台塑生醫科技股份有限公司
FORMOSA BIOMEDICAL TECHNOLOGY CORP.

GLUCOSE-U.V.METHOD GLU

FOR BECKMAN CX AND LX SYSTEMS

INTENDED USE

For the quantitative determination of glucose in serum or plasma.

CLINICAL SIGNIFICANCE

The most common disease associated with abnormal carbohydrate metabolism is diabetes mellitus, with its accompanying high blood glucose levels. Other conditions which may also result in abnormal blood glucose levels include: disorders of the pituitary gland, hyperthyroidism, cushing's disease, traumatic injury, convulsive disorders, mental stress and phenochromocytoma. Acute and chronic infection, eclampsia , hypertension and severe liver disease may also exhibit transitory elevation of blood glucose level. On the other hand, hyperinsulinism from either exogenous insulin overdose or from lesions of the pancreas can result in low level of blood glucose.

PRINCIPLE

The reagent used here is based on the hexokinase (HK) – glucose-6-phosphate dehydrogenase (G-6-PDH) U.V. end point method. The reactions is as follows:

$$\text{Glucose} + \text{ATP} \xrightarrow{\text{HK}} \text{glucose-6-phosphate} + \text{ADP}$$

$$\text{Glucose-6-phosphate} + \text{NAD}^+ \xrightarrow{\text{G-6-PDH}} \text{6-phosphogluconate} + \text{NADH} + \text{H}^+$$

The increase in NADH concentration is directly proportional to the glucose concentration.

SPECIMEN COLLECTION AND PREPARA

Both serum and plasma samples can be used. For serum samples, collect whole blood and allow it to clot in clean test tube at room temperature. Separate and then transfer the serum without delay to a clean test tube. Do the test as soon as possible or store at 2~8℃ to avoid degradation.

For plasma specimens, collect whole blood into a tube containing a suitable anticoagulant, (EDTA, heparin, etc.), separate and transfer the plasma into a clear test tube.

To avoid degradation by glycolysis, fluoride (up to 10 mg/dl) may be added without affecting test results.

REAGENT

·Each kit contains 2 cartridges of glucose reagent (2 ×300 tests)

·Ready-to-use.

·Components:

ATP	3.8 mmol/l
NAD^+	2.7 mmol/l
Hexokinase	2.0 ku/l
G-6-P DH	3.0 ku/l

STORAGE: 2~8℃

PRECAUTIONS:

1. For in vitro diagnostic use only.
2. Since all specimens are potentially infectious, they should be handled with appropriate precautions and practices in accordance with Biosafety level 2 as recommended by USA NIH manual Biosafety in Microbiological and Biomedical Laboratories, and in accordance with National or local regulations related to the safety precautions of such materials.
3. Each laboratory has to perform the quality control test to assure the results being reliable before running the specimen tests

PROCEDURES: Use bar code reading to follow the Beckman CX-4 and LX-20 parameters and procedures.

NORMAL RANGES: 65~110 mg/dl (3.6~6.1 mmol/L)

REFERENCES:

1. Henry, J.B., “Clinical Diagnosis and Management by Laboratory Method.” W.B. Saunders and Company Philadelphia, PA, p. 153 (1979).
2. Barthelmai, W., and Czek, R., Klin. Wochenscht., 40:585 (1962).
3. Tietz, N.W., Fundamentals of Clinical Chemistry, 2nd. Ed., W.B. Saunders Co., Philadelphia, PA243 (1976).

GLUCOSE TEST GLU-HK

Hexokinase Method

INTENDED USE
For the quantitative determination of glucose activity in serum

CLINICAL SIGNIFICANCE
The most common disease associated with abnormal carbohydrate metabolism is diabetes mellitus, with its accompanying high blood glucose levels. Other conditions which may also result in abnormal blood glucose levels include: disorders of the pituitary gland, hyperthyroidism, Cushing's disease, traumatic injury, convulsive disorders, mental stress and pheochromocytoma. Acute and chronic infection, eclampsia, hypertension and severe liver disease may also exhibit transitory elevation of blood glucose level. In the other hand, hyperinsulinism from either exogenous insulin overdose or from lesions of the pancreas can result in low level of blood glucose.

PRINCIPLE
There are many methods for the determination of glucose. The reagent used here for glucose test is involved of hexokinase (HK) and glucose-6-phosphate dehydrogenase.(G-6-PD)

$$\beta\text{-D-glucose} + ATP \xrightarrow{\text{hexokinase}} \text{glucose-6-phosphate} + ADP$$

$$\text{Glucose-6-phosphate} + NAD^{+} \xrightarrow{\text{G-6-PD}} \text{6-phosphogluconate} + NADH + H^{+}$$

SPECIMEN COLLECTION AND PREPARATION
Glucose in blood samples is easily destroyed by cellular enzymes or by enzymes from bacteria contamination through glycolysis if the specimen are not suitable treated. Both serum and plasma samples can be used. For serum samples, collect whole blood and allow it to clot in clean glass test tube at room temperature. Separate and then transfer the serum without delay to a clean test tube. Do the test as soon as possible or store at 2~8℃ to avoid degradation.
For plasma specimens, collect whole blood into a tube containing a suitable anticoagulant, (EDTA, heparin, etc.), separate and transfer theplasma into a clean test tube.
To avoid degradation by glycolysis, a suitable amount of fluoride (up to 10 mg/dl) may be added without affecting test results.

REAGENT
1. Package: R1: 2×40 ml R2: 2×10 ml Common
   R1: 4×60 ml R2: 4×15 ml Hitachi 7170
   R1: 4×80 ml R2: 4×20 ml Hitachi 7060
   R1: 4×50 ml R2: 2×25 ml Hitachi 7020
2. Components: HK, G-6-PD, ATP, NADH and buffer

Glucose standard: 5.55 mmol/L (100 mg/dl) store all the above reagent at 2~8℃.

PRECAUTIONS:
For in vitro diagnostic use only.
Since all specimens are potentially infectious, they should be handled with appropriate precautions and practices in accordance with Biosafety level2 as recommended by USA NIH manual Biosafety in Microbiological and Biomedical Laboratories, and in accordance with National or local regulations related to the safety precautions of such materials.
Each laboratory has to perform the quality control test to assure the results being reliable before running the specimen tests.

PROCEDURE
Wavelength: 340 nm; Cuvette: 1 cm light path; Temperature: 37℃
Reagents are ready –to –use.

		Blank	Standard	Unknown
R1	ml	0.8	0.8	0.8
R1	ml	0.2	0.2	0.2
Water	ml	0.01	-	-
Standard	ml	-	0.01	-
Serum sample	ml	-	-	0.01
Incubate at 37℃ for 3 minutes, then measured the absorbance at 340 nm against blank..				

***** The Hitachi reagents are used directly on Hitachi analyzers in accordant with Hitachi parameters.

RESULT CALCULATION

$$\text{Glucose (mmol/L)} = \frac{\text{Abs. Of unknown}}{\text{Abs .of standard}} \times \text{standard concentration}$$

EXPECTED BALUES

3.6-6.1 mmol/L (65-110 mg/dl)

It is generally recommended that each laboratory establish its own rangs of normal values for commonly performed tests.

PERFORMANCE:

Linearity: 26 mmol/L of glucose

Sensitivity: A change in absorbance of 0.001 in the range of linearity corresponds to 0.018 mmol/L of glucose

Precision:

	Within run		Between run	
Samples	Level Ⅰ	Level Ⅱ	Level Ⅰ	Level Ⅱ
Number n	20	20	20	20
Mean mmol/L	5.6	15.6	4.6	14.7
SD mmol/L	0.118	0.237	0.130	0.361
CV %	2.11	1.52	2.82	2.45

*PROCEDURAL NOTE

specimens with glucose concentrations exceeding 400 mg/dl should be diluted with distilled water, or used only 5µl of serum and re-tested. Multiply results by an appropriate dilution factor.

REFERENCES:

1. Henry R.J. and R.L. Dryer, 1963. standard Methods of Clin. Chem., Vol.4, Academic Press, New York.
2. Trinders, p.1969 Ann Clin. Bio Chem. 6:24.
3. Raabo E, and T.C. Terkildsen, 1960. on the enzymatic determination of blood glucose. Scand. J. Clinical Lab. Invest. 12:402.
4. Young D.S. te.al. 1975. Clinical Chem. 21: 304 D.