Glucose Kit

CliniQuant – FSR

Trinder' s Method, End Point

Meril Diagnostics

IVD For *in vitro* diagnostic use
Read this pack insert thoroughly before use

REF	Pack Size	R1 Glucose Reagent	R2 Glucose Standard
GLUFSR-01	4 x 50ml	4 x 50ml	1 x 5ml
GLUFSR-02	5 x 100ml	5 x 100ml	1 x 5ml
GLUFSR-03	4 x 250ml	4 x 250ml	2 x 5ml
GLUFSR-04	4 x 500ml	4 x 500ml	2 x 5ml

INTENDED USE

This reagent is intended for quantitative determination of glucose concentration in human serum or plasma.

CLINICAL SIGNIFICANCE

Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, hypoglycaemia and various other conditions.

PRINCIPLE OF THE METHOD

Glucose in the sample is oxidised to yield gluconic acid and hydrogen peroxide in the presence of Glucose oxidase. The enzyme peroxidase catalyses the oxidative coupling of 4-aminoantipyrine with phenol to yield a coloured quinonemine complex, with absorbance proportional to the concentration of glucose in sample.

$$\text{Glucose} + O_2 + H_2O \xrightarrow{\text{Glucose Oxidase}} \text{Gluconic acid} + H_2O_2$$

$$H_2O_2 + \text{phenol} + 4\text{AAP} \xrightarrow{\text{Peroxidase}} \text{Quinonemine dye} + 2H_2O$$

KIT COMPONENTS

Composition

R1 - Glucose Reagent: Dipotassium hydrogen phosphate 21.7 g/l , Potassium dihydrogen phosphate 10.2 g/l ,4-AAP 0.081 g/l , Phenol 0.282 g/l , Peroxidase 0.8ku/l ,Glucose oxidase 15 ku/l, Sodium glutamate 15 g/l, p-Chloro meta cresol 0.01 % ,Sodium Azide 0.025 %

R2 - Glucose Standard : 100 mg/dl, Benzoic acid 0.2 %, Dextrose 1 g/l

MATERIALS REQUIRED BUT NOT PROVIDED

Laboratory instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi automated, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/ rack, heating bath, controls, saline.

REAGENT PREPARATION, STORAGE & STABILITY

Reagent is ready to use. Keep away from direct light sources.

Stability: up to expiration date on labels at 2-8 °C.

Stability since first opening of bottle: preferable within 60 days at 2-8 °C.

REAGENT DETERIORATION

1. Discard the reagent if absorbance exceeds 0.3 against distilled water.
2. Keep the Standard vial plugged after use, in order to avoid deterioration.

WARNINGS AND PRECAUTIONS

1. Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully, avoiding contact with skin and ingestion.
2. Specimens should be considered infectious and handled appropriately.
3. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

SPECIMEN

Use fresh unhaemolysed serum. The stability of glucose in specimen is reduced by bacterial contamination and by glycolysis. Serum or plasma should be separated from the cells, as soon as possible, to prevent glycolysis. The addition of sodium fluoride is recommended to inhibit glycolysis. Serum / plasma is stable for 3 days at 2-8 °C. It is recommended to perform the assay with freshly collected samples, as glycolysis decreases serum glucose by approximately 5 to 10 mg/dl in 1 hr in normal uncentrifuged coagulated blood at room temperature.

Programme Parameter for MERILYZER CliniQuant

Assay protocol1: Normal	
Reading Mode	End Point
Standard Conc.	100 (mg/dl)
Filter – 1 (nm)	505
Filter – 2 (nm)	620
Temperature	37 °C
Volume (µl)	500
Delay Time (Sec)	5
Reaction Direction	Increase
Reference Low	70
Reference High	110
Linearity Limit	500

Assay protocol2: High linearity	
Reading Mode	Fixed Time
Standard Conc.	100 (mg/dl)
Filter – 1 (nm)	505
Temperature	37 °C
Volume (µl)	500
Delay Time (Sec)	30
Read Time (Sec)	60
Reaction Direction	Increase
Reference Low	70
Reference High	110
Linearity Limit	800

CE
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TEST PROCEDURE

Assay Protocol1:

Dispense	Blank	Standard	Sample
Reagent 1	1ml	1ml	1ml
Distilled water	10 µl	-	-
Standard	-	10 µl	-
Sample	-	-	10 µl
Mix, incubate for 10 min at 37°C. Read absorbance of standard (As) and samples (Ax) against reagent blank.			

Assay Protocol2:

Dispense	Standard	Sample
Reagent 1	1000 µl	1000 µl
Standard	10 µl	-
Sample	-	10 µl
Mix, incubate 30 seconds at 37°C, then record absorbance as A1. After exactly 60 seconds, record again absorbance as A2.		

RESULT CALCULATION

Serum/plasma:

Glucose mg/dl = Ax/As x Concentration of Standard

or

Glucose mg/dl = A2-A1(sample)/A2-A1(standard) x concentration of Standard.

SI conversion factor: 1 mg/dl x 0.0555 = 1 mmol/l

EXPECTED VALUES

Glucose Fasting:	70 - 110 mg/dl	OR	3.8 – 6.1 mmol/l
Post Prandial:	90 - 140 mg/dl	OR	5.0 – 7.8 mmol/l

It is recommended that each laboratory verifies this range or derives reference interval for the population it serves.

QUALITY CONTROL AND CALIBRATION

It is recommended to perform internal quality control with assayed normal (BioNorm) and assayed abnormal (BioPath), to confirm the validity of the test and assure the accuracy of patient result.

Using the recommended Calibrator (BioCal) or the Standard included, calibrate the assay:

a. When using a new reagent or lot

b. When QC values are out of range

PERFORMANCE CHARACTERISTICS

1. Linearity

As per assay protocol1: The linearity is up to 500 mg/dl (27.5 mmol/l).

As per assay protocol2: The linearity is up to 800 mg/dl (44 mmol/l).

2. Sensitivity/ Limit of detection (LOD)

The limit of detection is 4 mg/dl (0.22 mmol/l).

The limit of quantification is 13 mg/dl (0.72 mmol/l).

3. Interferences

No interference has been observed for the following

Hemoglobin up to 750mg/dl; Bilirubin up to 20 mg/dl

Triglycerides up to 500 mg/dl

4. Precision

Intra-assay precision

	Mean	SD	CV
n = 20	mg/dl	mg/dl	%
sample 1	97.77	0.61	0.63
sample 2	261.55	1.32	0.50

Inter-assay precision

	Mean	SD	CV
n = 20	mg/dl	mg/dl	%
sample 1	92.41	4.47	4.84
sample 2	252.24	2.77	1.16

5. Methods Comparison

Comparison was done between reference Glucose Reagent and CliniQuant - FSR Glucose Reagent (test)

N = 23 $y = 0.961x + 13.74$

$r^2 = 0.987$

LIMITATIONS

Samples with values above 800 mg/dl should be diluted with 0.9% saline, re-run and multiply results by dilution factor.

WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for correct waste disposal.

REFERENCES

1. Thomas L.: Clinical Laboratory Diagnostics, 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998, p. 131 - 7.

2. Sacks, D.B.: Carbohydrates. In: Burtis, C.A., Ashwood, E.R., editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia, W.B. Saunders Company, 1999, p. 750 – 808.

3. Barham, D., Trinder, P.: An improved color reagent for the determination of blood glucose by the oxidase system. Analyst, 1972, 97; 142 - 5.

4. Data on file: Meril Diagnostics.

IFU/GLUFSR01/00

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Symbols used on Meril Diagnostics labels:

REF	Catalogue No.		Attention See Instruction for Use
LOT	Batch No.	IVD	*In vitro* Diagnostics
	Expiry Date		Consult Instruction for Use
	Manufacturer		Storage Temperature
	Keep Dry		Keep Away from Sunlight
	Manufacturing Date		Do not use if package is damaged

EC REP Authorized European Representative in the European Community