TECO DIAGNOSTICS
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GLUCOSE
U.V. METHOD
FOR TC MATRIX

INTENDED USE
For the quantitative determination of glucose in serum or plasma on TC Matrix analyzer

SUMMARY AND EXPLANATION OF THE TEST
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.
The reagent used here is based on the hexokinase (HK) – glucose-6-phosphate dehydrogenase (G-6-PDH) U.V. end point method.
The TC Matrix System automatically proportions the appropriate sample and reagent volumes into the cuvette. The system monitors the change in absorbance at 340 nanometers. This change in absorbance is directly proportional to the concentration of glucose in the sample and is used by the TC Matrix System to calculate and express the glucose concentration.

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

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

REAGENT CONTENTS:
Each kit contains: Four Glucose Reagent 1 (4×40 ml)
Four Glucose Reagent 2 (4×8 ml)
Instruction Insert.

REAGENT PREPARATION
No preparation is required.

REAGENT COMPOSITION
Adenosine triphosphate: 3.8 mmol/L
NAD^+: 2.7 mmol/L
Hexokinase: 2000 IU/L
Glucose-6-phosphate dehydrogenase: 3000 IU/L
Also contains non-reactive chemicals for optimal system performance.

REAGENT STORAGE AND STABILITY
Glucose Reagent stored unopened at 2ºC to 8ºC is stable until the expiration date shown on the bottle label. Once opened, Glucose Reagent is stable for 21 days at 2ºC to 8ºC, or until the expiration date on the bottle label whichever occurs first.
DO NOT FREEZE.

SPECIMEN COLLECTION AND HANDLING
1. The test can be performed on serum or plasma. For serum, blood is drawn into a tube which does not contain anticoagulant. After the blood is allowed to clot, the serum should be separated from the clot. A maximum limit of two hours from the time of collection is recommended.
2. Separated serum or plasma should not remain at room temperature longer than 8 hours. If assays can not be completed within 8 hours, serum and plasma should be stored at 2ºC to 8ºC. If assays can not be completed within 48 hours, or if the separated sample is to be stored beyond 48 hours, samples should be frozen at -15ºC to -20ºC. Frozen samples should be thawed only once. Analyte deterioration may occur in samples that are repeatedly frozen and thawed.
3. For plasma, add whole blood directly into a tube containing anticoagulant. Acceptable anticoagulants are listed in the "LIMITATIONS" section.

CALIBRATION
1. Calibrator required: TECO MULTI Calibrator (not supplied with the kit).
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.

LIMITATIONS
1. The anticoagulants EDTA and Sodium Citrate were found to be incompatible with this method.
2. The anticoagulants Ammonium Heparin, Lithium Heparin, Potassium Oxalate, Sodium Fluoride and Sodium Heparin were found to be compatible with this method.

INTERFERENCE
1. Hemoglobin levels up to 400 mg/dl, Triglyceride levels up to 1000mg/dl and Bilirubin levels up to 30 mg/dl were found to exhibit negligible interference.
2. On this method, refer to the work of Young for a review of drugs and comprehensive list of substances which affect glucose level.

EXPECTED VALUE
70-105 mg/dL or 3.9 to 5.8 mmol/L

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 should perform quality control testing with at least 2 levels of control material with known values within the clinical range to assure the results are reliable before testing the specimens.

PROCEDURE

TEST NAME:	Glu (hexo)	R1:	180
TEST NO.		R2:	36
FULL NAME:	Glucose (UV Method)	SAMPLE VOLUME:	5
REFERENCE NO.:		R1 BLANK:	/
ANALY.TYPE:	Endpoint	MIX REAG. BLANK:	0.1 - 1.5
PRI. WAVE :	340 nm	CONCENTRATION:	/
SECON. WAVE:	/	LINEARITY LIMIT:	5-500
TREND:	Ascending	SUBSTRATE LIMIT:	/
REACT. TIME:	0 - 18	FACTOR:	/
INCUBATE TIME:	3	PROZONE CHECK:	/
UNIT:	mg/dl	Q1: / Q2: / Q3: / Q4: /	
PRECISION:	Integer	PC: / ABS.: /	
Calibration Type: Calibrate+Reag.Blank		Calibration Rule: Two-point linear	

PERFORMANCE CHARACTERISTICS

Analytical Range: 5- 500mg/dL

For Glucose analyte using Glucose Reagent on TC Matrix System, this method has been demonstrated to be linear from 5-500 mg/dL

Accuracy: Comparison study was performed on TC Matrix System from 40 samples. Beckman Coulter glucose reagent was used to compare with Glucose Reagent. The results of this study yielded a correlation coefficient of 0.98 with a regression equation of y=0.98X -3.14.

Precision: Within Run precision for Glucose Reagent Set was determined following a modification of NCCLS EP5-A.Two commercial human serum were assayed on TC Matrix System for 25 times.

Sample	Sample 1	Sample 2
N	25	25
Mean (mg/dl)	93	305
Standard Deviation (mg/dl)	2.7	13.3
Coefficient of Variation (%)	2.8	4.4

Run-to-Run precision for Glucose Reagent was determined following a modification of NCCLS EP5-A.Two commercial human serum were assayed on TC Matrix Systems five times per day for five days for the total of 25 values.

Sample	Sample 1	Sample 2
N	25	25
Mean (mg/dl)	93	305
Standard Deviation (mg/dl)	2.7	13.1
Coefficient of Variation (%)	2.8	4.5

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G516-870TM: **10/10**