

DETAILED SCOPE OF ACCREDITATION (5)
for the organisation under the NAH-8-0002/2018 registration number

1.) The name and address of the accredited organisation:

QualiCont In Vitro Diagnostic Quality Control Nonprofit Ltd.

6720 Szeged, Feketesas u. 19-21. ¹

2.) Accreditation standard:

MSZ EN ISO/IEC 17043:2010

3.) Accreditation category:

Proficiency Testing Provider

4.) The duration of the accredited status:

Start date of the accredited status: **8th March 2018**

Expiry date of the accredited status: **8th March 2023**

5.) The scope of accreditation⁴:

No.	Name of proficiency test	Scope of proficiency test	Material/Product	Parameter(s) to be measured
1.	100. Clinical chemistry (wet)	Clinical chemistry / Immune chemistry	lyophilized serum	Albumin, Albumin (elpho), Alkaline phosphatase, Alpha-amylase, α -HBDH, Bilirubin (total), Bilirubin (conjugate), CK, Phosphate (inorganic), Gamma-GT, Gamma globulin (elpho), Glucose, GLDH, GOT/ASAT, GPT/ALAT, HDL cholesterol, Uric acid, IgA, IgG, IgM, Calcium, Potassium, Urea, Chloride, Cholesterol, Cholinesterase, Creatinine, Lactate, LAP, LDH, Lipase, Lithium, Magnesium, Sodium, Osmolality, Total protein, Pancreatic amylase, Copper, Acid phosphatase (total), Acid phosphatase (prostatic), Transferrin, Triglycerides, Total Iron-Binding Capacity (TIBC), Iron, Bicarbonate ²
2.	100eGFR ³			Calculated value, taking into account the given creatinine value and case history ³
3.	110. Neonatal bilirubin		lyophilized serum	Bilirubin (total)
4.	131. Faecal diagnostics: (FOB) ²		lyophilized faecal samples	Haemoglobin (Qualitative and Quantitative)
5.	145. Glycated proteins I.	Clinical chemistry / Immune chemistry/ Diabetes tests	lyophilized hemolysate	HbA1, HbA1C
6.	146. Glycated proteins II. (Fructosamine)	Clinical chemistry / Immune chemistry	lyophilized hemolysate, lyophilized serum	Fructosamine ³

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7.	151. Lipids/lipoproteins	Clinical chemistry / Immune chemistry	lyophilized serum	Apolipoprotein A1, Apolipoprotein B, Phospholipids, HDL- and LDL-cholesterol, Cholesterol, Lp(a), Triglycerides
8.	171. Urine chemistry, qualitative	Clinical chemistry / Immune chemistry / Urine chemistry	liquid human urine	Ascorbic acid, Bilirubin, Specific gravity, Total Protein, Leucocyte (WBC), Glucose, HCG, Ketone bodies, Nitrite, pH, Urobilinogen, Erythrocyte (RBC), Microscopic sediment examination
9.	173. Urine chemistry, quantitative		lyophilized urine / aqueous solution	Alpha-amylase, Total protein, Phosphate (inorganic), Glucose, Uric acid, Calcium, Potassium, Urea, Chloride, Creatinine, Magnesium, Microalbuminuria, Sodium, Osmolality, Copper, Iron
10.	178. Narcotic drugs in human urine, qualitative and quantitative ³		lyophilized urine	Amphetamine, Metamphetamine, MDMA (Exstas), Barbiturate-Phenobarbital, Benzodiazepin-Lorazepam, 11-nor-Delta-9-THC-COOH, Benzoylcegonine, Cocaine, Morphine, Buprenorphine, EDDP, Methadone Opiates, LSD
11.	195. Therapeutic drugs	Clinical chemistry/ Immune chemistry	lyophilized serum	Amikacin, Cyclosporine, Digoxin, Ethosuximide, Phenytoin, Phenobarbital, Gentamicin, Carbamazepine, Caffeine, Lithium, Methotrexate, Paracetamol, Primidone, Salicylate, Theophylline, Tobramycin, Valproic acid, Vancomycine
12.	196. Therapeutic drugs, hormones			11-Deoxycortisol, 17 α -hydroxyprogesterone, Acetaminophen, ACTH, Aldosterone, Amikacin, Vitamin B12 (cobalamin), C-Peptide, Vitamin D (25-OH-Cholecalciferol), Desipramine, DHEA, DHEA sulphate, Digoxin, Phenytoin, Phenobarbital, Ferritin, FSH, Gastrin, Gentamicin, HCG (total), HCG (total+ β), β -HCG, HGH, IgE, Imipramine, Insulin, Calcitonin, Carbamazepine, Quinidine, Chloramphenicol, Cortisol, LH, Lithium, Nortriptyline, Estradiol, Estriol, Primidone, Progesterone, Prolactin, Propranolol, PTH, Salicylate, Theophylline, Testosterone (total), Testosterone (free), Tobramycin, Valproic acid, Vancomycine
13.	198. Hormones			11-Deoxycortisol, 17 α -hydroxyprogesterone, ACTH, Aldosterone, β -HCG, C-Peptide, Vitamin D (25-OH-Cholecalciferol), DHEA, DHEA-sulphate, FSH, Gastrin, HCG (total), HCG (total+ β), HGH, IgE, Insulin, Calcitonin, Cortisol, LH, Estradiol, Estriol, Progesterone, Prolactin, PTH intact, PTH biointact, Testosterone (total), Testosterone (free)
14.	244. High sensitive CRP	Clinical chemistry/ Immune chemistry	plasma	High sensitive CRP

No.	Name of proficiency test	Scope of proficiency test	Material/Product	Parameter(s) to be measured
15.	292. Tumour markers	Clinical chemistry/ Immune chemistry	serum	AFP, β -HCG, β 2- microglobulin, CA 15-3, CA 19-9, CA 72-4, CA 125, CEA, CYFRA 21-1, HCG (total), HCG (total + β), HE4 (Human epididymis protein 4), HER2, NSE, PSA (complex), PSA (total), PSA (free), ROMA, SCC, S100, Thyreoglobuline, TPA, TPS, Calcitonin, ProGRP
16.	293. Thyroid tumour markers		lyophilized serum	Anti-Thyreoglobuline (Anti-TG), Anti-thyroid peroxidase (Anti-TPO), C Peptide, Insulin, Insulin Like Growth Factor I (IGF-I), Vitamin D3 (1.25-(OH) ² -Cholecalciferol, Calcitriol), Vitamin D (25-OH-Cholecalciferol), Osteocalcin, Procalcitonin, PTH intact, PTH biointact
17.	294. Thyroid hormones		serum / plasma	FT3, FT4, T3, T4, TSH
18.	295. Thyroid gland antibodies ²		lyophilized serum/ plasma	Anti-Thyreoglobulin (Anti-TG)
				Anti-thyroid peroxidase (Anti-TPO)
				Antibody against TSH receptor (TRAK/THYBIA)
19.	320. Procalcitonin		lyophilized serum	Procalcitonin
20.	321. AST		serum	Antibodies against streptococcal antigens: O-Streptolysin, Streptodornase, Streptokinase
21.	322. CRP			C-reactive protein
22.	323. Rheumatoid factor			Rheumatoid factor (RF)
23.	550. Urinary stone analysis	pulverized material		Urinary stone components
24.	700. Ethanol	serum or plasma	Ethanol	
25.	760. Myocardiac markers	lyophilized plasma	BNP, CK-MB, CK-total, Homocysteine, Myoglobin, NT-proBNP, proBNP, troponin-I, troponin-T	
26.	120. Dry chemistry - Reflotron	POCT tests	lyophilized serum / plasma	Alkaline phosphatase, α - amylase, Bilirubin (total), CK, γ -GT, Glucose, GOT/ASAT, GPT/ALAT, HDL-cholesterol, Uric acid, Potassium, Urea, Cholesterol, Creatinine, Pancreatic amylase, Triglycerides
27.	121. Dry chemistry - Vitros		Albumin, Alkaline phosphatase, α -amylase, Bilirubin (total, conjugate and unconjugate), CK, CK-MB, Phosphate (inorganic), γ -GT, Glucose, GOT/ASAT, GPT/ALAT, HDL-cholesterol, Uric acid, Calcium, Potassium, Urea, Chloride, Cholesterol, Cholinesterase, Creatinine, Lactate, LDH, Lipase, Lithium, Magnesium, Sodium, Total protein, Triglycerides, Iron	

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28.	147. Glycated proteins – POCT	POCT tests	hemolysate	HbA1C
29.	161. Blood gas analysis		aqueous solution	Glucose, Calcium ion, Potassium, Chloride, Lactate, Sodium, pCO ₂ , pH, pO ₂
30.	286. Haemostasis (INR) – POCT		lyophilized plasma	INR
31.	321C. Streptococcus, A antigen detection – POCT ²		liquid plasma	Streptococcus A antigen
32.	326. CRP – POCT		serum	C-reactive protein
33.	800. Glucose		plasma / serum	Glucose
34.	211. Blood cell count	Haematology	preserved, coagulation-inhibited blood	Leucocyte, Haematocrit (centrifugated and electronic) Haemoglobin, MCV, Platelet count, Erythrocytes
			preserved, coagulation-inhibited blood ²	MCH
				MCHC
				MPV
35.	221. Haemostasis I.		lyophilized plasma	Activated partial thromboplastin time (APTT), APTT rate, INR, Prothrombin time (PT)
36.	222. Haemostasis II.			Fibrinogen, TT-rate, Thrombin time (TT)
37.	223. Haemostasis III.			Coagulation factors: II. (Prothrombin), V. (Proaccelerin), VII. (Proconvertin), X. (Stuart-Prower)
38.	224. Haemostasis IV.			Coagulation factors: IX. (Antihemophilic globulin B), XI. (Rosenthal), XII.(Hagemann), XIII. (Laki-Lorand, fibrin stabilizing)
39.	225. Haemostasis V.			lyophilized plasma ²
40.	226. Haemostasis VI.		lyophilized plasma	Antithrombin III., C1 esterase inhibitor, Protein C, Protein S
41.	227. Haemostasis VII.			D-Dimer (quantitative)
			Coagulation factors: VIII. (Antihemophilic globulin A), WF Ag, WF CBA, WF RiCof (WF= Willebrand factor)	

No.	Name of proficiency test	Scope of proficiency test	Material/Product	Parameter(s) to be measured
42.	231. Blood group serology		fresh human blood clothed in coagulation	ABO blood grouping, Rh system: D antigen, Rh-phenotyping, Irregular antibody screening, Direct Coombs-testing, Kell antigen, antibody identifying
43.	240. Sedimentation		blood sample	Erythrocyte sedimentation
44.	2401. Sedimentation			
45.	613. Blood cell count and WBC differentiation by automata		fresh human blood clothed in coagulation	Leucocytes, Leucocyte types in %, Haematocrit (automated), Haemoglobin, MCV, Platelet count, Erythrocytes
				Neutrophil granulocyte (G/L) ²
				Eosinophil granulocyte (G/L) ²
				Basophil granulocyte (G/L) ²
				Lymphocyte (G/L) ²
				Monocyte (G/L) ²
				MCH ²
				MCHC ²
				MPV ²
				Mid cells (Eo, Baso, Mono) (%) ²
				Mid cells (Eo, Baso, Mono) (G/L) ²
				RDW-CV ²
				RDW-SD ²
				Mentzer-index ²
46.	311. Infection serology: Lues serology	Clinical Microbiology / Infection Serology	serum	Antibodies against Treponema pallidum: IgM and IgG; TPHA, TPPA, FTA-antitest, VDRL, RPR
47.	344. Virus serology: Hepatitis B-I. (HBsAg, Anti HBsAg, Anti-HBcAg)	Clinical Microbiology / Virus Serology	lyophilized serum	HBsAg, anti-HBsAg, anti-HBc total (IgM+IgG)
48.	346. Virus serology: Hepatitis C			anti-HCV
49.	351. Virus serology: Cytomegalovirus			anti-CMV IgG, anti-CMV IgM, IgG avidity
50.	352. Virus serology: Epstein Barr virus			anti-VCA IgG, anti-VCA IgM, anti-EBNA IgG, anti-EA IgG, avidity, heterophile antibodies
51.	411. Bacteriology (aerob)	Clinical Microbiology / Bacteriology	lyophilized bacterial cultures	Identification of test strains and determination of antibiotic resistance sensitivity. Interpretation of the finding to the clinician.

No.	Name of proficiency test	Scope of proficiency test	Material/Product	Parameter(s) to be measured
52.	411An. Bacteriology (anaerobic) ²	Clinical Microbiology / Bacteriology	lyophilized, anaerobic test sample reflecting real clinical condition	Identification of test strains on species level and determination of antibiotic resistance sensitivity.
53.	412. Micology	Clinical Microbiology / Mycology	lyophilized or fungus culture on transport medium	Identification of strains involved in fungus infection and determination of antimycotic sensitivity.
54.	3400. Virus nucleic acid determination: SARS-CoV-2 ²	Clinical Microbiology	respiratory VTM sample on transport medium	SARS-CoV-2 RNS
55.	3401. POCT: SARS-CoV-2 ²		lyophilized or ready-to-use serum	SARS-CoV-2 IgG-, IgM and total immunoglobulin (IgG + IgM)
56.	3402. Virus serology: SARS-CoV-2 ²		ready-to-use serum	IgG-, IgM-, IgA and total immunoglobulin (IgG + IgM) against SARS-CoV-2

¹ Modification due to the change in address ordered by the decision of the National Accreditation Authority issued on 14th March 2019.

² Extending the area of the accredited status ordered by the decision of the National Accreditation Authority issued on 10th December 2020.

³ Modifying the area of the accredited status ordered by the decision of the National Accreditation Authority issued on 21st December 2021.

⁴ Modifying the 5th point of the Detailed Scope of Accreditation issued and ordered by the decision of the National Accreditation Authority on 10th February 2022.

Data on the current accredited status are available on the website of the National Accreditation Authority (<https://www.nah.gov.hu/en/categories>).

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Csaba Bodroghelyi
National Accreditation Authority
Vice-President

ATTENTION!

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The translation of the official Hungarian version is performed by the QualiCont Nonprofit Ltd. in order to inform its partners about the detailed scope of Accreditation and it corresponds to the original document in every detail.