cobas c 701 and c 702 analyzers

Within-Run Precision Guidelines

Roche

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Revision History

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Publication Reference Number	Date	Revision purpose
4157-00-1110 Version 0	November 2010	Document creation with **cobas c** 701 analyzer data
4157-01-1014 Version 1	October 2014	Added new **cobas c** 701 and c 702 data.
4157-02-0817 Version 2	August 2017	Added new HDLC4 and LDLC3 within run precision guidelines.
4157-03-0817 Version 3	August 2017	Updated Ion Selective Electrodes section.
VV-06833-02 Version 4	November 2020	Updated customer website URL; Deleted HDL-C plus gen.3, LDL-C plus gen.2, T4 and T Uptake; Added Ethyl Alcohol, B2-Microglobulin (urine), Tina-quant C-Reactive Protein IV and Transferrin ver2 (urine); Updated Ammonia gen.2, CK, Total Protein U/CSF (CSF), Total Protein U/CSF (urine), B2-Microglobulin (serum/plasma), Rheumatoid Factors II and Transferrin ver2 (serum/plasma).

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Clinical Chemistry

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.

Assay	SD	Sample Concentration	%CV Guideline
Albumin BCG, gen. 2	≤ 0.07 g/dL	3.5 g/dL	≤ 2 %
Albumin BCP	≤ 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	≤ 1.1 U/L	35 U/L	≤ 3 %
Ammonia gen. 2	≤ 4.3 µg/dL	85 µg/dL	≤ 5 %
p-Amylase/EPS (serum)	≤ 1 U/L	50 U/L	≤ 2 %
p-Amylase/EPS (urine)	≤ 11 U/L	350 U/L	≤ 3 %
t-Amylase/EPS (serum)	≤ 2 U/L	100 U/L	≤ 2 %
t-Amylase/EPS STAT (serum)	≤ 2 U/L	100 U/L	≤ 2 %
t-Amylase/EPS (urine)	≤ 14 U/L	460 U/L	≤ 3 %
t-Amylase/EPS STAT (urine)	≤ 14 U/L	460 U/L	≤ 3 %
AST	≤ 0.9 U/L	30 U/L	≤ 3 %
AST STAT	≤ 0.9 U/L	30 U/L	≤ 3 %
AST/P-5-P	≤ 1.2 U/L	40 U/L	≤ 3 %
Bilirubin Total Gen.3	≤ 0.03 mg/dL	0.99 mg/dL	≤ 3 %
Bilirubin, Direct	≤ 0.012 mg/dL	0.30 mg/dL	≤ 3 %
Calcium Gen.2 (serum, urine, STAT, routine)	≤ 0.16 mg/dL	OR	≤ 2 %
Cholesterol (Abell-Kendall)	≤ 3.87 mg/dL	201 mg/dL	≤ 2 %
CK	≤ 3 U/L	140 U/L	≤ 2 %
CO2-L	≤ 0.7 mmol/L	22 mmol/L	≤ 3 %
Creatinine Plus ver 2 (serum)	≤ 0.02 mg/dL	0.90 mg/dL	≤ 2 %
Creatinine Plus ver 2 (urine)	≤ 0.85 mg/dL	28.3 mg/dL	≤ 3 %
Creatinine/Jaffe, rate blanked, compensated (serum)	≤ 0.03 mg/dL	0.90 mg/dL	≤ 3 %
Creatinine/Jaffe, rate blanked (urine)	≤ 0.85 mg/dL	28.3 mg/dL	≤ 3 %
Creatinine/Jaffe STAT (serum)	≤ 0.03 mg/dL	0.90 mg/dL	≤ 3 %
Creatinine/Jaffe STAT (urine)	≤ 0.85 mg/dL	28.3 mg/dL	≤ 3 %
Ethyl Alcohol (serum/plasma/urine)	≤ 1.84 mg/dL	100 mg/dL	≤ 2 %
Fructosamine	≤ 6.0 µmol/L	285 µmol/L	≤ 2 %
GGT ver 2	≤ 0.8 U/L	40 U/L	≤ 2 %

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Assay	SD	Sample Concentration	%CV Guideline
Glucose/HK gen. 3 (serum)	≤ 1.44 mg/dL	70.3 mg/dL	≤ 2 %
Glucose/HK gen. 3 STAT (serum)	≤ 1.44 mg/dL	70.3 mg/dL	≤ 2 %
Glucose/HK ver 3 (CSF)	≤ 0.72 mg/dL	39.6 mg/dL	≤ 2 %
Glucose/HK ver 3 STAT (CSF)	≤ 0.72 mg/dL	39.6 mg/dL	≤ 2 %
Glucose/HK ver 3 (urine)	≤ 0.54 mg/dL	19.8 mg/dL	≤ 3 %
Glucose/HK ver 3 STAT (urine)	≤ 0.54 mg/dL	19.8 mg/dL	≤ 3 %
HDL-C gen 4	---	---	≤ 3 %
Iron gen 2	≤ 3.0 µg/dL	150 µg/dL	≤ 2 %
Lactate gen 2 (plasma)	≤ 0.36 mg/dL	19.8 mg/dL	≤ 2 %
Lactate gen 2 STAT (plasma)	≤ 0.36 mg/dL	19.8 mg/dL	≤ 2 %
Lactate gen 2 (CSF)	≤ 0.63 mg/dL	19.8 mg/dL	≤ 3 %
Lactate gen 2 STAT (CSF)	≤ 0.63 mg/dL	19.8 mg/dL	≤ 3 %
LDH ver. 2	≤ 4 U/L	200 U/L	≤ 2 %
LDL-C gen 3	≤ 3.09 mg/dL	155 mg/dL	≤ 2 %
Lipase	≤ 1.2 U/L	60 U/L	≤ 2 %
Lipase STAT	≤ 1.2 U/L	60 U/L	≤ 2 %
Magnesium gen. 2 (serum)	≤ 0.05 mg/dL	1.7 mg/dL	≤ 2 %
Magnesium gen. 2 STAT (serum)	≤ 0.05 mg/dL	1.7 mg/dL	≤ 2 %
Magnesium gen. 2 (urine)	≤ 0.17 mg/dL	4.13 mg/dL	≤ 3 %
Magnesium gen. 2 STAT (urine)	≤ 0.17 mg/dL	4.13 mg/dL	≤ 3 %
Phosphorus (serum)	≤ 0.06 mg/dL	2.70 mg/dL	≤ 2 %
Phosphorus STAT (serum)	≤ 0.06 mg/dL	2.70 mg/dL	≤ 2 %
Phosphorus (urine)	≤ 1.21 mg/dL	40.3 mg/dL	≤ 3 %
Phosphorus STAT (urine)	≤ 1.21 mg/dL	40.3 mg/dL	≤ 3 %
Total Protein	≤ 0.13 g/dL	6.6 g/dL	≤ 2 %
Total STAT Protein	≤ 0.13 g/dL	6.6 g/dL	≤ 2 %
Total Protein U/CSF (CSF)	≤ 1.4 mg/dL	45 mg/dL	≤ 3 %
Total Protein U/CSF (Urine)	≤ 0.36 mg/dL	12.0 mg/dL	≤ 3 %
Triglycerides/GPO	≤ 4.43 mg/dL	204 mg/dL	≤ 2 %
Triglycerides/GB	≤ 4.43 mg/dL	204 mg/dL	≤ 2 %
UIBC (serum/plasma)	≤ 13.4 µg/dL	335 µg/dL	≤ 4 %
Urea/BUN (serum)	≤ 0.48 mg/dL	23.2 mg/dL	≤ 2 %
Urea/BUN STAT (serum)	≤ 0.48 mg/dL	23.2 mg/dL	≤ 2 %
Urea/BUN (urine)	≤ 14 mg/dL	420 mg/dL	≤ 3 %
Urea/BUN STAT (urine)	≤ 14 mg/dL	420 mg/dL	≤ 3 %

Assay	SD	Sample Concentration	%CV Guideline
Uric Acid ver. 2 (serum)	≤ 0.1 mg/dL	7.0 mg/dL	≤ 2 %
Uric Acid ver. 2 (urine)	≤ 2.8 mg/dL	92 mg/dL	≤ 3 %

n = 21 for all tests

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Ion Selective Electrodes (ISE)

Assay	SD	Sample Concentration	%CV Guideline
Chloride (serum/plasma)	≤ 1.7 mmol/L	100 mmol/L	≤ 1.7%
Chloride (urine)	≤ 2.2 mmol/L	110.0 mmol/L	≤ 2.0%
Potassium (serum/plasma)	≤ 0.05 mmol/L	4.0 mmol/L	≤ 1.2%
Potassium (urine)	≤ 0.5 mmol/L	25 mmol/L	≤ 2.0%
Sodium (serum/plasma)	≤ 1.35 mmol/L	135.0 mmol/L	≤ 1.0%
Sodium (urine)	≤ 1.2 mmol/L	20 - 40 mmol/L	---
	---	40 - 60 mmol/L	≤ 3.0%
		> 60 mmol/L	≤ 2.0%

n = 21 for all tests

Specific Proteins

Assay	SD	Sample Concentration	%CV Guideline
α1-Acid Glycoprotein Gen.2	≤ 0.05 g/L	1.2 g/L	≤ 4%
α1-Antitrypsin, ver.2	≤ 4 mg/dL	90 mg/dL	≤ 4%
Antistreptolysin O	≤ 4 IU/mL	100 IU/mL	≤ 4 %
Apolipoprotein A-1 ver.2	≤ 4 mg/dL	100 mg/dL	≤ 4%
Apolipoprotein B ver.2	≤ 4 mg/dL	100 mg/dL	≤ 4%
Albumin TQ (urine)	≤ 0.8 mg/L	20 mg/L	≤ 4%
Albumin TQ (serum)	≤ 1.4 g/L	35 g/L	≤ 4%
Albumin TQ (CSF)	≤ 10 mg/L	240 mg/L	≤ 4%
β2-Microglobulin (serum/plasma)	≤ 0.09 mg/L	2.2 mg/L	≤ 4%
β2-Microglobulin (urine)	≤ 0.05 mg/L	1.0 mg/L	≤ 4%
C-Reactive Protein Gen.3	≤ 0.08 mg/L	0.2 - 1.4 mg/L	---
	---	> 1.4 - 5 mg/L	≤ 5 %
	---	> 5 mg/L	≤ 3 %
Tina-quant C-Reactive Protein IV	---	3 - 5 mg/L	≤ 5 %
	---	> 5 mg/L	≤ 3 %
Cardiac C-Reactive Protein (Latex) High Sensitive	≤ 0.04 mg/L	1.0 mg/L	≤ 4%
Ceruloplasmin	≤ 1 mg/dL	30 mg/dL	≤ 4%
Complement C3c ver.2	≤ 4 mg/dL	90 mg/dL	≤ 4%
Complement C4 ver.2	≤ 0.4 mg/dL	10 mg/dL	≤ 4%
Ferritin Gen.4	< 1.5 µg/L	15 µg/L	---
	---	15 - 40 µg/L	< 10%
	---	> 40 µg/L	< 5%
Haptoglobin ver.2	≤ 1.2 mg/dL	30 mg/dL	≤ 4%
Homocysteine Enzymatic Assay	≤ 0.75 µmol/L	15 µmol/L	≤ 5%
IgA Gen.2 standard	≤ 3.0 mg/dL	70 mg/dL	≤ 4 %
IgA Gen.2 sensitive	≤ 2.0 mg/dL	40 mg/dL	≤ 4 %
IgG Gen.2 standard	≤ 30 mg/dL	700 mg/dL	≤ 4 %
IgG Gen.2 sensitive (CSF)	≤ 0.08 mg/dL	1.5 mg/dL	≤ 5 %
IgM Gen.2 standard	≤ 2.0 mg/dL	40 mg/dL	≤ 4 %
IgM Gen.2 sensitive	≤ 1.0 mg/dL	20 mg/dL	≤ 4 %
Lipoprotein (a) Gen.2	≤ 1.2 mg/dL	30 mg/dL	≤ 4%
Myoglobin Gen.2	≤ 2.4 ng/mL	OR	≤ 4%
Prealbumin	≤ 2 mg/dL	40 mg/dL	≤ 4%
Rheumatoid Factors II	≤ 0.8 IU/mL	14 IU/mL	≤ 6 %
Soluble Transferrin Receptor (sTfR)	≤ 0.1 mg/L	2 mg/L	≤ 4%

Specific Proteins

Assay	SD	Sample Concentration	%CV Guideline
Transferrin ver.2 (serum/plasma)	≤ 10 mg/dL	200 mg/dL	≤ 4%
Transferrin ver.2 (urine)	≤ 0.25 mg/L	5 mg/L	≤ 5%

n = 21 for all tests