

cobas® pro c 703
cobas® pro ISE neo

Within-Run Precision Guidelines

Version 1.0

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 %

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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)

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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 %
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 %