

Supplementary Table 2. Examples of analytical performance specifications as acceptance limits for proficiency testing based on The Royal College of Pathologists of Australasia and other resources (Milan model 3) (last accessed on May 15 2023)

Measurand	Matrix	RCPA		CLIA 2024	Other		
		Lower limit	Upper limit		Imprecision (%)	Allowable bias (%)	TEa (%)
17- α -hydroxyprogesterone	Serum/plasma	± 2.0 (≤ 10.0 nmol/L)	$\pm 20\%$ (> 10.0 nmol/L)				
25-hydroxy vitamin D3	Serum/plasma	± 9 (≤ 60 nmol/L)	$\pm 15\%$ (60 nmol/L)				
4-Hydroxy-3-methoxymandelic acid (HMMA)	Plasma	± 6 (≤ 40 μ mol/L)	$\pm 15\%$ (> 40 μ mol/L)				
5-hydroxyindoleacetic acid (5-HIAA)	Plasma	± 8 (≤ 40 μ mol/L)	$\pm 20\%$ (> 40 μ mol/L)				
Acetaminophen	Serum/plasma		$\pm 15\%$ or ± 3 mcg/dL				
Adrenaline	Plasma	± 30 (≤ 100 nmol/L)	$\pm 30\%$ (> 100 nmol/L)				
Adrenocorticotrophic hormone (ACTH)	Plasma	± 2.0 (≤ 20 pmol/L)	$\pm 10\%$ (> 20 pmol/L)				
Alanine transaminase (ALT)	Serum/plasma	± 5 (≤ 40 U/L)	$\pm 12\%$ (> 40 U/L)	$\pm 15\%$ or ± 6 U/L			
Albumin	Serum/plasma	± 0.2 (≤ 3.3 g/dL)	$\pm 6\%$ (> 3.3 g/dL)	$\pm 8\%$			
Alcohol	Serum/plasma	± 2.0 (≤ 20.0 mmol/L)	$\pm 10\%$ (> 20.0 mmol/L)	$\pm 20\%$			
Aldosterone	Serum/plasma	± 24 (≤ 160 pmol/L)	$\pm 15\%$ (> 160 pmol/L)				
Alkaline phosphatase (ALP) bone isoenzyme	Serum/plasma	± 15 (≤ 125 U/L)	$\pm 12\%$ (> 125 U/L)	$\pm 20\%$			
Alkaline phosphatase (ALP), liver type	Serum/plasma	± 15 (≤ 125 U/L)	$\pm 12\%$ (> 125 U/L)	$\pm 20\%$			
Alpha-1 antitrypsin	Serum/plasma	± 0.10 (≤ 0.50 g/L)	$\pm 20\%$ (> 0.50 g/L)	$\pm 20\%$			
Alpha fetoprotein (AFP)	Serum/plasma	± 2 (≤ 17 kIU/L)	$\pm 12\%$ (> 17 kIU/L)	$\pm 20\%$			
Aluminium	Serum/plasma	± 0.08 (≤ 0.40 μ mol/L)	$\pm 20\%$ (> 0.40 μ mol/L)				
Amikacin	Serum/plasma	± 2.0 (≤ 19.9 mg/L)	$\pm 10\%$ (> 19.9 mg/L)				
Ammonia	Plasma	± 5 (≤ 50 μ mol/L/L)	$\pm 10\%$ (> 50 μ mol/L/L)	$\pm 10\%$			
Amylase	Serum/plasma	± 10 (≤ 100 U/L)	$\pm 10\%$ (> 100 U/L)				
Androstenedione	Serum/plasma	± 1.5 (≤ 10 nmol/L)	$\pm 15\%$ (> 10 nmol/L)				
Angiotensin-converting enzyme (ACE)	Serum/plasma	± 1.0 (≤ 10.0 U/L)	$\pm 10\%$ (> 10.0 U/L)				
Apolipoprotein A1	Serum/plasma	± 0.2 (≤ 2.0 g/L)	$\pm 10\%$ (> 2.0 g/L)				
Apolipoprotein B	Serum/plasma	± 0.2 (≤ 2.0 g/L)	$\pm 10\%$ (> 2.0 g/L)				
Aspartate transaminase (AST)	Serum/plasma	± 5 (≤ 40 U/L)	$\pm 12\%$ (> 40 U/L)	$\pm 15\%$ or ± 6 U/L			
Beta-2-microglobulin	Serum/plasma	± 0.2 (≤ 2.0 mg/L)	$\pm 10\%$ (> 2.0 mg/L)				
Bicarbonate	Serum/plasma	± 2.0 (≤ 20.0 mmol/L)	$\pm 10\%$ (> 20.0 mmol/L)				
Bilirubin, conjugated	Serum/plasma	± 3 (≤ 15 μ mol/L)	$\pm 20\%$ (> 15 μ mol/L)				
Bilirubin, total	Serum/plasma	± 3 (≤ 25 μ mol/L)	$\pm 12\%$ (> 25 μ mol/L)	$\pm 20\%$ or 0.4 mg/dL			
B-natriuretic peptide (BNP)	Serum/plasma	± 20 (≤ 100 ng/L)	$\pm 20\%$ (> 100 ng/L)	$\pm 30\%$			
Calcitonin	Serum/plasma	± 2 (≤ 20 ng/L)	$\pm 10\%$ (> 20 ng/L)				
Calcium	Serum/plasma	± 0.10 (≤ 2.50 mmol/L)	$\pm 4\%$ (> 2.50 mmol/L)	± 1.0 mg/dL			
Calcium, ionized	Whole blood	± 0.04 (≤ 1.00 mmol/L)	$\pm 4\%$ (> 1.00 mmol/L)				
Cancer antigen 125 (CA 125)	Serum/plasma	± 6 (≤ 50 kU/L)	$\pm 12\%$ (> 50 kU/L)	$\pm 20\%$			
Cancer antigen 15-3 (CA 15-3)	Serum/plasma	± 3 (≤ 30 kU/L)	$\pm 10\%$ (> 30 kU/L)				
Cancer antigen 19-9 (CA 19-9)	Serum/plasma	± 6 (≤ 40 kU/L)	$\pm 15\%$ (> 40 kU/L)				
Carbamazepine	Serum/plasma	± 0.5 (≤ 4.7 mg/L)	$\pm 10\%$ (> 4.7 mg/L)	$\pm 20\%$ or ± 1.0 mcg/dL			

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Supplementary Table 2. Continued

Measurand	Matrix	RCPA		CLIA 2024	Other					
		Lower limit	Upper limit		Imprecision (%)	Allowable bias (%)	TEa (%)	Reference		
Carbon dioxide, total (tCO ₂)	Whole blood									
Carcinoembryonic antigen (CEA)	Serum/plasma	± 0.6 (≤ 5.0 µg/L)	± 12% (>5.0 µg/L)	± 15% or ± 1 ng/dL						
Ceruloplasmin	Serum/plasma	± 0.03 (≤ 0.20 g/L)	± 15% (>0.20 g/L)							
Chloride	Serum/plasma	± 3 (≤ 100 mmol/L)	± 3% (>100 mmol/L)	± 5%						
Cholesterol	Serum/plasma	± 0.30 (≤ 5.00 mmol/L)	± 6% (>5.00 mmol/L)	± 10%			3.0	3.0	8.9	NCEP
Chromium	Serum/plasma	± 3 (≤ 25 nmol/L)	± 12% (>25 nmol/L)							
Cobalt	Serum/plasma	± 1 (≤ 10 nmol/L)	± 10% (>10 nmol/L)							
Complement 3 (C3)	Serum/plasma	± 0.10 (≤ 1.0 g/L)	± 10% (>1.0 g/L)	± 15%						
Complement 4 (C4)	Serum/plasma	± 0.02 (≤ 0.20 g/L)	± 10% (>0.20 g/L)	± 5 mg/dL or ± 20%						
Copper	Serum/plasma	± 1.6 (≤ 20.0 µmol/L)	± 8% (>20.0 µmol/L)							
Cortisol	Serum/plasma	± 15 (≤ 100 nmol/L)	± 15% (>100 nmol/L)	± 20%						
C-peptide	Serum/plasma	± 0.15 (≤ 1.25 nmol/L)	± 12% (>1.25 nmol/L)							
C-reactive protein (CRP)	Serum/plasma	± 0.8 (≤ 4.0 mg/L)	± 20% (>4.0 mg/L)							
C-reactive protein (CRP) - high-sensitive	Serum/plasma	± 0.6 (≤ 3.0 mg/L)	± 20% (>3.0 mg/L)	± 1 mg/dL or ± 30%						
Creatine kinase (CK)	Serum/plasma	± 15 (≤ 125 U/L)	± 12% (>125 U/L)	± 20%						
Creatine kinase MB isoenzymes (CK-MB)	Serum/plasma	± 3 (≤ 15 U/L or µg/L)	± 20% (>15 U/L or µg/L)	± 25% or ± 3 ng/mL						
Creatinine	Serum/plasma	± 8.0 (≤ 100.0 µmol/L)	± 8% (>100.0 µmol/L)	± 0.2 mg/dL or ± 10%						
Cyclosporin	Whole blood	± 10 (≤ 100 µg/L)	± 10% (>100 µg/L)							
Dehydroepiandrosterone sulphate (DHEAS)	Serum/plasma	± 1.2 (≤ 10.0 µmol/L)	± 12% (>10.0 µmol/L)							
Digoxin	Serum/plasma	± 0.2 (≤ 1.6 µg/L)	± 10% (>1.6 µg/L)	± 15% or ± 0.2 ng/mL						
Dopamine	Plasma	± 0.20 (≤ 2.0 µmol/L)	± 10% (>2.0 µmol/L)							
Estradiol	Serum/plasma	± 25 (≤ 100 pmol/L)	± 25% (>100 pmol/L)	± 30%						
Ferritin	Serum/plasma	± 4.0 (≤ 27.0 µg/L)	± 15% (>27.0 µg/L)	± 20%						
Folate	Serum/plasma	± 1.5 (≤ 6.0 nmol/L)	± 25% (>6.0 nmol/L)	± 1 ng/mL or ± 30%						
Follicle stimulating hormone (FSH)	Serum/plasma	± 1.0 (≤ 10.0 IU/L)	± 10% (>10.0 IU/L)	± 2 IU/L or ± 18%						
Fructosamine	Serum/plasma	± 15 (≤ 250 µmol/L)	± 6% (>250 µmol/L)							
Gamma-glutamyl transferase (GGT) activity	Serum/plasma	± 5 (≤ 40 U/L)	± 12% (>40 U/L)	± 5 U/L or ± 15%						
Gastrin	Serum/plasma	± 10 (≤ 100 pmol/L)	± 10% (>100 pmol/L)							
Gentamicin	Serum/plasma	± 0.2 (≤ 2.0 mg/L)	± 10% (>2.0 mg/L)	± 25%						
Glucose	Serum/plasma	± 0.4 (≤ 5.0 mmol/L)	± 8% (>5.0 mmol/L)	± 6 mg/dL or ± 8%						
Growth hormone (GH)	Serum/plasma	± 1 (≤ 7 mIU/L)	± 15% (>7 mIU/L)							
Hemoglobin A1c (IFCC) (mmol/mol)	Whole blood	± 4 (≤ 45 mmol/mol)	± 8% (>45 mmol/mol)	± 8%						
Hemoglobin A1c (NGSP) (%)	Whole blood	± 0.4 (≤ 6.7%)	± 6% (>6.7%)	± 8%						
Haptoglobin	Serum/plasma	± 0.10 (≤ 0.80 g/L)	± 10% (>0.80 g/L)							
HDL cholesterol	Serum/plasma	± 0.10 (≤ 0.80 mmol/L)	± 12% (>0.80 mmol/L)	± 20% or ± 6 mg/dL			4.0	5.0	13.0	NCEP
Homocysteine	Serum/plasma	± 1.5 (≤ 15.0 µmol/L)	± 10% (>15.0 µmol/L)							

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Supplementary Table 2. Continued

Measurand	Matrix	RCPA		CLIA 2024	Other		Reference
		Lower limit	Upper limit		Imprecision (%)	Allowable bias (%)	
Homovanillic acid (HVA)	Plasma	± 6 (≤ 40 µmol/L)	± 15% (> 40 µmol/L)				
Human chorionic gonadotropin (hCG)	Serum/plasma	± 1.0 (≤ 10.0 IU/L)	± 10% (> 10.0 IU/L)	± 18% or ± 3 IU/L			
Hydrogen ion (H ⁺)	Whole blood	as pH, ± 0.04	as pH, ± 0.04	as pH, ± 0.04			
Immunoglobulin A (IgA)	Serum/plasma	± 0.06 (≤ 0.60 g/L)	± 10% (> 0.60 g/L)	± 20%			
Immunoglobulin D (IgD)	Serum/plasma	± 0.2 (≤ 1.0 g/L)	± 20% (> 1.0 g/L)				
Immunoglobulin E (IgE)	Serum/plasma	± 20 (≤ 100 kU/L)	± 20% (> 100 kU/L)	± 20%			
Immunoglobulin G (IgG)	Serum/plasma	± 0.6 (≤ 6.0 g/L)	± 10% (> 6.0 g/L)	± 20%			
Immunoglobulin M (IgM)	Serum/plasma	± 0.08 (≤ 0.50 g/L)	± 15% (> 0.50 g/L)	± 20%			
Insulin	Serum/plasma	± 0.6 (≤ 5.0 mU/L)	± 12% (> 5.0 mU/L)				
Insulin-like growth factor binding protein-3 (IGFBP-3)	Serum/plasma	± 15.0 (≤ 100 nmol/L)	± 15% (> 100 nmol/L)				
Insulin-like growth factor-1 (IGF-1)	Serum/plasma	± 3 (≤ 25 nmol/L)	± 12% (> 25 nmol/L)				
Iron	Serum/plasma	± 3.0 (≤ 25.0 µmol/L)	± 12% (> 25.0 µmol/L)	± 15%			
Lactate	Whole blood	± 0.5 (≤ 4.0 mmol/L)	± 12% (> 4.0 mmol/L)				
Lactate dehydrogenase (LDH) activity	Serum/plasma	± 20 (≤ 250 U/L)	± 8% (> 250 U/L)	± 15%			
LDL Cholesterol	Serum/plasma	± 0.2 (≤ 2.0 mmol/L)	± 10% (> 2.0 mmol/L)	± 20%	4.0	12.0	NCEP
Lead (Pb)	Whole blood			± 10% or 2 mcg/dL			
Lipase	Serum/plasma	± 12 (≤ 60 U/L)	± 20% (> 60 U/L)				
Lipoprotein (a)	Serum/plasma	± 0.06 (≤ 0.3 g/L)	± 20% (> 0.3 g/L)				
Lithium	Serum/plasma	± 0.20 (≤ 2.0 mmol/L)	± 10% (> 2.0 mmol/L)	± 15% or ± 0.3 mmol/L			
Luteinizing hormone (LH)	Serum/plasma			± 20%			
Magnesium	Serum/plasma	± 0.10 (≤ 1.25 mmol/L)	± 8% (> 1.25 mmol/L)	± 15%			
Metanephrine	Plasma	± 75 (≤ 500 pmol/L)	± 15% (> 500 pmol/L)				
Methoxytyramine	Plasma	± 36 (≤ 120 pmol/L)	± 30% (> 120 pmol/L)				
Neuron specific enolase (NSE)	Serum/plasma	± 2.0 (≤ 20 µg/L)	± 10% (> 20 µg/L)				
Normetanephrine	Plasma	± 200 (≤ 1,000 pmol/L)	± 20% (> 1,000 pmol/L)				
Osmolality	Serum	± 8 (≤ 266 mmol/kg)	± 3% (> 266 mmol/kg)				
Parathyroid hormone (PTH)	Serum/plasma	± 1.0 (≤ 8.0 pmol/L)	± 12% (> 8.0 pmol/L)	± 30%			
Partial pressure of carbon dioxide (pCO ₂)	Whole blood	± 2.0 (≤ 34.0 mm Hg)	± 6% (> 34.0 mm Hg)	± 5 mmHg or ± 8%			
Partial pressure of oxygen (pO ₂)	Whole blood	± 5 (≤ 83 mm Hg)	± 6% (> 83 mm Hg)	± 15 mmHg or ± 15%			
Phenobarbital	Serum/plasma	± 0.7 (≤ 7.0 mg/L)	± 10% (> 7.0 mg/L)	± 15% or ± 2 mcg/mL			
Phenytoin	Serum/plasma	± 0.8 (≤ 7.6 mg/L)	± 10% (> 7.6 mg/L)	± 15% or ± 2 mcg/dL			
Phosphate	Serum/plasma	± 0.06 (≤ 0.75 mmol/L)	± 8% (> 0.75 mmol/L)	± 0.3 mg/dL or 10%			
Potassium	Serum/plasma	± 0.2 (≤ 4.0 mmol/L)	± 5% (> 4.0 mmol/L)	± 0.3 mmol/L			
Prealbumin	Serum/plasma	± 0.04 (≤ 0.20 g/L)	± 20% (> 0.20 g/L)				
Pro B-natriuretic peptide (proBNP)	Serum/plasma	± 25 (≤ 125 ng/L)	± 20% (> 125 ng/L)	± 30%			
Procalcitonin	Serum/plasma	± 0.05 (≤ 0.15 ng/mL)	± 30% (> 0.15 ng/mL)				

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Supplementary Table 2. Continued

Measurand	Matrix	RCPA		CLIA 2024	Other		Reference
		Lower limit	Upper limit		Imprecision (%)	Allowable bias (%)	
Progesterone	Serum/plasma	± 2 (≤ 10 nmol/L)	± 15% (> 10 nmol/L)	± 25%			
Prolactin	Serum/plasma	± 40 (≤ 400 mIU/L)	± 10% (> 400 mIU/L)	± 20%			
Prostate specific antigen - free (fPSA)	Serum/plasma	± 0.2 (≤ 1.4 µg/L)	± 15% (> 1.4 µg/L)				
Prostate specific antigen (PSA)	Serum/plasma	± 0.4 (≤ 5.0 µg/L)	± 8% (> 5.0 µg/L)	± 0.2 ng/dL or ± 20%			
Protein (total)	Serum/plasma	± 0.3 (≤ 6.0 g/dL)	± 5% (> 6.0 g/dL)	± 8%			
Rheumatoid factor (RF)	Serum/plasma	± 12 (≤ 60 IU/mL)	± 20% (> 60 IU/mL)				
Salicylate	Serum/plasma	± 14.0 (≤ 143.0 mg/L)	± 10% (> 143.0 mg/L)	± 15% or ± 2 mcg/dL			
Selenium	Serum/plasma	± 0.18 (≤ 1.50 µmol/L)	± 12% (> 1.50 µmol/L)				
Serotonin	Serum/plasma	± 0.2 (≤ 1.0 µmol/L)	± 20% (> 1.0 µmol/L)				
Sexual-hormone-binding-globulin (SHBG)	Serum/plasma	± 6 (≤ 50 nmol/L)	± 12% (> 50 nmol/L)				
Sirolimus	Whole blood	± 0.5 (≤ 5.0 µg/L)	± 10% (> 5.0 µg/L)				
Sodium	Serum/plasma	± 3 (≤ 150 mmol/L)	± 2% (> 150 mmol/L)	± 4 mmol/L			
Tacrolimus	Whole blood	± 0.5 (≤ 5.0 µg/L)	± 10% (> 5.0 µg/L)				
Testosterone	Serum/plasma	± 0.4 (≤ 2.7 nmol/L)	± 15% (> 2.7 nmol/L)	± 20 ng/dL or ± 30%			
Thallium	Serum/plasma	± 1 (≤ 10 nmol/L)	± 10% (> 10 nmol/L)				
Theophylline	Serum/plasma	± 0.5 (≤ 5.4 mg/L)	± 10% (> 5.4 mg/L)	± 20%			
Thyroglobulin	Serum/plasma	± 0.2 (≤ 1.7 µg/L)	± 12% (> 1.7 µg/L)		4.4	2.2	10.8
Thyroid stimulating hormone (TSH)	Serum/plasma	± 0.10 (≤ 0.50 mIU/L)	± 20% (> 0.50 mIU/L)	± 20% or ± 2 mIU/L	10.3	5.2	25.4
Thyroxine - free (fT4)	Serum/plasma	± 1.5 (≤ 12.0 pmol/L)	± 12% (> 12.0 pmol/L)	± 0.3 ng/dL or ± 15%	4.8	2.4	11.8
Thyroxine - total (T4)	Serum/plasma	± 12 (≤ 120 nmol/L)	± 10% (> 120 nmol/L)	± 20% or ± 1.0 mcg/dL	2.7	1.3	6.6
Tobramycin	Serum/plasma	± 0.2 (≤ 2.0 mg/L)	± 10% (> 2.0 mg/L)	± 20%			
Total Iron Binding Capacity (TIBC)	Serum/plasma	± 4.0 (≤ 50.0 µmol/L)	± 8% (> 50.0 µmol/L)	± 20%			
Transferrin	Serum/plasma	± 0.20 (≤ 2.50 g/L)	± 8% (> 2.50 g/L)				
Triglycerides	Serum/plasma	± 0.20 (≤ 1.60 mmol/L)	± 12% (> 1.60 mmol/L)	± 15%	5.0	5.0	15.0
Triiodothyronine - free (fT3)	Serum/plasma	± 0.7 (≤ 3.5 pmol/L)	± 20% (> 3.5 pmol/L)		4.0	2.0	9.9
Tri-iodothyronine - total (T3)	Serum/plasma	± 0.2 (≤ 1.3 nmol/L)	± 15% (> 1.3 nmol/L)	± 30%	2.8	1.4	6.9
Triiodothyronine (T3) uptake	Serum/plasma			± 18%			
Troponin I, cardiac - high-sensitive	Serum/plasma	± 0.002 (≤ 0.010 µg/L)	± 20% (> 0.010 µg/L)	± 0.9 ng/mL or ± 30%			
Troponin T, cardiac - high-sensitive	Serum/plasma	± 0.01 (≤ 0.050 µg/L)	± 20% (> 0.050 µg/L)	± 0.2 ng/mL or ± 30%	10.0		
Tryptase	Serum/plasma	± 0.6 (≤ 4.0 µg/L)	± 15% (> 4.0 µg/L)				
Urate	Serum/plasma	± 0.030 (≤ 0.380 mmol/L)	± 8% (> 0.380 mmol/L)	± 10%			
Urea	Serum/plasma	± 0.5 (≤ 4.0 mmol/L)	± 12% (> 4.0 mmol/L)	± 2 mg/dL or ± 9%			
Valproic acid	Serum/plasma	± 4.0 (≤ 36.0 mg/L)	± 10% (> 36.0 mg/L)	± 20%			
Vanadium	Serum/plasma	± 1 (≤ 10 nmol/L)	± 10% (> 10 nmol/L)				
Vancomycin	Serum/plasma	± 2.0 (≤ 20.3 mg/L)	± 10% (> 20.3 mg/L)	± 15% or ± 2 mcg/dL			
Vitamin A	Serum/plasma	± 0.2 (≤ 1.7 µmol/L)	± 12% (> 1.7 µmol/L)				

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Supplementary Table 2. Continued

Measurand	Matrix	RCPA		CLIA 2024	Other		
		Lower limit	Upper limit		Imprecision (%)	Allowable bias (%)	TEa (%)
Vitamin B12 (cobalamin)	Serum/plasma	± 18 (≤ 120 pmol/L)	± 15% (> 120 pmol/L)	± 25% or ± 30 pg/mL			
Vitamin B2 (riboflavin)	Plasma	± 25 (≤ 250 nmol/L)	± 10% (> 250 nmol/L)				
Vitamin B6 (pyridoxine)	Plasma	± 9 (≤ 60 nmol/L)	± 15% (> 60 nmol/L)				
Vitamin C	Serum/plasma	± 7 (≤ 35 μmol/L)	± 20% (> 35 μmol/L)				
Vitamin E	Serum/plasma	± 3 (≤ 25 μmol/L)	± 12% (> 25 μmol/L)				
Zinc	Serum/plasma	± 2.0 (≤ 20.0 μmol/L)	± 10% (> 20.0 μmol/L)				

Abbreviations: RCPA, The Royal College of Pathologists of Australasia; CLIA, Clinical Laboratory Improvement Amendments regulated by The Food and Drug Administration (FDA), Center for Medicaid Services (CMS), and the Centers for Disease Control and Prevention (CDC) of the United States; TEa, allowable total error; NCEP, the National Cholesterol Education Program; NACB, the National Academy of Clinical Biochemistry.