

# HEMOGLOBIN A1c

## CONVENIENCE OF NO SAMPLE PRETREATMENT, APPROVED TO DIAGNOSE DIABETES MELLITUS

### Fully automated HbA1c assay available on DXC 700 AU clinical chemistry analyzers



#### Background

Today, an estimated 425 million people worldwide—8.8% of adults between the ages of 20 and 79—have diabetes. If all current trends continue, 629 million people in this demographic will have diabetes by the year 2045.

Diabetes mellitus is a chronic disease that occurs when there are raised levels of glucose in the blood, a condition called hyperglycaemia, because the body cannot produce any insulin (type 1 diabetes), or it cannot produce enough or use the hormone effectively (type 2 diabetes). Hyperglycaemia, if left unchecked over the long term, can cause damage to various body organs and the development of disabling—even life-threatening—health complications such as cardiovascular disease, neuropathy, nephropathy, and eye disease, the latter leading to retinopathy and blindness.<sup>1</sup>

Early diagnosis of diabetes increases the individual's chances of preventing harmful and costly complications. It has been estimated that half of all people with diabetes are unaware of their disease. Since 50 percent of the people with diabetes are undiagnosed, there is an urgent need to screen, diagnose and provide appropriate care for individuals with diabetes.<sup>1</sup>

Measuring HbA1c every two to three months serves as the accepted standard for glycemic control in the care and treatment of patients with diabetes mellitus. The American Diabetes Association recommends using a Hemoglobin A1c (HbA1c) method that is certified by the NGSP and standardized to the Diabetes Control and Complications Trial (DCCT).<sup>2</sup>

Beckman Coulter now offers a fully automated HbA1c Advanced Kit that eliminates the need for manual sample pretreatment. The assay is approved as an aid for diagnosing diabetes mellitus, monitoring long-term glucose control in individuals with diabetes mellitus and for identifying patients who may be at risk of developing diabetes mellitus. The recommended quality-control material for the HbA1c Advanced Kit is extendSURE® Hemoglobin A1c Liquid Controls.

#### Test principle

The HbA1c advanced assay involves the use of three reagents: Total Hemoglobin (THb), HbA1c, and Hemolyzing Reagent. The DxC 700 AU chemistry analyzer automatically performs the whole blood hemolysis by delivering whole blood sample and hemolyzing reagent in a cuvette. The hemolyzed whole blood is then added to both the THb and HbA1c assay cuvettes for analysis. THb is determined by a colorimetric method and HbA1c is determined by a turbidimetric immunoinhibition method. THb and HbA1c concentrations are used in the calculation of the reported HbA1c/THb ratio, which is expressed either as mmol/mol (IFCC) or % (DCCT/NGSP).

#### Features of the HbA1c Advanced Kit

- > Clinically effective results with improved accuracy and precision that meets the latest recommendations from NGSP and IFCC for diagnosing and monitoring diabetes
- > No significant interference from common hemoglobin variants (HbC, HbD, HbE, HbA2 and HbS), minimizing misdiagnosis or missed diagnosis for patients with these blood conditions
- > Broad analytical range of 20 to 140 mmol/mol HbA1c (IFCC); 4 to 15% HbA1c (NGSP)
- > Onboard stability of 30 days and calibration stability of 15 days, maximizing reagent efficiency and reducing waste
- > Whole blood analysis integrates with routine and STAT analysis for optimized overall TAT with random-access sample processing
- > System cleans specific “targeted” cuvettes, eliminating potential carryover and the need for time-consuming maintenance
- > Variety of whole blood sample tube options: K2 EDTA, K3 EDTA, lithium heparin and sodium heparin



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## Precision

Testing was conducted using three lots of the HbA1c Advanced kit (REF B93009) and three DxC 700 AU analyzers. Samples were analyzed over 20 days, following CLSI EP05-A3 guidelines. The tables below present the results in %HbA1c (NGSP) and mmol/mol (IFCC) units.

HbA1c Advanced	Mean % HbA1c	Repeatability (Within-run)		Between-run		Between-day		Between-lot		Between-instrument		Total Precision	
		% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD
Human Whole Blood 1	5.07	0.96	0.05	0.57	0.03	0.64	0.03	0.99	0.05	0.74	0.04	1.78	0.09
Human Whole Blood 2	6.72	1.00	0.07	0.41	0.03	0.55	0.04	1.05	0.07	0.56	0.04	1.69	0.11
Human Whole Blood 3	8.07	0.79	0.06	0.51	0.04	0.58	0.05	1.22	0.10	0.57	0.05	1.74	0.14
Human Whole Blood 4	11.71	0.74	0.09	0.36	0.04	0.71	0.08	0.46	0.05	0.32	0.04	1.22	0.14
Spiked Human Whole Blood	14.03	0.72	0.10	0.51	0.07	0.56	0.08	0.58	0.08	0.12	0.02	1.20	0.17
Whole Blood Control 1	5.29	1.12	0.06	0.78	0.04	0.67	0.04	1.34	0.07	0.50	0.03	2.09	0.11
Whole Blood Control 2	9.84	0.73	0.07	0.43	0.04	0.61	0.06	1.17	0.12	0.70	0.07	1.72	0.17

HbA1c Advanced	Mean HbA1c mmol/mol	Repeatability (Within-run)		Between-run		Between-day		Between-lot		Between-instrument		Total Precision	
		% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD	% CV	SD
Human Whole Blood 1	31.91	1.66	0.53	1.27	0.41	1.08	0.34	1.73	0.55	1.31	0.42	3.20	1.02
Human Whole Blood 2	49.95	1.45	0.72	0.63	0.31	0.81	0.41	1.53	0.76	0.82	0.41	2.49	1.24
Human Whole Blood 3	64.75	1.08	0.70	0.69	0.45	0.79	0.51	1.66	1.07	0.77	0.50	2.37	1.53
Human Whole Blood 4	104.51	1.04	1.09	0.23	0.24	0.87	0.91	0.57	0.60	0.40	0.42	1.54	1.61
Spiked Human Whole Blood	129.84	0.85	1.10	0.58	0.76	0.67	0.87	0.69	0.89	0.14	0.19	1.42	1.84
Whole Blood Control 1	34.32	1.91	0.66	1.26	0.43	1.15	0.39	2.26	0.78	0.87	0.30	3.52	1.21
Whole Blood Control 2	84.10	0.93	0.78	0.54	0.46	0.78	0.66	1.50	1.26	0.90	0.76	2.20	1.85

## Accuracy and correlation

Comparison was performed using Human K2 EDTA whole blood specimen for the HbA1c Advanced Kit on a DxC 700 AU analyzer with an NGSP secondary reference-laboratory method. Results of Deming regression in %HbA1c (NGSP) units were as follows:

	N	Slope	Y-intercept	Correlation coefficient (r)	Sample Range
DxC 700 AU vs. secondary reference-laboratory method	138	0.99	0.01 %HbA1c	0.998	4.7 to 14.2 %HbA1c

## Ordering information

HbA1c Advanced Kit (2 x 250 tests)	2 x 41.4 mL HbA1c (R1) 2 x 9.9 mL HbA1c (R2) 2 x 38.3 mL Total Hemoglobin (R1) 2 x 54.7 mL Hemolyzing Reagent (R1) 5 x 2.0 mL HbA1c Calibrator (Levels 2 to 6)*	<b>B93009</b>
extendSURE® HbA1c Liquid Controls	12 vials x 1.0 mL per two control levels	<b>B12397</b>
	2 vials x 1.0 mL per two control levels	<b>B12396</b>

\* Calibrator level 1 is saline.

Hemoglobin A1c is part of a comprehensive assay menu featured on DxC 700 AU chemistry analyzers. To learn more, visit [www.beckmancoulter.com/chemistry](http://www.beckmancoulter.com/chemistry)

## References:

- IDF Diabetes Atlas, Eighth Edition, 2017.
- Diabetes Care 2018; 41 (Supplement 1): S13-S27. Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes, 2018.

For distribution outside the U.S.

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