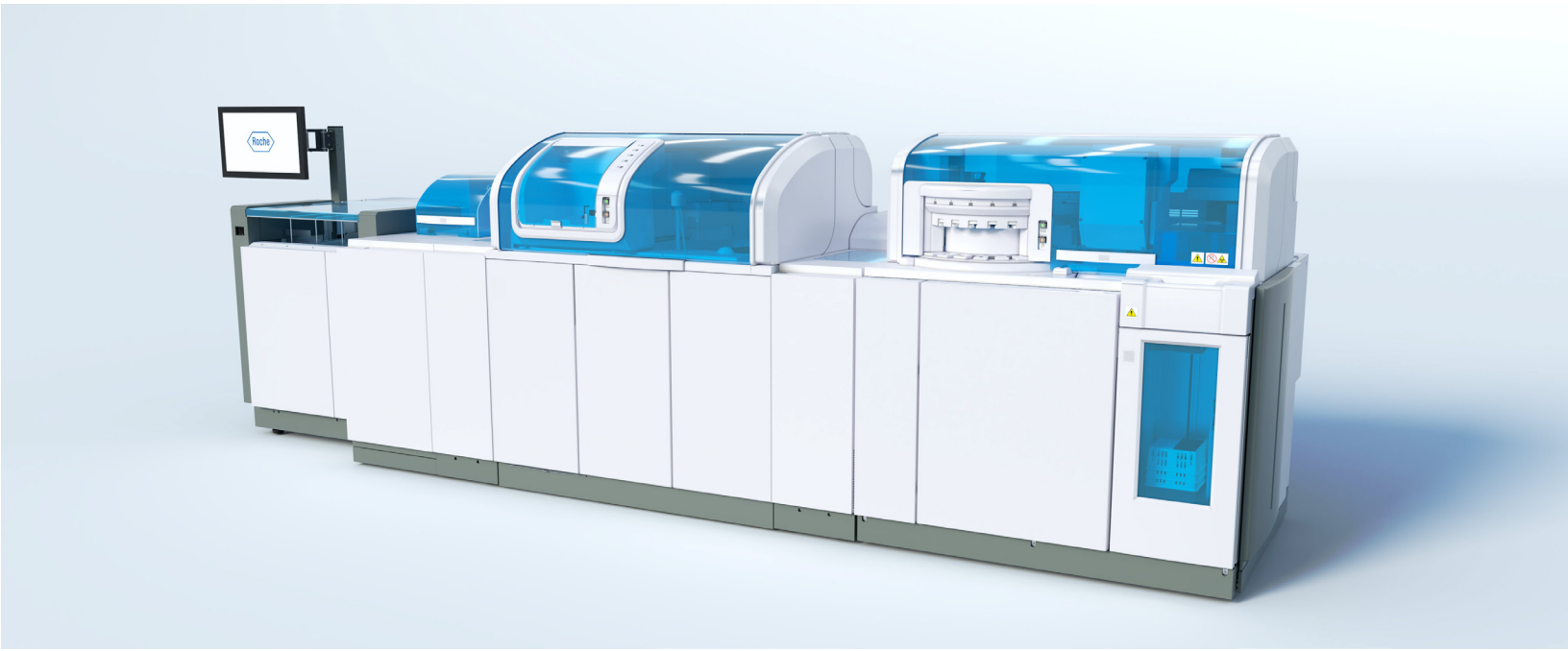

cobas® c 303, cobas® c 503, and cobas® pro ISE analytical unit

Within-Run Precision Guidelines

Version 5.0

OS-01612-05

US Publication information

Publication version	Revision date	Change description
OS-01612-01	March 2020	New document
OS-01612-02	April 2020	Removed MYO, STFR, and QUIN
OS-01612-03	October 2020	Added Tina-quant C-Reactive Protein IV, HbA1cDx Gen.3 (hemolysate), and HbA1cDx Gen.3 (whole blood). Updated data for Amphetamine II, Benzodiazepines Plus, Cannabinoids II (THC), Methadone II, Methaqualone, Opiates II, DRI Oxycodone, Phencyclidine Plus and Propoxyphene Plus.
OS-01612-04	June 2022	Added D-Dimer, Soluble Transferrin Receptor (sTfR), and Quinidine. Updated data for . Lipoprotein (a) Gen.2, Rheumatoid Factors II, Transferrin ver.2 (urine), Barbiturates Plus, Cocaine II, DRI Oxycodone2, Phencyclidine Plus, and Propoxyphene Plus. Updated table for DAT Testing to include Standard Deviation (SD), and Sample Concentration.
OS-01612-05	November 2023	Removed C-Reactive Protein Gen. 3. Updated data for Albumin TQ (Urine). Updated data for Tina-quant C-Reactive Protein IV and Cardiac C-Reactive Protein (Latex) High Sensitive. Added Benzodiazepines Gen.2. Added Phenytoin, Free

Revision history

Edition notice

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Document availability

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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/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/plasma)	≤ 2 U/L	100 U/L	≤ 2 %
t-Amylase/EPS (urine)	≤ 14 U/L	460 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	9.2 mg/dL	≤ 2 %
Cholesterol/HP Gen.2	≤ 3.87 mg/dL	201 mg/dL	≤ 2 %
Cholinesterase/butyrylthiocholine	≤ 40 U/L	2000 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 %
Creatinine/Jaffe, rate blanked, (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 %

N = 21 for all tests

Assay	Standard deviation (SD)	Sample concentration	%CV Guideline
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)	≤ 0.75 mg/dL	25.0 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	23.2 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 Electrodes (ISE)

N = 21 for all tests

Assay	Standard deviation (SD)	Sample concentration	%CV Guideline
Chloride (serum/plasma)	≤ 1.7 mmol/L	100 mmol/L	≤ 1.7%
Chloride (urine)	≤ 2.2 mmol/L	110 mmol/L	≤ 2.0%
Potassium (serum/plasma)	≤ 0.05 mmol/L	4.0 mmol/L	≤ 1.2%
Potassium (urine)	≤ 0.5 mmol/L	25.0 mmol/L	≤ 2.0%
Sodium (serum/plasma)	≤ 1.35 mmol/L	135.0 mmol/L	≤ 1.0%
Sodium (urine)	≤ 0.8 mmol/L	40.0 mmol/L	≤ 2.0%

Specific Proteins

N = 21 for all tests

Assay	Standard deviation (SD)	Sample concentration	%CV Guideline
α 1-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)	≤ 0.008 mg/L ≤ 0.8 mg/L	2.0 mg/dL 20 mg/L	≤ 4 % ≤ 4 %
Albumin TQ (serum)	≤ 0.14 g/dL	3.5 g/dL	≤ 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 %
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	0.10 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 %
D-Dimer	≤ 0.04 µg/mL --- --- ---	≤ 0.5 µg/mL > 0.5 - 1.7 µg/mL > 1.7 - 3.4 µg/mL > 3.4 µg/mL	--- 7% 4% 3%
Ferritin Gen.4	≤ 1.5 ng/mL --- ---	15 ng/mL 15 - 40 ng/mL > 40 ng/mL	--- ≤ 10% ≤ 5 %
Fructosamine	≤ 6 µmol/L	285 µmol/L	≤ 2 %
Haptoglobin ver.2	≤ 1.2 mg/dL	30.0 mg/dL	≤ 4 %
HbA1cDx Gen.3 (whole blood)	---	---	2.5 %
HbA1cDx Gen.3 (hemolysate)	---	---	2.5 %
Homocysteine Enzymatic Assay	≤ 0.75 µmol/L	15 µmol/L	≤ 5 %

Specific Proteins

Assay	Standard deviation (SD)	Sample concentration	%CV Guideline
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	60 ng/mL	≤ 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 %

Drugs of Abuse Testing Semiquantitative Assays (DAT)[1]

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

Assay	Assay Cut Off	Standard deviation (SD)	Sample Concentration	%CV Guideline	Materials or equivalents at same concentrations
Amphetamine II	300 ng/mL 500 ng/mL 1000 ng/mL	--- --- ---	--- --- ---	≤ 10 % ≤ 10 % ≤ 10 %	300 Control Set DAT III 500 Control Set DAT I 1000 Control Set DAT II
Barbiturates Plus	200 ng/mL	≤ 8 ng/mL	100 ng/mL	≤ 8 %	200 Control Set DAT I
Benzodiazepines Plus	100 ng/mL 200 ng/mL 300 ng/mL	≤ 4 ng/mL ≤ 8 ng/mL ≤ 12 ng/mL	50 ng/mL 100 ng/mL 150 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 Gen. 2	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	≤ 0.8 ng/mL ≤ 2 ng/mL ≤ 4 ng/mL	10 ng/mL 25 ng/mL 50 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	≤ 6 ng/mL ≤ 12 ng/mL	75 ng/mL 150 ng/mL	≤ 8 % ≤ 8 %	150 Control Set DAT I 300 Control Set DAT III
Ethanol Gen.2	---	≤ 1.84 mg/dL	100 mg/dL	≤ 2.0 %	Ethyl Alcohol low control and high control
Methadone II	300 ng/mL	≤ 12 ng/mL	150 ng/mL	≤ 8 %	300 Control Set DAT I
Methaqualone	300 ng/mL	≤ 12 ng/mL	150 ng/mL	≤ 8 %	300 Control Set DAT I
Opiates II	300 ng/mL 2000 ng/mL	≤ 12 ng/mL ≤ 80 ng/mL	150 ng/mL 1000 ng/mL	≤ 8 % ≤ 8 %	300 Control Set DAT II 2000 Control Set DAT I
DRI Oxycodone[2]	100 ng/mL 300 ng/mL	--- ---	--- ---	≤ 5 % ≤ 5 %	100 Oxycodone Control Set 100 300 Oxycodone Control Set 300
Phencyclidine Plus	25 ng/mL	≤ 1 ng/mL	12.5 ng/mL	≤ 8 %	25 Control Set DAT I
Propoxyphene Plus	300 ng/mL	≤ 12 ng/mL	150 ng/mL	≤ 8 %	300 Control Set DAT I

1 CV% applies to Semi-Quantitative and all available cutoffs.
2 For qualitative DRI Oxycodone, positive agreement or negative agreement shall be > 90% correct results of number of high control samples tested or low control samples tested, respectively.

Drugs of Abuse Testing (DAT)

Assay	Sample Concentration Cut Off	Standard deviation (SD)	Sample Concentration	%CV Guideline	Materials or equivalents at same concentrations
Specimen Validity Test Chromate	50 mg/L	---	---	≤ 5 %	SVT Control 1
Specimen Validity Test Creatinine	2 and 20 ng/mL	≤ 0.125 mg/dL	2.5 mg/dL	≤ 5 %	SVT Control 1, 2, 3, 5
Specimen Validity Test Nitrate	500 mg/L	---	---	≤ 5 %	SVT Control 3, 4, 5
Specimen Validity Test Oxidant	200 mg/L	---	---	≤ 5 %	SVT Control 4, 5
Specimen Validity Test pH	4 and 11	---	---	≤ 5 %	SVT Control 1, 2, 3, 4, 5
Specimen Validity Test Specific Gravity	1.001, 1.003, 1.020	≤ 2 g/L	---	---	SVT Control 1, 2, 3, 4, 5

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	5.0 µg/mL	≤ 5 %
Digoxin	≤ 0.1 ng/mL	1.43 ng/mL	≤ 7 %
Lithium	≤ 0.03 mmol/L	1.0 mmol/L	≤ 3 %
NAPA	≤ 0.14 µg/mL	2.0 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	≤ 0.05 µg/mL	1.0 µg/mL	≤ 5 %
Procainamide	≤ 0.14 µg/mL	2.0 µg/mL	≤ 7 %
Quinidine	≤ 0.14 µg/mL	2.0 µg/mL	≤ 7%
Salicylate	≤ 2.5 µg/mL	50 µg/mL	≤ 5 %
Theophylline II	≤ 0.7 µg/mL	18 µg/mL	≤ 4 %
Tobramycin	≤ 0.10 µg/mL	2.0 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 %