Glucose Assay Kit (GLU)

Method: Hexokinase

Cat .No.	size	Instrument
GS9121T	R1:3×60 ml R2:3×15 ml	For Hitachi917 & OlympusAU640/400/600
GB9120T	R1:3×60 ml R2:3×15 ml	For Hitachi 717 & ShimadzuCL7200/8000
GX9121T	R1:3×60 ml R2:3×15 ml	For SYNCHRON CX4-5-7-9/LX20/DXC600-800
GT9121T	R1:3×40 ml R2:3×10 ml	For TOSHIBA
GH9121T	R1:3×40 ml R2:3×10 ml	For Hitachi902
GD9121T	R1:24×3.8 ml R2:6×3.8 ml	For DATE DEMENSION

INTENDED USE
For the in vitro quantitative determination of glucose in serum.

CLINICAL SIGNIFICANCE
Determination of glucose concentration is important in the diagnosis and treatment disorders of carbohydrate metabolism. Increased levels of glucose are found in diabetes mellitus, hyperparathyroidism, pancreatitis, renal failure. Decreased levels are found in insulinoma, hypothyroidism, hypopituitarism and extensive liver disease.

ASSAY PRINCIPLES
According to the equation, the formation rate of NADPH is directly proportion to the glucose concentration.. NADPH has a absorption peak in wavelengh 340nm, the increase rate of absorbance is directly proportion to the GLU concentration of the sample.

$$GLU + ATP \longrightarrow G6P + ADP$$

$$G6P + NADP \xrightarrow{G6PD} 6PG + NADPH + H^+$$

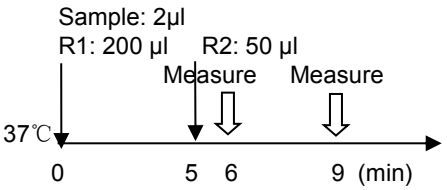
REAGENT COMPOSITION

Contents	Concentration of Solutions
Reagent 1 (R1)	
Tris Buffer	50 mmol/L
ATP	2mmol/L
Reagent 2 (R2)	
Tris Buffer	50 mmol/L
NADP	5 mmol/L
HK	≥8KU/L
G6PD	14KU/L

SAMPLE COLLECTION AND PREPARATION
Fresh serum or EDTA, heparin plasma.

STABILITY AND PREPARATION OF REAGENTS
All reagents are ready to use.
Stable up to the expiry date when stored at 2-8℃.
The reagent is stable for 28 days on-board the analyzer after opening and kept at 2-8℃.

ASSAY PROCEDURE
Test Procedure for Analyzers (HITACHI 917)
Assay Mode: Rate A 16-34
Wave Length (main/sub): 340 nm/405 nm



1. Mix 2 μl sample with 200 μl R1 and incubate at 37℃ for 5 minutes.
2. Add 50 μl R2 into cuvette, mix and incubate at 37℃ for 1 minute.
3. Read initial absorbance and start timer simultaneously, read again after 1, 2 and 3 minutes.
4. Calculate absorbance change per minute (ΔA/min).

CALIBRATION
Recommend that this assay should be calibrated using Randox Calibration Serum Level 3 or Level 2.

CALCULATION OF RESULTS
Calculation using calibration

$$\text{Concentration} = \frac{\Delta A_{sample}/min}{\Delta A_{calibrator}/min} \times \text{calibrator value}$$

QUALITY CONTROL
Randox Assayed Multisera, Level 2 and Level 3 are recommended for daily quality control. Two levels of controls should be assayed at least once a day. Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error, the following steps should be taken:
1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

NORMAL VALUE
Serum : 3.9-6. 1 mmol/L.
It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY
In 0.2 - 44 mmol/L range, the linear correlation coefficient $r^2 \geq 0.990$, in 0.2 - 2 mmol/L range, the measurement deviation should be no more than ±0.2mmol/L. In 2 - 44 mmol/L range, the measurement deviation should be no more than ±10%.

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PRECISION

The CV of the test should be less than 5%

Intar assay precision		
N=20	level 1	level 2
Mean(mmol/L)	5.97	15.62
SD	0.06	0.13
CV(%)	0.96	0.84

Inter assay precision			
N=5	Batch 1	Batch 2	Batch 3
Mean(mmol/L)	5.98	5.88	5.91
$\bar{x}$	5.925555556		
(Xmax-Xmin)/$\bar{x}$	(5.98-5.88)/5.93*100=1.63%		

INTERFERENCE

The following analytes were tested up to the levels indicated and found not to interfere:

Hemoglobin: up to 1000 mg/dl
Bilirubin: up to 40 mg/dl
Ascorbic Acid: up to100mg/dl
Intralipid: up to 1000mg/dl

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.
2. Reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide from building up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
5. Reagents with different lot numbers should not be interchanged or mixed.

REFERENCES

1. Yanan Zhang Clinical Significance of Serum Glucose Determination, Modern Chinese medicine application 2012 6（9）43-45
2. Shenyuan Yan, Guangran Yang Hypoglycemia Foreign Medical Archies of Endocrinology 2005 1（25）70-72
3. Xiuming Zhang, jianzhai Li, Ming Wei etc. Mordern Clinical Biochemical[M].Beijing People's Military Medical Press，2011：84-85.

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention:See instruction for use
EC REP	Authorized Representative in the European Company

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