GLUC3

cobas®

Glucose HK Gen.3

Order information

REF		CONTENT		Analyzer(s) on which **cobas c** pack(s) can be used
08057800190*	08057800500	Glucose HK Gen.3 (3300 tests)	System-ID 2063 001	**cobas c** 303, **cobas c** 503, **cobas c** 703
08057800214*	08057800500	Glucose HK Gen.3 (3300 tests)	System-ID 2063 001	**cobas c** 303, **cobas c** 503, **cobas c** 703

Materials required (but not provided):

10759350190	Calibrator f.a.s. (12 x 3 mL)	Code 20401	
05117003190	PreciControl ClinChem Multi 1 (20 x 5 mL)	Code 20391	
05947626190	PreciControl ClinChem Multi 1 (4 x 5 mL)	Code 20391	
05117216190	PreciControl ClinChem Multi 2 (20 x 5 mL)	Code 20392	
05947774190	PreciControl ClinChem Multi 2 (4 x 5 mL)	Code 20392	
08063494190	Diluent NaCl 9 % (123 mL)	System-ID 2906 001	

* Some kits shown may not be available in all countries.

English

System information

GLUC3: ACN 20630 (Serum/plasma)

GLUC3U: ACN 20631 (Urine)

GLUC3C: ACN 20632 (CSF)

Intended use

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

Summary

Glucose measurement in serum and plasma with this device can be used to aid in diagnosis and monitoring of hypo- and hyperglycemia, in the context of an altered carbohydrate metabolism state.

In urine, glucose measurement with this device can be used as an aid in diagnosing glycosuria in the context of altered carbohydrate metabolism states and/or kidney disease.

In CSF glucose measurement with this device can be used to aid in diagnosis and monitoring of central nervous system infections, such as meningitis and encephalitis of different etiologies.

Glucose is the major carbohydrate present in the peripheral blood.[1] Oxidation of glucose is the major source of cellular energy in the body.[2] 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.[1,2] The most frequent cause of hyperglycemia is diabetes mellitus resulting from a deficiency in insulin secretion or action.[1] Hypoglycemia is less frequently observed.[2] A variety of conditions may cause low blood glucose levels such as insulinoma, insulin induced hypoglycemia, or hypopituitarism.[2,3]

Under normal circumstances, almost all the glucose filtered by the glomerulus is reabsorbed in the proximal convoluted tubule.[4] In case of hyperglycemia, as occurs in diabetes mellitus, the tubular transport capacity of glucose is overwhelmed and glucose appears in the urine (glycosuria).[5] Furthermore, glycosuria occurs in the absence of hyperglycemia when the reabsorption of glucose by renal tubules is compromised.[4]

CSF glucose level and the corresponding plasma glucose ratio are usually altered (low) in certain types of central nervous system infections, such as bacterial and tuberculous meningitis. Whereas CSF glucose level and plasma glucose ratio concentration is typically normal during most viral CNS infections.[6,7] However, the spectrum of CSF glucose levels in bacterial meningitis is wide and there is substantial overlap with the findings in viral infection. Therefore, clinical evaluation and other laboratory tests are needed to guide treatment decisions besides the results of the CSF glucose and CSF plasma glucose ratio.[8]

Test principle

Enzymatic reference method with hexokinase.[9,10]

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 MES buffer: 5.0 mmol/L, pH 6.0; Mg^{2+}: 24 mmol/L; ATP: ≥ 4.5 mmol/L; NADP: ≥ 7.0 mmol/L; preservative

R3 HEPES buffer: 200 mmol/L, pH 8.0; Mg^{2+}: 4 mmol/L; HK (yeast): ≥ 300 µkat/L; G-6-PDH (E. coli): ≥ 300 µkat/L; preservative

R1 is in position B and R3 is in position C.

Precautions and warnings

For in vitro diagnostic use for health care professionals. Exercise the normal precautions required for handling all laboratory reagents.

Infectious or microbial waste:
Warning: handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards:
Apply all relevant local disposal regulations to determine the safe disposal.

Safety data sheet available for professional user on request.

This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:

Warning

H315 Causes skin irritation.

H319 Causes serious eye irritation.

Prevention:

P264 Wash skin thoroughly after handling.

P280 Wear protective gloves/ eye protection/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.

P332 + P313 If skin irritation occurs: Get medical advice/attention.

P337 + P313 If eye irritation persists: Get medical advice/attention.

P362 + P364 Take off contaminated clothing and wash it before reuse.

Product safety labeling follows EU GHS guidance.
Contact phone: all countries: +49-621-7590

Reagent handling
Ready for use

Storage and stability

Shelf life at 2-8 °C:	See expiration date on **cobas c** pack label.
On-board in use and refrigerated on the analyzer:	26 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.

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.[11]

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.

Centrifuge samples containing precipitates before performing the assay.

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

Stability:[10]	8 hours at 15-25 °C
	72 hours at 2-8 °C
Stability in fluoride plasma:[12]	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.[13] Therefore, keep samples on ice during collection.[10] If stabilizers are added to the sample, the sample index feature must not be used.

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 2-8 °C or -20 °C (± 5 °C).[13,10]

Freeze only once.

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

Test definition

Reporting time	10 min	
Wavelength (sub/main)	700/340 nm	
Reagent pipetting		Diluent (H_2O)
R1	21 µL	106 µL
R3	8 µL	15 µL

Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	1.5 µL	–	–
Decreased	3 µL	20 µL	60 µL
Increased	1.5 µL	–	–

For further information about the assay test definitions refer to the application parameters setting screen of the corresponding analyzer and assay.

Calibration

Application for serum/plasma (ACN 20630)

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

Application for urine (ACN 20631)
Transfer of calibration from serum/plasma application (ACN 20630)

Application for CSF (ACN 20632)
Transfer of calibration from serum/plasma application (ACN 20630)

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.

Serum/plasma:	PreciControl ClinChem Multi 1, PreciControl ClinChem Multi 2
Urine:	Quantitative urine controls are recommended for routine quality control.
CSF:	Quantitative CSF controls are recommended for routine quality control.

The control intervals and limits should be adapted to each laboratory's individual requirements. It is recommended to perform quality control always after lot calibration and subsequently at least every 26 weeks.

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 in the unit mmol/L (mg/dL, g/L).

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

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Limitations - interference

Serum/plasma

Criterion: Recovery within ± 0.39 mmol/L of initial values of samples ≤ 3.9 mmol/L and within ± 10 % of samples > 3.9 mmol/L.

Icterus:[14] 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:[14] No significant interference up to an H index of 1000 (approximate hemoglobin concentration: 621 µmol/L or 1000 mg/dL).

Lipemia (Intralipid):[14] 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.[15,16]

In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.[17]

Urine

Criterion: Recovery within ± 0.11 mmol/L of initial values of samples ≤ 1.1 mmol/L and within ± 10 % of samples > 1.1 mmol/L.

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

Hemolysis: No significant interference up to an H index of 750 (approximate hemoglobin concentration: 466 µmol/L or 750 mg/dL).

Drugs: No interference was found at therapeutic concentrations using common drug panels.[16]

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

CSF

Criterion: Recovery within ± 0.22 mmol/L of initial values of samples ≤ 2.2 mmol/L and within ± 10 % of samples > 2.2 mmol/L.

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

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

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. The latest version of the carry-over evasion list can be found with the NaOHD/SMS/SCCS Method Sheet. For further instructions, refer to the operator's manual.

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

Limit of Blank, Limit of Detection and Limit of Quantitation

Limit of Blank	= 0.11 mmol/L (2 mg/dL)
Limit of Detection	= 0.11 mmol/L (2 mg/dL)
Limit of Quantitation	= 0.11 mmol/L (2 mg/dL)

The Limit of Blank, Limit of Detection and Limit of Quantitation were determined in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP17-A2 requirements.

The Limit of Blank is the 95th percentile value from n ≥ 60 measurements of analyte-free samples over several independent series. The Limit of Blank corresponds to the concentration below which analyte-free samples are found with a probability of 95 %.

The Limit of Detection is determined based on the Limit of Blank and the standard deviation of low concentration samples.

The Limit of Detection corresponds to the lowest analyte concentration which can be detected (value above the Limit of Blank with a probability of 95 %).

The Limit of Quantitation is the lowest analyte concentration that can be reproducibly measured with a total error of 20 %. It has been determined using low concentration glucose samples.

Expected values

mmol/L

Plasma[18]

Fasting	4.11-6.05 mmol/L

*Urine**[19]

1st morning urine	0.3-1.1 mmol/L
24-hour urine	0.3-0.96 mmol/L
	(average of 1350 mL urine/24 h)

* calculated by unit conversion factor

acc. to Tietz:[10]

Serum, plasma

Adults	4.11-5.89 mmol/L
60-90 years	4.56-6.38 mmol/L
> 90 years	4.16-6.72 mmol/L
Children	3.33-5.55 mmol/L
Neonates (1 day)	2.22-3.33 mmol/L
Neonates (> 1 day)	2.78-4.44 mmol/L

Urine

24-hour urine	< 2.78 mmol/24 h
Random urine	0.06-0.83 mmol/L

CSF

Children	3.33-4.44 mmol/L
Adults	2.22-3.89 mmol/L

mg/dL

Plasma[18]

Fasting	74-109 mg/dL

*Urine**[19]

1st morning urine	6-20 mg/dL
24-hour urine	6-17 mg/dL
	(average of 1350 mL urine/24 h)

* calculated by unit conversion factor

acc. to Tietz:[10]

Serum, plasma

Adults	74-106 mg/dL
60-90 years	82-115 mg/dL
> 90 years	75-121 mg/dL
Children	60-100 mg/dL
Neonates (1 day)	40-60 mg/dL
Neonates (> 1 day)	50-80 mg/dL

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Urine	
24-hour urine	< 2.78 mmol/24 h (< 0.5 g/24 h)
Random urine	1-15 mg/dL

CSF	
Children	60-80 mg/dL
Adults	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.

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. These data represent the performance of the analytical procedure itself.

Results obtained in individual laboratories may differ due to heterogenous sample materials, aging of analyzer components and mixture of reagents running on the analyzer.

Precision

Precision was determined using human samples and controls in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP05-A3 requirements with repeatability (n = 84) and intermediate precision (2 aliquots per run, 2 runs per day, 21 days). Results for repeatability and intermediate precision were obtained on the **cobas c** 503 analyzer.

Serum/plasma

Repeatability	*Mean* *mmol/L*	*SD* *mmol/L*	*CV* *%*
PCCC1[a)]	5.61	0.0315	0.6
PCCC2[b)]	12.6	0.0523	0.4
Human serum 1	0.188	0.0174	9.2
Human serum 2	3.57	0.0181	0.5
Human serum 3	5.46	0.0233	0.4
Human serum 4	19.6	0.121	0.6
Human serum 5	38.6	0.188	0.5

Intermediate precision	*Mean* *mmol/L*	*SD* *mmol/L*	*CV* *%*
PCCC1[a)]	5.61	0.0559	1.0
PCCC2[b)]	12.8	0.106	0.8
Human serum 1	0.188	0.0188	10.0
Human serum 2	3.57	0.0212	0.6
Human serum 3	5.46	0.0297	0.5
Human serum 4	19.6	0.136	0.7
Human serum 5	38.6	0.216	0.6

a) PreciControl ClinChem Multi 1

b) PreciControl ClinChem Multi 2

Urine

Repeatability	*Mean* *mmol/L*	*SD* *mmol/L*	*CV* *%*
Control 1[c)]	1.09	0.0215	2.0
Control 2[c)]	16.4	0.0655	0.4
Human urine 1	0.227	0.0188	8.3
Human urine 2	0.733	0.0143	1.9
Human urine 3	4.10	0.0418	1.0
Human urine 4	22.0	0.182	0.8
Human urine 5	40.6	0.173	0.4

Intermediate precision	*Mean* *mmol/L*	*SD* *mmol/L*	*CV* *%*
Control 1[c)]	1.09	0.0278	2.5
Control 2[c)]	16.4	0.122	0.7
Human urine 1	0.215	0.0183	8.5
Human urine 2	0.744	0.0180	2.4
Human urine 3	4.07	0.0478	1.2
Human urine 4	22.0	0.452	2.1
Human urine 5	40.4	0.344	0.8

CSF

Repeatability	*Mean* *mmol/L*	*SD* *mmol/L*	*CV* *%*
Control 1[c)]	3.31	0.0119	0.4
Control 2[c)]	1.66	0.00970	0.6
Human CSF 1	0.273	0.00831	3.0
Human CSF 2	2.16	0.0180	0.8
Human CSF 3	3.81	0.0172	0.5
Human CSF 4	20.2	0.0824	0.4
Human CSF 5	39.9	0.193	0.5

Intermediate precision	*Mean* *mmol/L*	*SD* *mmol/L*	*CV* *%*
Control 1[c)]	3.34	0.0163	0.5
Control 2[c)]	1.66	0.0109	0.7
Human CSF 1	0.273	0.00966	3.5
Human CSF 2	2.16	0.0212	1.0
Human CSF 3	3.81	0.0240	0.6
Human CSF 4	20.2	0.0994	0.5
Human CSF 5	39.9	0.230	0.6

c) commercially available control material

The data obtained on **cobas c** 503 analyzer(s) are representative for **cobas c** 303 analyzer(s) and **cobas c** 703 analyzer(s).

Method comparison

Glucose values for human serum, plasma, urine and CSF samples obtained on a **cobas c** 503 analyzer (y) were compared with those determined using the corresponding reagent on a **cobas c** 501 analyzer (x).

Serum/plasma

Sample size (n) = 74

Passing/Bablok[20]	Linear regression
y = 1.000x - 0.0200 mmol/L	y = 0.997x - 0.00454 mmol/L
τ = 0.987	r = 1.000

The sample concentrations were between 0.320 and 40.3 mmol/L.

Urine

Sample size (n) = 67

Passing/Bablok[20]	Linear regression
y = 0.995x - 0.0447 mmol/L	y = 0.995x - 0.0402 mmol/L
τ = 0.982	r = 1.000

The sample concentrations were between 0.170 and 40.9 mmol/L.

CSF
Sample size (n) = 75

Passing/Bablok[20]	Linear regression
y = 1.000x + 0.00400 mmol/L	y = 1.001x + 0.0287 mmol/L
τ = 0.957	r = 0.999

The sample concentrations were between 0.200 and 40.8 mmol/L.

Glucose values for human serum, plasma, urine and CSF samples obtained on a **cobas c** 303 analyzer (y) were compared with those determined using the corresponding reagent on a **cobas c** 501 analyzer (x).

Serum/plasma
Sample size (n) = 69

Passing/Bablok[20]	Linear regression
y = 1.006x - 0.00351 mmol/L	y = 1.009x - 0.0366 mmol/L
τ = 0.977	r = 1.000

The sample concentrations were between 0.110 and 40.3 mmol/L.

Urine
Sample size (n) = 71

Passing/Bablok[20]	Linear regression
y = 1.012x - 0.0233 mmol/L	y = 1.022x - 0.0527 mmol/L
τ = 0.982	r = 1.000

The sample concentrations were between 0.130 and 40.3 mmol/L.

CSF
Sample size (n) = 66

Passing/Bablok[20]	Linear regression
y = 1.019x + 0.0138 mmol/L	y = 1.020x + 0.0122 mmol/L
τ = 0.975	r = 1.000

The sample concentrations were between 0.290 and 39.4 mmol/L.

Glucose values for human serum, plasma, urine and CSF samples obtained on a **cobas c** 703 analyzer (y) were compared with those determined using the corresponding reagent on a **cobas c** 503 analyzer (x).

Serum/plasma
Sample size (n) = 74

Passing/Bablok[20]	Linear regression
y = 0.995x - 0.00537 mmol/L	y = 0.999x - 0.0120 mmol/L
τ = 0.990	r = 1.000

The sample concentrations were between 0.200 and 40.2 mmol/L.

Urine
Sample size (n) = 67

Passing/Bablok[20]	Linear regression
y = 0.998x + 0.0116 mmol/L	y = 1.001x + 0.0119 mmol/L
τ = 0.950	r = 1.000

The sample concentrations were between 0.113 and 40.5 mmol/L.

CSF
Sample size (n) = 75

Passing/Bablok[20]	Linear regression
y = 0.987x - 0.0130 mmol/L	y = 0.989x - 0.0144 mmol/L
τ = 0.984	r = 1.000

The sample concentrations were between 0.154 and 40.5 mmol/L.

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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.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

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 for reconstitution

GLUC3

Glucose HK Gen.3

GTIN	Global Trade Item Number
Rx only	For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

CE 0123

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