Automation for OLYMPUS™
GLUCOSIO - GLUCOSE UV

REF	Σ IVD	REAGENTS
101294290O	Content : 2x90 ml	R1:2x60 ml R2:2x30 ml

Test Automation :
OLYMPUS AU400/640/600 …….. 2.533
OLYMPUS AU480/640,AU2700/5400 …….. 3.000

1.0 SUMMARY

Glucose is the primary energy source for the human body. It is derived from the breakdown of carbohydrates in the diet and in body stores, as well as by endogenous synthesis from protein or the glycerol moiety of triglycerides. When energy intake exceeds expenditure, the excess is converted to fat and glycogen for storage in adipose tissue and liver or muscle, respectively. When energy expenditure exceeds calorie intake, endogenous glucose formation occurs from the breakdown of carbohydrate stores and from noncarbohydrate sources. The glucose level in the blood is maintained within a fairly narrow range under diverse conditions by regulatory hormones such as insulin, glucagon, or epinephrine. Measurement of glucose is one of the most commonly performed procedures in most hospital chemistry laboratories. The most frequently encountered disorder of carbohydrate metabolism is high blood glucose due to diabetes. The incidence of hypoglycaemia (low blood glucose) is unknown but is much lower. Diabetes mellitus is a group of metabolic disorders of carbohydrate metabolism in which glucose is underutilized, producing hyperglycemia. Some patients may develop acute life-threatening hyperglycemic episodes, such as ketoacidosis or hyperosmolar coma. As the disease progresses, patients are at increased risk of developing specific complications, including retinopathy leading to blindness, renal failure, neuropathy and atherosclerosis. The last may result in stroke, gangrene, or coronary disease. The diagnosis of diabetes mellitus depends solely on the demonstration of hyperglycemia. For type I diabetes, the diagnosis is usually easy because hyperglycemia appears abruptly, is severe, and is accompanied by serious metabolic derangements. It is in type II diabetes that diagnosis is difficult because glucose abnormalities may be mild, but the development of complications makes it important to identify people with the disease. Hypoglycemia is a blood glucose concentration below the fasting range, but it is difficult to define specific limits. A transient decline may occur 11/2 to 2 h after a meal, and it is not uncommon for a plasma glucose concentration as low as 50 mg/dl to be observed 2 h after ingestion of an oral glucose load. Even in the fasting state, extremely low blood glucose values may occasionally be noted without symptoms or evidence of underlying disease. No symptoms are specific for hypoglycemia. A rapid decrease in plasma glucose to hypoglycemic levels usually triggers a sympathetic response, with the release of epinephrine, which produces the classical signs and symptoms of hypoglycemia: weakness, shakiness, sweating, nausea, rapid pulse, lightheadedness, hunger, and epigastric discomfort. The brain is totally dependent on blood glucose, and very low levels of plasma glucose (less than 20 or 30 mg/dl) cause severe central nervous system (CNS) dysfunction. glucose levels. In the past, analyses were often performed with relatively nonspecific methods that resulted in falselyelevated values. Almost all commonly used techniques are now enzymatic (e.g., hexokinase or glucose oxidase), and older methods, such as colorimetric or oxidation-reduction techniques, are rarely used.

2.0 PRINCIPLE

The enzyme glucose oxidase catalyzes the oxidation of glucose to gluconic acid and H2O2. The H2O2 reacts with phenol and 4-aminoantipyrine in the presence of peroxidase to form a quinoneimine dye. The intensity of color formed is proportional to the glucose oncentration and can be measured photometrically between 480 and 520 nm.

3.0 SPECIMEN

Serum, plasma, urine, CSF (cerebrospinal fluid).
Separated and nonhemolyzed samples are stable 8 hours at 25℃ and 3 days at 2-8℃. Variable stability is observed with longe r storage periods. Glycolysis decreases serum glucose by approximately 5 to 7% in 1 h (5 to 10 mg/dl) in normal uncentrifuged coagulated blood at room temperature. The rate of in vitro glycolysis is higher in the presence of leukocytosis or bacterial contamination. Plasma, removed from the cells after moderate centrifugation, contains leukocytes that also metabolize glucose, although cell-free sterile plasma has no glycolytic activity. Glycolysis can be inhibited and glucose stabilized for as long as 3 d at room temperature by adding sodium iodoacetate or sodium fl uoride (NaF) to the specimen. Although fl uoride maintains long-term blood glucose stability, the rate of decline in the fi rst hour after sample collection is not altered. Cerebrospinal fl uid (CSF) may be contaminated with bacteria or other cells and should be analyzed for glucose immediately. If a delay in measurement is unavoidable, the sample should be centrifuged and stored at 4℃ or -20 ℃. In 24-h co llections of urine, glucose may be preserved by adding 5 ml of glacial acetic acid to the container before starting the collection. The fi nal pH of the urine is usually between 4 and 5, which inhibits bacterial activity. Urine samples may lose as much as 40% of their glucose after 24 h at room temperature.

4.0 REFERENCE VALUES

Plasma/serum (fasting patient)
Adults..... 70 - 105 mg/dl
Children..... 70 - 105 mg/dl
premature neonates..... 25 - 80 mg/dl
term neonates.....30 - 90 mg/dl
CSF..... 40 – 75 mg/dl
(60% of plasma value)
Urine (fasting patient)
random urine .....< 30 mg/dl
24h urine.....< 500 mg/24h
Each laboratory should establish appropriate reference intervals related to its population.

5.0 REAGENTS

For in vitro diagnostic use only.The components of the kit are stable until expiration date on the label.Keep away from direct light sources.
Reagent 1 : 2 x 60 ml (liquid)
Reagent 1 : 2 x 30 ml (liquid)

R1 Liquido pronto all'uso	TRIS pH 7.80 80 mM, MgCl2 5mM, ATP 2mM, NAD 2 mM,
R2 Liquido pronto all'uso	hexokinase > 2 kU/l, glucose-6-phosphate dehydrogenase > 2 kU/l.

Store all components at 2-8℃.

6.0 PREPARATION AND STABILITY OF REAGENTS

Reagents are ready to use and must be installed on your Olympus analyzer as they are Stability: up to expiration date on labels at 2-8℃.
Stability since first opening of vials: ≥60 days at 2-8℃.
ON BOARD stability : regants installed on analyzer are stable up to 30 days.

7.0 MATERIALS REQUIRED BUT NOT PROVIDED

Current laboratory instrumentation. Spectrophotometer UV/VIS with thermostatic cuvette holder. Automatic micropipettes. Glass or high quality polystyrene cuvettes. Saline solution.

8.0 PRECAUTIONS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

9.0 PROCEDURE MANUAL

Wavelenght: 510 (500-520) nm
Temperature: 37℃
Reading: against reagent
Reaction: end point

	BLANK	STANDARD	SAMPLE
Reagent	2000 uL	2000 uL	2000 uL
Dist.water	20 uL	-	-
Standard	-	20 uL	-
Sample	-	-	20 uL

Mix, incubate at 37℃ for 5 minutes. Read absorbanc es of standard (As) and samples (Ax) against reagent blank.

9.1 PROCEDURE AUTOMATION OLYMPUS™ SYSTEMS

For automation procedure on Olympus systems, read operator manual and Olympus applications. All applications not expressly approved by MeDia diagnostici cannot be guaranteed regarding performances and must be defined by operator.

Protocollo applicativo AU 400/600/640

REAGENT ID.....		021	
TEST NAME		GLU	
Specific test parameter , GENERAL			
Sample volume		2 ul	
Dilution		0 ul	
Reagents	R1.....	50ul	
Dilution		150ul	
	R2.....	25 ul	
Diluition		25 ul	
Wavelenght.....		Pri.340	sec.380
Method.....		END	
Reaction slope.....		+	
Measuring point 1		First 0	Last 27
Measuring point 2		First 0	Last 10
Linearity		%	
No.Lag Time			
Min OD L			
Max OD H			
Reagent OD Limit		First L -0.1	First H 0.5
		Last L -0.1	Last H 0.5
Dynamic range		L 0.6 **	H 45.0**
Correlation factor.....		A1	B 0
On board stability period		30	
Unit		Mmol/L	

Calibration

TEST NAME [GLU] [<] [>] TYPE [SERUM]

Cal.type [AB] ∇ Formula [Y=AX+B] ∇ counts [#] Proc. [CONC]

	Cal.No.	OD	CONC.	FACTOR/OD-L	FACTOR/OD-H
POINT 1	#		†	21 **	35 **
POINT 2					
POINT 3					
POINT 4					
POINT 5					
POINT 6					
POINT 7					

1 point cal point [ ] □ with conc–0 slope check [N] ∇ ad.cal. [#]

MB Type Factor: [ ] Calibration Stability Period: [Ω]

MeDia Diagnostici

If You need to be sure !

Range

TEST NAME	GLU	<	>	TYPE	SE
Value/flag	#	∇	Level L	#	H #

Normal range

		Age L sex		Age L year	Age L month	Age H year	Age H month	L	H
□	1	#	∇	#	#	#	#	#	#
□	2	#	∇	#	#	#	#	#	#
□	3	#	∇	#	#	#	#	#	#
□	4	#	∇	#	#	#	#	#	#
□	5	#	∇	#	#	#	#	#	#
□	6	#	∇	#	#	#	#	#	#
	7	None selected						#	#
	8	Out of range						#	#
								L	H
Panic Value								#	#

\# Valore definito dall'utente

† Calibratore 101031103 BIOCAL HUMAN

** Valore per unità mmol/L . Per mg/dL moltiplicare per 18

Ω Dipende dall'uso del laboratrorio.

10.0 QUALITY CONTROL AND CALIBRATION

It is suggested to perform an internal quality control. For this purpose the following human based control sera are available :
101265 PRECISE NORMAL with normal or close to normal control values.
101267 PRECISE PATH with pathological control values.
If required, a multiparametric, human based calibratori s available : 101031 BIOCAL HUMAN

11.0 CALCULATION OF RESULTS

Serum/plasma/random urine sample:
glucose mg/dl = Ax/As x 100 (standard value)
24 hours urine sample (glucose mg/24h):
glucose mg/24h = Ax/As x 100 x diuresis (dl) (standard value and diuresis in dl)

12.0 TEST PERFORMANCES

12.1 Linearity. Reaction is linear up to 500 mg/dL
12.2 Sensitivity/limit of detection (LOD). The limit of detection is 2 mg/dl.
12.3 Interferences
no interference was observed by the presence of:
hemoglobin 00 mg/dl
bilirubin 15 mg/dl
lipids 00 mg/dl
12.4 Precision :

intra-assay (n=10)	Mean (U/L)	SD (U/L)	CV%
Sample 1	98.78	0.88	0.90
Sample 2	246.28	1.29	0.50
Inter-assay (n=10)	Mean (U/L)	SD (U/L)	CV%
Sample 1	98.80	1.34	1.40
Sample 2	250.91	3.55	1.40

12.5 Methods comparison
a comparison between MEDIA and a commercially available product gave the following results:
GLUCOSE MEDIA = x
GLUCOSE competitor = y
n = 100
y=0.978 x +2.24 mg/dL r=0.99

13.0 WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for a correct waste disposal.
S56:dispose of this material and its container at hazardous or special waste collection point.
S57:use appropriate container to avoid environmental contamination.
S61:avoid release in environment. Refer to special instructions/safety data sheet.

14.0 REFERENCES

Trinder P., - J. Clin. Path. 22, 158 (1969);
Tietz Textbook of Clinical Chemistry, Second Edition, Burtis-Ashwood (1994).

SYMBOLS – 98/79/EC DIRECTIVE

SCADENZA/EXPIRY

LOTTO / LOT

CAT N.

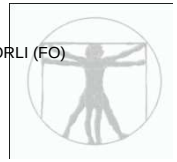
CE MARK

DIAGN. IN VITRO

TEMPERATURE

TAGLIO/SIZE

MANUFACTURER
MEDIA diagnostici SRL
Via Costiera 31 D/E– 47100 FORLI (FO)
TEL 0543 782.786
FAX 0543 782.787
Email: info@mediagnostic.biz
WEB: www.mediagnostics.biz



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