Liquid Glucose (Hexokinase) Reagent Set

Intended Use
For the *in vitro* quantitative measurement of glucose in serum using the Mindray BS-480 analyzer.

Test Summary
The measurement of glucose concentrations in biological fluids has been well documented. Glucose testing can be diagnostically significant in diabetes, hypoglycemia, and various adrenal and pituitary disorders.

Enzymatic methods for the measurement of glucose were first described by Keilin and Hartree.[1] The U.S. Food and Drug Administration has proposed as the reference method for glucose a totally enzymatic procedure using hexokinase and glucose-6-phosphate dehydrogenase.[2] Passey, et.al.[3] have critically reviewed ten glucose methods and have used the hexokinase procedure as the reference method.

Principle
$$\text{Glucose} + \text{ATP} \xrightarrow[Mg^{2+}]{HK} G_6P + \text{ADP}$$

$$G_6P + NAD^+ \xrightarrow{G_6PDH} \text{6-Phosphogluconate} + \text{NADH} + H^+$$

Glucose is phosphorylated by hexokinase (HK) in the presence of adenosine triphosphate (ATP) and magnesium to form glucose-6-phosphate (G-6-P) and adenosine diphosphate (ADP). G-6-P is then oxidized by glucose-6-phosphate dehydrogenase (G-6-PDH) in the presence of nicotinamide adenine dinucleotide (NAD) producing 6-phosphogluconate and NADH.
The formation of NADH causes increase in absorbance at 340 nm which is directly proportional the concentration of glucose in the sample.

Reagents
Glucose Reagent: A buffered solution containing 2 mmol/L nicotinamide adenine dinucleotide, 4 mmol/L adenosine triphosphate, 2 mmol/L magnesium, > 2000 U/L hexokinase (yeast), > 4000 U/L glucose-6-phosphate dehydrogenase (microbial), stabilizers, and preservatives.

Warnings and Precautions for Use
S24/25: Avoid contact with skin and eyes.
Hazard Classifications: Not a hazardous substance or mixture.
Pictogram and Signal Word: Not required.
Hazard Statements: Not a hazardous substance or mixture.
Precautionary Statements: Not a hazardous substance or mixture. **Refer to the Safety Data Sheet for this product (SDS-GLU600) available at www.medtestdx.com.**

Reagent Preparation, Storage and Stability
Reagents are ready for use.
Supplied reagent is stable at 2-8°C until expiry date. Stability claims are based on real time studies. Manufacturer studies have shown reagent is stable for 30 days once placed in the refrigerated reagent carousel (2-10°C), however reagent stability may vary based on individual laboratory conditions.

Reagent Deterioration
The reagent solution should be clear. Turbidity would indicate deterioration.

Disposal
Reagents must be disposed of in accordance with all Federal, State, and local regulations.

Specimen Collection and Storage
1. Fresh, clear, unhemolyzed serum. Serum should be separated from cells as soon as possible to minimize glucose decomposition by glycolysis.
2. In properly handled samples, glucose concentrations are stable for up to 3 days at 4°C.

Analytical Specificity (CLSI EP7)[5]
Cross contamination studies have not been performed on automated instruments. Certain reagent/ instrument combinations used in sequence with this assay may interfere with reagent performance and test results. The existence of, or effects of, any potential cross contamination issues are unknown.
Interferences from icterus, lipemia, and hemolysis were evaluated for this method on a Mindray BS-480 analyzer.

Concentration of Analyte		Substance Tested	Concentration of interferent where interference is insignificant	
Conventional Units	SI Units			
262 mg/dL	14.5 mmol/L	Hemoglobin	240.9 mg/dL	37 µmol/L
258 mg/dL	14.3 mmol/L	Bilirubin	20 mg/dL	342 µmol/L
259 mg/dL	14.4 mmol/L	Intralipid	100 mg/dL	300 mg/dL (3.4 mmol/L) Simulated triglycerides

When assaying turbid or lipemic samples, it is recommended that a serum blank correction be performed. The blank can be prepared using 25 µL of sample and 2.5mL of deionized water. The absorbance of this solution is determined at 340 nm and subtracted from the absorbance of that sample with reagent.

A summary of the influence of drugs on clinical laboratory tests may be found by consulting Young, D.S.[6]
The information presented above is based on results from the manufacturer's studies and is current at the date of publication.

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Materials Provided
Glucose (Hexokinase) Reagent.

Materials Required but not Provided
1. Mindray BS-480 Analyzer
2. BS-480 Operation manual
3. Chemistry Calibrator, catalog number CHEC480
4. Chemistry Control, catalog number CHEQ480

Test Conditions
For the data presented in this insert, studies using this reagent were performed on an automated analyzer using the parameters listed below.

Limitations
A sample with a glucose concentration exceeding the linearity limit should be diluted with 0.9% saline and reassayed incorporating the dilution factor in the calculation of the value.

Calibration
Calibration material should be used to calibrate the procedure. The frequency of calibration using an automated system is dependent on the system and the parameters used. If control results are found to be out of range, the test may need to be re-calibrated. Under typical operating conditions manufacturer calibration stability studies have shown the calibration curve will be stable for at least 14 days.

Quality Control
A normal and abnormal concentration control should be analyzed as required in accordance with local, state and federal guidelines. The results should fall within the acceptable range as established by the laboratory.

Reference Intervals[4]
70-105 mg/dL (3.9-5.8 mmol/L)
These values are suggested guidelines. It is recommended that each laboratory establish the normal range for the area in which it is located.

Performance Characteristics
Data presented was collected on a Mindray BS-480 analyzer unless otherwise stated.
1. Assay Range: 0.6-- 600 mg/dl (0.03 to 33.3 mmol/L).
2. Comparison: A study was performed between the Mindray BS-480 and a similar analyzer using this method[5], resulting in the following:

Method	Glucose
N	115
Mean Glucose (mg/dL)	164.8
Range (mg/dL)	25-572
Standard Deviation	108.0
Regression Analysis	y = 0.943x -1.5
Correlation Coefficient	0.9870

3. Precision studies were performed using the Mindray BS-480 analyzer following a modification of the guidelines which are contained in CLSI document EP5-T2.[5]

Within Day

Sample	LOW	MID	HIGH
N	20	20	20
Mean	81.5	271.6	526.4
Standard Deviation	0.7	0.9	2.0
Coefficient of Variation (%)	0.8%	0.3%	0.4%

Total

Sample	LOW	MID	HIGH
N	40	40	40
Mean	83.7	277.9	544.8
Standard Deviation	2.9	6.4	12.1
Coefficient of Variation (%)	3.5%	2.3%	2.2%

4. Sensitivity: 2SD Limit of Detection (95% Conf) = 0.1 mg/dL

References

1. Keilin, D. Hartree, E.F., Biochem. J. 42, 250 (1948).
2. United States Department of Health, Education and Welfare, Food and Administration. *In Vitro Diagnostic Products for Human Use, Proposed Establishment of Glucose*, Fed. Regist. 39, No. 126, 24136-24147 (1974).
3. Passey, R.B., Gillum, R.L., Fuller, J.B., Urry, F.M., Giles, M.L., *Evaluation and Comparison of Ten Glucose Methods and the Reference Method Recommended inthe Proposed Product Class Standard* (1974), Clin. Chem. 23, 131-139 (1977).
4. Burtis, C.A., Ashwood, E.R., Editors, *Tietz Textbook of Clinical Chemistry,Second Edition*, W.B. Saunders Company, Philadelphia, PA (1994).
5. *CLSI Method Evaluation Protocols*, Clinical and Laboratory Standards Institute, Wayne, PA.
6. Young, D.S., *Effects of Drugs on Clinical Laboratory Tests*, 3rd ed., AACC Press, Washington (1990).

MEDTEST DX
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CHEMISTRY PARAMETERS

Chem:	GLU	No.:	216	Sample Type:	Serum
Chemistry:	Glucose			Print Name:	GLU
Reaction Type:	End Point			Reaction Direction:	Positive
Pri Wave:	340			Sec Wave:	412
Unit:	mg/dL			Decimal	0
Blank Time:	10 12			Reaction Time:	34 36

	Sample Vol.	Aspirated	Diluent	Reagent Vol.	Diluent
Standard:	1.5 ul	--- ul	--- ul	R1: 150 ul	--- ul
Decreased:	--- ul	--- ul	--- ul	R2: --- ul	-- ul
Increased:	--- ul	--- ul	--- ul	R3: --- ul	-- ul
	☐ Sample Blank	☑ Auto Rerun		R4: --- ul	--- ul

Slope/Offset Adjustment

Slope: 1 Offset: 0

Linearity Range (Standard)	0.6	600	Linearity Limit:	
Linearity Range (Decreased)	____	____	Substrate Depletion:	
Linearity Range (Increased)	____	____	Mixed Blank Abs:	
R1 Blank Abs:	____	____	Uncapping Time	
Blank Response:	____	____	Reagent Alarm Limit:	
Twin Chemistry:			☐ Enzyme Linear Extension	

☐ Prozone Check ○ Rate Check ○ Antigen Addition

Q1: Q2: Q3: Q4:

PC: ABS:

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CALIBRATION PARAMETERS

Calibrator Definition

Calibrator:	*	Lot No.:	*
Exp Date:	*		

Carousel	**Pos**
Sample Carousel 1	*
Sample Carousel 2	
Sample Carousel 3	

Reagent/Calibration

Calibrator	Pos	Lot No	Exp Date	Chem	Conc	Unit
Water	W	*	*	GLU	0	mg/dL
Chemistry Calibrator	*	*	*	GLU	*	mg/dL

Calibration Setup

Chem: GLU

Calibration Settings

Math Model:	Two-Point Linear		
Factor:		Replicates:	2

Acceptance Limits

Cal Time:	*	Hour	
Slope Diff:	---	SD:	---
Sensitivity :	---	Repeatability:	---
Deter Coeff:	---		

Auto Calib.

☐ Bottle Changed ☐ Lot Changed ☐ Cal Time

It is recommended that two levels of control material be assayed daily.
* Indicates user defined parameter.

REF GLU480

Manufactured for MedTest DX
5449 Research Drive Canton, MI 48188

2°C 8°C

IVD

Symbol Key

Use by (YYYY-MM-DD)	LOT Lot and batch code	REF Catalog number	Manufacturer
Temperature limitation	Consult instructions for use	IVD *In vitro* diagnostic medical device	