cobas® c 501 and c® 502 modules
cobas® c 311 analyzer and
cobas® c 513 analyzer

Within-Run Precision Guidelines
Version 14.0

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1658-00-0806, v0.0	August 2006	New document
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1658-05-0409, v5.0	April 2009	Added: Added cobas c 311 analyzer
1658-06-1209, v6.0	December 2009	Revised for reagent launches.
1658-07-1014, v7.0	October 2014	Added: **cobas**® c 502 analyzer and new reagent launch data.
1658-08-0415, v8.0	April 2015	Corrected: ISE Chloride values.
1658-09-0615, v9.0	June 2015	• Added: Albumin BCG. • Corrected: Albumin TQ (urine/serum) and Specimen Validity Tests values.
1658-10-0516, v10.0	May 2016	• Added: DAT materials and Cystatin Gen.2. • Removed: Assays no longer available. • Minor modifications in reformatting.
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1658-13-0817, v12.0	August 2017	Added: **cobas**® c 513 analyzer and HbA1c Gen 3.
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Edition notice

This publication is intended for operators of the **cobas**® c 501 and c 502 analyzers, the **cobas**® c 311 analyzer, and the **cobas**® c 513 analyzer.

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Document availability

This document is available on the Roche Diagnostics USA website at navifyportal.roche.com.

How to use these guidelines

Where the SD and CV% information are 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

N = 21 for all tests

Assay	Standard deviation (SD)	Sample concentration	%CV Guideline
Albumin BCG	≤ 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	≤ 1.0 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/plasma)	≤ 2 U/L	100 U/L	≤ 2 %
t-Amylase/EPS (urine)	≤ 14 U/L	460 U/L	≤ 3 %
AST	≤ 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	≤ 0.01 mg/dL	0.3 mg/dL	≤3 %
Calcium Gen.2 (serum, urine, STAT, routine)	≤ 0.16 mg/dL	OR	≤ 2 %
Cholesterol/HP Gen.2	≤ 3.87 mg/dL	201 mg/dL	≤ 2 %
Cholinesterase/butyrylthiocholine	≤ 40 U/L	---	≤ 2 %
CK	≤ 3 U/L	140 U/L	≤ 2 %
CO2-L	≤ 0.7 mmol/L	22 mmol/L	≤ 3 %
Creatinine Plus ver 2 (serum/plasma)	≤ 0.02 mg/dL	0.9 mg/dL	≤ 2 %
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 %

N = 21 for all tests

Assay	Standard deviation (SD)	Sample concentration	%CV Guideline
Creatinine/Jaffe, rate blanked, compensated (urine)	≤ 0.85 mg/dL	28 mg/dL	≤ 3 %
Creatinine/Jaffe STAT, compensated (serum/plasma)	≤ 0.03 mg/dL	0.9 mg/dL	≤ 3 %
Creatinine/Jaffe STAT, compensated (urine)	≤ 0.85 mg/dL	28 mg/dL	≤ 3 %
Cystatin C Gen.2	≤ 0.04 mg/L	0.8 mg/L	≤ 4 %
Ethyl Alcohol (serum/plasma/urine)	≤ 1.84 mg/dL	100 mg/dL	≤ 2 %
GGT ver 2	≤ 0.8 U/L	40 U/L	≤ 2 %
Glucose/HK gen. 3 (serum/plasma)	≤ 1.4 mg/dL	70 mg/dL	≤ 2 %
Glucose/HK ver 3 (CSF)	≤ 0.7 mg/dL	40 mg/dL	≤ 2 %
Glucose/HK ver 3 (urine)	≤ 0.5 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 (CSF)	≤ 0.63 mg/dL	19.8 mg/dL	≤ 3 %
LDH ver. 2	≤ 4 U/L	200 U/L	≤ 2 %
LDL-C gen.3	≤ 3.1 mg/dL	155 mg/dL	≤ 2 %
Lipase	≤ 1.2 U/L	60 U/L	≤ 2 %
Magnesium gen. 2 (serum/plasma)	≤ 0.05 mg/dL	1.7 mg/dL	≤ 2 %
Magnesium gen. 2 (urine)	≤ 0.17 mg/dL	4.13 mg/dL	≤ 3 %
Phosphorus (serum/plasma)	≤ 0.06 mg/dL	2.70 mg/dL	≤ 2 %
Phosphorus (urine)	≤ 1.2 mg/dL	40 mg/dL	≤ 3 %
Total 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	≤ 4.4 mg/dL	203.6 mg/dL	≤ 2 %
UIBC (serum/plasma)	≤ 13.42 µg/dL	335 µg/dL	≤ 4 %
Urea/BUN (serum/plasma)	≤ 0.48 mg/dL	23.3 mg/dL	≤ 2 %
Urea/BUN (urine)	≤ 14 mg/dL	420 mg/dL	≤ 3 %
Uric Acid ver. 2 (serum/plasma)	≤ 0.1 mg/dL	7.0 mg/dL	≤ 2 %
Uric Acid ver. 2 (urine)	≤ 2.8 mg/dL	92 mg/dL	≤ 3 %

Ion Selective Electrode (ISE)

N = 21 for all tests

Assay	Standard deviation (SD)	Sample concentration	%CV Guideline
Chloride (serum/plasma)	≤ 2.0 mmol/L	100 mmol/L	≤ 2.0%
Chloride (urine)	≤ 3.3 mmol/L	110 mmol/L	≤ 3.0%
Potassium (serum/plasma)	≤ 0.08 mmol/L	4.0 mmol/L	≤ 2.0%
Potassium (urine)	≤ 0.75 mmol/L	25.0 mmol/L	≤ 3.0%
Sodium (serum/plasma)	≤ 2.7 mmol/L	135.0 mmol/L	≤ 2.0%
Sodium (urine)	≤ 1.2 mmol/L	40.0 mmol/L	≤ 3.0%

Specific Proteins

N = 21 for all tests

Assay	Standard deviation (SD)	Sample concentration	%CV Guideline
α1-Acid Glycoprotein Gen.2	≤ 0.05 g/L	1.2 g/L	≤ 4 %
α1-Antitrypsin, ver.2	≤ 4.0 mg/dL	90 mg/dL	≤ 4 %
Antistreptolysin O	≤ 4 IU/mL	100 IU/mL	≤ 4 %
Apolipoprotein A-1 ver.2	≤ 4.0 mg/dL	100 mg/dL	≤ 4 %
Apolipoprotein B ver.2	≤ 4.0 mg/dL	100 mg/dL	≤ 4 %
Albumin TQ (urine)	≤ 0.08 mg/dL ≤ 0.8 mg/L	2 mg/dL 20 mg/L	≤ 4 % ≤ 4 %
Albumin TQ (serum)[1]	≤ 0.14 g/dL	3.5 g/dL	≤ 4 %
Albumin TQ (CSF)[1]	≤ 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 %
Tina-Quant C-Reactive Protein IV	--- --- --- ---	0.3 - 0.5 mg/dL > 0.5 mg/dL 3 - 5 mg/L > 5 mg/L	≤ 5 % ≤ 3 % ≤ 5 % ≤ 3 %
Cardiac C-Reactive Protein (Latex) High Sensitive	≤ 0.004 mg/dL ≤ 0.04 mg/L	0.1 mg/dL 1.0 mg/L	≤ 4 % ≤ 4 %
Ceruloplasmin	≤ 1.0 mg/dL	30 mg/dL	≤ 4 %
Complement C3c ver.2	≤ 4.0 mg/dL	90.0 mg/dL	≤ 4 %
Complement C4 ver.2	≤ 0.4 mg/dL	10.0 mg/dL	≤ 4 %

Assay	Standard deviation (SD)	Sample concentration	%CV Guideline
D-Dimer	≤ 0.04 µg FEU/mL --- ---	0.5 - 1.7 µg FEU/mL 1.7 - 3.4 µg FEU/mL > 3.4 µg FEU/mL	≤ 7 % ≤ 4 % ≤ 3 %
Ferritin Gen.4	≤ 1.5 µg/L --- ---	15 µg/L 15 - 40 µg/L > 40 µg/L	--- ≤ 10% ≤ 5 %
Fructosamine	≤ 6 µmol/L	285 µmol/L	≤ 2 %
Haptoglobin ver.2	≤ 1.2 mg/dL	30.0 mg/dL	≤ 4 %
Homocysteine Enzymatic Assay	≤ 0.75 µmol/L	15 µmol/L	≤ 5 %
HbA1c Gen.3 (whole blood)	≤ 0.25% HbA1c	5% HbA1c	≤ 4 %
HbA1c Gen.3 (Hemolysate)	≤ 0.25% HbA1c	5% HbA1c	≤ 4 %
cobas c 513 HbA1cDx Gen.3 (whole blood)	---	---	≤ 2.5 %
cobas c 513 HbA1cDx Gen.3 (Hemolysate)	---	---	≤ 2.5 %
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	≤ 2.0 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 %
Transferrin ver.2 (serum/plasma)	≤ 10 mg/dL	200 mg/dL	≤ 4 %
Transferrin ver.2 (urine)	≤ 0.25 mg/L	5.0 mg/L	≤ 5 %

[1]Assay is not available on the **cobas** c 311 analyzer.

N = 21 for all tests

Drugs of Abuse Testing Qualitative Assays (DAT)[2]

N = 10 for all tests upon installation
N = 20 for all tests when troubleshooting

To run precision on a qualitative DAT, set the S1 ABS to 0 (zero) and the K factor to 1000. Do not run a STD 1 calibrator. Results display in absolute milliabsorbance. After running the precision, reset the K factor to -1000 and recalibrate, using STD 1, prior to assaying samples.

Drugs of Abuse Testing Semiquantitative Assays (DAT)[2]

N = 10 for all tests upon installation
N = 20 for all tests when troubleshooting

Assay	Sample Concentration Cut Off	%CV Guideline	Materials or equivalents at same concentrations
Amphetamine II	1000 ng/mL 500 ng/mL 300 ng/mL	≤ 8 % ≤ 8 % ≤ 8 %	1000 Control Set DAT II 500 Control Set DAT I 300 Control Set DAT III
Barbiturates Plus	200 ng/mL	≤ 8 %	200 Control Set DAT I
Benzodiazepines Plus	100 ng/mL 200 ng/mL 300 ng/mL	≤ 8 % ≤ 8 % ≤ 8 %	100 Control Set DAT II or Control Set DAT Clinical 200 Control Set DAT III 300 Control Set DAT I
Benzodiazepines II	100 ng/mL 200 ng/mL 300 ng/mL	≤ 8 % ≤ 8 % ≤ 8 %	100 Control Set DAT II or Control Set DAT Clinical 200 Control Set DAT III 300 Control Set DAT I
Cannabinoids II (THC)	20 ng/mL 50 ng/mL 100 ng/mL	≤ 8 % ≤ 8 % ≤ 8 %	20 Control Set DAT II 50 Control Set DAT I 100 Control Set DAT III
Cocaine II	150 ng/mL 300 ng/mL	≤ 8 % ≤ 8 %	150 Control Set DAT I 300 Control Set DAT III
Ethanol Gen.2	≤ 100 mg/dL SD ≤ 1.84 mg/dL > 100 mg/dL CV% of ≤ 2.0		Ethyl Alcohol low and high control
LSD[1]	0.5 ng/mL	≤ 8 %	LSD QC
Methadone II	300 ng/mL	≤ 8 %	300 Control Set DAT I
Methaqualone	300 ng/mL	≤ 8 %	300 Control Set DAT I
Opiates II	300 ng/mL 2000 ng/mL	≤ 8 % ≤ 8 %	300 Control Set DAT II 2000 Control Set DAT I
DRI Oxycodone[3]	100 ng/mL 300 ng/mL	≤ 7 % ≤ 7 %	100 Oxycodone Control Set 100 300 Oxycodone Control Set 300

Assay	Sample Concentration Cut Off	%CV Guideline	Materials or equivalents at same concentrations
Phencyclidine Plus	25 ng/mL	≤ 8 %	25 Control Set DAT I
Propoxyphene Plus	300 ng/mL	≤ 8 %	300 Control Set DAT I
Specimen Validity Test Chromate[1]	50 mg/L	≤ 5 %	SVT Control 1
Specimen Validity Test Creatinine[1]	2 and 20 mg/L	≤ 5 %	SVT Control 1, 2, 3, 5
Specimen Validity Test Nitrate[1]	500 mg/L	≤ 5 %	SVT Control 3, 4, 5
Specimen Validity Test Oxidant[1]	200 mg/L	≤ 5 %	SVT Control 4, 5
Specimen Validity Test pH[1]	4 and 11	≤ 5 %	SVT Control 1, 2, 3, 4, 5
Specimen Validity Test Specific Gravity[1]	1.001, 1.003, 1.020	≤ 5 %	SVT Control 1, 2, 3, 4, 5

1 Assay is not available on the **cobas c** 311 analyzer.
2 CV% applies to Qualitative in precision mode as well as Semi-Quantitative and all available cutoffs.
3 For qualitative DRI Oxycodone, the %CV guideline is 2% and no cross-overs. The K factor is not set to -1000, but remains at 1000.

N = 21 for all tests

Therapeutic Drug Monitoring

N = 21 for all tests

Assay	Standard deviation (SD)	Sample concentration	%CV Guideline
Acetaminophen 2	≤ 0.7 µg/mL	10.0 µg/mL	≤ 7 %
Amikacin	≤ 0.56 µg/mL	8.0 µg/mL	≤ 7 %
Carbamazepine Gen.4	≤ 0.25 µg/mL	5 µg/mL	≤ 5 %
Digoxin	≤ 0.1 ng/mL	1.0 ng/mL	≤ 7 %
Lithium	≤ 0.03 mmol/L	1.0 mmol/L	≤ 3 %
NAPA	≤ 0.14 µg/mL	2 µg/mL	≤ 7 %
Online Phenobarbital	≤ 0.75 µg/mL	15 µg/mL	≤ 5 %
Phenytoin II	≤ 0.5 µg/mL	10 µg/mL	≤ 5 %
Phenytoin, Free[1]	≤ 0.05 µg/mL ---	≤ 1.0 µg/mL >1.0 µg/mL	--- ≤ 5 %
Procainamide	≤ 0.14 µg/mL	2 µg/mL	≤ 7 %
Quinidine	≤ 0.14 µg/mL	2 µg/mL	≤ 7 %
Salicylate	≤ 2.5 µg/mL	50 µg/mL	≤ 5 %
Theophylline II	≤ 0.7 µg/mL	10 µg/mL	≤ 4 %
Tobramycin	≤ 0.10 µg/mL	2 µg/mL	≤ 5 %
Total MPA	≤ 0.05 µg/mL	1.0 µg/mL	≤ 5 %
Valproic Acid II	≤ 2.1 µg/mL	30 µg/mL	≤ 7 %
Vancomycin 3	≤ 0.5 µg/mL --- ---	≤ 10 µg/mL 10 - 40 µg/mL > 40 µg/mL	--- ≤ 5 % ≤ 8 %

[1]Assay is not available on the **cobas** c 311 analyzer.