GLUC2

cobas®

Glucose HK

Order information

REF	CONTENT		Analyzer(s) on which **cobas c** pack(s) can be used
20767131 322	Glucose HK 200 tests	System-ID 07 6713 1	Roche/Hitachi **cobas c** 311, **cobas c** 501/502
10759350 190	Calibrator f.a.s. (12 x 3 mL)	Code 401	
12149435 122	Precinorm U plus (10 x 3 mL)	Code 300	
12149443 122	Precipath U plus (10 x 3 mL)	Code 301	
10171743 122	Precinorm U (20 x 5 mL)	Code 300	
10171735 122	Precinorm U (4 x 5 mL)	Code 300	
10171778 122	Precipath U (20 x 5 mL)	Code 301	
10171760 122	Precipath U (4 x 5 mL)	Code 301	
05117003 190	PreciControl ClinChem Multi 1 (20 x 5 mL)	Code 391	
05947626 190	PreciControl ClinChem Multi 1 (4 x 5 mL)	Code 391	
05117216 190	PreciControl ClinChem Multi 2 (20 x 5 mL)	Code 392	
05947774 190	PreciControl ClinChem Multi 2 (4 x 5 mL)	Code 392	
04489357 190	Diluent NaCl 9 % (50 mL)	System-ID 07 6869 3	

English

System information

Serum/plasma/urine/CSF application

For **cobas c** 311/501 analyzers:

GLUC2: ACN 767

SGLU2: ACN 525 (STAT, reaction time: 5)

For **cobas c** 502 analyzer:

GLUC2: ACN 8767

SGLU2: ACN 8525 (STAT, reaction time: 5)

Separate working instructions for hemolysate applications are available. (Not for USA.)

Hemolysate application

For **cobas c** 311/501 analyzers:

GLUH2: ACN 409 (hemolysate)

SGLH2: ACN 408 (hemolysate STAT, reaction time: 5)

For **cobas c** 502 analyzer:

GLUH2: ACN 8409 (hemolysate)

SGLH2: ACN 8408 (hemolysate STAT, reaction time: 5)

Hemolysate application plasma-level

For **cobas c** 311/501 analyzers:

GLU2P: ACN 756 (hemolysate)

SGL2P: ACN 757 (hemolysate STAT, reaction time: 5)

For **cobas c** 502 analyzer:

GLU2P: ACN 8756 (hemolysate)

SGL2P: ACN 8757 (hemolysate STAT, reaction time: 5)

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.

$$\text{Glucose} + \text{ATP} \xrightarrow{\text{HK}} \text{G-6-P} + \text{ADP}$$

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.

$$\text{G-6-P} + \text{NADP}^+ \xrightarrow{\text{G-6-PDH}} \text{gluconate-6-P} + \text{NADPH} + \text{H}^+$$

Reagents - working solutions

R1 TRIS buffer: 100 mmol/L, pH 7.8; Mg^{2+}: 4 mmol/L; ATP: ≥ 1.7 mmol/L; NADP: ≥ 1.0 mmol/L; preservative

R2 HEPES buffer: 30 mmol/L, pH 7.0; Mg^{2+}: 4 mmol/L; HK (yeast): ≥ 130 µkat/L; G-6-PDH (E. coli): ≥ 250 µkat/L; preservative

R1 is in position B and 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.

Reagent handling

Ready for use

Storage and stability

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Shelf life at 2-8 °C:	See expiration date on **cobas c** pack label.
On-board in use and refrigerated on the analyzer:	8 weeks
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:	12 weeks

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, K_2-EDTA, NaF/Na_2EDTA, KF/Na_2EDTA, NaF/K-Oxalate and NaF/citrate/Na_2-EDTA.

Collect blood by venipuncture from fasting individuals using an evacuated tube system. 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.

Stability (no hemolysis):[5]	8 hours at 15-25 °C
	72 hours at 2-8 °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 311 **test definition**

Assay type	2-Point End	
Reaction time / Assay points	10 / 6-24 (STAT 5 / 6-24)	
Wavelength (sub/main)	700/340 nm	
Reaction direction	Increase	
Units	mmol/L (mg/dL, g/L)	
Reagent pipetting		Diluent (H_2O)
R1	150 µL	–
R2	30 µL	20 µL

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	2 µL	–	–
Decreased	10 µL	15 µL	135 µL
Increased	2 µL	–	–

cobas c 501 **test definition**

Assay type	2-Point End	
Reaction time / Assay points	10 / 10-34 (STAT 5 / 10-34)	
Wavelength (sub/main)	700/340 nm	
Reaction direction	Increase	
Units	mmol/L (mg/dL, g/L)	
Reagent pipetting		Diluent (H_2O)
R1	150 µL	–
R2	30 µL	20 µL

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	2 µL	–	–
Decreased	10 µL	15 µL	135 µL
Increased	2 µL	–	–

cobas c 502 **test definition**

Assay type	2-Point End	
Reaction time / Assay points	10 / 10-34 (STAT 5 / 10-34)	
Wavelength (sub/main)	700/340 nm	
Reaction direction	Increase	
Units	mmol/L (mg/dL, g/L)	
Reagent pipetting		Diluent (H_2O)
R1	150 µL	–
R2	30 µL	20 µL

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	2 µL	–	–
Decreased	10 µL	15 µL	135 µL
Increased	4 µL	–	–

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Calibration

Calibrators	S1: H_2O S2: C.f.a.s.
Calibration mode	Linear
Calibration frequency	2-point calibration • after reagent lot change • as required following quality control procedures

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

Quality control

Serum/plasma/CSF/urine

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

Roche/Hitachi **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.[8,9]

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

ACTION REQUIRED

Special Wash Programming: The use of special wash steps is mandatory when certain test combinations are run together on Roche/Hitachi **cobas c** systems. The latest version of the carry-over evasion list can be found with the NaOHD/SMS/Multiclean/SCCS or the NaOHD/SMS/SmpCln1+2/SCCS Method Sheets. For further instructions refer to the operator's manual. **cobas c** 502 analyzer: All special wash programming necessary for avoiding carry-over is available via the **cobas** link, manual input is not required.

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

Serum, plasma, urine and CSF

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).

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: with repeatability (n = 21) and intermediate precision (3 aliquots per run, 1 run per day, 21 days); urine/CSF: with repeatability (n = 21) and intermediate precision (3 aliquots per run, 1 run per day, 10 days). The following results were obtained:

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Serum/plasma

Repeatability	*Mean mmol/L (mg/dL)*	*SD mmol/L (mg/dL)*	*CV %*
Precinorm U	5.58 (101)	0.05 (1)	0.9
Precipath U	13.7 (247)	0.11 (2)	0.8
Human serum 1	5.51 (99.2)	0.04 (0.7)	0.8
Human serum 2	6.58 (119)	0.05 (1)	0.7
Intermediate precision	*Mean mmol/L (mg/dL)*	*SD mmol/L (mg/dL)*	*CV %*
Precinorm U	5.53 (99.7)	0.08 (1.4)	1.5
Precipath U	13.7 (247)	0.2 (4)	1.4
Human serum 3	5.49 (98.9)	0.07 (1.3)	1.2
Human serum 4	6.55 (118)	0.09 (2)	1.4

Urine

Repeatability	*Mean mmol/L (mg/dL)*	*SD mmol/L (mg/dL)*	*CV %*
Control Level 1	1.61 (29.0)	0.01 (0.2)	0.9
Control Level 2	16.6 (299)	0.1 (2)	0.6
Human urine 1	12.4 (223)	0.1 (2)	0.8
Human urine 2	7.65 (138)	0.08 (1)	1.0
Intermediate precision	*Mean mmol/L (mg/dL)*	*SD mmol/L (mg/dL)*	*CV %*
Control Level 1	1.61 (29.0)	0.04 (0.7)	2.3
Control Level 2	16.4 (296)	0.2 (4)	1.4
Human urine 3	12.4 (223)	0.1 (2)	1.1
Human urine 4	7.60 (137)	0.08 (1)	1.1

CSF

Repeatability	*Mean mmol/L (mg/dL)*	*SD mmol/L (mg/dL)*	*CV %*
Precinorm U	5.36 (96.6)	0.03 (0.5)	0.6
Precipath U	13.3 (240)	0.1 (2)	0.8
Human CSF 1	3.87 (69.7)	0.02 (0.4)	0.6
Human CSF 2	7.80 (141)	0.08 (1)	1.0
Intermediate precision	*Mean mmol/L (mg/dL)*	*SD mmol/L (mg/dL)*	*CV %*
Precinorm U	5.40 (97.3)	0.07 (1.3)	1.3
Precipath U	13.3 (240)	0.1 (2)	0.9
Human CSF 3	3.87 (69.7)	0.05 (0.9)	1.2
Human CSF 4	7.78 (140)	0.09 (2)	1.1

Method comparison

Glucose values for human serum, plasma, urine and CSF samples obtained on a Roche/Hitachi **cobas c** 501 analyzer (y) were compared with those determined using the corresponding reagent on a Roche/Hitachi 917 analyzer (x).

Serum/plasma

Sample size (n) = 149

Passing/Bablok[13]	Linear regression
y = 1.006x + 0.072 mmol/L	y = 1.008x + 0.070 mmol/L
τ = 0.969	r = 1.000

The sample concentrations were between 2.22 and 30.5 mmol/L (40.0 and 550 mg/dL).

Urine

Sample size (n) = 136

Passing/Bablok[13]	Linear regression
y = 0.974x + 0.018 mmol/L	y = 0.965x + 0.048 mmol/L
τ = 0.949	r = 1.000

The sample concentrations were between 0.10 and 39.6 mmol/L (1.80 and 713 mg/dL).

CSF

Sample size (n) = 72

Passing/Bablok[13]	Linear regression
y = 0.998x + 0.009 mmol/L	y = 0.994x + 0.042 mmol/L
τ = 0.958	r = 1.000

The sample concentrations were between 1.88 and 38.7 mmol/L (33.9 and 697 mg/dL).

References

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9 Sonntag O, Scholer A. Drug interference in clinical chemistry: recommendation of drugs and their concentrations to be used in drug interference studies. Ann Clin Biochem 2001;38:376-385.

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A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard.

CONTENT	Contents of kit
→	Volume after reconstitution or mixing

Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim
www.roche.com