmol/mol	38.9	31.1 - 46.7
Roche Cobas c303/c503 (DCCT/NGSP)	%HbA1c	5.82	4.66 - 6.98
Roche Cobas c303/c503 (IFCC)	mmol/mol	40.1	32.1 - 48.1
Roche Cobas c513 (DCCT/NGSP)	%HbA1c	5.83	4.66 - 7.00
Roche Cobas c513 (IFCC)	mmol/mol	40.2	32.2 - 48.2
Roche Integra (DCCT/NGSP)	%HbA1c	5.72	4.58 - 6.86
Roche Integra (IFCC)	mmol/mol	39.0	31.2 - 46.8
Roche Modular P/Cobas c111 (DCCT/NGSP)	%HbA1c	5.82	4.66 - 6.98
Roche Modular P/Cobas c111 (IFCC)	mmol/mol	40.1	32.1 - 48.1
Sebia Capillarys / Minicap (DCCT/NGSP)	%HbA1c	5.51	4.41 - 6.61
Sebia Capillarys / Minicap (IFCC)	mmol/mol	36.7	29.4 - 44.0
Shenzhen Lifotronic HbA1c (DCCT/NGSP)	%HbA1c	5.73	4.58 - 6.88
Shenzhen Lifotronic HbA1c (IFCC)	mmol/mol	39.1	31.3 - 46.9
Siemens Atellica CH A1c_3 (DCCT/NGSP)	%HbA1c	4.94	3.95 - 5.93
Siemens Atellica CH A1c_3 (IFCC)	mmol/mol	30.5	24.4 - 36.6
Siemens Atellica CH A1c_E (DCCT/NGSP)	%HbA1c	5.05	4.04 - 6.06
Siemens Atellica CH A1c_E (IFCC)	mmol/mol	31.7	25.4 - 38.0
Siemens DCA2000/Vantage (DCCT/NGSP)	%HbA1c	5.97	4.78 - 7.16
Siemens DCA2000/Vantage (IFCC)	mmol/mol	41.7	33.4 - 50.0

Method	Units	Target	Range
Siemens/Dade Dimension (DCCT/NGSP)	%HbA1c	5.84	4.67 - 7.01
Siemens/Dade Dimension (IFCC)	mmol/mol	40.3	32.2 - 48.4
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
Wondfo Finecare Meter (DCCT/NGSP)	%HbA1c	6.27	5.02 - 7.52
Wondfo Finecare Meter (IFCC)	mmol/mol	45.0	36.0 - 44.0

Total Haemoglobin	Units	Target	Range
Beckman AU Instruments	g/dl	14.2	11.4 - 17.0
Randox RX Series	g/dl	14.5	11.6 - 17.4
Roche Cobas 6000/8000	g/dl	15.7	12.6 - 18.8

LEVEL 2

Method	Units	Target	Range
Abbott Architect c / Alinity c (DCCT/NGSP)	%HbA1c	10.7	8.55 - 12.9
Abbott Architect c / Alinity c (IFCC)	mmol/mol	93.4	74.7 - 112
Abbott Architect c(Direct Turbidimetric) (DCCT/NGSP)	%HbA1c	12.0	9.58 - 14.4
Abbott Architect c(Direct Turbidimetric) (IFCC)	mmol/mol	108	86.4 - 130
Agappe Mispa i3 (DCCT/NGSP)	%HbA1c	13.0	10.4 - 15.6
Agappe Mispa i3 (IFCC)	mmol/mol	119	95.2 - 143
Arkray/Adams/Menarini A1c HA-8000 Series (DCCT/NGSP)	%HbA1c	11.0	8.82 - 13.2
Arkray/Adams/Menarini A1c HA-8000 Series (IFCC)	mmol/mol	96.7	77.4 - 116
Beckman AU Instruments (DCCT/NGSP)	%HbA1c	11.7	9.34 - 14.1
Beckman AU Instruments (IFCC)	mmol/mol	104	83.2 - 125
Beckman DxC600/DxC800 (DCCT/NGSP)	%HbA1c	11.7	9.33 - 14.1
Beckman DxC600/DxC800 (IFCC)	mmol/mol	104	83.2 - 125
BioHermes Hb A1c (DCCT/NGSP)	%HbA1c	11.5	9.18 - 13.8
BioHermes Hb A1c (IFCC)	mmol/mol	102	81.6 - 122
Biorad D-10 (DCCT/NGSP)	%HbA1c	11.7	9.32 - 14.1
Biorad D-10 (IFCC)	mmol/mol	104	83.2 - 125
Biorad D-100 (DCCT/NGSP)	%HbA1c	11.6	9.27 - 13.9
Biorad D-100 (IFCC)	mmol/mol	103	82.4 - 124
Biorad Variant II (ion exchange) (DCCT/NGSP)	%HbA1c	11.5	9.17 - 13.8
Biorad Variant II (ion exchange) (IFCC)	mmol/mol	102	81.6 - 122
Centronic HbA1c (DCCT/NGSP)	%HbA1c	11.6	9.30 - 13.9
Centronic HbA1c (IFCC)	mmol/mol	103	82.4 - 124
Clover A1c (DCCT/NGSP)	%HbA1c	11.0	8.79 - 13.2
Clover A1c (IFCC)	mmol/mol	96.7	77.4 - 116
EKF Quotient Quo-Lab A1c Test (DCCT/NGSP)	%HbA1c	11.9	9.49 - 14.3
EKF Quotient Quo-Lab A1c Test (IFCC)	mmol/mol	107	85.6 - 128
Erba XL Series (DCCT/NGSP)	%HbA1c	11.1	8.85 - 13.4
Erba XL Series (IFCC)	mmol/mol	97.8	78.2 - 117
Labnovation LD-500 (DCCT/NGSP)	%HbA1c	10.5	8.37 - 12.6
Labnovation LD-500 (IFCC)	mmol/mol	91.3	73.0 - 110
Menarini HB Next (DCCT/NGSP)	%HbA1c	10.7	8.53 - 12.9
Menarini HB Next (IFCC)	mmol/mol	93.4	74.7 - 112
Mindray BS200/300/400/800 (DCCT/NGSP)	%HbA1c	11.7	9.32 - 14.1
Mindray BS200/300/400/800 (IFCC)	mmol/mol	104	83.2 - 125
Mindray H50/ H50P (DCCT/NGSP)	%HbA1c	11.4	9.10 - 13.7
Mindray H50/ H50P (IFCC)	mmol/mol	101	80.8 - 121
Nycocard Reader (DCCT/NGSP)	%HbA1c	10.5	8.39 - 12.6
Nycocard Reader (IFCC)	mmol/mol	91.3	73.0 - 110
Ortho Vitros A1C1 (Enzymatic) (DCCT/NGSP)	%HbA1c	12.3	9.84 - 14.8
Ortho Vitros A1C1 (Enzymatic) (IFCC)	mmol/mol	111	88.8 - 133
Ortho Vitros d%A1c (DCCT/NGSP)	%HbA1c	11.7	9.35 - 14.1
Ortho Vitros d%A1c (IFCC)	mmol/mol	104	83.2 - 125
Randox Rx HbA1c (DCCT/NGSP)	%HbA1c	13.9	11.08 - 16.6
Randox Rx HbA1c IFCC	mmol/mol	128	103 - 154
Randox Rx HbA1c II (DCCT/NGSP)	%HbA1c	11.8	9.44 - 14.2
Randox Rx HbA1c II (IFCC)	mmol/mol	105	84.0 - 126
Roche Cobas 4000/c311 (DCCT/NGSP)	%HbA1c	11.6	9.32 - 13.9
Roche Cobas 4000/c311 (IFCC)	mmol/mol	103	82.4 - 124
Roche Cobas 6000/8000 (DCCT/NGSP)	%HbA1c	11.5	9.19 - 13.8
Roche Cobas 6000/8000 (IFCC)	mmol/mol	102	81.6 - 122
Roche Cobas c303/c503 (DCCT/NGSP)	%HbA1c	11.7	9.39 - 14.0
Roche Cobas c303/c503 (IFCC)	mmol/mol	104	83.2 - 125
Roche Cobas c513 (DCCT/NGSP)	%HbA1c	11.6	9.30 - 13.9
Roche Cobas c513 (IFCC)	mmol/mol	103	82.4 - 124
Roche Integra (DCCT/NGSP)	%HbA1c	11.8	9.42 - 14.2
Roche Integra (IFCC)	mmol/mol	105	84.0 - 126
Roche Modular P/Cobas c111 (DCCT/NGSP)	%HbA1c	12.0	9.58 - 14.4
Roche Modular P/Cobas c111 (IFCC)	mmol/mol	108	86.4 - 130
Sebia Capillarys / Minicap (DCCT/NGSP)	%HbA1c	11.1	8.90 - 13.3
Sebia Capillarys / Minicap (IFCC)	mmol/mol	97.8	78.2 - 117
Shenzhen Lifotronic HbA1c (DCCT/NGSP)	%HbA1c	11.4	9.09 - 13.7
Shenzhen Lifotronic HbA1c (IFCC)	mmol/mol	101	80.8 - 121
Siemens Atellica CH A1c_3 (DCCT/NGSP)	%HbA1c	10.8	8.60 - 13.0
Siemens Atellica CH A1c_3 (IFCC)	mmol/mol	94.5	75.6 - 113
Siemens Atellica CH A1c_E (DCCT/NGSP)	%HbA1c	10.8	8.60 - 13.0
Siemens Atellica CH A1c_E (IFCC)	mmol/mol	94.5	75.6 - 113
Siemens DCA2000/Vantage (DCCT/NGSP)	%HbA1c	12.2	9.76 - 14.6
Siemens DCA2000/Vantage (IFCC)	mmol/mol	110	88.0 - 132

Method	Units	Target	Range
Siemens/Dade Dimension (DCCT/NGSP)	%HbA1c	11.5	9.22 - 13.8
Siemens/Dade Dimension (IFCC)	mmol/mol	102	81.6 - 122
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
Wondfo Finecare Meter (DCCT/NGSP)	%HbA1c	11.5	9.21 - 13.8
Wondfo Finecare Meter (IFCC)	mmol/mol	102	81.6 - 122

Total Haemoglobin	Units	Target	Range
Beckman AU Instruments	g/dl	13.4	10.7 - 16.1
Randox RX Series	g/dl	14.5	11.6 - 17.4
Roche Cobas 6000/8000	g/dl	15.3	12.2 - 18.4

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

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