TECO DIAGNOSTICS
1268 N. Lakeview Ave.
Anaheim, CA 92807
1-800-222-9880

GLUCOSE OXIDASE REAGENT SET (PHENOL FREE) TC MATRIX-240/480

INTENDED USE
For the quantitative determination of total glucose in human serum on TC Matrix analyzers.

INTRODUCTION
Glucose is the major carbohydrate present in the peripheral blood. The oxidation of glucose is the major source of cellular energy in the body. Glucose determinations are run primarily to aid in the diagnosis and treatment of diabetes mellitus. Elevated levels glucose levels may be associated with pancreatitis, pituitary or thyroid dysfunction, renal failure and liver disease, whereas low glucose levels may be associated with insulinoma hypopituitaryism, neoplasms, or insulin-induced hypoglycemia.[1,2]

Early enzymatic methods for glucose determination involve glucose oxidase to catalyze the oxidation of glucose. Keston modified this method in the early 1950's using a glucose oxidase/peroxidase enzyme system and o-Dianisidine Chromogen system.[3] Since then various alternative chromogen systems have been proposed. The Trinder method replaces carcinogenic o-Dianisidine with phenol plus 4-aminoantipyrine.[4] This method is less influenced by interfering substances and does not suffer from the many drawbacks of earlier methods.

PRINCIPLE
The enzymatic reaction sequence employed in the assay of glucose is as follows:

$$\beta\text{-D-Glucose} + H_2O + O_2 \xrightarrow{\text{Glucose Oxidase}} H_2O_2 + \text{D-Gluconic Acid}$$

$$H_2O_2 + \text{4-Aminoantipyrine} + \text{p-HBS} \xrightarrow{\text{Peroxidase}} \text{Iminoquinone} + H_2O$$

β-D-Glucose is oxidized by glucose oxidase to produce D-gluconic acid and hydrogen peroxide. The hydrogen peroxide is then oxidatively coupled with 4-aminoantipyrine and phenol substitute, p-HBS, in the presence of peroxidase to yield a red quinoneimine dye. The amount of colored complex formed is proportional to glucose concentration and can be photometrically measured.

REAGENT PREPARATION
No preparation is required.

REAGENT COMPOSITION
Glucose Oxidase 15 µl/ml
Peroxidase (horseradish) 1.2 µl/ml
Mutarotase 4.0 µl/ml
4-Aminoantipyrine 0.38 mM
p-Hydroxybenzene sulfonate 10 mM

REAGENT STORAGE AND STABILITY
The reagent should be stored at 2 - 8°C. The reagent may be used until the expiration date indicated on the package label.

REAGENT DETERIORATION
The reagent should be discarded if:
1. Turbidity has occurred; turbidity may be a sign of contamination.
2. The reagent fails to meet linearity claims or fails to recover control values in the stated range.

SPECIMEN COLLECTION
1. Test specimens should be serum and free from hemolysis.
2. Plasma containing citrate, EDTA, heparin or oxalate as an anticoagulant may not be used.
3. Serum must be separated from the clot promptly since the rate of glucose decrease is approximately 7% per hour in whole blood.[5]
4. Glucose in serum or plasma is stable for twenty-four (24) hours when stored 2 - 8°C.[5]

INTERFERING SUBSTANCES
Grossly lipemic or icteric sera will cause false glucose values and require the use of a serum blank.[5] Add 0.02 ml (20 µl) of patient sera to 3.0 ml distilled water and read against a water blank. Subtract this absorbance from the patient test absorbance to correct for the lipemia or icterus. Young et al. give a comprehensive review of drug interferences.[6]

CALIBRATION
1. Calibrator required: TECO MULTI Calibrator.
2. The system must have a valid calibration in memory before controls or patient samples can be run.
3. The TC Matrix system will automatically perform checks on the calibration and produce data at the end of calibration.

Note: Refer to the TC Matrix manual for further instructions on calibrating the instrument

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT
TECO MULTI Calibrator
At least two levels of control material.

PROCEDURE
Settings for TC-Matrix 240/480

Test Name:	GLU-O	R1:	200
Full Name:	Glucose Oxidase	R2:	/
Pri. Wave:	505 nm	Sample volume:	2
Sec. Wave:	700 nm	Calibration Type:	2 point linear
Assay/ Point:	1 point end	K Value:	/
Start - End:	1 - 21	Point:	2
Decimal place:	1	Blank Type:	Reagent
Unit:	mg/dL	Point 0 (Blank) Con.:	0.0
Linearity Range:	2.0 - 500.0	Point 1 (STD) Con.:	Calibrator/ standard
Correlation Factor:	1.0000 - 0.0000		

EXPECTED VALUES
70 - 105 mg/dl[5]
It is strongly recommended that each laboratory establish its own normal range.

PERFORMANCE CHARACTERISTICS
1. *Linearity:* 2-500 mg/dl.
2. *Comparison:* A comparison between this procedure and one utilizing phenol free produced a regression equation of:
   y = 0.99 x + 2.6 with a coefficient of correlation of 0.99.
3. *Precision:*

	Within Run	
Mean (mg/dl)	S.D.	C.V.
62.35	1.14	1.8%
123	1.5	1.2%

364	2.47	0.7%

	Run-to-Run	
Mean (mg/dl)	S.D.	C.V.
61.9	1.38	2.2%
123	2.54	2.1%
361	5.3	1.5%

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use.
   CAUTION: In vitro diagnostic reagents may be hazardous. Handle in accordance with good laboratory procedures which dictate avoiding ingestion, and eye or skin contact.
2. Specimens should be considered infectious and handled appropriately.
3. Use distilled or deionized water where indicated.

REFERENCES

1. Holvey, D.N. ed.: *The Merck Manual of Diagnostic and Therapy*, Merck and Co., Inc. Rahway, N.J. (1972).
2. Cooper, G.R., CRC Crit *Rev. Clin Lab. Sci.* 101-145 (1973).
3. Keston, A.S. Colorimetric, "Enzymatic Reagents for glucose." *Abstracts of Papers*, 129th Meeting ACS, 131C (1956).
4. Trinder, P., "Determination of Blood Glucose Using 4-Aminophenazone." *.J. Clin. Path.*, 22:246 (1969).
5. Tietz, N.W., *Fundamentals of Clin. Chem*., Philadelphia, W.B. Saunders (1970).
6. Young, D.S. et al., *Clin Chem*. 21:5 (1975).

G520-TC2/TC4: 05/2024

Manufactured by:

TECO DIAGNOSTICS
1268 N. LAKEVIEW AVE.
ANAHEIM, CA 92807
U.S.A.