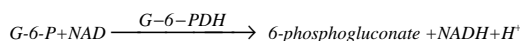
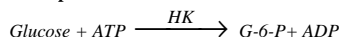


Reagent kit for the quantitative determination of glucose concentration in serum, liquor and urine.
Enzymatic test.

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



HK = Hexokinase

G-6-P = Glucose-6-phosphate

G-6-PDH = Glucose-6-phosphate dehydrogenase

Reference values

Serum: 3.61-6.11 mmol/l (65-110 mg/dl)

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

Urine: 0-1.1 mmol/l (0-20 mg/dl)

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

Reagents

1. Reagent (R1)

Pipes buffer, pH=7.60	80 mmol/l
NAD	3 mmol/l
ATP	1.7 mmol/l

2. Reagent (2)

Magnesium salt	4 mmol/l
Hexokinase	1700 U/l
G-6-PDH	1700 U/l

3. Glucose standard

Ready for use. For details please check the insert.

Available only in Cat. No.: 47361S and 47362S

Precaution

Discard cloudy reagent. Avoid contamination by using clean laboratory material (pipettes, plastic vials for analyzers, ...). These reagents contain 0.1 % sodium azide. 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, urine, cerebrospinal fluid.

PROCEDURE

Preparation and stability of working reagent

• One-reagent procedure

Mix 4 volumes of the reagent 1 (R1) with 1 volume of the reagent 2 (R2).

Stability: at 20-25°C: 2 weeks
at 2-8°C 1 month

• Two-reagent procedure

Reagents are ready to use.

If the absorbance of working reagent is higher than 0.5 at 334 nm the reagent can not be used.

Assay conditions

Wavelength:	340 (334-365) nm
Temperature:	37 °C
Cuvette:	1 cm light path
Method:	endpoint (increasing)
Read against:	reagent blank

• **One-reagent procedure**

	Blank	Standard	Sample
Dist. water	10 µl		
Standard		10 µl	
Sample			10 µl
Working reagent	1 ml	1 ml	1 ml

Mix and read the absorbance (A) after a 5-minute incubation.

• **Two-reagent procedure**

	Blank	Standard	Sample
Dist. water	10 µl		
Standard		10 µl	
Sample			10 µl
R1	800 µl	800 µl	800 µl

Mix and wait 1 minute and add:

R2	200 µl	200 µl	200 µl
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Mix and read the absorbance (A) after a 5-minute incubation.

Calibration (37°C, HK 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

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 600 analyzer (37°C).

Linearity

The test is linear up to 33.33 mmol/l (600 mg/dl).

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 0.016 mmol/l (0.29mg/dl) Glucose concentration at 334 nm.

Precision

	Reproducibility		
	Average concentration (mmol/l)	SD	CV%
Sample I.	5.8	0.090	1.56
Sample II.	14.2	0.214	1.51

	Repeatability		
	Average concentration (mmol/l)	SD	CV%
Sample I.	4.4	0.065	1.49
Sample II.	18.1	0.214	1.18

Correlation

Comparative studies were done to compare our reagent with another commercial Glucose assay, on 54 human samples.

The results from these studies are detailed below.

Correlation coefficient: r=0.9949

Linear regression: y (mmol/l) = 0.982x+0.271

(x=other reagent, y= glucose HK reagent).

Specificity


Bilirubin 855 µmol/l (50 mg/dl), lipid 1000 mg/dl and ascorbic acid 2.84 mmol/l (50 mg/dl) don't interfere with the assay at levels up to the given levels.

Note

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

1. Peterson, J.L., Young, D.S., Anal Biochem., 23, (1968); 301
2. Bondar, R.J.L., Mead, D.C. Clin. Chem., 20, (1974); 586
3. Young, D.S., Pestaner, L.C., Gibberman, V., Clin. Chem., 5, 10, (1975)