

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

**CAT. NO:** HA5072

**LOT NO:** 2261HA & 2264HA

**SIZE:** 2 x 2 x 0.5 ml

**EXPIRY:** 2024-02-28

**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.** 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 HbA1c & 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<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   | 5.33   | 4.26 - 6.40 |
| Abbott Architect c / Alinity c (IFCC)                | mmol/mol | 34.8   | 27.8 - 41.8 |
| Abbott Architect c(Direct Turbidimetric) (DCCT/NGSP) | %HbA1c   | 5.86   | 4.69 - 7.03 |
| Abbott Architect c(Direct Turbidimetric) (IFCC)      | mmol/mol | 40.5   | 32.4 - 48.6 |
| Agappe Mispa i3 (DCCT/NGSP)                          | %HbA1c   | 6.52   | 5.22 - 7.82 |
| Agappe Mispa i3 (IFCC)                               | mmol/mol | 47.8   | 38.2 - 57.4 |
| Arkray PocketChem A1c (DCCT/NGSP)                    | %HbA1c   | 6.75   | 5.40 - 8.10 |
| Arkray PocketChem A1c (IFCC)                         | mmol/mol | 50.3   | 40.2 - 60.4 |
| Arkray/Adams/Menarini A1c HA-8000 Series (DCCT/NGSP) | %HbA1c   | 5.62   | 4.50 - 6.74 |
| Arkray/Adams/Menarini A1c HA-8000 Series (IFCC)      | mmol/mol | 37.9   | 30.3 - 45.5 |
| Beckman AU Instruments (DCCT/NGSP)                   | %HbA1c   | 5.81   | 4.65 - 6.97 |
| Beckman AU Instruments (IFCC)                        | mmol/mol | 40.0   | 32.0 - 48.0 |
| Bioanalytic Diagnostic HbA1c (DCCT/NGSP)             | %HbA1c   | 5.56   | 4.45 - 6.67 |
| Bioanalytic Diagnostic HbA1c (IFCC)                  | mmol/mol | 37.3   | 29.8 - 44.8 |
| Biorad D-10 (DCCT/NGSP)                              | %HbA1c   | 5.77   | 4.62 - 6.92 |
| Biorad D-10 (IFCC)                                   | mmol/mol | 39.6   | 31.7 - 47.5 |
| Biorad D-100 (DCCT/NGSP)                             | %HbA1c   | 5.78   | 4.62 - 6.94 |
| Biorad D-100 (IFCC)                                  | mmol/mol | 39.7   | 31.8 - 47.6 |
| Biorad Variant II (ion exchange) (DCCT/NGSP)         | %HbA1c   | 5.76   | 4.61 - 6.91 |
| Biorad Variant II (ion exchange) (IFCC)              | mmol/mol | 39.5   | 31.6 - 47.4 |
| Boditech Med Inc i-CHROMA (DCCT/NGSP)                | %HbA1c   | 5.89   | 4.71 - 7.07 |
| Boditech Med Inc i-CHROMA (IFCC)                     | mmol/mol | 40.9   | 32.7 - 49.1 |
| Centronic HbA1c (DCCT/NGSP)                          | %HbA1c   | 5.76   | 4.61 - 6.91 |
| Centronic HbA1c (IFCC)                               | mmol/mol | 39.5   | 31.6 - 47.4 |
| Ceragem Labona Check (DCCT/NGSP)                     | %HbA1c   | 5.59   | 4.47 - 6.71 |
| Ceragem Labona Check (IFCC)                          | mmol/mol | 37.6   | 30.1 - 45.1 |
| Clover A1c (DCCT/NGSP)                               | %HbA1c   | 6.36   | 5.09 - 7.63 |
| Clover A1c (IFCC)                                    | mmol/mol | 46.0   | 36.8 - 55.2 |
| EKF Quotient Quo-Lab A1c Test (DCCT/NGSP)            | %HbA1c   | 7.07   | 5.66 - 8.48 |
| EKF Quotient Quo-Lab A1c Test (IFCC)                 | mmol/mol | 53.8   | 43.0 - 64.6 |
| Erba XL Series (DCCT/NGSP)                           | %HbA1c   | 6.15   | 4.92 - 7.38 |
| Erba XL Series (IFCC)                                | mmol/mol | 43.7   | 35.0 - 52.4 |
| Mindray BS200/300/400/800 (DCCT/NGSP)                | %HbA1c   | 5.64   | 4.51 - 6.77 |
| Mindray BS200/300/400/800 (IFCC)                     | mmol/mol | 38.1   | 30.5 - 45.7 |
| Mindray H50/ H50P (DCCT/NGSP)                        | %HbA1c   | 5.73   | 4.58 - 6.88 |
| Mindray H50/ H50P (IFCC)                             | mmol/mol | 39.1   | 31.3 - 46.9 |
| MTI Diagnostics HA-1500 (DCCT/NGSP)                  | %HbA1c   | 6.99   | 5.59 - 8.39 |
| MTI Diagnostics HA-1500 (IFCC)                       | mmol/mol | 52.9   | 42.3 - 63.5 |
| Ortho Vitros 4600/5600/5.1 FS/XT 7600 (DCCT/NGSP)    | %HbA1c   | 5.73   | 4.58 - 6.88 |
| Ortho Vitros 4600/5600/5.1 FS/XT 7600 (IFCC)         | mmol/mol | 39.1   | 31.3 - 46.9 |
| Randox Rx HbA1c (DCCT/NGSP)                          | %HbA1c   | 5.82   | 4.66 - 6.98 |
| Randox Rx HbA1c (IFCC)                               | mmol/mol | 40.1   | 32.1 - 48.1 |
| Randox Rx HbA1c II (DCCT/NGSP)                       | %HbA1c   | 5.27   | 4.22 - 6.32 |
| Randox Rx HbA1c II (IFCC)                            | mmol/mol | 34.1   | 27.3 - 40.9 |
| Roche Cobas 4000/c311 (DCCT/NGSP)                    | %HbA1c   | 5.64   | 4.51 - 6.77 |
| Roche Cobas 4000/c311 (IFCC)                         | mmol/mol | 38.1   | 30.5 - 45.7 |
| Roche Cobas 6000/8000 (DCCT/NGSP)                    | %HbA1c   | 5.69   | 4.55 - 6.83 |
| Roche Cobas 6000/8000 (IFCC)                         | mmol/mol | 38.7   | 31.0 - 46.4 |
| Roche Cobas c503 (DCCT/NGSP)                         | %HbA1c   | 5.81   | 4.65 - 6.97 |
| Roche Cobas c503 (IFCC)                              | mmol/mol | 40.0   | 32.0 - 48.0 |
| Roche Cobas c513 (DCCT/NGSP)                         | %HbA1c   | 5.80   | 4.64 - 6.96 |
| Roche Cobas c513 (IFCC)                              | mmol/mol | 39.9   | 31.9 - 47.9 |
| Roche Integra (DCCT/NGSP)                            | %HbA1c   | 5.77   | 4.62 - 6.92 |
| Roche Integra (IFCC)                                 | mmol/mol | 39.6   | 31.7 - 47.5 |
| Roche Modular P/Cobas c111 (DCCT/NGSP)               | %HbA1c   | 5.73   | 4.58 - 6.88 |
| Roche Modular P/Cobas c111 (IFCC)                    | mmol/mol | 39.1   | 31.3 - 46.9 |

**LEVEL I (continued)**

|                                        |          |      |             |
|----------------------------------------|----------|------|-------------|
| Sebia Capillarys / Minicap (DCCT/NGSP) | %HbA1c   | 5.59 | 4.47 - 6.71 |
| Sebia Capillarys / Minicap (IFCC)      | mmol/mol | 37.6 | 30.1 - 45.1 |
| Siemens Advia CH A1c_E (DCCT/NGSP)     | %HbA1c   | 5.26 | 4.21 - 6.31 |
| Siemens Advia CH A1c_E (IFCC)          | mmol/mol | 34.0 | 27.2 - 40.8 |
| Siemens Atellica CH A1c_E (DCCT/NGSP)  | %HbA1c   | 5.45 | 4.36 - 6.54 |
| Siemens Atellica CH A1c_E (IFCC)       | mmol/mol | 36.1 | 28.9 - 43.3 |
| Siemens DCA2000/Vantage (DCCT/NGSP)    | %HbA1c   | 5.97 | 4.78 - 7.16 |
| Siemens DCA2000/Vantage (IFCC)         | mmol/mol | 41.7 | 33.4 - 50.0 |
| Siemens/Dade Dimension (DCCT/NGSP)     | %HbA1c   | 5.86 | 4.69 - 7.03 |
| Siemens/Dade Dimension (IFCC)          | mmol/mol | 40.5 | 32.4 - 48.6 |

| <b><u>Total Haemoglobin</u></b> | <b><u>Units</u></b> | <b><u>Target</u></b> | <b><u>Range</u></b> |
|---------------------------------|---------------------|----------------------|---------------------|
| Beckman AU Instruments          | g/dl                | 14.25                | 11.40 - 17.10       |
| Randox Rx Series                | g/dl                | 14.19                | 11.35 - 17.03       |
| Roche Cobas 4000/c311           | g/dl                | 13.46                | 10.77 - 16.15       |
| Roche Cobas 6000/8000           | g/dl                | 15.66                | 12.53 - 18.79       |

## LEVEL 2

| Method                                               | Units    | Target | Range       |
|------------------------------------------------------|----------|--------|-------------|
| Abbott Architect c / Alinity c (DCCT/NGSP)           | %HbA1c   | 10.7   | 8.56 - 12.8 |
| Abbott Architect c / Alinity c (IFCC)                | mmol/mol | 93.4   | 74.7 - 112  |
| Abbott Architect c(Direct Turbidimetric) (DCCT/NGSP) | %HbA1c   | 11.4   | 9.12 - 13.7 |
| Abbott Architect c(Direct Turbidimetric) (IFCC)      | mmol/mol | 101    | 80.9 - 121  |
| Agappe Mispa i3 (DCCT/NGSP)                          | %HbA1c   | 12.7   | 10.2 - 15.2 |
| Agappe Mispa i3 (IFCC)                               | mmol/mol | 115    | 92.2 - 138  |
| Arkray PocketChem A1c (DCCT/NGSP)                    | %HbA1c   | 11.4   | 9.12 - 13.7 |
| Arkray PocketChem A1c (IFCC)                         | mmol/mol | 101    | 80.9 - 121  |
| 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  |
| Bioanalytic Diagnostic HbA1c (DCCT/NGSP)             | %HbA1c   | 11.3   | 9.04 - 13.6 |
| Bioanalytic Diagnostic HbA1c (IFCC)                  | mmol/mol | 100    | 80.0 - 120  |
| Biorad D-10 (DCCT/NGSP)                              | %HbA1c   | 11.2   | 8.96 - 13.4 |
| Biorad D-10 (IFCC)                                   | mmol/mol | 98.9   | 79.1 - 119  |
| 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   | 11.0   | 8.80 - 13.2 |
| Biorad Variant II (ion exchange) (IFCC)              | mmol/mol | 96.7   | 77.4 - 116  |
| Boditech Med Inc i-CHROMA (DCCT/NGSP)                | %HbA1c   | 10.4   | 8.32 - 12.5 |
| Boditech Med Inc i-CHROMA (IFCC)                     | mmol/mol | 90.2   | 72.2 - 108  |
| Centronic HbA1c (DCCT/NGSP)                          | %HbA1c   | 10.2   | 8.16 - 12.2 |
| Centronic HbA1c (IFCC)                               | mmol/mol | 88.0   | 70.4 - 106  |
| Ceragem Labona Check (DCCT/NGSP)                     | %HbA1c   | 9.90   | 7.92 - 11.9 |
| Ceragem Labona Check (IFCC)                          | mmol/mol | 84.7   | 67.8 - 102  |
| Clover A1c (DCCT/NGSP)                               | %HbA1c   | 10.3   | 8.24 - 12.4 |
| Clover A1c (IFCC)                                    | mmol/mol | 89.1   | 71.3 - 107  |
| EKF Quotient Quo-Lab A1c Test (DCCT/NGSP)            | %HbA1c   | 11.3   | 9.04 - 13.6 |
| EKF Quotient Quo-Lab A1c Test (IFCC)                 | mmol/mol | 100    | 80.0 - 120  |
| Erba XL Series (DCCT/NGSP)                           | %HbA1c   | 11.2   | 8.96 - 13.4 |
| Erba XL Series (IFCC)                                | mmol/mol | 98.9   | 79.1 - 119  |
| Mindray BS200/300/400/800 (DCCT/NGSP)                | %HbA1c   | 11.0   | 8.80 - 13.2 |
| Mindray BS200/300/400/800 (IFCC)                     | mmol/mol | 96.7   | 77.4 - 116  |
| Mindray H50/ H50P (DCCT/NGSP)                        | %HbA1c   | 11.1   | 8.88 - 13.3 |
| Mindray H50/ H50P (IFCC)                             | mmol/mol | 97.8   | 78.2 - 117  |
| MTI Diagnostics HA-1500 (DCCT/NGSP)                  | %HbA1c   | 11.6   | 9.28 - 13.9 |
| MTI Diagnostics HA-1500 (IFCC)                       | mmol/mol | 103    | 82.6 - 124  |
| Ortho Vitros 4600/5600/5.1 FS/XT 7600 (DCCT/NGSP)    | %HbA1c   | 11.1   | 8.88 - 13.3 |
| Ortho Vitros 4600/5600/5.1 FS/XT 7600 (IFCC)         | mmol/mol | 97.8   | 78.2 - 117  |
| Randox Rx HbA1c (DCCT/NGSP)                          | %HbA1c   | 12.6   | 10.1 - 15.1 |
| Randox Rx HbA1c (IFCC)                               | mmol/mol | 114    | 91.4 - 137  |
| Randox Rx HbA1c II (DCCT/NGSP)                       | %HbA1c   | 10.6   | 8.48 - 12.7 |
| Randox Rx HbA1c II (IFCC)                            | mmol/mol | 92.4   | 73.9 - 111  |
| Roche Cobas 4000/c311 (DCCT/NGSP)                    | %HbA1c   | 11.1   | 8.88 - 13.3 |
| Roche Cobas 4000/c311 (IFCC)                         | mmol/mol | 97.8   | 78.2 - 117  |
| Roche Cobas 6000/8000 (DCCT/NGSP)                    | %HbA1c   | 11.0   | 8.80 - 13.2 |
| Roche Cobas 6000/8000 (IFCC)                         | mmol/mol | 96.7   | 77.4 - 116  |
| Roche Cobas c503 (DCCT/NGSP)                         | %HbA1c   | 11.0   | 8.80 - 13.2 |
| Roche Cobas c503 (IFCC)                              | mmol/mol | 96.7   | 77.4 - 116  |
| Roche Cobas c513 (DCCT/NGSP)                         | %HbA1c   | 11.2   | 8.96 - 13.4 |
| Roche Cobas c513 (IFCC)                              | mmol/mol | 98.9   | 79.1 - 119  |
| Roche Integra (DCCT/NGSP)                            | %HbA1c   | 11.2   | 8.96 - 13.4 |
| Roche Integra (IFCC)                                 | mmol/mol | 98.9   | 79.1 - 119  |
| Roche Modular P/Cobas c111 (DCCT/NGSP)               | %HbA1c   | 11.1   | 8.88 - 13.3 |
| Roche Modular P/Cobas c111 (IFCC)                    | mmol/mol | 97.8   | 78.2 - 117  |

## LEVEL 2 (continued)

|                                        |          |      |             |
|----------------------------------------|----------|------|-------------|
| Sebia Capillarys / Minicap (DCCT/NGSP) | %HbA1c   | 10.7 | 8.56 - 12.8 |
| Sebia Capillarys / Minicap (IFCC)      | mmol/mol | 93.4 | 74.7 - 112  |
| Siemens Advia CH A1c_E (DCCT/NGSP)     | %HbA1c   | 10.5 | 8.40 - 12.6 |
| Siemens Advia CH A1c_E (IFCC)          | mmol/mol | 91.3 | 73.0 - 110  |
| Siemens Atellica CH A1c_E (DCCT/NGSP)  | %HbA1c   | 10.7 | 8.56 - 12.8 |
| Siemens Atellica CH A1c_E (IFCC)       | mmol/mol | 93.4 | 74.7 - 112  |
| Siemens DCA2000/Vantage (DCCT/NGSP)    | %HbA1c   | 11.4 | 9.12 - 13.7 |
| Siemens DCA2000/Vantage (IFCC)         | mmol/mol | 101  | 80.9 - 121  |
| Siemens/Dade Dimension (DCCT/NGSP)     | %HbA1c   | 10.9 | 8.72 - 13.1 |
| Siemens/Dade Dimension (IFCC)          | mmol/mol | 95.6 | 76.5 - 115  |

| <u>Total Haemoglobin</u> | <u>Units</u> | <u>Target</u> | <u>Range</u>  |
|--------------------------|--------------|---------------|---------------|
| Beckman AU Instruments   | g/dl         | 14.10         | 11.28 - 16.92 |
| Randox Rx Series         | g/dl         | 13.70         | 10.96 - 16.44 |
| Roche Cobas 4000/c311    | g/dl         | 13.70         | 10.96 - 16.44 |
| Roche Cobas 6000/8000    | g/dl         | 15.00         | 12.00 - 18.00 |

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