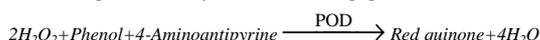
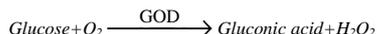


Reagent kit for the quantitative determination of glucose concentration in serum and liquor. Enzymatic colorimetric method (GOD/POD/PAP).

Determination of glucose concentration is important in the diagnosis and treatment of disorders of carbohydrate metabolism. Values higher or lower than the reference are of diagnostic significance. The levels are increased in diabetes mellitus, hyperthyroidism and in the hyperactivity of the pituitary gland. Decreased levels are observed in cases of overproduction of insulin by the pancreas, with tumors of the pancreas, as well as with hypofunction of the organs involved in glucose synthesis and carbohydrate metabolism.

Principle

Glucose oxidase (GOD) converts the sample Glucose into gluconate. The Hydrogenperoxide (H₂O₂) produced in the reaction is degraded by peroxidase (POD) and gives a colored product Phenol and 4-Aminoantipyrine which is measurable using Trinder indicator reaction at 505 nm. The increase in absorbance correlates with the glucose concentration of the sample.



Reference values

Serum: 3.89-5.84 mmol/l (70-105 mg/dl)

Cerebrospinal fluid: 2.78-3.89 mmol/l (50-70 mg/dl)

It is recommended that each laboratory should assign its own normal range.

Reagents

1. Reagent (R1)

Phosphatase buffer, pH:7.40	100 mmol/l
Phenol	10 mmol/l
4-Aminoantipyrine	0.3 mmol/l
Glucose oxidase	10000 U/l
Peroxidase	700 U/l

2. Glucose standard

Ready for use. For details please check the insert.

Available only in Cat. No.: 46861S and 46862S

Precautions

Discard cloudy reagent. Avoid contamination by using clean laboratory material (pipettes, plastic vials for analyzers, ...).

The reagent contains sodium azide (0.1 %). To avoid the possible build-up of azide compounds, flush waste-pipes with water after the disposal of undiluted reagent.

Sample

Serum free of haemolysis.

Cerebrospinal fluid.

PROCEDURE

Preparation and stability of working reagent

The reagent is ready for use.

If the absorbance of working reagent is higher than 0.1 at 492 nm the reagent can not be used.

Assay conditions

Wavelength:	505 (492-520) nm
Temperature:	37 °C
Cuvette:	1 cm light path
Method:	endpoint (increasing)
Read against:	reagent blank

Pipette into cuvette

	Blank	Standard	Sample
Working reagent	1 ml	1 ml	1 ml
Distilled water	10µl		
Standard		10µl	
Sample			10µl

Mix and measure the absorbance (A) after a five-minute incubation.

Calibration (37°C, GOD/PAP test)

S1: Distilled water

S2: Glucose standard Cat. No.: 50411 or

Roche C.F.A.S. (Calibrator for automated system)

Randox Calibration Serum Level I or

Randox Calibration Serum Level II

Calibration frequency

Two-point calibration is recommended:

- after reagent lot change,

- as required following quality control procedures.

Calculation

$$\frac{A_{\text{sample}}}{A_{\text{standard}}} \times C_{\text{standard}} = C_{\text{sample}}$$

A = Absorbance

C = Concentration

Quality control

A quality control program is recommended for all clinical laboratories. The analysis of control material in both the normal and abnormal ranges with each assay is recommended for monitoring the performance of the procedure. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

PERFORMANCES DATA

The following data were obtained using the Olympus 400 analyzer (37°C).

Linearity

The test is linear up to 40 mmol/l (720 mg/dl) glucose concentration.

Sensitivity

It is recommended that each laboratory establishes its own range of sensitivity as this is limited by the sensitivity of the spectrophotometer used. Under manual conditions however, a change of 0.001 Abs is equivalent to 0.019 mmol/l (0.34mg/dl) Glucose concentration at 492 nm.

Precision

Sample	Reproducibility		
	Average concentration (mmol/l)	SD	CV%
sample I	5.54	0.08	1.47
sample II	13.9	0.16	1.17

Sample	Repeatability		
	Average concentration (mmol/l)	SD	CV%
sample I	4.5	0.04	0.88
sample II	15.4	0.12	0.75

Correlation

Comparative studies were done to compare our reagent with another commercial Glucose PAP reagent. The results from these studies are detailed below.

Correlation coefficient: r = 0.9999

Linear regression: y (mmol/l) = 0.980x + 0.099

(x = other commercial reagent, y = own reagent).

Specificity

Bilirubin 855 µmol/l (50 mg/dl), lipid 1000 mg/dl and ascorbic acid 0.14 mmol/l (25 mg/dl) don't interfere with the assay up to the given levels.

Note

With this assay the determination of glucose concentration in urine is not acceptable, because ascorbic acid influences the measurement. The reference method of glucose determination is the hexokinase and the glucose-6-phosphate-dehydrogenase (HK/G-6-PDH) UV test (It is also suitable for the determination of glucose concentration in urine). Do not use reagents after the expiry date stated on each reagent container label. Do not use products, test solutions and reagents described above for any purpose other than described herein.

For in vitro diagnostic use only.

The following symbols are used on labels

 For in vitro diagnostic use

 Use by (last day of the month)

 Temperature limitation

 Batch Code

 Code

Bibliography

Trinder P.,: *Ann. Clin. Biochem.* 6,(1969),24.