MEDICA

IVD CE

REF 10201-4 4 x 39 mL

GLUCOSE-Trinder (GLU-T)

Wedges each contain a usable volume of 39 mL of reagent.

INTENDED USE

The EasyRA GLU-T reagent is intended for the quantitative measurement of glucose (GLU-T) in human serum and plasma (with heparin and fluoride/oxalate as anticoagulants), using the MEDICA "EasyRA® Clinical Chemistry Analyzer." Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders, including diabetes mellitus, neonatal hypoglycemia and idiopathic hypoglycemia and the diagnosis and treatment of pancreatic islet cell carcinoma.
For *in vitro* diagnostic use only. For professional use only.

SUMMARY AND EXPLANATION

Glucose is the major carbohydrate present in the peripheral blood. Glucose derived from dietary sources is converted to glycogen for storage in the liver or transformed to fatty acids for storage in adipose tissue. The most frequent cause of hyperglycemia is diabetes mellitus. Increased blood glucose levels can arise from pancreatitis, pituitary or thyroid dysfunction, renal failure, and liver disease.[1]
A variety of conditions may cause low blood glucose levels, such as insulinoma, hypopituitarism, neoplasms, or insulin-induced hypoglycemia.[2]

PRINCIPLE OF THE PROCEDURE

The enzymatic endpoint reaction, based on the early work of Trinder[3] and the later method of Burrin[4] is as follows:

$$\text{Glucose} + O_2 \xrightarrow[\text{oxidase}]{\text{Glucose}} \text{Gluconic Acid} + 2H_20_2$$

$$2H_20_2 + \text{4-aminoantipyrine} + \text{phenol} \xrightarrow{\text{peroxidase}} \text{quinoneimine dye} + 4\ H_20$$

The quinoneimine dye component is measured spectrophotometrically at an absorbance peak of 520 nm. The rate of the formation of the dye is directly proportional to the Glucose in the sample.

REAGENT

Phosphate Buffer, pH 7.4	13.8 mmol/L
Phenol	10 mmol/L
4-Aminoantipyrine	0.3 mmol/dL
Glucose oxidase	≥ 10,000 U/L
Peroxidase	≥ 700 U/L

PRECAUTIONS

1. Good laboratory safety practices should be followed when handling any laboratory reagent. (CLSI, GP17-A2).
2. Do NOT inhale or swallow, and avoid any contact with skin and eyes. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Any contact with the skin should be washed immediately with water for 10 minutes. If swallowed, seek medical advice immediately.
3. The reagent contains less than 0.1% sodium azide, which may react with lead and copper plumbing to form highly explosive metal azides. Refer to the Safety Data Sheet for risk, hazard and safety information.
4. As with any diagnostic test procedure, results should be interpreted considering all other test results and the clinical status of the patient.
5. Do not use washed cuvettes.

INSTRUCTIONS FOR REAGENT HANDLING, STORAGE AND STABILITY

The reagent is ready to use as supplied. Unopened reagent is stable until the expiration date listed on the label if stored at 2 – 8°C. The reagent is stable on-board in the refrigerated reagent area of the EasyRA Analyzer for the number of days programmed on the RFID chip on the reagent wedge. Do not use the reagent if it is turbid or cloudy or if it fails to recover known serum control values.

SPECIMEN COLLECTION AND STORAGE / STABILITY

Use serum and plasma free from significant hemolysis. Heparin or fluoride/oxalate coated tubes may be used for plasma collection. Serum and plasma samples without a preservative should be separated from cells and clots as soon as possible due to glycolysis. Though not as critical plasma samples collected in fluoride/oxalate tubes should be separated from cells within a half hour of being drawn. Glucose from serum or plasma should be analyzed within 8 hours if stored at 25° C or within 3 days if stored at 2 – 8° C.

PROCEDURE

Materials Provided

Medica GLU-T Reagent Wedge, REF 10201

Additional materials required

Medica EasyCal Chemistry, REF 10651
Medica EasyQC® Chemistry/Electrolytes – Level A, REF 10793
Medica EasyQC Chemistry/Electrolytes – Level B, REF 10794
Medica Precision Test Dye Wedge, REF 10764
Medica Cleaner Wedge – Chemistry & ISE, REF 10660 *or*
Medica Cleaner Wedge – Chemistry, REF 10661

INSTRUCTIONS FOR USE

The reagent is ready to use as supplied. Remove the cap and place the reagent in the EasyRA Analyzer reagent tray located in the reagent area. The on-board stability (60 days maximum) is programmed on the RFID chip on the reagent wedge.

Note: Check inside the neck of the wedge for foam after removing the cap and placing the wedge on the EasyRA Analyzer. If there is foam, remove it with a swab or a disposable pipette before performing the test.

Calibration

Medica EasyCal Chemistry (REF 10651) is recommended for the calibration of the assay. The calibration interval (30 days maximum) is programmed on the RFID chip on the reagent wedge. Recalibration is required whenever there is a change in reagent lot number or if a shift in quality control values occurs.

Quality Control

It is recommended that two levels of human serum based controls (normal and abnormal) be run with the assay daily whenever patient testing is performed and with each reagent lot change. Failure to obtain the proper range of values in the assay of control material may indicate reagent deterioration, instrument malfunction or procedural errors. The laboratory should follow local, state and federal quality control guidelines when using quality control materials.

Results

After completion of the assay, the EasyRA Analyzer calculates the glucose concentration from the ratio of the absorbance of the unknown sample to the absorbance of the calibrator, multiplied by the calibrator value.

$$\text{GLU-T (mg/dL)} = \frac{[(A_U - A_{Blk})_{520} - (A_U - A_{Blk})_{600}]}{[(A_C - A_{Blk})_{520} - (A_C - A_{Blk})_{600}]} \times \text{CalValue}$$

Where A_U and A_C are the absorbance values of the unknown and the calibrator respectively, A_{Blk} is the absorbance of the reagent blank, and “Cal Value” is the concentration of glucose in the calibrator (mg/dL).

Expected Values[5]

The reference range for glucose in serum and plasma is as follows:

Normal: 70 – 105 mg/dL

These values are guidelines. It is recommended that each laboratory establish its own range of expected values, since differences exist among instruments, laboratories and local populations.

Procedural Limitations (e.g. if sample is above assay range)

Use only serum and plasma without significant hemolysis.

The EasyRA Analyzer flags any result above 400 mg/dL as Linearity High “LH”. If the “Re-run” icon is selected by the operator, the sample may be re-tested using one half (1/2) the sample volume. The retest results are calculated to reflect the use of the smaller sample volume. This will extend the reportable range of the GLU-T test to 800 mg/dL.

PERFORMANCE CHARACTERISTICS[6]

Reportable Range
The reportable range is 1 to 400 mg/dL. Extended range is 1 to 800 mg/dL when half of the sample is used (1:1 dilution).

Inaccuracy/ Correlation (CLSI, EP9-A2)
The following table lists the data obtained in a comparison of the Medica Reagent for GLU-T (y) on the EasyRA Analyzer to the performance of a similar GLU-T reagent (x) on the Roche COBAS MIRA* Analyzer. The data shown below represents single determinations obtained on the EasyRA Analyzer vs. the average of two replicate values obtained on the COBAS MIRA Analyzer.

Number of Samples	46	Range of Samples	1 to 383 mg/dL
Slope	1.02	y Intercept	-3.2
Correlation Coefficient	0.9977	Regression Equation	Y = 1.02*X - 3.2

The following table lists the data obtained in a comparison of matched serum (x) and plasma (y) samples using the Medica Reagent for GLU-T on the EasyRA Analyzer. The data below represents a single plasma determination vs. the average of two replicate serum values.

Number of Samples	75	Range of Samples	9 to 383 mg/dL
Slope	1.004	y Intercept	-0.5347
Correlation Coefficient	0.9964	Regression Equation	Y = 1.004*X – 0.5347

**Cobas Mira is a registered trademark of Roche Diagnostics Operations, INC., Indianapolis, IN.*

Imprecision (CLSI, EP5-A2)
Duplicate measurements of each of three levels of QC material were tested twice a day for 20 days. Both within-run precision and total precision were determined from these data.

Within run imprecision:

QC Level mg/dL	Within Run SD mg/dL	Within Run CV %
272	1.9	0.7
109	0.9	0.8
60	1.0	1.7

Total Imprecision:

QC Level mg/dL	Total Imprecision SD mg/dL	Total Imprecision CV %
264	4.4	1.7
106	1.6	1.5
60	1.3	2.2

Linearity (CLSI, EP6-A)
Linear from 1 to 400 mg/dL, based on the linear regression Y = 1.021*X + 1.098.

Interfering Substances (CLSI, EP7-A)
Less than 10% interference was classified as “no significant interference.”
No significant interference was found with levels up to 300 mg/dL of hemoglobin.
No significant interference was found with levels up to 5 mg/dL of bilirubin.
No significant interference was found with levels up to 5 mg/dL of ascorbic acid. Ascorbic acid above 10 mg/dL produces a negative bias in glucose levels.

There is significant positive interference to triglycerides above 200 mg/dL (using *Intralipid***).

**Intralipid is a registered trademark of Pharmacia AB, Clayton, NC.*

Young provides a list of drugs and other substances that interfere with clinical chemistry tests. [7,8]

REFERENCES

1. Sacks, D.B., *Carbohydrates.* Tietz Fundamentals of Clinical Chemistry, 5th Ed. Burtis, C.A. & Ashwood, E.R. (W.B Saunders, Eds. Philadelphia USA) 2001: 427.
2. Neeley W.E.: *Clin. Chem.* 1972; 18:509.
3. Trinder, P., *Determination of Glucose in Blood Using Glucose Oxidase with an Alternative Oxygen Acceptor*. Ann. Clin. Biochem. 1969: 6:24.
4. Burrin, JM., Price, C.P., *Measurement of Blood Glucose*. Ann. Clin. Biochem. 1985:22, 327.
5. Tietz NW. *Clincal Guide to Laboratory Tests* 3rd ed. WB Saunders and Co., Philadelphia, PA, 1995: p268.
6. Data on file at Medica.
7.Young DS. *Effects of Drugs on Clinical Laboratory Tests* 4th ed. Washington, DC: AACC Press; 1995.
8. Young DS. *Effects of Preanalytical Variables on Clinical Laboratory Tests*. 2nd ed. Washington, DC. AACC Press;1997.

EASYRA ASSAY PARAMETERS (GLU-T)

Primary Wavelength (nm)	520
Secondary Wavelength (nm)	600
Reaction Type	End Point (2)
Reaction Direction	Increase
Reagent Blank	Yes (with each calibration)
Sample Blank	No
Reaction Time	10.4 min
Calibration interval (max.)	30 days
Reagent on-board stability	60 days

Serum/Plasma

Sample volume (µl)	3.0
Diluent volume (µl)	20
Reagent volume (µl)	220
Decimal Places (default)	0
Units (default values)	mg/dL
Dilution Factor	1:1 (To extend measuring range)
Linearity	1 to 400 mg/dL

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