

## GLUCOSE (GLUC-PAP)

GOD/PAP  
RX DAYTONA PLUS

### INTENDED USE

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

### Cat. No.

GL 8318 R.I. Buffer/Enzyme 4 x 20 ml

### GTIN:

05055273208757

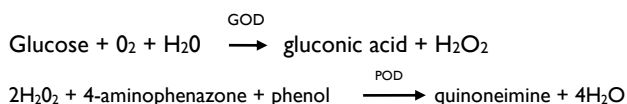
### CLINICAL SIGNIFICANCE

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.



This assay uses an endpoint method and single point calibration.

### SPECIMEN COLLECTION AND PREPARATION (2,4)

Glucose is stable for 24 hours at +2 to +8°C if the serum is prepared within 30 minutes after collection. By adding a glycolysis inhibitor (NaF, KF), the sample can be stored up to 24 hours at +15 to +25°C or 3 days at +2 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.

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 to +8°C if not used immediately.

### REAGENT COMPOSITION

Contents	Initial Concentration of Solutions
<b>R.I. Buffer/Enzyme</b>	
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, <i>Aspergillus niger</i> , @ +25°C]	≥1.5 kU/l
Peroxidase	
[EC 1.1.1.7, Horse radish, @ +20°C]	≥1.5 kU/l
Sodium Azide	0.04% w/v

### 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 R.I. 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

#### R.I. Buffer/Enzyme

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

### MATERIALS PROVIDED

Glucose (GOD/PAP) Buffer/Enzyme

### MATERIALS REQUIRED BUT NOT PROVIDED

RX series Saline (Cat. No. SA 8396)  
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](http://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 **daytona plus** 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 9445 1070.

### NOTE

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

### RX DAYTONA PLUS 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.

### NORMAL VALUES (4, 5)

Serum	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.

### SERUM

#### SPECIFIC PERFORMANCE CHARACTERISTICS

The following performance characteristics were obtained using the RX **daytona plus**.

#### INTERFERENCE

The following analytes were tested up to the levels indicated at Glucose concentrations of 2.90 mmol/l and 14.5 mmol/l and found not to interfere:

	2.90 mmol/l	14.5 mmol/l
Haemoglobin	250 mg/dl	1000 mg/dl
Total Bilirubin	15 mg/dl	30 mg/dl
Conjugate Bilirubin	interferes	60 mg/dl
Triglycerides	2000 mg/dl	2000 mg/dl
Intralipid®	interferes	interferes

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<sup>(6)</sup>. 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.

#### REPORTABLE RANGE

Linearity data demonstrates that the reportable range for Glucose on the RX **daytona plus** is 0.2 to 46.5 mmol/l.

#### SENSITIVITY

The limit of Quantitation (LoQ), the limit of Detection (LoD) and the limit of Blank (LoB) were determined consistent with CLSI guidelines EP17-A. LoQ is the lowest concentration that can be detected with ≤40% Total error. LoD is the lowest concentration that can be detected to determine the presence or absence of Glucose. LoB is the highest concentration that is likely to be observed in a blank sample.

#### RX daytona plus

Limit of Blank (mmol/l)	0.010
Limit of Detection (mmol/l)	0.021
Limit of Quantitation (mmol/l)	0.200

#### PRECISION

##### Within Run Precision

	Level 1	Level 2	Level 3
Mean (mmol/l)	2.81	6.31	15.7
SD	0.049	0.124	0.311
CV (%)	1.73	1.96	1.98
n	80	79	80

##### Total Precision

	Level 1	Level 2	Level 3
Mean (mmol/l)	2.81	6.31	15.7
SD	0.071	0.124	0.325
CV (%)	2.52	1.96	2.08
n	80	79	80

### CORRELATION

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

$$Y = 1.046X - 0.098$$

and a correlation coefficient of  $r = 0.999$

97 patient samples were analysed spanning the range 0.67 to 45.6 mmol/l.

### URINE

#### SPECIFIC PERFORMANCE CHARACTERISTICS

The following performance characteristics were obtained using the RX **daytona plus**.

#### LINEARITY

The test is linear up to a glucose concentration 35.6 mmol/l (641 mg/dl).

#### SENSITIVITY

The minimum detectable concentration of Glucose with an acceptable level of precision was determined as 0.47 mmol/l.

#### PRECISION

##### Within Run Precision

	Level 1	Level 2	Level 3
Mean (mmol/l)	0.632	2.50	24.2
SD	0.015	0.065	0.343
CV (%)	2.37	2.60	1.42
n	20	20	20

### CORRELATION

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

$$Y = 1.02X - 0.32$$

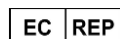
and a correlation coefficient of  $r = 0.995$

59 patient samples were analysed spanning the range 0.385 to 35.9 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. Tietz, N.W. *Clinical Guide to laboratory tests*. 2<sup>nd</sup> edition. Philadelphia, Pa: W.B. Saunders Co.; 1990: 246-250.
5. Thomas, L. Labor und Diagnose. 2<sup>nd</sup> edition. Die Medizinische Verlagsgesellschaft Marburg/ Lahn 1984: 114.
6. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Washington, DC: AACC Press; 2000.

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



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

Revised 09 Jan 24 Id

**THIS PAGE IS INTENTIONALLY BLANK**