GLUCOSE (GLUC-PAP)

GOD/PAP
RX SERIES

INTENDED USE

A glucose test system is a device intended for the quantitative *in vitro* determination of Glucose concentration in serum, plasma and urine. This product is suitable for use on RX **series** instruments which includes the RX **daytona** and the RX **imola**.

Cat. No.		
GL 3815	R1. Buffer/Enzyme	9 x 51 ml

GTIN: 05055273203240

CLINICAL SIGNIFICANCE

The accurate measurement of glucose in serum or plasma is important in the diagnosis and treatment of carbohydrate metabolism disorders such as diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia and of pancreatic islet cell carcinoma. Glucose is often measured in conjunction with various tolerance tests after the administration of doses of leucine, insulin, glucagon or glucose.

PRINCIPLE[1]
COLORIMETRIC METHOD WITHOUT DEPROTEINISATION

Glucose is determined after enzymatic oxidation in the presence of glucose oxidase. The hydrogen peroxide produced, reacts catalysed by peroxidase, with phenol and 4-aminophenazone to form a red - violet quinoneimine dye as indicator. The intensity of the final colour is directly proportional to the glucose concentration and is measured at 505 nm.

$$\text{Glucose} + 0_2 + H_20 \xrightarrow{\text{GOD}} \text{gluconic acid} + H_2O_2$$

$$2H_20_2 + \text{4-aminophenazone} + \text{phenol} \xrightarrow{\text{POD}} \text{quinoneimine} + 4H_2O$$

This assay uses an endpoint method and single point calibration.

SPECIMEN COLLECTION AND PREPARATION[2,4]

Glucose is stable for 24 hours at +2°C to +8°C if the serum is prepared within 30 min after collection. By adding a glycolysis inhibitor (NaF, KF), the sample can be stored up to 24 hours at +15°C to +25°C or 3 days at +2°C to +8°C. For long term storage, the samples should be placed in sealed containers and frozen at –20°C.
Haemolysed samples must not be used since haemolysis interferes with this test.
Plasma: use of lithium heparin as an anticoagulant is allowed.
Urine: 24 hour urine should be collected in a dark bottle and kept on ice.
Random urine - a fresh sample should be used. Sample should be stored at +2°C to +8°C if not used immediately.

REAGENT COMPOSITION

Contents	Initial Concentration of Solutions
R1. Buffer/Enzyme	
Phosphate Buffer	50 mmol/l, pH 7.0
MOPS Buffer	50 mmol/l, pH 7.0
Phenol	11 mmol/l
4-aminophenazone	0.77 mmol/l
Glucose oxidase [EC 1.1.3.4, *Aspergillus niger*, @ 25°C]	≥1.5 kU/l
Peroxidase [EC 1.11.1.7, Horse radish, @ 20°C]	≥1.5 kU/l

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Solution R1 contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.

Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents, flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

Safety Data Sheets are available on request.

Please dispose of all Biological and Chemical materials according to local guidelines.

The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.

STABILITY AND PREPARATION OF REAGENT

R1. Buffer/Enzyme
Contents ready for use. Stable up to the expiry date when stored at +2°C to +8°C.

MATERIALS PROVIDED

Glucose (GOD/PAP) Buffer/Enzyme

MATERIALS REQUIRED BUT NOT PROVIDED

RX **series** Saline (Cat. No. SA 3854)
Randox Assayed Multisera Level 2 (Cat. No. HN 1530) and Level 3 (Cat. No. HE 1532)
Randox Calibration Serum Level 3 (Cat. No. CAL 2351)

PROCEDURE NOTES

To avoid the potential for reagent carryover, it is recommended that the testing order of the reagents is confirmed. Please consult the reagent carryover document available on www.randox.com under support and documentation - Reagent product inserts or by contacting Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 9445 1070.

The Chemistry Parameters for Randox Dedicated RX **series** Assays are predefined on the hard drive of the analyser PC. The required programs should be downloaded to the analyser software. Please note that the predefined chemistry parameters use SI units. If alternative units are required, these can be edited by the user. In this case, the technical range should be edited in accordance with the users selected units. All necessary instructions are encoded on the bar code. If the barcode cannot be read by the analyser, enter manually the series of numbers given beneath the barcode. If problems continue, contact Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 94451070.

NOTE

If measurement of urine samples is required, please ensure that the appropriate urine program on the parameters disk is used.

CALIBRATION
The use of Saline and Randox Calibration Serum Level 3 is recommended for calibration.

STANDARDISATION
Randox Calibration Serum Level 3 is traceable to Glucose reference materials NIST 917b and NIST 965a.

QUALITY CONTROL
Randox Assayed Multisera, Level 2 and Level 3 are recommended for daily quality control. Two levels of controls should be assayed at least once a day. Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check cleanliness of all equipment in use.
3. Check water, contaminants i.e. bacterial growth may contribute to inaccurate results.
4. Check reaction temperature.
5. Check expiry date of kit and contents.
6. Contact Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 9445 1070.

Quality control requirements should be determined in conformance with government regulations or accreditation requirements.

INTERFERENCES
The analytes below were tested up to the following levels and were found not to interfere:

Haemoglobin	1000 mg/dl
Free Bilirubin	25 mg/dl
Conjugate Bilirubin	25 mg/dl
Triglycerides	1000 mg/dl
Intralipid	400 mg/dl

Physiological changes in serum or plasma analyte concentrations can be caused by a number of substances. Comprehensive discussion of possible interfering substances, their serum or plasma concentrations, and their possible physiological involvements is beyond the scope of this document. The listed reference contains specific details on known potential interfering substances[4]. The user must remain vigilant to the possible effect on results of unknown interferences from medications or endogenous substances. All patient results must be evaluated in light of the total clinical status of the patient.

NORMAL VALUES[5,6]

Serum/Plasma	4.16-6.38 mmol/l (75-115 mg/dl)
Random urine	0.1 – 0.8 mmol/l (1 – 15 mg/dl)
24 hour urine	<2.78 mmol/d (<0.5 g/d)

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

SPECIFIC PERFORMANCE CHARACTERISTICS
The following performance characteristics were obtained using the RX **daytona**.

SERUM
LINEARITY
The test is linear up to a glucose concentration of 34.1 mmol/l (614 mg/dl). In the event of a rerun, the upper limit of the assay range is increased to 341 mmol/l (6140 mg/dl).

RX **imola** users: The test is linear up to a glucose concentration of 26.2 mmol/l (473 mg/dl).

SENSITIVITY
The minimum detectable concentration of Glucose with an acceptable level of precision was determined as 0.335 mmol/l (6.04 mg/dl).

PRECISION

Intra assay

	Level 1	Level 2	Level 3
Mean (mmol/l)	1.70	5.77	16.8
SD (mmol/l)	0.076	0.113	0.375
CV (%)	4.48	1.96	2.23
n	20	20	20

Inter assay

	Level 1	Level 2	Level 3
Mean (mmol/l)	1.87	4.88	15.8
SD (mmol/l)	0.066	0.286	0.657
CV (%)	3.51	5.87	4.09
n	20	20	20

CORRELATION
This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:

Y = 1.04 X - 0.15
and a correlation coefficient of r = 0.99

40 patient samples were analyzed spanning the range 3.9 mmol/l to 11.6 mmol/l.

URINE
LINEARITY
The test is linear up to a glucose concentration of 35 mmol/l (630 mg/dl). In the event of a rerun, the upper limit of the assay range is increased to 350 mmol/l (6300 mg/dl).

RX **imola** users: The test is linear up to a glucose concentration of 26.2 mmol/l (473 mg/dl).

SENSITIVITY
The minimum detectable concentration of Glucose with an acceptable level of precision was determined as 0.54 mmol/l (9.73 mg/dl).

PRECISION

Intra Assay

	Level 1	Level 2	Level 3
Mean (mmol/l)	2.3	7.2	14.5
SD (mmol/l)	0.038	0.082	0.255
CV (%)	1.64	1.13	1.76
n	20	20	20

Inter Assay

	Level 1	Level 2	Level 3
Mean (mmol/l)	2.57	6.53	15.4
SD (mmol/l)	0.042	0.10	0.287
CV (%)	1.64	1.52	1.86
n	20	20	20

CORRELATION

This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:

Y = 1.08 X - 0.04
and a correlation coefficient of r = 1.00

57 patient samples were analyzed spanning the range 0 mmol/l to 31 mmol/l.

REFERENCES

1. Barham, D, and Trinder, P. Analyst 1972; **97**: 142.
2. Clinical Chemistry Principles and Techniques, Second Edition, R.J. Henry, D.C. Cannon and J.W. Winkelman Editors, Harper and Row, Maryland, USA, 1288, 1974.
3. Teuscher, A. and Richterich, P. Schweiz Med. Wschr. 1971; **101**: 345 and 390.
4. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Washington, DC: AACC Press; 2000.
5. Tietz, N.W. *Clinical Guide to laboratory tests.* 2nd edition. Philadelphia, Pa: WB Saunders Co.; 1990: 246-250.
6. Thomas, L. Labor und Diagnose. 2nd edition. Die Medizinische Verlagsgesellschaft Marburg/ Lahn 1984: 114.

The presence of a vertical bar in the margin indicates a technical update from the previous revision.

EC REP

Randox Teoranta, Meenmore,
Dungloe, Donegal,
F94 TV06, Ireland

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Randox Laboratories Ltd, 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
T +44 (0) 28 9442 2413 **F** +44 (0) 28 9445 2912 **E** applications@randox.com **I** www.randox.com