RANDOX REAGENTS

ANALYTICAL EVALUATION OF AN ASSAY KIT INCORPORATING NEW READY TO USE LIQUID STABLE REAGENTS FOR THE DETERMINATION OF GLUCOSE, THROUGH CONVERSION BY HEXOKINASE, IN DIFFERENT BIOLOGICAL FLUIDS

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INTRODUCTION

Carbohydrates provide the human body with glucose, a simple sugar used as source of energy by the cells. The body must maintain proper glucose levels to ensure that a person remains healthy. Glucose determination is useful in the diagnosis and monitoring of carbohydrate metabolism disorders (i.e. diabetes mellitus, hypoglycaemia, pancreatic islet cell carcinoma) as well as in research and drug discovery processes.

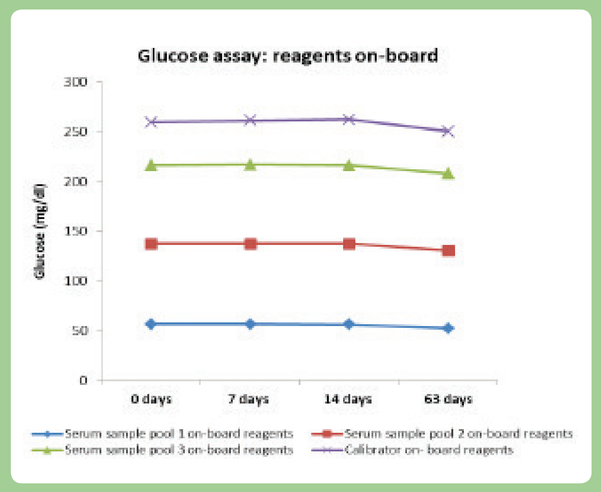
This study reports the evaluation of an assay for the determination of glucose by hexokinase-mediated reaction in serum, plasma, urine, cerebrospinal fluid (CSF) samples. This assay is applicable to automated systems and incorporates new ready to use liquid stable reagents, which facilitates the application in test settings by simplifying the experimental procedure and reducing handling errors.

METHODOLOGY

- The assay involves a series of steps, initiated by the conversion of glucose to glucose-6-phosphate by hexokinase. The glucose-6-phosphate is then oxidized by glucose-6-phosphate dehydrogenase, causing the reduction of oxidized nicotinamide adenine dinucleotide (NAD) to reduced nicotinamide adenine dinucleotide (NADH). The absorbance of NADH is measured as endpoint reaction at 340/410 nm.
- Calibrator traceable to National Institute of Standards and Technology (NIST) Standard Reference Material SRM 965a.
- The assay is applicable to a variety of analysers.
- The reagents are liquid stable and ready to use.
- On-board and calibration stabilities were tested by storing the reagents uncapped on the analyser for a period of 63 days. The performance was compared to fresh reagent.
  Within-run and total precision were assessed by testing samples at defined medical decision levels, 2 replicates of each sample of serum and urine were assayed twice a day for 20 days, 2 replicates of each CSF sample were assayed twice a day for 10 days. Correlation studies were conducted using a commercially available assay system.

RESULTS

Reagents on-board stability



08/004/GLUH

Assay sensitivity & linearity

Glucose assay		
Sensitivity (mg/dl)	Linearity (mg/dl)	Sample type
4	700	Serum Plasma Urine CSF

10/012/GLUH

Traceability to NIST Standard Reference Material 965a

Glucose assay: traceability to NIST Standard Reference Material			
Sample	Target (mg/dl)	Measured (mg/dl)	% Recovery
SRM 965a 1	34.56	0.0	101.5
SRM 965a 2	78.48	1.3	100.0
SRM 965a 3	122.04	2.2	100.7
SRM 965a4	292.32	0.0	100.2

10/011/GLUH

Precision

Glucose assay			
Sample type	Glucose Mean concentration (mg/dl)	Within-run %CV	Total precision %CV
Serum (n=80)	51	0.4	0.9
	87	0.5	0.8
	297	0.5	0.47
Urine (n=80)	49	0.6	1.1
	301	0.4	1.9
CSF (n=40)	56	0.4	1.0
	97	0.3	0.8

09/005/GLUH

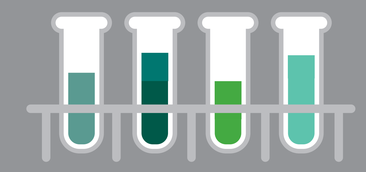
Correlations with other commercially available assay system

Sample type	n	Regression equation	r	Range mg/dl
Serum	99	y = 1.001x + 0.3	1.0	5-676
Plasma (lithium heparin)	88	y = 1.001x + 0.2	1.0	5-686
Plasma (potassium EDTA)	87	y = 1.002x - 0.0	1.0	5-676
Urine	51	y = 0.989x - 0.3	1.0	4-664
CSF	113	y = 1.005x - 0.1	1.0	20-654

09/006/GLUH

CONCLUSION

The results of this evaluation indicate that this assay is applicable to the determination of glucose in different biological fluids. This assay kit exhibits good correlation with existing commercial assay systems for all the analysed matrices. Furthermore, it incorporates liquid stable reagents, which simplifies the experimental procedure and reduces handling errors.



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