COBAS INTEGRA® 400 plus analyzer

Within-Run Precision Guidelines

Version 12

VV-06632-03

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Any screenshots in this publication have been added exclusively for the purpose of illustration. Configurable and variable data such as parameters, results, path names etc. visible therein must not be used for laboratory purposes.

This document is intended for the US market only.

Caution: Federal law restricts this device to sale by or on the order of a physician.

This document was created by the Roche Diagnostics Engineering Operations department. Direct questions or concerns regarding the contents of this document to:

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Revision History

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Publication Reference Number	Date	Revision purpose
0637-00-0904 Version 0	September 2004	Document creation.
0637-01-0106 Version 1	January 2006	Revised entire document to include precision values from the individual Method Sheets.
0637-02-0307 Version 2	March 2007	Revised entire document to include precision values for newly launched assays: CHE2, CREJ2, GLU3, HDL3, MYO2, CRPHS, ALBU2 and Tina-quant Hemoglobin A1c gen. 2
0637-03-0108 Version 3	January 2008	Revised entire document to include precision values for newly launched assays: Tina-quant Albumin Gen. 2, Iron Gen. 2, Total Mycophenolic Acid and Total Protein Urine/CSF Gen. 3 and to remove all assays and analyzers which Roche no longer supports.
0637-04-1108 Version 4	November 2008	Removed obsolete total protein products and corrected typos for other protein products.
0637-05-1208 Version 5	December 2008	Added Cystatin C assay.
0637-06-0709 Version 6	July 2009	Updated Cyclosporine II assay
0637-07-0110 Version 7	January 2010	Revised to reflect actual %CV. Calculation must be performed based on the information presented.
0637-08-1014 Version 8	October 2014	Added Bilirubin, Total Gen.3, Calcium Gen.2, Homocysteine, Lipoprotein (a), Gen.2. Removed Calcium (serum/plasma/urine).
0637-09-0516 Version 9	May 2016	Added DAT materials and Acetaminophen 2. Minor modifications in reformatting.
0637-10-0817 Version 10	August 2017	Added CK2, HDLC4, HbA1c Gen. 3, and LDLC3. Updated Prescription use statement.
VV-06632-02 Version 11	August 2020	Added CRP4X and Vancomycin Gen.3. Removed COBAS INTEGRA 800 system and assay information. Removed Quinidine and Vancomycin. Updated title as this applies to only the COBAS INTEGRA 400 plus analyzer.
VV-06632-03 Version 12	October 2023	Removed CRP/Latex Updated Albumin TQ (Urine) Updated Homocysteine

COBAS INTEGRA 400 plus analyzer Within Precision Guidelines

Clinical Chemistry

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 = 20 or 21 for all tests

Assay	Standard Deviation (SD)	Sample Concentration	%CV Guideline
Albumin gen.2	≤ 0.7 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	≤ 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	≤ 1.0 U/L	35 U/L	≤ 3 %
Bilirubin, Total Gen.3	≤ 0.03 mg/dL	0.99 mg/dL	≤ 5 %
Bilirubin, Direct	≤ 0.01 mg/dL	0.3 mg/dL	≤ 3 %
Calcium Gen.2 (serum/plasma)	≤ 0.16 mg/dL	---	≤ 2 %
Calcium Gen.2 (urine)	≤ 0.16 mg/dL	---	≤ 2 %
Cholesterol/HP gen 2	≤ 3.87 mg/dL	201 mg/dL	≤ 2 %
Cholinesterase/butyrylthiocholine	≤ 40 U/L	---	≤ 2 %
CK2	≤ 3 U/L	140 U/L	≤ 2 %
CO2-L	≤ 0.36 mmol/L	12 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, 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/dL	≤ 4 %
Ethanol ver.2	≤ 2.8 mg/dL	100 mg/dL	≤ 3 %

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Clinical Chemistry

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Assay	Standard Deviation (SD)	Sample Concentration	%CV Guideline
Ethanol Urine. Ver.2	≤ 1.5 mg/dL	49.8 mg/dL	≤ 3 %
GGT ver 2	≤ 0.8 U/L	40 U/L	≤ 2 %
Glucose/HK ver 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 plus gen 4			≤ 3 %
Iron gen 2	≤ 3.02 µg/dL	150.4 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	≤ 10 U/L	480 U/L	≤ 2 %
LDL-C Plus gen 3	≤ 3.1 mg/dL	≤ 154.6 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	4.1 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)	≤ 14 mg/L	450 mg/L	≤ 3 %
Total Protein U/CSF (Urine)	≤ 3.6 mg/L	120 mg/L	≤ 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 (serum/plasma)	≤ 0.1 mg/dL	5.0 mg/dL	≤ 2 %
Uric Acid (urine)	≤ 0.7 mg/dL	37 mg/dL	≤ 2 %

ISE

N = 20 or 21 for all tests

Assay	Standard Deviation (SD)	Sample Concentration	%CV Guideline
Sodium (serum/plasma)	≤ 3 mmol/L	20-140 mmol/L	
		141-190 mmol/L	≤ 1 %
	≤ 3 mmol/L	191-250 mmol/L	
Sodium (urine)	≤ 6 mmol/L	20-120 mmol/L	
		121-250 mmol/L	≤ 5 %
Potassium (serum/plasma)	≤ 0.15 mmol/L	0.20-4.0 mmol/L	
		4.1-8.0 mmol/L	≤ 1.0 %
	≤ 0.15 mmol/L	8.1-30 mmol/L	
Potassium (urine)	≤ 1 mmol/L	1-10 mmol/L	
		11-150 mmol/L	≤ 5 %
Chloride (serum/plasma)	≤ 2.5 mmol/L	20-90 mmol/L	
		91-130 mmol/L	≤ 1 %
	≤ 2.5 mmol/L	131-250 mmol/L	
Chloride (urine)	≤ 6 mmol/L	20-90 mmol/L	
		91-350 mmol/L	≤ 5 %
Lithium (serum/plasma)	≤ 0.03 mmol/L	0.1-0.4 mmol/L	
	≤ 0.02 mmol/L	0.5-1.5 mmol/L	
	≤ 0.03 mmol/L	1.6-2.6 mmol/L	
	≤ 0.10 mmol/L	2.7-4.0 mmol/L	

Specific Proteins

N = 20 or 21 for all tests

Assay	Standard Deviation (SD)	Sample Concentration	%CV Guideline
a-1 Acid Glycoprotein gen 2	≤ 0.05 g/L	1.2 g/L	≤ 4 %
Albumin TQ (serum/plasma)	≤ 0.14 g/dL	3.5 g/dL	≤ 4 %
Albumin TQ (urine)	≤ 0.08 mg/dL ≤ 0.8 mg/L	2.0 mg/dL 20 mg/L	≤ 4 % ≤ 4 %
Albumin TQ (CSF)	≤ 10 mg/L	240 mg/L	≤ 4 %
a-1-Antitrypsin	≤ 4.0 mg/dL	90 mg/dL	≤ 4 %
APO A-1- ver.2	≤ 4.0 mg/dL	100 mg/dL	≤ 4 %
APO B ver.2	≤ 4.0 mg/dL	100 mg/dL	≤ 4 %
ASLO	≤ 4 IU/mL	100 IU/mL	≤ 4 %
C3c ver 2	≤ 4.0 mg/dL	90.0 mg/dL	≤ 4 %
C4	≤ 0.4 mg/dL	10.0 mg/dL	≤ 4 %
Ceruloplasmin	≤ 1.0 mg/dL	30 mg/dL	≤ 4 %
CRP (Latex) HS	≤ 0.004 mg/dL	0.1 mg/dL	≤ 4 %
CRP4X	≤ 0.02 mg/dL	0.5 mg/dL	≤ 4 %
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 %
Fructosamine	≤ 6 µmol/L	285 µmol/L	≤ 2 %
Haptoglobin ver 2	≤ 1.2 mg/dL	30.0 mg/dL	≤ 4 %
HbA1c Gen.3 (whole blood)	---	---	≤ 2.5%
HbA1c Gen.3 (Hemosylate)	---	---	≤ 2.5%
Homocysteine	≤ 0.75 µmol/L ---	≤ 15 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)	≤ 0.04 mg/dL	1.0 mg/dL	≤ 4 %
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 ≥ 30 mg/dL	--- ≤ 4 %
Myoglobin	≤ 2.4 ng/mL	---	≤ 4 %

Specific Proteins

N = 21 for all tests

Assay	Standard Deviation (SD)	Sample Concentration	%CV Guideline
Prealbumin	< 2.0 mg/dL	40 mg/dL	≤ 4 %
RF II	≤ 0.6 IU/mL	14 IU/mL	≤ 4 %
Soluble Transferrin Receptor	≤ 0.1 mg/L	2 mg/L	≤ 4 %
Transferrin ver.2	n/a	n/a	≤ 5.0

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Drugs of Abuse Testing (DAT)

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

Qualitative Drugs of Abuse Testing (DAT)

Assay
Run DAT controls at levels 0.75x (PreciNeg) and 1.25x (PreciPos) in multiples of 10.
At least 95% of the 0.75x samples should be negative.
At least 95% of the 1.25x samples should be positive.

Drugs of Abuse Testing Semiquantitative Assays (DAT)

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
Amphetamines II	300 ng/mL 500 ng/mL 1000 ng/mL	≤ 8 % ≤ 8 % ≤ 8 %	300 Control Set DAT II 500 Control Set DAT I 1000 Control Set DAT III
Barbiturates	200 ng/mL	≤ 8 %	200 Control Set DAT I
Benzodiazepines	100 ng/mL	≤ 12%	100 Control Set DAT II
Cannabanoids 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 ≤ 2%		Ammonia/Ethanol/CO2 control normal and abnormal
LSD		≤ 8 %	LSD QC
Methadone II	300 ng/mL	≤ 8 %	300 Control Set DAT I
DRI Methadone Metabolite (EDDP)	300 ng/mL 1000 ng/mL	≤ 8 % ≤ 8 %	100 Methadone Metabolite Control Set 100 300 Methadone Metabolite Control Set 300
Methaqualone	300 ng/mL	≤ 8 %	300 Control Set DAT I
Opiates II	300 ng/mL 2000 ng/mL	≤ 5 % ≤ 5 %	300 Control Set DAT II 2000 Control Set DAT I
DRI Oxycodone	100 ng/mL 300 ng/mL	≤ 5 % ≤ 5 %	100 Oxycodone Control Set 100 300 Oxycodone Control Set 300
Phencyclidine (PCP)	25 ng/mL	≤ 10 %	25 Control Set DAT I
Propoxyphene	300 ng/mL	≤ 8 %	300 Control Set DAT I

Therapeutic Drug Monitoring (TDM)

N = 20 or 21 for all tests

Assay	Standard Deviation (SD)	Sample Concentration	%CV Guideline
Acetaminophen	≤ 0.7 µg/mL	10.0 µg/mL	≤ 7 %
Acetaminophen 2	≤ 0.7 µg/mL	10.0 µg/mL	≤ 7%
Amikacin	≤ 0.56 µg/mL	8.0 µg/mL	≤ 7 %
Carbamazepine	≤ 0.20 µg/mL	4 µg/mL	≤ 5 %
Cyclosporine II	≤ 9 ng/mL	75 ng/mL	≤ 12 %
Digoxin	n/a	≤ 1.0 ng/mL > 1.0 ng/mL	≤ 11 % ≤ 7 %
Gentamicin	≤ 0.09 µg/mL	1.7 µg/mL	≤ 5 %
Lidocaine	≤ 1.4 µg/mL	2.0 µg/mL	≤ 7 %
NAPA	≤ 0.14 µg/mL	2 µg/mL	≤ 7 %
Phenobarbital	≤ 0.75 µg/mL	15 µg/mL	≤ 5 %
Phenytoin	≤ 0.5 µg/mL	10 µg/mL	≤ 5 %
Free Phenytoin	≤ 0.1 µg/mL	1.0 µg/mL	≤ 7 %
Primidone	≤ 0.2 µg/mL	5 µg/mL	≤ 5 %
Procainamide	≤ 0.14 µg/mL	2 µg/mL	≤ 7 %
Salicylate	≤ 2.5 µg/dL	50 µg/dL	≤ 5 %
Theophylline	≤ 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	≤ 2.1 µg/mL	30 µg/mL	≤ 5 %
Free Valproic Acid	≤ 0.5 µg/mL	10 µg/mL	≤ 5 %
Vancomycin Gen.3	≤ 0.5 µg/mL --- ---	≤ 10 µg/mL 10 - ≤40 µg/mL 40 µg/mL	--- ≤ 5 % ≤ 8 %