HbA1c Control

For Monitoring Diabetes

HbA1c Control - Level 1 / Level 2

fortress diagnostics

Global Healthcare Solutions

CE

QUALITY MANAGEMENT SYSTEM
ISO 13485 CERTIFIED COMPANY

Phone: +39 (0)95 725 68 69 | Website: www.meridianhealthcare.it

HbA1c Controls

REF		
BXC0675A	Level I & II	2 x 2 x 0.5ml
BXC0675B	Level I & II	1 x 2 x 0.5ml
BXC0676A	Level I	2 x 0.5ml
BXC0677A	Level II	2 x 0.5ml

CE 2025 / 10

LOT L1 676-01-045
L2 677-02-045

IVD 2°C 8°C

INTENDED USE

Fortress HbA1c Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.

SUMMARY AND PRINCIPLE

The use of quality control materials is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practices. Two levels of control are available to allow performance monitoring within the clinical range.

REAGENT

This product is prepared from human whole blood and contains preservatives and stabilizers. The control is provided in lyophilized form for increased stability.

STORAGE AND STABILITY

This product will be stable until the expiration date when stored unopened at 2 to 8°C. Once the control is reconstituted, all analytes will be stable for 7 days when stored tightly capped at 2 to 8°C. This product is shipped under ambient conditions.

RECONSTITUTION

Using a volumetric pipet, reconstitute each vial with 0.5 mL of distilled or deionized water. Replace the stopper, and allow the control to stand for approximately 5 to 10 minutes. Before sampling, gently swirl the vial several times to ensure homogeneity.

PROCEDURE

This product should be treated the same as patient specimens and run in accordance with instructions accompanying the instrument, kit or reagent being used.

The reconstituted control exhibits column elution profiles and temperature sensitivities comparable to those of patient whole blood samples. Hemoglobin A1C results for the control must be corrected for temperature as recommended by the reagent manufacturer to achieve the assigned values.

Dispose of any discarded materials in accordance with the requirements of your local waste management authorities. In the event of damage to packaging, contact Fortress Diagnostics.

LIMITATIONS

1. This product should not be used past the expiration date.
2. If there is evidence of microbial contamination or excessive turbidity in the reconstituted control, discard the vial.
3. This product is not intended for use as a standard.

ASSIGNMENT OF VALUES

The mean values printed in this insert were derived from replicate analyses and are specific for this lot of product. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of control. Individual laboratory means should fall within the corresponding acceptable range; however, laboratory means may vary from the listed values during the life of this control. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by manufacturer test method modifications. It is recommended that each laboratory establish its own means and acceptable ranges and use those provided only as guides.

How to Order

To place an order please contact your local Fortress Diagnostics Distributor.

AUTHORISED DISTRIBUTOR

Meridian Healthcare srl
Via Caronda, 446 SC/A - 95129 Catania - Italy
Tel. +39 095 725 68 69 - Fax:. +39 095 725 44 54
info@meridianhealthcare.it
www.meridianhealthcare.it

When Ordering: Please quote your:
Name
Address
Telephone Number
Fax number
Email Address
Purchase Order Number
Product Description
Catalogue Number
Quantity Required

Please contact us if you are unsure who your local Distributor is in your country:

Manufacturer: Fortress Diagnostics Limited,
Antrim Technology Park,
Muckamore, Antrim,
N. Ireland, BT41 1QS,
United Kingdom

Ordering Details

CAT NO	LEVELS	PACK SIZE
BXC0675A	Level I & II	2 x 2 x 0.5ml
BXC0675B	Level I & II	1 x 2 x 0.5ml
BXC0676A	Level I	2 x 0.5ml
BXC0677A	Level II	2 x 0.5ml

Assigned Values - Fortress

		Level 1		Level 2	
INSTRUMENTS / ANALYTE	**Units**	**Target**	**Range**	**Target**	**Range**
HEMOGLOBIN A1C					
HbA1c (Immunoturbidimetric)	%	6.72	5.37 - 8.06	12.01	9.61 - 14.42
HbA1c (Direct Enzymatic)	%	5.88	4.70 - 7.05	10.98	8.78 - 13.17
HbA1c (Modified Enzymatic)	%	5.09	4.07 - 6.11	10.34	8.27 - 12.41
HbA1c (Microcolumn)	%	5.40	4.32 - 6.48	8.71	6.97 - 10.45
HbA1c (HPLC)	%	6.02	4.81 - 7.22	12.33	9.86 - 14.79

Methods

		Level 1		Level 2	
INSTRUMENTS / ANALYTE	**Units**	**Target**	**Range**	**Target**	**Range**
HEMOGLOBIN A1C					
Abbott ARCHITECT cSystems	%	5.60	4.48 - 6.72	10.32	8.26 - 12.39
Abbott ARCHITECT iSystems	%	6.28	5.03 - 7.54	10.90	8.72 - 13.08
Beckman Coulter AU Systems	%	5.93	4.74 - 7.11	10.31	8.25 - 12.37
Beckman Coulter Synchron LX/UniCel DxC Series	%	6.03	4.83 - 7.24	11.01	8.81 - 13.22
Bio-Rad D-10 Dual A1C Program	%	6.13	5.42 - 6.83	11.01	9.75 - 12.28
Bio-Rad Variant II TURBO Hemoglobin A1C	%	6.01	5.29 - 6.73	10.90	9.59 - 12.21
Diazyme Direct Enzymatic HbA1c	%	4.83	3.87 - 5.80	8.68	6.94 - 10.41
HemoCue HbA1c 501	%	5.66	4.53 - 6.79	10.23	8.19 - 12.28
Infopia Clover A1c	%	5.89	4.71 - 7.07	10.57	8.45 - 12.68
Ortho VITROS MicroTip Series	%	6.08	4.86 - 7.30	10.83	8.67 - 13.00
Pointe Scientific Inc.	%	5.66	4.81 - 6.51	11.24	9.55 - 12.92
Roche cobas c Systems	%	5.79	4.63 - 6.94	10.41	8.33 - 12.49
Roche cobas INTEGRA - Tina-quant Hemoglobin A1c Gen.2	%	5.60	4.48 - 6.72	10.38	8.30 - 12.45
Sebia Capillarys HbA1c / Capillarys 2 Flex Piercing Instrument	%	6.15	4.92 - 7.38	10.58	8.46 - 12.69
Siemens ADVIA Chemistry Systems Hemoglobin A1c_3	%	5.54	4.82 - 6.26	10.90	9.48 - 12.32
Siemens DCA Series	%	6.09	4.87 - 7.31	10.48	8.38 - 12.57
Siemens Dimension Series HB1C	%	5.93	4.74 - 7.11	10.38	8.30 - 12.45
Siemens Dimension VISTA Systems HbA1C	%	6.10	4.88 - 7.33	10.45	8.36 - 12.53
TOSOH G7 Automated HPLC Analyzer	%	6.01	5.41 - 6.61	10.57	9.51 - 11.62
TOSOH G8 Automated HPLC Analyzer	%	5.99	5.39 - 6.59	10.67	9.60 - 11.73
TOSOH ST AIA-PACK HbA1c	%	6.72	4.70 - 8.73	10.35	7.24 - 13.45
Trinity Biotech Affinity HPLC	%	5.66	5.32 - 6.00	10.57	9.93 - 11.20
Trinity Biotech Premier Hb9210	%	5.66	5.32 - 6.00	10.68	10.04 - 11.32
HEMOGLOBIN, TOTAL GLYCATED					
Trinity Biotech Affinity HPLC	%	6.25	5.68 - 6.81	14.79	13.69 - 15.90

Instruments

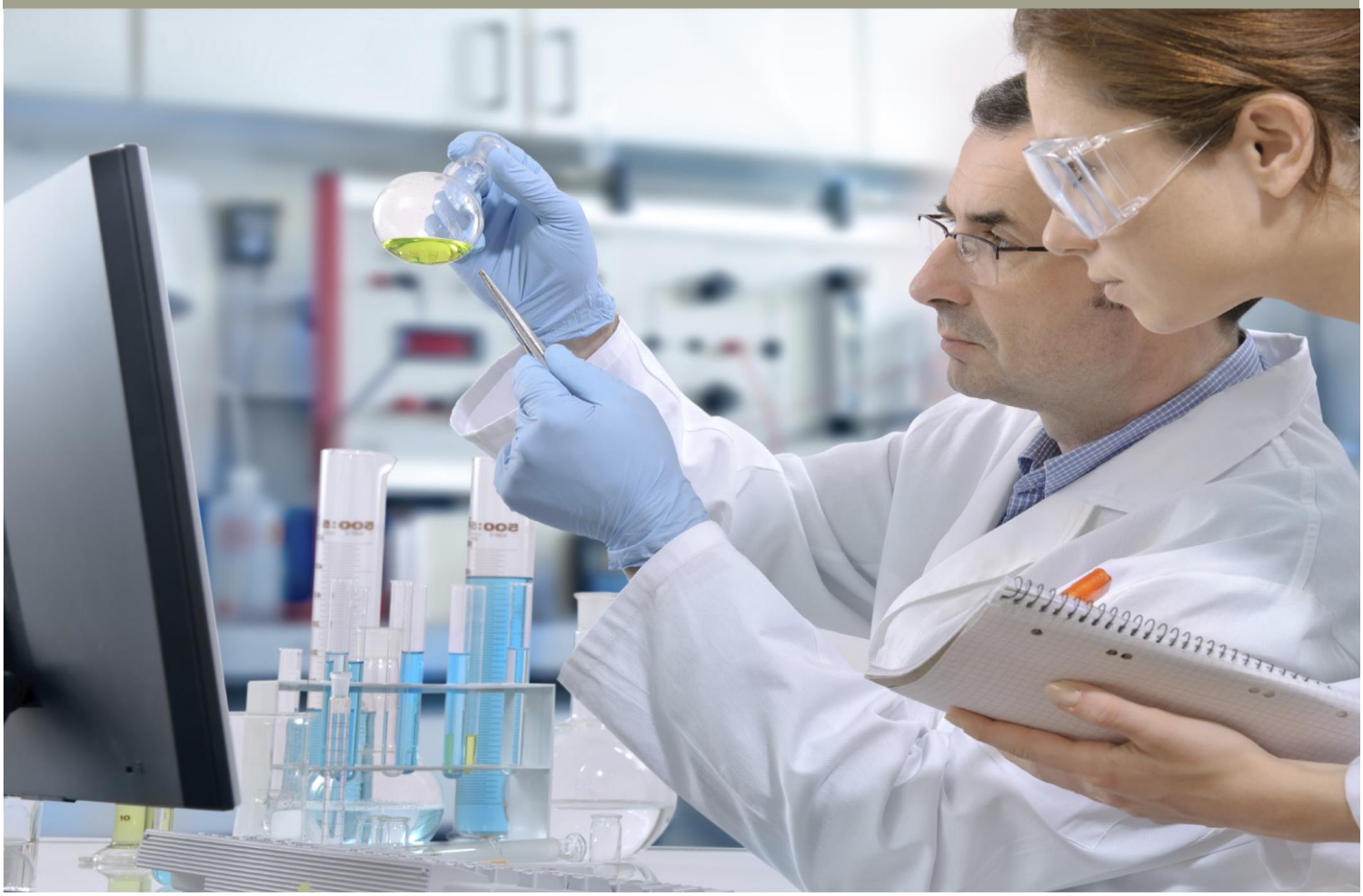
		Level 1		Level 2	
INSTRUMENTS / ANALYTE	**Units**	**Target**	**Range**	**Target**	**Range**
BECKMAN COULTER AU SYSTEMS					
Hemoglobin A1C	g/dL	0.54	0.43 - 0.64	1.07	0.85 - 1.28
Hemoglobin A1C (NGSP)	%	5.93	4.74 - 7.11	10.31	8.25 - 12.37
Hemoglobin, Total	g/dL	17.09	13.67 - 20.51	13.68	10.95 - 16.42
BECKMAN COULTER SYNCHRON LX / UniCel DxC SERIES					
Hemoglobin A1C	g/dL	0.53	0.42 - 0.63	1.01	0.81 - 1.21
Hemoglobin A1C (NGSP)	%	6.03	4.83 - 7.24	11.01	8.81 - 13.22
Hemoglobin, Total	g/dL	16.38	13.11 - 19.66	11.90	9.52 - 14.28
ORTHO VITROS MICROTIP SERIES					
Hemoglobin A1C	g/dL	0.56	0.45 - 0.67	1.09	0.87 - 1.30
Hemoglobin A1C (NGSP)	%	6.08	4.86 - 7.30	10.83	8.67 - 13.00
Hemoglobin, Total	g/dL	17.09	13.67 - 20.51	13.13	10.50 - 15.75
ROCHE COBAS C SYSTEMS					
Hemoglobin A1C	g/dL	0.32	0.26 - 0.39	0.70	0.56 - 0.84
Hemoglobin A1C (NGSP)	%	5.60	4.48 - 6.72	10.38	8.30 - 12.45
Hemoglobin, Total	g/dL	11.61	9.29 - 13.93	8.98	7.18 - 10.77
ROCHE COBAS INTEGRA					
Hemoglobin A1C (Tina-quant Hemoglobin A1c Gen.2)	g/dL	0.61	0.49 - 0.74	1.15	0.92 - 1.37
Hemoglobin A1C Tina-quant Hemoglobin A1c Gen.2 (NGSP)	%	6.15	4.92 - 7.38	10.58	8.46 - 12.69
Hemoglobin, Total (Tina-quant Hemoglobin A1c Gen.2)	g/dL	18.15	14.52 - 21.78	14.13	11.30 - 16.95
SIEMENS ADVIA CHEMISTRY SYSTEMS					
Hemoglobin A1C_3	umol/L	3.13	2.51 - 3.76	4.78	3.83 - 5.74
Hemoglobin A1C_3 (NGSP)	%	5.87	4.70 - 7.04	10.06	8.04 - 12.07
Hemoglobin, Total (tHB_3)	g/dL	17.09	13.67 - 20.51	13.35	10.68 - 16.02

Fortress Diagnostics Limited
Antrim Technology Park
Belfast Road Antrim, BT41 1QS
Northern Ireland
United Kingdom

Authorized Distributor:

Meridian Healthcare®
medical diagnostics and equipment

Get In Touch



Seraqual External Quality Assessment Scheme

Website: www.seqasonline.com

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