

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

Cat. No: HA5072

Lot Nos: 1722HA & 1724HA

Size: 2 x 2 x 0.5 ml

Expiry: 2018-04

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. 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}	5.36	4.29 - 6.43
Abbott Architect c Systems (IFCC)	mmol/mol	35.6	28.5 - 42.7
Abbott Architect I Systems (DCCT/NGSP)	%HbA _{1c}	6.88	5.50 - 8.26
Abbott Architect I Systems (IFCC)	mmol/mol	51.7	41.4 - 62.0
Agappe Mispai	%HbA _{1c}	5.77	4.62 - 6.92
Agappe Mispai	mmol/mol	39.6	31.7 - 47.5
Arkray Menarini HA8121/40/60/80 (DCCT/NGSP)	%HbA _{1c}	5.69	4.55 - 6.83
Arkray Menarini HA8121/40/60/80 (IFCC)	mmol/mol	38.8	31.0 - 46.6
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}	5.91	4.73 - 7.09
Beckman DxC 600/DxC 800 (IFCC)	mmol/mol	41.1	32.9 - 49.3
Biorad D-10 (DCCT/NGSP)	%HbA _{1c}	5.70	4.56 - 6.84
Biorad D-10 (IFCC)	mmol/mol	38.3	30.6 - 46.0
Biorad Variant II (ion exchange) (DCCT/NGSP)	%HbA _{1c}	5.79	4.63 - 6.95
Biorad Variant II (ion exchange) (IFCC)	mmol/mol	39.4	31.5 - 47.3
Goldsite Diagnostics HbA _{1c} kit	%HbA _{1c}	5.93	4.74 - 7.12
Goldsite Diagnostics HbA _{1c} kit	mmol/mol	41.3	33.0 - 49.6
Hitachi 9 Series (DCCT/NGSP)	%HbA _{1c}	5.93	4.74 - 7.12
Hitachi 9 Series (IFCC)	mmol/mol	41.3	33.0 - 49.6
Konelab 20/30/60 (DCCT/NGSP)	%HbA _{1c}	5.95	4.76 - 7.14
Konelab 20/30/60 (IFCC)	mmol/mol	41.5	33.2 - 49.8
Mindray BS200/300/400	%HbA _{1c}	5.35	4.28 - 6.42
Mindray BS200/300/400	mmol/mol	35.0	28.0 - 42.0
Nycocard Reader	%HbA _{1c}	7.87	6.30 - 9.44
Nycocard Reader	mmol/mol	62.5	50.0 - 75.0
Ortho Vitros 4600/5600/5.1 FS (DCCT/NGSP)	%HbA _{1c}	5.83	4.66 - 7.00
Ortho Vitros 4600/5600/5.1 FS (IFCC)	mmol/mol	40.2	32.2 - 48.2
Quotient Quo-Lab A _{1c} Test	%HbA _{1c}	6.78	5.42 - 8.14
Quotient Quo-Lab A _{1c} Test	mmol/mol	50.6	40.5 - 60.7
Randox Rx Daytona/ Imola (DCCT/NGSP)	%HbA _{1c}	5.80	4.64 - 6.96
Randox Rx Daytona/ Imola (IFCC)	mmol/mol	39.9	31.9 - 47.9
Roche Cobas 4000/C311 (DCCT/NGSP)	%HbA _{1c}	5.65	4.52 - 6.78
Roche Cobas 4000/C311 (IFCC)	mmol/mol	38.3	30.6 - 46.0
Roche Cobas 6000/8000 (DCCT/NGSP)	%HbA _{1c}	5.73	4.58 - 6.88
Roche Cobas 6000/8000 (IFCC)	mmol/mol	38.4	30.7 - 46.1
Roche Integra (DCCT/NGSP)	%HbA _{1c}	5.62	4.50 - 6.74
Roche Integra (IFCC)	mmol/mol	42.1	33.7 - 50.5
Roche Modular P/ Cobas c111 (DCCT/NGSP)	%HbA _{1c}	5.89	4.71 - 7.07
Roche Modular P/ Cobas c111 (IFCC)	mmol/mol	40.9	32.7 - 49.1
Sebia Capillarys 2	%HbA _{1c}	5.42	4.34 - 6.50
Sebia Capillarys 2	mmol/mol	35.4	28.3 - 42.5
Siemens/ Bayer ADVIA 1200/1650/2400 (DCCT/NGSP)	%HbA _{1c}	5.88	4.70 - 7.06
Siemens/ Bayer ADVIA 1200/1650/2400 (IFCC)	mmol/mol	40.8	32.6 - 49.0
Siemens/Dade Dimension (DCCT/NGSP)	%HbA _{1c}	5.97	4.78 - 7.16
Siemens/Dade Dimension (IFCC)	mmol/mol	45.7	36.6 - 54.8
Siemens DCA2000/Vantage	%HbA _{1c}	6.03	4.82 - 7.24
Siemens DCA2000/Vantage	mmol/mol	42.2	33.8 - 50.6

LEVEL 1 (Continued)

Method	Units	Target	Range
Tokyo Boeki / Prestige 24i	%HbA _{1c}	6.11	4.89 – 7.33
Tokyo Boeki / Prestige 24i	mmol/mol	43.3	34.6 – 52.0
TOSOH HLC723/G7/G8 (DCCT/NGSP)	%HbA _{1c}	5.66	4.53 – 6.79
TOSOH HLC723/G7/G8 (IFCC)	mmol/mol	38.8	31.0 – 46.6
TrinBio CLC385/PDQ/Ultra 2	%HbA _{1c}	6.13	4.90 – 7.36
TrinBio CLC385/PDQ/Ultra 2	mmol/mol	43.5	34.8 – 52.5
Trinity Biotech Tri-Stat	%HbA _{1c}	6.87	5.50 – 8.24
Trinity Biotech Tri-Stat	mmol/mol	51.6	41.3 – 61.9
Trinity/Menarini Premier Hb9210 (DCCT/NGSP)	%HbA _{1c}	6.39	5.11 – 7.67
Trinity/Menarini Premier Hb9210 (IFCC)	mmol/mol	46.1	36.9 – 55.3
Total Haemoglobin		Target	Range
Randox Rx Daytona/Imola	g/dl	12.7	10.2 – 15.2

LEVEL 2

Method	Units	Target	Range
Abbott Architect c Systems (DCCT/NGSP)	%HbA _{1c}	10.5	8.40 – 12.6
Abbott Architect c Systems (IFCC)	mmol/mol	90.9	72.7 – 109
Abbott Architect I Systems (DCCT/NGSP)	%HbA _{1c}	12.8	10.2 – 15.4
Abbott Architect I Systems (IFCC)	mmol/mol	116	92.8 – 139
Arkray Menarini HA8121/40/60/80 (DCCT/NGSP)	%HbA _{1c}	10.8	8.64 – 13.0
Arkray Menarini HA8121/40/60/80 (IFCC)	mmol/mol	94.8	75.8 – 114
Agappe Mispai	%HbA _{1c}	11.2	8.96 – 13.4
Agappe Mispai	mmol/mol	98.9	79.1 – 119
Beckman AU400/600/640/2700/5400 (DCCT/NGSP)	%HbA _{1c}	11.6	9.28 – 13.9
Beckman AU400/600/640/2700/5400 (IFCC)	mmol/mol	103	82.4 – 124
Beckman DxC 600/DxC 800 (DCCT/NGSP)	%HbA _{1c}	11.8	9.44 – 14.2
Beckman DxC 600/DxC 800 (IFCC)	mmol/mol	105	84.0 – 126
Biorad D-10 (DCCT/NGSP)	%HbA _{1c}	11.0	8.80 – 13.2
Biorad D-10 (IFCC)	mmol/mol	99.0	79.2 – 119
Biorad Variant II (ion exchange) (DCCT/NGSP)	%HbA _{1c}	11.0	8.80 – 13.2
Biorad Variant II (ion exchange) (IFCC)	mmol/mol	98.0	78.4 – 118
Goldsite Diagnostics HbA _{1c} kit	%HbA _{1c}	11.7	9.36 – 14.0
Goldsite Diagnostics HbA _{1c} kit	mmol/mol	104	83.2 – 125
Hitachi 9 Series (DCCT/NGSP)	%HbA _{1c}	11.0	8.80 – 13.2
Hitachi 9 Series (IFCC)	mmol/mol	96.7	77.4 – 116
Konelab 20/30/60 (DCCT/NGSP)	%HbA _{1c}	10.7	8.56 – 12.8
Konelab 20/30/60 (IFCC)	mmol/mol	93.4	74.7 – 112
Mindray BS200/300/400	%HbA _{1c}	10.6	8.48 – 12.7
Mindray BS200/300/400	mmol/mol	92.4	73.9 – 111
Nycocard Reader	%HbA _{1c}	11.0	8.80 – 13.2
Nycocard Reader	mmol/mol	96.7	77.4 – 116
Ortho Vitros 4600/5600/5.1 FS (DCCT/NGSP)	%HbA _{1c}	11.1	8.88 – 13.3
Ortho Vitros 4600/5600/5.1 FS (IFCC)	mmol/mol	97.8	78.2 – 117
Quotient Quo-Lab A1c Test	%HbA _{1c}	11.7	9.36 – 14.0
Quotient Quo-Lab A1c Test	mmol/mol	104	83.2 – 125
Randox Rx Daytona/ Imola (DCCT/NGSP)	%HbA _{1c}	12.4	9.92 – 14.9
Randox Rx Daytona/ Imola (IFCC)	mmol/mol	112	89.6 – 134

LEVEL 2 (Continued)

Method	Units	Target	Range
Roche Cobas 4000/C311 (DCCT/NGSP)	%HbA _{1c}	10.9	8.72 – 13.1
Roche Cobas 4000/C311 (IFCC)	mmol/mol	95.6	76.5 – 115
Roche Cobas 6000/8000 (DCCT/NGSP)	%HbA _{1c}	11.0	8.80 – 13.2
Roche Cobas 6000/8000 (IFCC)	mmol/mol	97.8	78.2 – 117
Roche Integra (DCCT/NGSP)	%HbA _{1c}	10.9	8.72 – 13.1
Roche Integra (IFCC)	mmol/mol	99.1	79.3 – 119
Roche Modular P/ Cobas c111 (DCCT/NGSP)	%HbA _{1c}	11.0	8.80 – 13.2
Roche Modular P/ Cobas c111 (IFCC)	mmol/mol	96.7	77.4 – 116
Siemens/ Bayer ADVIA 1200/1650/2400 (DCCT/NGSP)	%HbA _{1c}	10.5	8.40 – 12.6
Siemens/ Bayer ADVIA 1200/1650/2400 (IFCC)	mmol/mol	91.3	73.0 – 110
Sebia Capillarys 2	%HbA _{1c}	10.7	8.56 – 12.8
Sebia Capillarys 2	mmol/mol	93.0	74.4 – 112
Siemens/Dade Dimension (DCCT/NGSP)	%HbA _{1c}	11.1	8.88 – 13.3
Siemens/Dade Dimension (IFCC)	mmol/mol	97.8	78.2 – 117
Siemens DCA2000/Vantage	%HbA _{1c}	11.5	9.20 – 13.8
Siemens DCA2000/Vantage	mmol/mol	104	83.2 – 125
Tokyo Boeki / Prestige 24i	%HbA _{1c}	11.1	8.88 – 13.3
Tokyo Boeki / Prestige 24i	mmol/mol	97.8	78.2 – 117
TOSOH HLC723/G7/G8 (DCCT/NGSP)	%HbA _{1c}	10.8	8.64 – 13.0
TOSOH HLC723/G7/G8 (IFCC)	mmol/mol	95.5	76.4 – 115
TrinBio CLC385/PDQ/Ultra 2	%HbA _{1c}	11.1	8.88 – 13.3
TrinBio CLC385/PDQ/Ultra 2	mmol/mol	97.8	78.2 – 117
Trinity Biotech Tri-Stat	%HbA _{1c}	12.2	9.76 – 14.6
Trinity Biotech Tri-Stat	mmol/mol	110	88.0 – 132
Trinity/Menarini Premier Hb9210 (DCCT/NGSP)	%HbA _{1c}	11.1	8.88 – 13.3
Trinity/Menarini Premier Hb9210 (IFCC)	mmol/mol	97.4	77.9 – 116

Total Haemoglobin		Target	Range
Randox Rx Daytona/Imola	g/dl	12.2	9.76 – 14.6

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