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DEVELOPMENT OF A NEW LATEX ENHANCED IMMUNOTURBIDIMETRIC ASSAY FOR THE RAPID DIRECT MEASUREMENT OF GLYCATED HAEMOGLOBIN (HbAIc) APPLICABLE TO RX SERIES ANALYSERS

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Introduction

Diabetes mellitus is a disease associated with poor glycaemic control. In the diabetic patient, where blood glucose levels are abnormally elevated, the level of HbAIc also increases proportionally to the level of glucose in the blood and has been widely accepted as an indicator of the mean daily blood glucose concentration over the preceding 6-8 weeks. It is therefore, a long term indicator of diabetic control, whereas, blood glucose is a short term indicator. The availability of assay kits allowing rapid, accurate and reproducible measurement of HbAIc facilitates long term monitoring of diabetes mellitus.

This study reports the development of a new liquid stable latex enhanced immunoturbidimetric assay kit with enhanced precision and accuracy for the rapid direct measurement of HbAIc in human whole blood. The assay was applied to the fully automated RX series analysers with sample pre-treatment being completed on-board.

Methodology

The assay is based on latex immunoagglutination, HbAIc in the test sample is absorbed onto latex particles, and then cross-linked anti-HbAlc 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 the NGSP HPLC method, 81 whole blood patient samples were tested.



RX modena Random access continuous loading floor standing analyser

Results

1					
	Assay	Limit of Quantitation (%)	Linearity (%)	Within run precisi	on
	HbAIc	2.78	15.76	Assay	

Day 28

17/009/MODENA2

On-board Stability

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

HbAlc assay : on-board stability



	Level I (n=80) (3.47%)	Level 2 (n=80) (4.89%)	Level 3 (n=80) (7.62%)	Level 4 (n=80) (9.61%)
HbAlc	CV(%)	CV(%)	CV(%)	CV(%)
	4.3	1.2	3.3	1.7

17/008/MODENA

Total precision								
Assay								
	Level I (n=80) (3.47%)	Level 2 (n=80) (4.89%)	Level 3 (n=80) (7.62%)	Level 4 (n=80) (9.61%)				
HbAIc	CV(%)	CV(%)	CV(%)	CV(%)				
	6.8	2.5	3.6	1.8				

17/008/MODENA2

Correlation with HPLC

In the correlation study the following linear regression equation was achieved (n=81):

y = 0.979x + 0.0252; r = 0.997.

0 Day 1 Day 7

17/006/MODENA2

Day 21 Day 14 Time (Days)

Conclusion

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 HbAIc in human whole blood.