

Order information

REF	CONTENT	Analyzer(s) on which cobas c pack(s) can be used
05168791 190	Glucose HK Gen.3 (2200 tests)	System-ID 05 6831 6 cobas c 701/702
10759350 360	Calibrator f.a.s. (12 x 3 mL)	Code 401
12149435 160	Precinorm U plus (10 x 3 mL)	Code 300
12149443 160	Precipath U plus (10 x 3 mL)	Code 301
05947626 160	PreciControl ClinChem Multi 1 (4 x 5 mL)	Code 391
05947774 160	PreciControl ClinChem Multi 2 (4 x 5 mL)	Code 392
05172152 190	Diluent NaCl 9 % (119 mL)	System-ID 08 6869 3

English

For use in the USA only

System information

GLUC3: ACN 8717**SGLU3:** ACN 8668 (STAT, reaction time: 7)

Intended use

In vitro test for the quantitative determination of glucose in human serum, plasma, urine and CSF on Roche/Hitachi **cobas c** systems.

Summary^{1,2,3}

Glucose is the major carbohydrate present in the peripheral blood. Oxidation of glucose is the major source of cellular energy in the body. Glucose derived from dietary sources is converted to glycogen for storage in the liver or to fatty acids for storage in adipose tissue. The concentration of glucose in blood is controlled within narrow limits by many hormones, the most important of which are produced by the pancreas.

The most frequent cause of hyperglycemia is diabetes mellitus resulting from a deficiency in insulin secretion or action. A number of secondary factors also contribute to elevated blood glucose levels. These include pancreatitis, thyroid dysfunction, renal failure and liver disease.

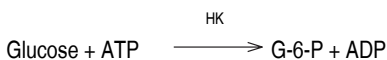
Hypoglycemia is less frequently observed. A variety of conditions may cause low blood glucose levels such as insulinoma, hypopituitarism or insulin induced hypoglycemia. Glucose measurement in urine is used as a diabetes screening procedure and to aid in the evaluation of glycosuria, to detect renal tubular defects, and in the management of diabetes mellitus. Glucose measurement in cerebrospinal fluid is used for evaluation of meningitis, neoplastic involvement of meninges and other neurological disorders.

Test principle

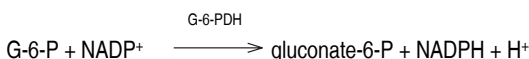
UV test

Enzymatic reference method with hexokinase.^{4,5}

Hexokinase catalyzes the phosphorylation of glucose to glucose-6-phosphate by ATP.



Glucose-6-phosphate dehydrogenase oxidizes glucose-6-phosphate in the presence of NADP to gluconate-6-phosphate. No other carbohydrate is oxidized. The rate of NADPH formation during the reaction is directly proportional to the glucose concentration and is measured photometrically.



Reagents - working solutions

- R1** MES buffer: 5.0 mmol/L, pH 6.0; Mg²⁺: 24 mmol/L;
ATP: ≥ 4.5 mmol/L; NADP: ≥ 7.0 mmol/L; preservative
- R3** HEPES buffer: 200 mmol/L, pH 8.0; Mg²⁺: 4 mmol/L;
(STAT R2) HK (yeast): ≥ 300 μkat/L; G-6-PDH (E. coli): ≥ 300 μkat/L;
preservative

R1 is in position B and R3 (STAT R2) is in position C.

Precautions and warnings

For in vitro diagnostic use.

Exercise the normal precautions required for handling all laboratory reagents.

Disposal of all waste material should be in accordance with local guidelines. Safety data sheet available for professional user on request.

For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

Reagent handling

Ready for use

Storage and stability

GLUC3

Shelf life at 2-8 °C: See expiration date on **cobas c** pack label.

On-board in use and refrigerated on the analyzer: 4 weeks

On-board on the Reagent Manager: 24 hours

Diluent NaCl 9 %

Shelf life at 2-8 °C: See expiration date on **cobas c** pack label.

On-board in use and refrigerated on the analyzer: 4 weeks

On-board on the Reagent Manager: 24 hours

Specimen collection and preparation

For specimen collection and preparation only use suitable tubes or collection containers.

Only the specimens listed below were tested and found acceptable.

Serum

Plasma: Li-heparin, K₂-EDTA, NaF/Na₂EDTA, KF/Na₂EDTA, NaF/K-Oxalate.

The stability of glucose in specimens is affected by storage temperature, bacterial contamination, and glycolysis. Plasma or serum samples without preservative (NaF) should be separated from the cells or clot within half an hour of being drawn. When blood is drawn and permitted to clot and to stand uncentrifuged at room temperature, the average decrease in serum glucose is ~7 % in 1 hour (0.28 to 0.56 mmol/L or 5 to 10 mg/dL). This decrease is the result of glycolysis. Glycolysis can be inhibited by collecting the specimen in fluoride tubes.¹

The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, i.e. not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.

See the limitations and interferences section for details about possible sample interferences.

Sample stability claims were established by experimental data by the manufacturer or based on reference literature and only for the temperatures/time frames as stated in the method sheet. It is the responsibility of the individual laboratory to use all available references

and/or its own studies to determine specific stability criteria for its laboratory.

Stability:⁵ 8 hours at 25 °C
3 days at 4 °C

Stability in fluoride plasma:⁶ 3 days at 15-25 °C

Urine

Collect urine in a dark bottle. For 24-hour urine collections, glucose may be preserved by adding 5 mL of glacial acetic acid to the container before collection. Unpreserved urine samples may lose up to 40 % of their glucose after 24-hour storage at room temperature.³ Therefore, keep samples on ice during collection.⁵

CSF

Cerebrospinal fluid may be contaminated with bacteria and often contains other cellular constituents. CSF samples should therefore be analyzed for glucose immediately or stored at 4 °C or -20 °C.^{3,5}

Centrifuge samples containing precipitates before performing the assay.

Materials provided

See "Reagents – working solutions" section for reagents.

Materials required (but not provided)

See "Order information" section

General laboratory equipment

Assay

For optimum performance of the assay follow the directions given in this document for the analyzer concerned. Refer to the appropriate operator's manual for analyzer-specific assay instructions.

The performance of applications not validated by Roche is not warranted and must be defined by the user.

Application for serum, plasma, urine and CSF

cobas c 701/702 test definition

Assay type	2-Point End		
Reaction time / Assay points	10 / 18-38 (STAT 7 / 6-26)		
Wavelength (sub/main)	700/340 nm		
Reaction direction	Increase		
Units	mmol/L (mg/dL, g/L)		
Reagent pipetting	Diluent (H ₂ O)		
R1	28 µL	141 µL	
R3 (STAT R2)	10 µL	20 µL	
<i>Sample volumes</i>	<i>Sample</i>	<i>Sample dilution</i>	
		<i>Sample</i>	<i>Diluent (NaCl)</i>
Normal	2 µL	–	–
Decreased	10 µL	15 µL	135 µL
Increased	4 µL	–	–

Calibration

Calibrators	S1: H ₂ O S2: C.f.a.s.
Calibration mode	Linear
Calibration frequency	2-point calibration - after reagent lot change - as required following quality control procedures

Calibration interval may be extended based on acceptable verification of calibration by the laboratory.

Traceability: This method has been standardized against ID/MS.

Quality control

For quality control, use control materials as listed in the "Order information" section. In addition, other suitable control material can be used.

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

Follow the applicable government regulations and local guidelines for quality control.

Calculation

cobas c systems automatically calculate the analyte concentration of each sample.

Conversion factors: mmol/L x 18.02 = mg/dL
mmol/L x 0.1802 = g/L
mg/dL x 0.0555 = mmol/L

Limitations - interference

Criterion: Recovery within ± 10 % of initial value at a glucose concentration of 3.9 mmol/L (70.3 mg/dL).

Serum/plasma

Icterus:⁷ No significant interference up to an I index of 60 for conjugated and unconjugated bilirubin (approximate conjugated and unconjugated bilirubin concentration: 1026 µmol/L or 60 mg/dL).

Hemolysis:⁷ No significant interference up to an H index of 1000 (approximate hemoglobin concentration: 621 µmol/L or 1000 mg/dL).

Lipemia (Intralipid):⁷ No significant interference up to an L index of 1000. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration.

Drugs: No interference was found at therapeutic concentrations using common drug panels.^{8,9}

In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.¹⁰

Urine

Drugs: No interference was found at therapeutic concentrations using common drug panels.⁹

Criterion: Recovery within ± 10 % of initial value at a glucose concentration of 1.1 mmol/L (19.8 mg/dL).

Urea: No significant interference from urea up to a concentration of 1800 mmol/L (10811 mg/dL).

Tetracycline at therapeutic concentrations gives falsely low results in urine samples.

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

NOTE: Glucose values achieved on some proficiency testing materials, when evaluated against a glucose oxidase-oxygen electrode comparison method, demonstrate an approximate 3 % positive bias on average.

ACTION REQUIRED

Special Wash Programming: The use of special wash steps is mandatory when certain test combinations are run together on **cobas c** systems. All special wash programming necessary for avoiding carry-over is available via the **cobas** link, manual input is required in certain cases. The latest version of the carry-over evasion list can be found with the NaOHD/SMS/SmpCln1+2/SCCS Method Sheet and for further instructions refer to the operator's manual.

Where required, special wash/carry-over evasion programming must be implemented prior to reporting results with this test.

Limits and ranges

Measuring range

Serum, plasma, urine and CSF

0.11-41.6 mmol/L (2-750 mg/dL)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:2 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 2.

Lower limits of measurement

Lower detection limit of the test:

0.11 mmol/L (2 mg/dL)

The lower detection limit represents the lowest measurable analyte level that can be distinguished from zero. It is calculated as the value lying 3 standard deviations above that of the lowest standard (standard 1 + 3 SD, repeatability, n = 21).

Values below the lower detection limit (< 0.11 mmol/L) will not be flagged by the instrument.

Expected values*Plasma*¹¹

Fasting 4.11-6.05 mmol/L (74-109 mg/dL)

*Urine*¹²

1st morning urine 0.3-1.1 mmol/L (6-20 mg/dL)

24-hour urine 0.3-0.96 mmol/L (6-17 mg/dL)
(average of 1350 mL urine/24 h)

acc. to Tietz:⁵

Serum, plasma

Adults 4.11-5.89 mmol/L (74-106 mg/dL)

60-90 years 4.56-6.38 mmol/L (82-115 mg/dL)

> 90 years 4.16-6.72 mmol/L (75-121 mg/dL)

Children 3.33-5.55 mmol/L (60-100 mg/dL)

Neonates (1 day) 2.22-3.33 mmol/L (40-60 mg/dL)

Neonates (> 1 day) 2.78-4.44 mmol/L (50-80 mg/dL)

Urine

24-hour urine < 2.78 mmol/24 h (< 0.5 g/24 h)

Random urine 0.06-0.83 mmol/L (1-15 mg/dL)

CSF

Children 3.33-4.44 mmol/L (60-80 mg/dL)

Adults 2.22-3.89 mmol/L (40-70 mg/dL)

CSF glucose values should be approximately 60 % of the plasma values and must always be compared with concurrently measured plasma values for adequate clinical interpretation.

Roche has not evaluated reference ranges in a pediatric population.

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

Specific performance data

Representative performance data on the analyzers are given below. Results obtained in individual laboratories may differ.

Precision

Precision was determined using human samples and controls in an internal protocol. *Serum/plasma*: Repeatability (n = 21), intermediate precision (3 aliquots per run, 1 run per day, 21 days).

Urine/CSF: Repeatability (n = 21), intermediate precision (3 aliquots per run, 1 run per day, 10 days). The following results were obtained:

*Serum/plasma***GLUC3:**

<i>Repeatability</i>	<i>Mean</i> mmol/L (mg/dL)	<i>SD</i> mmol/L (mg/dL)	<i>CV</i> %
Precinorm U	5.17 (93.2)	0.04 (0.7)	0.8
Precipath U	13.4 (241)	0.1 (2)	0.7
Human serum A	3.27 (59.0)	0.02 (0.4)	0.5
Human serum B	19.1 (344)	0.1 (2)	0.7
Human serum C	36.1 (651)	0.3 (5)	0.7

SGLU3:

<i>Repeatability</i>	<i>Mean</i> mmol/L (mg/dL)	<i>SD</i> mmol/L (mg/dL)	<i>CV</i> %
Precinorm U	5.15 (92.8)	0.04 (0.7)	0.7
Precipath U	13.4 (241)	0.1 (2)	0.7
Human serum A	3.21 (57.8)	0.02 (0.4)	0.5
Human serum B	19.0 (342)	0.1 (2)	0.6
Human serum C	35.8 (645)	0.2 (4)	0.5

GLUC3 / SGLU3:

<i>Intermediate precision</i>	<i>Mean</i> mmol/L (mg/dL)	<i>SD</i> mmol/L (mg/dL)	<i>CV</i> %
Precinorm U	5.38 (96.9)	0.07 (1.3)	1.3
Precipath U	13.4 (241)	0.2 (4)	1.1
Human serum 3	7.61 (137)	0.09 (2)	1.2
Human serum 4	5.28 (95.1)	0.06 (1.1)	1.1

*Urine***GLUC3:**

<i>Repeatability</i>	<i>Mean</i> mmol/L (mg/dL)	<i>SD</i> mmol/L (mg/dL)	<i>CV</i> %
Control level 1	1.62 (29.2)	0.03 (0.5)	1.7
Control level 2	15.8 (285)	0.1 (2)	0.7
Human urine A	0.833 (15.0)	0.015 (0.3)	1.8
Human urine B	32.6 (587)	0.2 (4)	0.5
Human urine C	3.71 (66.9)	0.04 (0.7)	1.1

SGLU3:

<i>Repeatability</i>	<i>Mean</i> mmol/L (mg/dL)	<i>SD</i> mmol/L (mg/dL)	<i>CV</i> %
Control level 1	1.64 (29.6)	0.03 (0.5)	1.6
Control level 2	16.1 (290)	0.1 (2)	0.8
Human urine A	0.842 (15.2)	0.014 (0.3)	1.6
Human urine B	33.1 (596)	0.2 (4)	0.5
Human urine C	3.79 (68.3)	0.03 (0.5)	0.9

GLUC3 / SGLU3:

<i>Intermediate precision</i>	<i>Mean</i> mmol/L (mg/dL)	<i>SD</i> mmol/L (mg/dL)	<i>CV</i> %
Control level 1	1.51 (27.2)	0.01 (0.2)	1.0
Control level 2	15.4 (278)	0.1 (2)	0.8
Human urine 3	4.86 (87.6)	0.05 (0.9)	1.0
Human urine 4	10.3 (186)	0.1 (2)	0.8

*CSF***GLUC3:**

<i>Repeatability</i>	<i>Mean</i> mmol/L (mg/dL)	<i>SD</i> mmol/L (mg/dL)	<i>CV</i> %
Precinorm U	5.11 (92.1)	0.03 (0.5)	0.7
Precipath U	13.4 (241)	0.1 (2)	0.7
Human CSF A	1.57 (28.3)	0.01 (0.2)	0.6
Human CSF B	20.5 (369)	0.2 (4)	0.8
Human CSF C	35.7 (643)	0.1 (2)	0.4

SGLU3:

Repeatability	Mean mmol/L (mg/dL)	SD mmol/L (mg/dL)	CV %
Precinorm U	5.09 (91.7)	0.04 (0.7)	0.7
Precipath U	13.4 (241)	0.1 (2)	0.5
Human CSF A	1.57 (28.3)	0.01 (0.2)	0.6
Human CSF B	20.4 (368)	0.1 (2)	0.7
Human CSF C	35.5 (640)	0.2 (4)	0.4

GLUC3 / SGLU3:

Intermediate precision	Mean mmol/L (mg/dL)	SD mmol/L (mg/dL)	CV %
Precinorm U	5.37 (96.8)	0.07 (1.3)	1.3
Precipath U	13.4 (241)	0.2 (4)	1.1
Human CSF 3	3.00 (54.1)	0.04 (0.7)	1.5
Human CSF 4	8.30 (150)	0.10 (2)	1.2

Results for intermediate precision were obtained on the master system **cobas c** 501 analyzer.

Method comparison

Glucose values for human serum, plasma, urine and CSF samples obtained on a **cobas c** 701 analyzer (y) were compared with those determined using the corresponding reagent on a **cobas c** 501 analyzer (x).

*Serum/plasma***GLUC3:**

Sample size (n) = 98

Passing/Bablok ¹³	Linear regression
$y = 1.003x + 0.000$ mmol/L	$y = 1.003x - 0.006$ mmol/L
$\tau = 0.981$	$r = 1.000$

The sample concentrations were between 1.25 and 40.4 mmol/L (22.5 and 728 mg/dL).

SGLU3:

Sample size (n) = 98

Passing/Bablok ¹³	Linear regression
$y = 1.004x - 0.015$ mmol/L	$y = 1.008x - 0.061$ mmol/L
$\tau = 0.982$	$r = 1.000$

The sample concentrations were between 1.25 and 40.4 mmol/L (22.5 and 728 mg/dL).

*Urine***GLUC3:**

Sample size (n) = 73

Passing/Bablok ¹³	Linear regression
$y = 0.005x + 0.017$ mmol/L	$y = 1.009x - 0.000$ mmol/L
$\tau = 0.991$	$r = 1.000$

The sample concentrations were between 0.30 and 37.5 mmol/L (5.41 and 676 mg/dL).

SGLU3:

Sample size (n) = 74

Passing/Bablok ¹³	Linear regression
$y = 0.995x + 0.001$ mmol/L	$y = 0.994x - 0.047$ mmol/L
$\tau = 0.981$	$r = 1.000$

The sample concentrations were between 0.303 and 41.6 mmol/L (5.46 and 750 mg/dL).

CSF**GLUC3:**

Sample size (n) = 84

Passing/Bablok ¹³	Linear regression
$y = 1.000x + 0.030$ mmol/L	$y = 0.990x + 0.100$ mmol/L
$\tau = 0.982$	$r = 1.000$

The sample concentrations were between 0.18 and 41.6 mmol/L (3.24 and 750 mg/dL).

SGLU3:

Sample size (n) = 84

Passing/Bablok ¹³	Linear regression
$y = 0.993x + 0.017$ mmol/L	$y = 0.983x + 0.076$ mmol/L
$\tau = 0.985$	$r = 1.000$

The sample concentrations were between 0.18 and 41.6 mmol/L (3.24 and 750 mg/dL).

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Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see dialog.roche.com for definition of symbols used):

CONTENT

Contents of kit



Volume after reconstitution or mixing

GTIN

Global Trade Item Number

GLUC3

Glucose HK Gen.3



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