



cobas c 111 analyzer
Within-Run Precision Guidelines



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Revision History

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Publication Reference Number	Date	Revision purpose
2461-00-0907 Version 0	September 2007	Document creation
2461-01-1207 Version 1	December 2007	Added new clinical chemistries and specific proteins.
2461-02-0508 Version 2	May 2008	Added new clinical chemistries and specific proteins
2461-03-0314 Version 3	March 2014	Added Calcium Gen.2
2461-04-1014 Version 4	October 2014	Deleted Bilirubin direct and Calcium. Added Bilirubin Total, Gen.3

How to use these guidelines:

Where the SD and CV% information is provided, the SD specification is used to determine pass/fail criteria if the actual sample concentration is below the stated sample concentration in the table. If the actual sample concentration is equal to or above the stated sample concentration in the table, the CV% specification is used to determine pass/fail criteria.

Clinical Chemistry	SD	Sample Concentration	%CV Guideline
Albumin BCG	≤ 0.07 g/dL	3.5 g/dL	≤ 2
Alk Phos/IFCC gen. 2	≤ 2 U/L	100 U/L	≤ 2
ALT	≤ 0.9 U/L	30 U/L	≤ 3
ALT/P-5-P	≤ 1.0 U/L	35 U/L	≤ 3
Ammonia	≤ 6 µg/dL	85 µg/dl	≤ 5
p-Amylase/EPS (serum)	≤ 1 U/L	50 U/L	≤ 2
t-Amylase/EPS (serum/plasma)	≤ 2 U/L	100 U/L	≤ 2
AST	≤ 0.9 U/L	30 U/L	≤ 3
AST/P-5-P	≤ 1.0 U/L	35 U/L	≤ 3
Bilirubin, Total-Special	≤ 0.03 mg/dL	1.0 mg/dL	≤ 2.5
Bilirubin, Total Gen.3	≤ 0.05 mg/dL	0.99 mg/dL	≤ 5
Calcium Gen.2 (serum/plasma/urine)	≤ 0.16 mg/dL	8.8 mg/dL	≤ 2
Cholesterol/HP Gen 2	≤ 3.87 mg/dL	201 mg/dL	≤ 2
CK Liquid	≤ 3 U/L	140 U/L	≤ 2
CK-MB	≤ 0.8 U/L	25 U/L	≤ 3
CO2-L	≤ 0.36 mmol/L	12 mmol/L	≤ 3
Creatinine Plus ver 2-serum	≤ 0.03 mg/dL	0.9 mg/dL	≤ 3
Creatinine Plus ver 2-urine	≤ 0.85 mg/dL	28 mg/dL	≤ 3
Creatinine/Jaffe, rate blanked, compensated (serum/plasma)	≤ 0.03 mg/dL	0.9 mg/dL	≤ 3
Creatinine/Jaffe, rate blanked, compensated (urine)	≤ 0.85 mg/dL	28 mg/dL	≤ 3
GGT ver 2 (serum/plasma)	≤ 0.8 U/L	40 U/L	≤ 2
Glucose ver 2 (serum/plasma)	≤ 1.4 mg/dL	70 mg/dL	≤ 2
HDL-C plus Gen 3	≤ 1.16 mg/dL	38.7 mg/dL	≤ 3
Iron2	≤ 3.02 µg/dL	150.4 µg/dL	≤ 2
Lactate-Enzymatic	≤ 0.36 mg/dL	19.8 mg/dL	≤ 2
LDH	≤ 4 U/L	200 U/L	≤ 2
LDL-C Plus Gen 2	≤ 3.9 mg/dL	155 mg/dL	≤ 3
Lipase (colorimetric)	≤ 1.2 U/L	60 U/L	≤ 2
Magnesium	≤ 0.05 mg/dL	1.7 mg/dL	≤ 2
Phosphate ver 2	≤ 0.06 mg/dL	2.70 mg/dL	≤ 2
Total Protein	≤ 0.13 g/dL	6.6 g/dL	≤ 2
Triglycerides	≤ 4.4 mg/dL	203.6 mg/dL	≤ 2
Urea/BUN (serum/plasma)	≤ 0.48 mg/dL	23.2 mg/dL	≤ 2
Uric Acid (serum/plasma)	≤ 0.1 mg/dL	7.1 mg/dL	≤ 2

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Ion Selective Electrodes (ISE)

Clinical Chemistry	SD	Sample Concentration	%CV Guideline
Chloride (serum/plasma)	≤ 2.5 mmol/L	89 mmol/L	≤ 1.5
Chloride (urine)	≤ 3.5 mmol/L	89 mmol/L	≤ 6.0
Potassium (serum/plasma)	≤ 0.15 mmol/L	6.0 mmol/L	≤ 1.2
Potassium (urine)	≤ 1.0 mmol/L	10.0 mmol/L	≤ 5.0
Sodium (serum/plasma)	≤ 3.0 mmol/L	110.0 mmol/L	≤ 1.0
Sodium (urine)	≤ 6.0 mmol/L	120.0 mmol/L	≤ 5.0

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Specific Proteins

Specific Proteins	SD	Sample Concentration	%CV Guideline
Albumin TQ (urine)	≤ 0.8 mg/L	20 mg/L	≤ 4
CRP/Latex	≤ 0.02 mg/dL	0.5 mg/dL	≤ 4
CRP/High Sensitivity	≤ 0.004 mg/dL	0.1 mg/dL	≤ 4
HbA1c (whole blood)	$\leq 0.25\%$ HbA1c	5% HbA1c	≤ 4
HbA1c (hemolysate)	$\leq 0.25\%$ HbA1c	5% HbA1c	≤ 4