Glucose (Glu)
(Enzymatic/GOD-POD Method)

- **Kit Specifications:**

	Reagent/Quantity	Storage
Cat. No.: **GL0011**	R.1: 6 x 50 ml total 3·0 ml	2-8°C
Cat. No.: **GL0017**	R.1: 5 x 60 ml total 300 ml	2-8°C

- **Intended Use:**

In Vitro Diagnostic reagent pack for the quantitative determination of Glucose in human serum/plasma and urine on automated and semi-automated photometric systems.

- **Summary and Explanation:**

The measurement of glucose is essential to treatment of carbohydrate metabolic disorder. The high glucose is found in diabetes, Hyper parathyroidism, pancreatitis and kidney failure. However, the low glucose is found in hyperthyroidism, insulinoma, hypopituitarism, and liver disease. The low level of the glucose may cause the brain injury which is non-reversible. The main applicable of the glucose measurement is to identify, control and treatment diabetes. The glucose measurement can identify hypoglycemia in child, pancreas cancer and evaluated other carbohydrate metabolism.

The glucose is a kind of carbohydrate which provide the human body energy. The level of the glucose in blood which regulated by two hormones insulin and glucagon. In addition, other hormones such as corticosteroids, epinephrine, thyroxine and ACTH are influenced in this metabolism. The age increasing is influenced in level of the glucose in serum and plasma which means each year after 60s a one milligram is going to increase the level of glucose. The other disease and damage such as infections, burning, Cushing syndrome, chronic kidney failure and acute pancreatitis rise the level of glucose. Meanwhile, hypothyroidism, Addison disease and pituitary deficiency decline the glucose level in blood.

Principle of the Method:

This method is based on free oxygen which release by metabolize glucose in the present of glucosidase. Also, the hydrogen peroxide with 4-aminoantipyrine plus phenol in catalyzed by peroxidase which make color complex termed quinoneimine. The intensity of the color will have measured on 505 Nano meter wavelength which is correlate with the amount of glucose in sample.

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

$$H_2O_2 + \text{4-Aminoantipyrine} + \text{Phenol} \xrightarrow{\text{POD}} \text{Quinoneimine} + H_2O$$

- **Reagent Preparation and Stability:**

Reagent is ready for use.
Before use, mix reagent by gently inverting each bottle.
Reagent is stable until the expiration date on the label when stored tightly closed at 2-8°C, protected from light and contaminations prevented during their use.
Do not use reagents over the expiration date.
Do not freeze and protect from light.
The reagent is transparent and light yellow.

Waste Management:

Refer to local legal requirements for chemical disposal regulations.
Warning: Handle waste as potentially biohazardous material.
Dispose of waste according to accepted laboratory instructions and procedures.

- **Warnings and Precautions:**

For In Vitro Diagnostics Use Only.
For Professional Use Only.
Carefully read instructions for use.
In case of serious damage to the bottle or cap, resulting in product leakage or contamination, do not use the reagent pack and contact your distributor.
Take all necessary precautions required when handling laboratory reagents.
Do not use components past the expiry date stated on the Bottles.
Do not interchange caps among components as contamination may occur and compromise test results. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.

- **Type of Specimen:**

Use fresh serum, non-hemolysis, plasma heparinized with EDTA.
The serum and plasma should have collected during 1 hour after blood collection.
To prevent any glycolysis. Glucose will be stable on the samples for 3 days in 2-8°C.
The stability of glucose in the sample depends on added NaF or KF and keep at 2-8°C for 7 days or at 25-20°C for 1 day. Avoid any contamination between samples.

Required but not Supplied:

General chemistry calibrator from TKS or other valid calibrators.
General chemistry control Level 1 & 2 from TKS or other valid controls.
Saline solution 0.9 % NaCl
General laboratory equipments

- **Notes:**

Carefully read instructions for use.
It is recommended to use disposable material. If glassware is used the material should be scrupulously cleaned with hydrochloric acid 1 N and then thoroughly rinsed it with distilled water.
Use clean disposable pipette tips for its dispensation.
Disposable and glassware material used must be free of metals, ions and detergents.

Performance Characteristics:

Performance results can vary with the instrument used.
Data obtained in each individual laboratory may differ from these values.

Maximum determination in this assay is 400mg/dl
LOQ: 1 mg/dl
For samples with a higher concentration (400mg/dl), dilute 1:1 with 0.9 % NaCl and re-assay. Multiply result by 2.
Precision:
Intra Assay-Within run Glucose

Sample	n	Mean (mg/dl)	SD (mg/dl)	CV (%)
1	20	98.5	0.58	0.59
2	20	264.6	1.27	0.48

Inter Assay-Between run Glucose

Sample	n	Mean (mg/dl)	SD (mg/dl)	CV (%)
1	20	40.0	1.06	2.65
2	20	126	2.07	1.65

- **Accuracy:**

Results obtained using BIOMEDIC reagents (y) did not show systematic differences when compared with other commercial reagents (x).
Correlation coefficient (r): 0.9949
Regression equation: Y = 1.104 (X) - 1.249 mg/dl
The results of the performance characteristics depend on the analyzer used.

- **Interfering Substances:**

Bilirubin (mixed isomer)	Less than 10% interference up to 600 µmol/L Bilirubin
Lipemia	Less than 10% interference up to 1.25 g/L Intralipid.
Haemolysis	Less than 10% interference up to 5g/L Haemoglobin.

- **Reference Values:**
- **Infants**

Cord Blood	**63-158 mg/dl**
1 hour	**36-99 mg/dl**
2 hours	**36-89 mg/dl**
5-14 hours	**34-77 mg/dl**
10-28 hours	**46-81 mg/dl**
44-52 hours	**48-79 mg/dl**

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Child (fasting)

1-6 years	**74-127 mg/dl**
7-19 years	**V0-106 mg/dl**

Adults

Venous Plasma	**70-115 mg/dl**

Each laboratory should establish its own expected values. The Calcium results should always be reviewed with the patient's medical examination and history.

- **Assay Procedure:**

Allow reagents to reach working temperature before using.
A proportional variation of the reaction volumes indicated does not change the result

Assay conditions:

505(500-550)	**Wavelengths**
37 °C	**Incubation Temperature**
1 cm	**Cuvette**

Adjust the instrument to zero with distilled water.

Control/Sample/Calibrator	**Blank**	
1000 µl	1000 µl	**R**
10 µl	-	**Control/Sample/Calibrator**
Gently mix and incubate for 10 minute at 37°C. or 30 minutes at 25°C then measure the absorbance from sample A and A calibrator. The absorbance of sample and calibrator against the blank. The stability of color is 30 minutes. Avoiding in direct light.		

- **Calculations:**

Glucose (mg/dl) = Abs. Sample x Cal.Conc. (mg/dl)
Abs. Cal

Conversion units:
Glucose (mg/dl) x 0.0555 = Glucose (mmol/L)

TOSE'E KIMIA SA'ADAT has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.

- **References:**

1-Bahram D, Trinder P. An improved color reagent for the determination of blood glucose by the oxidase system. Analyst 1972; 97:142-5.
2-Rajko Reljic et.al. 38/4 Clin.Chem. (1882)552.
3-Sugiura et.al. A new colorimetric method for det. of Serum Glucose, Clin.Chem. Acta 75 (1977)387-391.
4-Tietz NW, Clinical guide to Laboratory tests, 3rd Edit.
5-Thomas L. Clinical Laboratory Diagnostics.
1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998.p 131-7.
6-Greiling H, Gressner AM, eds. Lehrbuch der Klinischen Chemie und Patgobiochemie, 3rd ed. Stuttgart/New York: Schattauer Verlag; 1995.

Symbols:

The following symbols are used in the labelling of TOSE'E KIMIA SA'ADAT systems:

IVD	In Vitro Diagnostics	Σ	Contains sufficient for <n> tests
LOT	Batch Code		Temperature limit
REF	Catalogue No.		Consult instruction for use
	Expiry Date		Caution
	Date of Manufacture		Keep dry
	Manufactured by		This way up
	Biological Risks		Keep away from sunlight

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ISO 13485:2016
ISO 9001:2015

IVD

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