GLUC3

Glucose HK Gen.3

cobas®

Substrates

Order information

REF	CONTENT		Analyzer(s) on which **cobas c** pack(s) can be used
04404483 190	Glucose HK Gen.3 (800 tests)	System-ID 07 6831 6	COBAS INTEGRA 400 plus COBAS INTEGRA 800
10759350 190	Calibrator f.a.s. (12 × 3 mL)	System-ID 07 3718 6	
12149435 122	Precinorm U plus (10 × 3 mL)	System-ID 07 7999 7	
12149443 122	Precipath U plus (10 × 3 mL)	System-ID 07 8000 6	
10171743 122	Precinorm U (20 × 5 mL)	System-ID 07 7997 0	
10171735 122	Precinorm U (4 × 5 mL)	System-ID 07 7997 0	
10171778 122	Precipath U (20 × 5 mL)	System-ID 07 7998 9	
10171760 122	Precipath U (4 × 5 mL)	System-ID 07 7998 9	
05117003 190	PreciControl ClinChem Multi 1 (20 × 5 mL)	System-ID 07 7469 3	
05947626 190	PreciControl ClinChem Multi 1 (4 × 5 mL)	System-ID 07 7469 3	
05117216 190	PreciControl ClinChem Multi 2 (20 × 5 mL)	System-ID 07 7470 7	
05947774 190	PreciControl ClinChem Multi 2 (4 × 5 mL)	System-ID 07 7470 7	

English

System information

Test GLUC3, test ID 0-031 (serum, plasma);
Test GLU3U, test ID 0-141 (urine);
Test GLU3C, test ID 0-051 (CSF);
Test SGLU3, test ID 0-231 (serum, plasma STAT);
Test SGL3U, test ID 0-241 (urine STAT);
Test SGL3C, test ID 0-251 (CSF STAT)

Intended use

In vitro test for the quantitative determination of glucose in serum, plasma, urine, and cerebrospinal fluid (CSF) on COBAS INTEGRA 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.

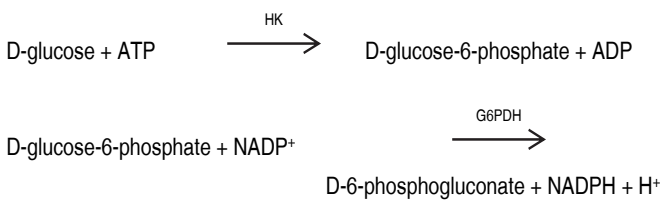
The most frequent cause of hyperglycemia is diabetes mellitus resulting from a deficiency in insulin secretion or action. A number of secondary factors also contribute to elevated blood glucose levels. These include pancreatitis, thyroid dysfunction, renal failure, and liver disease.

Hypoglycemia is less frequently observed. A variety of conditions may cause low blood glucose levels such as insulinoma, hypopituitarism, or insulin induced hypoglycemia. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus and idiopathic hypoglycemia. Glucose measurement in urine is used as a diabetes screening procedure and to aid in the evaluation of glucosuria, 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

Enzymatic reference method with hexokinase.[4,5]

Hexokinase (HK) catalyzes the phosphorylation of glucose by ATP to form glucose-6-phosphate and ADP. To follow the reaction, a second enzyme, glucose-6-phosphate dehydrogenase (G6PDH) is used to catalyze oxidation of glucose-6-phosphate by $NADP^+$ to form NADPH.



The concentration of the NADPH formed is directly proportional to the glucose concentration. It is determined by measuring the increase in absorbance at 340 nm.

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

SR HEPES buffer: 200 mmol/L; pH 8.0; Mg^{2+}: 4 mmol/L; HK (yeast): ≥ 300 µkat/L; G6PDH (microbial): ≥ 300 µkat/L

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

Precautions and warnings

Pay attention to all precautions and warnings listed in Section 1 / Introduction of this Method Manual.

Reagent handling

Ready for use

Storage and stability

Shelf life at 2-8 °C	See expiration date on **cobas c** pack label
COBAS INTEGRA 400 plus system	
On-board in use at 10-15 °C	8 weeks
COBAS INTEGRA 800 system	
On-board in use at 8 °C	8 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, K_3-EDTA, NaF/Na_2-EDTA, NaF/citrate/Na_2-EDTA, KF/Na_2-EDTA, and NaF/K-oxalate plasma.

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]

Centrifuge samples containing precipitates before performing the assay.

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]

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.

Materials provided

See "Reagents – working solutions" section for reagents.

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.

Applications for serum, plasma, urine and CSF

COBAS INTEGRA 400 plus test definition

Measuring mode	Absorbance
Abs. calculation mode	Endpoint
Reaction mode	R1-S-SR
Reaction direction	Increase
Wavelength A/B	340/652 nm
Calc. first/last	
Test IDs 0-031, 0-141, 0-051	33/69
Test IDs 0-231, 0-241, 0-251	33/46
Unit	mmol/L

Pipetting parameters

		Diluent (H_2O)
R1	28 µL	125 µL
Sample	2 µL	16 µL
SR	10 µL	20 µL
Total volume	201 µL	

COBAS INTEGRA 800 test definition

Measuring mode	Absorbance
Abs. calculation mode	Endpoint
Reaction mode	R1-S-SR
Reaction direction	Increase
Wavelength A/B	340/652 nm
Calc. first/last	
Test IDs 0-031, 0-141, 0-051	44/98
Test IDs 0-231, 0-241, 0-251	44/66
Unit	mmol/L

Pipetting parameters

		Diluent (H_2O)
R1	28 µL	125 µL
Sample	2 µL	16 µL
SR	10 µL	20 µL
Total volume	201 µL	

Calibration

Calibrator	Calibrator f.a.s. Use deionized water as zero calibrator.
Calibration mode	Linear regression
Calibration replicate	Duplicate recommended
Calibration interval	Each lot and as required following quality control procedures

Traceability: This method has been standardized against ID-MS[a)].

a) Isotope Dilution Mass Spectrometry

Quality control

Quality control serum/plasma	
Reference range	Precinorm U, Precinorm U plus or PreciControl ClinChem Multi 1
Pathological range	Precipath U, Precipath U plus or PreciControl ClinChem Multi 2
Quality control urine	Quantitative urine controls are recommended for routine quality control.
Quality control CSF	Quantitative CSF controls are recommended for routine quality control.
Control interval	24 hours recommended
Control sequence	User defined
Control after calibration	Recommended

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 INTEGRA analyzers automatically calculate the analyte concentration of each sample. For more details, please refer to Data Analysis in the Online Help (COBAS INTEGRA 400 plus/800 analyzers).

Conversion factor: mmol/L × 18.02 = mg/dL

Limitations - interference

Criterion: Recovery within ± 10 % of initial value.

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)[b)].

Hemolysis:[7] No significant interference up to an H index of 1200 (approximate hemoglobin concentration: 744 µmol/L or 1200 mg/dL)[b)].

Lipemia (Intralipid):[7] No significant interference up to an L index of 1900. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration[b)].

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]

Tetracyclin at therapeutic concentration 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.

b) measured at a glucose concentration of 3.5 mmol/L with the GLUC3 test

ACTION REQUIRED

Special Wash Programming: The use of special wash steps is mandatory when certain test combinations are run together on COBAS INTEGRA analyzers. Refer to the CLEAN Method Sheet for further instructions and for the latest version of the Extra wash cycle list.

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

Limits and ranges

Measuring range

Regular applications (test IDs 0-031, 0-141, 0-051)

0.24-40 mmol/L (4.32-720 mg/dL)

STAT applications (test IDs 0-231, 0-241, 0-251)

0.24-30 mmol/L (4.32-541 mg/dL)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:10 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 10.

Lower limits of measurement

Lower detection limit of the test:

Regular applications (test IDs 0-031, 0-141, 0-051)

STAT applications (test IDs 0-231, 0-241, 0-251)

Limit of Blank and Limit of Detection:

Limit of Blank	0.12 mmol/L (2.16 mg/dL)
Limit of Detection	0.24 mmol/L (4.32 mg/dL)

The Limit of Blank and Limit of Detection were determined in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP17-A 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 %).

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

according 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-h 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.

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 COBAS INTEGRA analyzers are given below. Results obtained in individual laboratories may differ.

Precision

Serum/plasma

Precision was determined using human samples and controls in an internal protocol with repeatability (n = 84) and intermediate precision (2 aliquots per run, 2 runs per day, 21 days).

For test **GLUC3** (test ID 0-031) the following results were obtained:

Repeatability	*Mean mmol/L (mg/dL)*	*SD mmol/L (mg/dL)*	*CV %*
Human serum 1	3.57 (64.3)	0.03 (0.5)	0.7
Human serum 2	6.65 (120)	0.05 (1)	0.8
Human serum 3	36.9 (665)	0.3 (5)	0.7
Precinorm U	5.04 (90.8)	0.03 (0.5)	0.6
Precipath U	13.7 (247)	0.1 (1)	0.6

Intermediate precision	*Mean µmol/L (mg/dL)*	*SD µmol/L (mg/dL)*	*CV %*
Human serum 1	3.57 (64.3)	0.05 (0.8)	1.3
Human serum 2	6.65 (120)	0.09 (2)	1.4
Human serum 3	36.9 (665)	0.5 (9)	1.3
Precinorm U	5.04 (90.8)	0.06 (1.1)	1.2
Precipath U	13.7 (247)	0.2 (3)	1.2

For test **SGLU3** (test ID 0-231) the following results were obtained:

Repeatability	*Mean mmol/L (mg/dL)*	*SD mmol/L (mg/dL)*	*CV %*
Human serum 1	3.59 (64.7)	0.02 (0.4)	0.6
Human serum 2	6.69 (121)	0.05 (1)	0.7
Human serum 3	27.0 (487)	0.2 (4)	0.7
Precinorm U	5.07 (91.4)	0.03 (0.5)	0.6
Precipath U	13.8 (249)	0.1 (1)	0.6

Intermediate precision	*Mean µmol/L (mg/dL)*	*SD µmol/L (mg/dL)*	*CV %*
Human serum 1	3.59 (64.7)	0.04 (0.7)	1.1
Human serum 2	6.69 (121)	0.09 (2)	1.4
Human serum 3	27.0 (487)	0.3 (5)	1.1
Precinorm U	5.07 (91.4)	0.06 (1.1)	1.2
Precipath U	13.8 (249)	0.1 (3)	1.1

Urine

Precision was determined using human samples and controls in an internal protocol with repeatability (n = 84) and intermediate precision (2 aliquots per run, 2 runs per day, 21 days).

For test **GLU3U** (test ID 0-141) the following results were obtained:

Repeatability	*Mean mmol/L (mg/dL)*	*SD mmol/L (mg/dL)*	*CV %*
Human urine 1	0.480 (8.65)	0.011 (0.20)	2.3
Human urine 2	0.962 (17.3)	0.010 (0.2)	1.1
Human urine 3	37.3 (672)	0.2 (4)	0.5
Precinorm U	5.04 (90.8)	0.03 (0.5)	0.6
Precipath U	13.7 (247)	0.1 (1)	0.6

Intermediate precision	*Mean µmol/L (mg/dL)*	*SD µmol/L (mg/dL)*	*CV %*
Human urine 1	0.480 (8.65)	0.014 (0.25)	2.8
Human urine 2	0.962 (17.3)	0.013 (0.2)	1.4
Human urine 3	37.3 (672)	0.4 (7)	1.0
Precinorm U	5.04 (90.8)	0.06 (1.1)	1.2
Precipath U	13.7 (247)	0.2 (3)	1.2

For test **SGL3U** (test ID 0-241) the following results were obtained:

Repeatability	*Mean mmol/L (mg/dL)*	*SD mmol/L (mg/dL)*	*CV %*
Human urine 1	0.476 (8.58)	0.013 (0.23)	2.7
Human urine 2	0.965 (17.4)	0.011 (0.2)	1.2
Human urine 3	26.4 (476)	0.2 (3)	0.6
Precinorm U	5.07 (91.4)	0.03 (0.5)	0.6
Precipath U	13.8 (249)	0.1 (1)	0.6

Intermediate precision	*Mean µmol/L (mg/dL)*	*SD µmol/L (mg/dL)*	*CV %*
Human urine 1	0.476 (8.58)	0.015 (0.27)	3.2
Human urine 2	0.965 (17.4)	0.016 (0.3)	1.7
Human urine 3	26.4 (476)	0.3 (5)	1.1
Precinorm U	5.07 (91.4)	0.06 (1.1)	1.2
Precipath U	13.8 (249)	0.1 (3)	1.1

CSF

Precision was determined using human samples and controls in an external protocol with repeatability (n = 21).

For test **GLU3C** (test ID 0-051) the following results were obtained:

Repeatability	*Mean mmol/L (mg/dL)*	*SD mmol/L (mg/dL)*	*CV %*
Human CSF 1	3.20 (57.7)	0.04 (0.6)	1.1
Human CSF 2	9.31 (168)	0.14 (3)	1.5
Precinorm U	5.12 (92.3)	0.02 (0.4)	0.4
Precipath U	13.3 (240)	0.1 (1)	0.5

For test **SGL3C** (test ID 0-251) the following results were obtained:

Repeatability	*Mean mmol/L (mg/dL)*	*SD mmol/L (mg/dL)*	*CV %*
Human CSF 1	2.20 (39.6)	0.01 (0.2)	0.6
Human CSF 2	15.7 (283)	0.1 (1)	0.4
Human CSF 3	28.7 (517)	0.2 (3)	0.5
Precinorm U plus	5.13 (92.4)	0.03 (0.5)	0.5
Precipath U plus	13.3 (240)	0.1 (1)	0.4

Method comparison

Serum/plasma

Glucose values for human serum samples obtained on a COBAS INTEGRA 800 analyzer using the COBAS INTEGRA Glucose HK Gen.3 reagent (GLUC3) (y) were compared with those determined using GC ID-MS (x). Sample size (n) represents all replicates.
Sample size (n) = 56

COBAS INTEGRA 800 analyzer

Passing/Bablok[13]	Linear regression
y = 0.974x + 0.132 mmol/L	y = 0.974x + 0.121 mmol/L
τ = 0.951	r = 1.00
SD (md 95) = 0.215	Sy.x = 0.107

The sample concentrations were between 3.63 and 31.1 mmol/L (65.4 and 560 mg/dL).

Glucose values for human serum samples obtained on a COBAS INTEGRA 800 analyzer using the COBAS INTEGRA Glucose HK Gen.3 reagent (GLUC3) (y) were compared with those determined using the COBAS INTEGRA Glucose HK Liquid reagent (GLUCL) on a COBAS INTEGRA 800 analyzer (x). Sample size (n) represents all replicates.
Sample size (n) = 59

COBAS INTEGRA 800 analyzer

Passing/Bablok[13]	Linear regression
y = 0.971x + 0.188 mmol/L	y = 0.969x + 0.211 mmol/L
τ = 0.986	r = 1.00
SD (md 95) = 0.101	Sy.x = 0.046

The sample concentrations were between 3.61and 11.3 mmol/L (65.1 and 204 mg/dL).

Glucose values for human serum samples obtained on a COBAS INTEGRA 800 analyzer using the COBAS INTEGRA Glucose HK Gen.3 reagent (GLUC3), test GLUC3 (regular application, test ID 0-031) (y) were compared with those determined using the corresponding reagent, but test SGLU3 (STAT application, test ID 0-231) on the same analyzer. Sample size (n) represents all replicates.
Sample size (n) = 79

COBAS INTEGRA 800 analyzer

Passing/Bablok[13]	Linear regression
y = 0.997x + 0.033 mmol/L	y = 0.997x + 0.032 mmol/L
τ = 0.999	r = 1.00
SD (md 95) = 0.067	Sy.x = 0.032

The sample concentrations were between 1.92 and 29.5 mmol/L (34.6 and 532 mg/dL).

Urine

Glucose values for human urine samples obtained on a COBAS INTEGRA 800 analyzer using the COBAS INTEGRA Glucose HK Gen.3 reagent (GLUC3) (y) were compared with those determined using GC ID-MS (x). Sample size (n) represents all replicates.
Sample size (n) = 64

COBAS INTEGRA 800 analyzer

Passing/Bablok[13]	Linear regression
y = 0.998x + 0.013 mmol/L	y = 0.979x + 0.052 mmol/L
τ = 0.951	r = 1.00
SD (md 95) = 0.282	Sy.x = 0.121

The sample concentrations were between 0.027 and 38.5 mmol/L (0.487 and 694 mg/dL).

Glucose values for human urine samples obtained on a COBAS INTEGRA 800 analyzer using the COBAS INTEGRA Glucose HK Gen.3 reagent (GLUC3), test GLU3U (regular application, test ID 0-141) (y) were compared with those determined using the corresponding reagent, but test SGL3U (STAT application, test ID 0-241),

on the same analyzer (x). Sample size (n) represents all replicates.
Sample size (n) = 50

COBAS INTEGRA 800 analyzer

Passing/Bablok[13]	Linear regression
y = 1.003x - 0.002 mmol/L	y = 1.003x - 0.003 mmol/L
τ = 0.996	r = 1.00
SD (md 95) = 0.082	Sy.x = 0.041

The sample concentrations were between 0.271 and 29.8 mmol/L (4.88 and 536 mg/dL).

CSF

Glucose values for human CSF samples obtained on a COBAS INTEGRA 800 analyzer using the COBAS INTEGRA Glucose HK Gen.3 reagent (GLUC3) (y) were compared with those determined using the previous generation reagent, namely COBAS INTEGRA Glucose HK *New Formulation* (GLUC2) (x). Sample size (n) represents all replicates.
Sample size (n) = 79

COBAS INTEGRA 800 analyzer

Passing/Bablok[13]	Linear regression
y = 0.999x + 0.009 mmol/L	y = 0.996x - 0.003 mmol/L
τ = 0.931	r = 0.996
SD (md 95) = 0.156	Sy.x = 0.076

The sample concentrations were between 1.25 and 11.3 mmol/L (22.5 and 203 mg/dL).

References

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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
GTIN	Global Trade Item Number

CE

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

Roche