ENVOY® 500 GLUCOSE REAGENT KIT

Product no. 55345

For *in vitro* diagnostic use

CAUTION : Federal Law restricts this device to sale by or on the order of a licensed healthcare practitioner (Rx ONLY)

INTENDED USE

Envoy® 500 Glucose Reagent is for the quantitative *in vitro* diagnostic determination of glucose in human serum and plasma on Envoy 500 Series Analysers. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabete mellitus, neonatal hypoglycemia and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

It is not intended for use in Point of Care settings.

CLINICAL SIGNIFICANCE [1-3]

Glucose is the main source of energy for the human body. Glucose is converted either into glycogen to be stocked in the liver or into triglycerides to be stocked in fatty tissues. Glucose concentration in blood is regulated by several hormones, including two antagonists : insulin and glucagon. Quantification of glucose in blood is used to diagnose metabolic carbohydrates disorders such as diabetes, idiopathic hypoglycemia and pancreatic disease. The main physiological troubles are linked to hyperglycaemia (type I Diabetes mellitus and type II Diabetes mellitus). Type I diabetes mellitus is insulin-dependent, and appears mainly before 30 years old. Type II diabetes mellitus is non-insulin-dependent, and usually appears after 40 years old, but can occur earlier for obese people. Other diabetes have secondary origin, and appear after endocrinal or hepatic diseases.

METHODOLOGY [4,5]

Enzymatic determination of glucose according to the following reactions (Trinder reaction -End point):

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

$$2H_2O_2 + \text{Phenol} + \text{4-AAP} \xrightarrow{\text{Peroxidase}} \text{Quinoneimine} + 4H_2O$$

4-AAP = 4-Aminoantipyrine

The red quinoneimine dye absorbs at 510 nm. The final absorbance at this wavelength is proportional to the concentration of glucose in the sample.

REAGENTS

COMPOSITION

Glucose Reagent contains 13.8 mmol/L Phosphate buffer, pH 7.4; 10 mmol/L Phenol; 0.3 mmol/L 4-Aminoantipyrine; ≥ 10,000 U/L Glucose oxidase (Aspergillus sp.); ≥ 700 U/L Peroxidase (horseradish); < 0.1% Sodium azide.

WARNINGS AND PRECAUTIONS

- This reagent is for professional *in vitro* diagnostic use only.
- Take normal precautions and adhere to good laboratory practice.
- Use clean or single use laboratory equipment only to avoid contaminations.
- The reagent R contains sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of these reagent always flush with copious amounts of water to prevent azide buildup.
- Dispose of contents in accordance with all local, state and federal regulations.
- For more information, Safety Data Sheet (SDS) is available on request for professional user.

PREPARATION

Glucose Reagent is ready for use on the Envoy 500 Analyzer as packaged.

STORAGE AND STABILITY

Store this reagent at 2 to 8 °C and protected from light. Do not freeze. Unopened reagents are stable to the expiration dates on the bottle labels.

The reagent is stable for 28 days onboard the Envoy 500 Analyzer.

☞SPECIMENS [1]

COLLECTION AND STORAGE

- Fresh unhemolyzed serum or lithium heparinized plasma is the preferred specimen. Do not analyze whole blood.
- Venipuncture should be performed prior to the administration of drugs. Of particular note, venipuncture performed during an acetaminophen overdose situation, when, N-acetyl-p-benzoquinone imine (NAPQI) an atypical metabolic breakdown product of acetaminophen, may be present, may lead to erroneously low glucose results. Venipuncture performed during or immediately after administration of N-acetylcysteine (NAC), a drug used to treat acetaminophen overdose, or Metamizole may lead to erroneously low glucose results.
- Samples must be separated from clot or cells promptly after collection to minimize loss of glucose through glycolysis (decrease of 5-7% in one hour in whole blood at room temperature).
- For best results, use only fresh specimens. Glucose in serum is stable for 8 hours at 25 °C or 72 hours at 2 to 8 °C.

PROCEDURE

MATERIALS PROVIDED

The Envoy 500 Glucose Reagent Kit includes the following components:

8 x 49.3 mL boats of Envoy 500 Glucose Reagent.

MATERIALS REQUIRED BUT NOT PROVIDED

- Envoy 500 Serum Calibrator (product no. 55111).
- Envoy 500 Serum Controls (product no. 55131).
- Normal saline.
- Analyzer specific consumables
- General Laboratory Equipment.

REAGENT INSTALLATION AND USE

Program the instrument using the application parameters and programming instructions provided at the end of this Instructions For Use.

Refer to the Operator Manual for additional information on installing reagents and programming the analyzer, and running samples, calibrators and controls.

The Envoy 500 Glucose Reagent is ready to use as packaged.

Do not remove the caps from the bottles until you are ready to install the reagent on the analyzer. Before installing, mix the reagents by gently inverting the reagent boats several times. Record the installation date on the label and insert the unit into the designated position on the reagent tray. Let the reagent equilibrate on the instrument for at least 30 minutes before use.

CALIBRATION

Calibrate the instrument after loading new reagent lot, after maintenance and whenever quality control results fall outside established limits. Under typical use conditions, calibration factors for this test are valid for 28 days. Refer to the Operator Manual for calibration procedures.

QUALITY CONTROL

Quality control requirements should be established in accordance with local, state and/or federal regulations or accreditation requirements.

Assay at least two levels of serum control daily. Serum Controls for Envoy500 level 1 and level 2 may be used. Controls should also be assayed after performing a reagent blank, calibrating, maintaining the instrument and after loading a new reagent unit.

Controls may be assayed more frequently based on laboratory workflow and the discretion of the user.

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CALCULATIONS

All calculations are performed by the instrument.

To calculate the result in SI units (mmol/L), multiply the result in conventional units (mg/dL) by 0.0555.

PERFORMANCE CHARACTERISTICS

MEASURING RANGE

Determined according to CLSI[6] EP6-A protocol, the measuring range is listed below. Samples that exceed the upper limit should be diluted 1:5 with NaCl 9 g/L solution (normal saline) and re-assayed. This extended measuring range was confirmed in a study where a high concentration of glucose was spiked into native serum samples. The recovery observed did not exceed the expected recovery by >±10%.

The «Re-run hyperactive» function performs the dilution automatically. Results take the dilution into account.

Range	Conventional Units	SI Units
Default	20.0 to 400.0 mg/dL	1.11 to 22.20 mmol/L
Hyperactive	400.0 to 2000.0 mg/dL	22.20 to 111.01 mmol/L

LIMIT OF DETECTION (LOD) AND LIMIT OF QUANTIFICATION (LOQ)

Determined according to CLSI[7] EP17-A protocol, the LoD is 1.9 mg/dL (0.11 mmol/L) and LoQ is 10.0 mg/dL (0.56 mmol/L).

EXPECTED VALUES [1,3]

Published glucose reference ranges for adults are listed below. Use these ranges only as guides. Each laboratory should establish its own reference ranges.

Reference Range	Conventional Units	SI Units
Serum/plasma	74 to 106 mg/dL	4.1 to 5.9 mmol/L

PRECISION

Determined according to CLSI[8] EP5-A2 protocol.

Sample	n	mean	Within-run	Total
		mg/dL	CV (%)	
Level 1	80	36.0	0.8	2.2
Level 2	80	112.8	0.5	2.3
Level 3	80	311.5	0.6	1.9

METHOD COMPARISON

A comparative study has been performed between an Envoy500 Analyzer and an FDA-approved system equipment (Glucose oxidase method) on 101 human serum samples according to CLSI[9] EP9-A2 protocol.

The sample concentrations were between 19.8 and 408.7 mg/dL (1.10 and 22.69 mmol/L).

The parameters of the linear regressions are as follows :

Correlation coefficient: (r) = 1.000

Linear regression: y = 0.986 x - 2.0 mg/dL (0.11 mmol/L)

☛ LIMITATIONS/INTERFERING SUBSTANCES

- Do not report results outside of the usable range.

- The results of this assay should only be interpreted in conjunction with other diagnostic test results, clinical findings and the patient's medical history.

- Studies have been performed to determine the level of interference from different compounds according to CLSI[10] EP7-A2 protocol. Recovery is within ± 10% of initial value of glucose concentration of 36.0 mg/dL, 108.1 mg/dL and 400.0 mg/dL.

Unconjugated bilirubin: No significant interference up to 6.0 mg/dL (103 µmol/L).

Conjugated bilirubin: No significant interference up to 5.9 mg/dL (101 µmol/L).

Hemoglobin: No significant interference up to 250 mg/dL .

Triglycerides: No significant interference up to 895 mg/dL (10.11 mmol/L).

Ascorbic acid: No significant interference up to 2.0 mg/dL (114 µmol/L).

Uric acid: No significant interference up to 20.0 mg/dL (1190 µmol/L).

Methyl dopa: No significant interference up to 0.8 mg/dL (37.9 µmol/L).

L-Dopa: Induces falsely low results at therapeutic concentrations.

Tolazamide: No significant interference up to 40.0 mg/dL (1.28 mmol/L).

Acetaminophen: No significant interference up to 30.0 mg/dL (1.98 mmol/L).

- In very rare cases, monoclonal gammopathies (multiple myeloma), in particular IgM type (Waldenstrom's macroglobulinemia) can cause unreliable results.[11]

- Results may be falsely low when the sample is taken while levels of NAC, NAPQI (a metabolite of acetaminophen (paracetamol)) or Metamizole are significant.

- Other compounds may interfere.[12,13]

☛REFERENCES

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11. Berth, M. & Delanghe, J. *Protein precipitation as a possible important pitfall in the clinical chemistry analysis of blood samples containing monoclonal immunoglobulins: 2 case reports and a review of literature*, Acta Clin Belg., (2004), **59**, 263.
12. Young, D. S., Effects of preanalytical variables on clinical laboratory tests, 2nd Ed., AACC Press, (1997).
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GLOSSARY OF SYMBOLS

CONT	Contents		Manufacturer	REF	Catalog No.
LOT	Batch Code		See instruction for use		Use by
OPENED	Date opened / Installation date	IVD	*In vitro* diagnostic device		Tempe-rature Limitation
STAB DAYS	Number of days onboard stability	R	Reagent		

☛ : Modification from previous version

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ENVOY® 500 GLUCOSE REAGENT KIT

ELITechGroup CLINICAL SYSTEMS

APPLICATION PARAMETERS

PRIMARY PARAMETERS

Code	GLU
Bar-Code	Active
Code for Bar-Code	331
Test Methodology	PAP
Method	End Point
Kind of Process	Linear
1st Filter	510
2nd Filter	700
Reaction direction	Increasing

REAGENTS

Number of reagents	1
Reagent 1 Volume µL	300
Concentrated	Inactive
Reagent 2 Volume µL	N/A
Concentrated	Inactive

SAMPLE

	Serum	Urine
Name	Glucose	N/A
Sample µL	3	N/A
Pre-Dilution 1:	1	N/A
Post-Dilution 1:	5	N/A

TIMES

Sample Starter	Inactive
Delay Time	0
Reading Time	60
Reagent 1 Incubation Time	420
Reagent 2 Incubation Time	N/A

CHECK PARAMETERS

Reagent Limit (mABS)	200
Curve Acceptance (%)	100

RE-RUN SERUM

Test Limit (Conc)	400
Low Test Limit (Conc)	1.9
Initial ABS (mABS)	N/A
Final ABS (mABS)	N/A
Max ABS Delta (mABS)	9999
Prozone Check	Inactive

Normal Range	Min	Max
Man	[User defined]	
Woman	[User defined]	
Child	[User defined]	

Re-run hyperactive	Active
Re-run pathological	Inactive

RE-RUN URINE

Test Limit (Conc)	N/A
Low Test Limit (Conc)	N/A
Initial ABS (mABS)	N/A
Final ABS (mABS)	N/A
Max ABS Delta (mABS)	N/A
Prozone Check	Inactive

Normal Range	Min	Max
Man	[User defined]	
Woman	[User defined]	
Child	[User defined]	

Re-run hyperactive	Inactive
Re-run pathological	Inactive

SECONDARY PARAMETERS

1st Unit Serum	mg/dL
2nd Unit Serum	Inactive
1st Unit Urine	N/A
2nd Unit Urine	Inactive
Dynamic Blank	Inactive
Needle washes	[From Settings Table]
Cuvette washes	[From Settings Table]
Special Wash	[From Settings Table]
Instrumental Factor	1.000
Shift	0.000
Reagent Blank	Every Day
Decimals	1

STANDARD PARAMETERS

Factor	[Determined by calibration]
Minimum	200
Maximum	500
Number of Samples	1
Max Var. (%)	10
Timed re-run	Inactive
N. replicates	3
Reagents ABS	[Determined by Envoy]
Pos.	[From Settings Table]
Conc.	[From calibrator labeling]
ABS	[Determined by Envoy]
% from last calibration	100

PROGRAMMING INSTRUCTIONS

Detailed instructions for programming reagent parameters are provided in the Envoy 500 Operator Manual and Envoy500 Settings Table.

If the Envoy 500 Chemistry System is not pre-programmed, a Glucose code must first be added before the parameters can be entered. On the menu bar, select «Test → Test Directory.» A new window will open up listing all the codes for the tests that are installed on the instrument. Click on the «New Code» button, type «GLU» into the Code field and select «Save.»

To program the application parameters, check the box next to the code for the GLU test, and select the «Parameters» button located at the bottom of the window. To program standard information, click the «Standards» button located at the bottom of the window.

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