

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

Cat. No: HA5072 **Lot Nos:** 1672HA & 1675HA
Size: 2 x 2 x 0.5 ml **Expiry:** 2017-10

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.

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}	5.34	4.27 - 6.41
Abbott Architect c Systems (IFCC)	mmol/mol	34.6	27.7 - 41.5
Abbott Architect I Systems (DCCT/NGSP)	%HbA _{1c}	6.66	5.33 - 7.99
Abbott Architect I Systems (IFCC)	mmol/mol	49.3	39.4 - 59.2
Arkray Menarini HA8121/40/60/80 (DCCT/NGSP)	%HbA _{1c}	5.72	4.58 - 6.86
Arkray Menarini HA8121/40/60/80 (IFCC)	mmol/mol	39.0	31.2 - 46.8
Beckman AU400/600/640/2700/5400 (DCCT/NGSP)	%HbA _{1c}	5.84	4.67 - 7.01
Beckman AU400/600/640/2700/5400 (IFCC)	mmol/mol	40.3	32.2 - 48.4
Beckman DxC 600/DxC 800 (DCCT/NGSP)	%HbA _{1c}	5.81	4.65 - 6.97
Beckman DxC 600/DxC 800 (IFCC)	mmol/mol	40.0	32.0 - 48.0
Biorad D-10 (DCCT/NGSP)	%HbA _{1c}	5.87	4.70 - 7.04
Biorad D-10 (IFCC)	mmol/mol	40.7	32.6 - 48.8
Biorad Variant II (ion exchange) (DCCT/NGSP)	%HbA _{1c}	5.75	4.60 - 6.90
Biorad Variant II (ion exchange) (IFCC)	mmol/mol	39.0	31.2 - 46.8
Hitachi 9 Series (DCCT/NGSP)	%HbA _{1c}	5.77	4.62 - 6.92
Hitachi 9 Series (IFCC)	mmol/mol	39.6	31.7 - 47.5
Konelab 20/30/60 (DCCT/NGSP)	%HbA _{1c}	5.77	4.62 - 6.92
Konelab 20/30/60 (IFCC)	mmol/mol	39.6	31.7 - 47.5
Ortho Vitros 4600/5600/5.1 FS (DCCT/NGSP)	%HbA _{1c}	5.72	4.58 - 6.86
Ortho Vitros 4600/5600/5.1 FS (IFCC)	mmol/mol	39.0	31.2 - 46.8
Randox Rx Daytona/ Imola (DCCT/NGSP)	%HbA _{1c}	6.03	4.82 - 7.24
Randox Rx Daytona/ Imola (IFCC)	mmol/mol	42.4	33.9 - 50.9
Roche Cobas 4000/C311 (DCCT/NGSP)	%HbA _{1c}	5.70	4.56 - 6.84
Roche Cobas 4000/C311 (IFCC)	mmol/mol	38.8	31.0 - 46.6
Roche Cobas 6000/8000 (DCCT/NGSP)	%HbA _{1c}	5.80	4.64 - 6.96
Roche Cobas 6000/8000 (IFCC)	mmol/mol	39.3	31.4 - 47.2
Roche Integra (DCCT/NGSP)	%HbA _{1c}	5.69	4.55 - 6.83
Roche Integra (IFCC)	mmol/mol	39.2	31.4 - 47.0
Roche Modular P/Cobas c111 (DCCT/NGSP)	%HbA _{1c}	5.90	4.72 - 7.08
Roche Modular P/Cobas c111 (IFCC)	mmol/mol	41.0	32.8 - 49.2
Siemens/Bayer ADVIA 1200/1650/2400 (DCCT/NGSP)	%HbA _{1c}	6.03	4.82 - 7.24
Siemens/Bayer ADVIA 1200/1650/2400 (IFCC)	mmol/mol	42.4	33.9 - 50.9
Siemens/Dade Dimension (DCCT/NGSP)	%HbA _{1c}	6.00	4.80 - 7.20
Siemens/Dade Dimension (IFCC)	mmol/mol	42.1	33.7 - 50.5
Siemens DCA 2000/Vantage (DCCT/NGSP)	%HbA _{1c}	5.95	4.76 - 7.14
Siemens DCA 2000/Vantage (IFCC)	mmol/l	41.5	33.2 - 49.8
TOSOH HLC723/G7/G8 (DCCT/NGSP)	%HbA _{1c}	5.74	4.59 - 6.89
TOSOH HLC723/G7/G8 (IFCC)	mmol/mol	39.2	31.4 - 47.0
Trinity Biotech Affinity HPLC (DCCT/NGSP/IFCC)	%HbA _{1c}	5.70	5.40 - 6.0
Trinity Biotech Affinity HPLC (DCCT/NGSP/IFCC)	mmol/mol	39.0	36.0 - 42.0
Trinity/Menarini Premier Hb9210 (DCCT/NGSP)	%HbA _{1c}	5.70	5.4 - 6.0
Trinity/Menarini Premier Hb9210 (IFCC)	mmol/mol	39.0	36.0 - 42.0

Total Haemoglobin		Target	Range
Randox Rx Daytona/Imola	g/dl	12.4	9.92 - 14.9

LEVEL 2

Method	Units	Target	Range
Abbott Architect c Systems (DCCT/NGSP)	%HbA _{1c}	10.8	8.64 - 13.0
Abbott Architect c Systems (IFCC)	mmol/mol	91.6	73.3 - 110
Abbott Architect I Systems (DCCT/NGSP)	%HbA _{1c}	13.6	10.9 - 16.3
Abbott Architect I Systems (IFCC)	mmol/mol	125	100 - 150
Arkray Menarini HA8121/40/60/80 (DCCT/NGSP)	%HbA _{1c}	11.0	8.80 - 13.2
Arkray Menarini HA8121/40/60/80 (IFCC)	mmol/mol	96.6	77.3 - 116
Beckman AU400/600/640/2700/5400 (DCCT/NGSP)	%HbA _{1c}	11.7	9.36 - 14.0
Beckman AU400/600/640/2700/5400 (IFCC)	mmol/mol	104	83.2 - 125
Beckman DxC 600/DxC 800 (DCCT/NGSP)	%HbA _{1c}	12.1	9.68 - 14.5
Beckman DxC 600/DxC 800 (IFCC)	mmol/mol	109	87.2 - 131
Biorad D-10 (DCCT/NGSP)	%HbA _{1c}	11.1	8.88 - 13.3
Biorad D-10 (IFCC)	mmol/mol	99.9	79.9 - 120
Biorad Variant II (ion exchange) (DCCT/NGSP)	%HbA _{1c}	11.1	8.88 - 13.3
Biorad Variant II (ion exchange) (IFCC)	mmol/mol	97.7	78.2 - 117
Hitachi 9 Series (DCCT/NGSP)	%HbA _{1c}	12.1	9.68 - 14.5
Hitachi 9 Series (IFCC)	mmol/mol	109	87.2 - 131
Konelab 20/30/60 (DCCT/NGSP)	%HbA _{1c}	10.8	8.64 - 13.0
Konelab 20/30/60 (IFCC)	mmol/mol	94.5	75.6 - 113
Ortho Vitros 4600/5600/5.1 FS (DCCT/NGSP)	%HbA _{1c}	11.2	8.96 - 13.4
Ortho Vitros 4600/5600/5.1 FS (IFCC)	mmol/mol	98.9	79.1 - 119
Randox Rx Daytona/ Imola (DCCT/NGSP)	%HbA _{1c}	12.9	10.3 - 15.5
Randox Rx Daytona/ Imola (IFCC)	mmol/mol	117	93.6 - 140
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	101	80.8 - 121
Roche Integra (DCCT/NGSP)	%HbA _{1c}	11.1	8.88 - 13.3
Roche Integra (IFCC)	mmol/mol	101	80.8 - 121
Roche Modular P/Cobas c111 (DCCT/NGSP)	%HbA _{1c}	11.3	9.04 - 13.6
Roche Modular P/Cobas c111 (IFCC)	mmol/mol	100	80.0 - 120
Siemens/Bayer ADVIA 1200/1650/2400 (DCCT/NGSP)	%HbA _{1c}	11.1	8.88 - 13.3
Siemens/Bayer ADVIA 1200/1650/2400 (IFCC)	mmol/mol	97.8	78.2 - 117
Siemens/Dade Dimension (DCCT/NGSP)	%HbA _{1c}	11.5	9.20 - 13.8
Siemens/Dade Dimension (IFCC)	mmol/mol	102	81.6 - 122
Siemens DCA 2000/Vantage (DCCT/NGSP)	%HbA _{1c}	11.5	9.20 - 13.8
Siemens DCA 2000/Vantage (IFCC)	mmol/l	105	84.0 - 126
TOSOH HLC723/G7/G8 (DCCT/NGSP)	%HbA _{1c}	11.0	8.80 - 13.2
TOSOH HLC723/G7/G8 (IFCC)	mmol/mol	97.9	78.3 - 118
Trinity Biotech Affinity HPLC (DCCT/NGSP/IFCC)	%HbA _{1c}	10.5	9.90 - 11.1
Trinity Biotech Affinity HPLC (DCCT/NGSP/IFCC)	mmol/mol	91.0	85.0 - 98.0
Trinity/Menarini Premier Hb9210 (DCCT/NGSP)	%HbA _{1c}	10.5	9.90 - 11.1
Trinity/Menarini Premier Hb9210 (IFCC)	mmol/mol	91.0	85.0 - 98.0

Total Haemoglobin		Target	Range
Randox Rx Daytona/Imola	g/dl	11.4	9.12 - 13.7

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