

RX SERIES

EDUCATIONAL GUIDE - DIRECT HBA1C TESTING
CAPABILITIES ON THE RX MODENA



RANDOX

INTRODUCTION

What is HbA1c?

The term HbA1c refers to glycated haemoglobin. It develops when haemoglobin, a protein within red blood cells that carries oxygen throughout your body, joins with glucose in the blood, becoming 'glycated'. By measuring glycated haemoglobin (HbA1c), clinicians are able to get an overall picture of what our average blood sugar levels have been over a period of weeks/months. For people with diabetes this is important as the higher the HbA1c, the greater the risk of developing diabetes-related complications. [1]

What is the HbA1c assay used for?

The concentration of HbA1c in the blood of diabetic patients increases with rising blood glucose levels and is representative of the mean blood glucose level over the preceding six to eight weeks. HbA1c can therefore be described as a long term indicator of diabetic control unlike blood glucose which is only a short term indicator of diabetic control. It is recommended that HbA1c levels are monitored every three to four months. In patients who have recently changed their therapy or in those who have gestational diabetes it may be beneficial to measure HbA1c levels more frequently, at two to four week intervals. [2]

Clinical Significance of HbA1c

The measurement of HbA1c is used in the long-term monitoring of diabetes mellitus. This assay should not be used in the diagnosis of diabetes mellitus or for day to day glucose monitoring. Diabetes Mellitus is a disease associated with poor glycaemic control. Numerous clinical studies, including the Diabetes Control and Complications Trial, have shown that diabetes related complications may be reduced by the long term monitoring and tight control of blood glucose levels. In the diabetic patient where blood glucose levels are abnormally elevated the level of

HbA1c also increases, the reason for this is that HbA1c is formed by the non-enzymatic glycation of the N-terminus of the β -chain of haemoglobin A₀. [3-11]

Expected Values

Depending upon the assay used, HbA1c is approximately 4 - 6% in non-diabetics, 6 - 8% in controlled diabetics, and can be as much as 20% in uncontrolled diabetics. 124 apparently healthy males and females undergoing physical examination ("Normals") were tested for HbA1c with this assay. The expected range of 4.5 - 6.2% and mean of 5.4% resulted. It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population. [12-15]

SCIENTIFIC STUDY

This study carried out by Randox Laboratories reports the development of a new liquid stable latex enhanced immunoturbidimetric assay kit with enhanced precision and accuracy for the rapid direct measurement of HbA1c in human whole blood. The assay was applied to the fully automated RX modena clinical chemistry analyzer with sample pre-treatment being completed on-board. This instrument can complete 1,200 tests per hour, which combined with its continuous loading capability, means instrument down time is reduced and cost effectiveness is increased. The application of this new instrument to the measurement of clinical chemistry parameters contributes to a reliable analytical assessment of samples thus benefiting the process of patient care.

Methodology

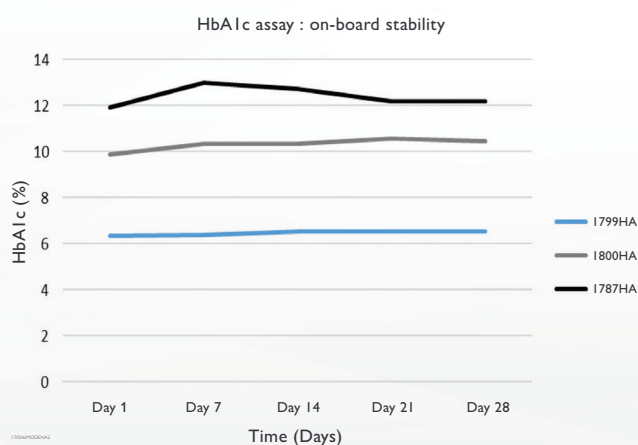
The assay is based on latex immunoagglutination, HbA1c in the test sample is absorbed onto latex particles, and then cross-linked anti-HbA1c is added to form an antigen-antibody complex. Concentrations are calculated from a 5 point spline calibration curve. On-board and calibration stabilities were tested by storing the reagents uncapped on the RX modena for 28 days. Within-run and total precision were assessed by testing whole blood samples at defined medical decision levels, 2 replicates twice a day for 20 days. Correlation studies were conducted against another commercially available method, and the NGSP HPLC method. 123 and 40 whole blood samples, respectively, were tested.

Result

Assay	Limit of quantitation (%)	Linearity (%)
HbA1c	2.78	16.12

ON-BOARD STABILITY

The Reagents presented an on-board stability and calibration frequency of 28 days.



WITHIN RUN PRECISION

Assays				
HbA1c	Level 1 (n=80) (3.47%)	Level 2 (n=80) (4.89%)	Level 3 (n=80) (7.62%)	Level 4 (n=80) (9.61%)
	CV (%)	CV (%)	CV (%)	CV (%)
	4.3	1.2	3.3	1.7

TOTAL PRECISION

Assays				
HbA1c	Level 1 (n=80) (3.47%)	Level 2 (n=80) (4.89%)	Level 3 (n=80) (7.62%)	Level 4 (n=80) (9.61%)
	CV (%)	CV (%)	CV (%)	CV (%)
	6.8	2.5	3.6	1.8

Correlation with another commercially available method

In the correlation study the following linear regression equation was achieved:

$$Y = 0.954x + 0.0432; r = 0.986 (n=123)$$

Correlation with the HPLC method

In the correlation study the following linear regression equation was achieved:

$$Y = 1.024x - 0.269; r = 0.984 (n=40)$$

Findings

This new immunoturbidimetric assay kit exhibits high accuracy and reproducibility with the added advantages of using liquid reagents with good stability, and on-board pre-treatment of samples. This represents an analytical improvement for use in the determination of HbA1c in human whole blood.

Further information on the assay and instrument used within this study

Randox HbA1c Assay features:

- Sample type – Suitable for use with whole blood samples
- Latex enhanced immunoassay method – The Randox assay utilises an immunoassay method making it simple and quick to perform.
- Liquid ready to use reagents – For ease of use and convenience
- Excellent stability – All reagents are stable to expiry date when stored at +2-8°C or 28 days on board the analyser at approximately 10°C.

Product Description	Method	Size (tests)	Size (mls)	Catalogue Number
HbA1c (Direct)	L.E.I	400	R1 = 2 x 16.2 R2 = 4 x 8.2	HA8123

Advantages of the RX modena for direct HbA1c Testing:

- Fully automated on-board haemolysis function for HbA1c testing
- Continuous loading & STAT sample functionality to enhance productivity in the laboratory
- Low sample volumes required
- 1200 tests per hour including ISE
- User friendly software
- Water consumption of 15L per hour [16]

Key Benefits of using the RX modena and Randox HbA1c assay include:

1. Inaccuracies in sample and QC recovery as the offline preparation stage is now eliminated.
2. Faster recovery times as there is no need for any offline calculations.
3. Quicker to calibrate and QC as only one assay being tested instead of two.
4. Samples can be ran immediately as there is no sample incubation step required.

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