List of activities within the flexible scope of accreditation

Accredited Body: Nemocnice Prachatice, a.s.

CAB Name: Oddělení klinické biochemie a hematologie (OKB-H)

CAB Number: 8009

Certificate of Accreditation No.: 406/2026

Field of Accreditation: Medical Laboratory - ČSN EN ISO 15189 ed. 3:2023

Updated: 09. 09. 2026

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom[1]
222 - Transfusion Medicine					
1.	Blood types	Gel column agglutination	SOPV KB 023, version 2; ERYTRA EFLEXIS	Blood	A, B
2.	Blood types	Gel column agglutination (manual)	SOPV KB 027, version 2; DG-Grifols (Therm/Centrifuge/Work Rack)	Blood	A, B
3.	Screening of anti-erythrocyte antibodies	Gel column agglutination	SOPV KB 025, version 2; ERYTRA EFLEXIS	Blood	A, B
4.	Screening of anti-erythrocyte antibodies	Gel column agglutination (manual)	SOPV KB 029, version 2; DG-Grifols (Therm/Centrifuge/Work Rack)	Blood	A, B
5.	Examination of compatibility	Gel column agglutination	SOPV KB 024, version 2; ERYTRA EFLEXIS	Blood	A, B
6.	Examination of compatibility	Gel column agglutination (manual)	SOPV KB 028, version 2; DG-Grifols (Therm/Centrifuge/Work Rack)	Blood	A, B
7.	Direct antiglobulin test	Gel column agglutination	SOPV KB 026, version 2; ERYTRA EFLEXIS	Blood	A, B
8.	Direct antiglobulin test	Gel column agglutination (manual)	SOPV KB 030, version 2; DG-Grifols (Therm/Centrifuge/Work Rack)	Blood	A, B

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801 – Clinical Biochemistry					
1.	Proteins	Absorption spectrophotometry	SOPV Ac 001 (ALB), version 3; SOPV Ac 022 (PROT), version 3; ARCHITECT c8000	Serum	A, B, C
2.	Enzymes	Absorption spectrophotometry	SOPV Ac 003 (ALT), version 2; SOPV Ac 004 (AMS), version 3; SOPV Ac 005 (AST), version 2; SOPV Ac 008 (CK), version 2; SOPV Ac 012 (GMT), version 3; SOPV Ac 019 (LDH), version 3; SOPV Ac 034 (ALP2), version 2; ARCHITECT c8000	Serum	A, B, C
3.	Pigments	Absorption spectrophotometry	SOPV Ac 006 (BILT), version 3; SOPV Ac 010 (BILD), version 2; ARCHITECT c8000	Serum	A, B, C
4.	Minerals	Absorption spectrophotometry	SOPV Ac 007 (Ca), version 3; SOPV Ac 020 (P), version 3; SOPV Ac 011 (Fe), version 3; ARCHITECT c8000	Serum	A, B, C
5.	Non-protein nitrogenous substances	Absorption spectrophotometry	SOPV Ac 009 (KREA), version 3; SOPV Ac 024 (KMOC), version 3; SOPV Ac 025 (UREA), version 3; ARCHITECT c8000	Serum	A, B, C
6.	Glucose	Absorption spectrophotometry	SOPV Ac 013, version 2; ARCHITECT c8000	Serum	A, B

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7.	Lipids	Absorption spectrophotometry	SOPV Ac 014 (UHDL), version 2; SOPV Ac 015 (CHOL), version 3; SOPV Ac 021 (TAG), version 3; ARCHITECT c8000	Serum	A, B, C
8.	Minerals	Potentiometry	SOPV Ac 026a/b/c (Na, K, Cl) version 2; ARCHITECT c8000	Serum	A, B, C
9.	Apolipoproteins	Immunoturbidimetry	SOPV Ac 028 (APO-A1), version 2; SOPV Ac 029 (APO-B), version 2; ARCHITECT c8000	Serum	A, B, C
10.	Cardiac markers	Immunoassay with luminometric detection	SOPV Ce 015 (pBNP), version 2; SOPV Ce 022 (hsTnT), version 2; COBAS e411	Serum	A, B, C
11.	Tumor markers	Immunoassay with luminometric detection	SOPV Ai 017 (CA 125), version 2; SOPV Ai 018 (C15-3), version 2; SOPV Ai 019 (C19-9), version 2; SOPV Ai 020 (CEA), version 2; SOPV Ai 016 (AFP), version 3; ARCHITECT i2000 SOPV BC 003 (freePSA), version 4; SOPV BC 002 (tPSA), version 2; ACCESS 2	Serum	A, B, C
12.	Acid-base balance	Amperometry; Potentiometry	SOPV ABR 001, version 2; ABL 835 Flex	Blood	A, B, C
13.	Glycated haemoglobin	High-Performance Liquid Chromatography	SOPV Ar 002, version 2; ADAMS A1C HA-8180V	Blood	A, B

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14.	Chemical examination of urine	Reflection photometry; Refractometry; Absorption spectrophotometry	SOPV Mch 003, version 2; IRIS iChem Velocity; SOPV Mch 001, version 2; Urisys 1800	Urine	A, B, C
15.	Morphological examination of urine	Microscopy	SOPV Mch 003, version 2; IRIS iChem Velocity	Urine	A, B, C
16.	Glucose	Amperometry	SOPV Bcl 001, version 2; BIOSEN C-line	Blood	A, B
17.	Myoglobin	Immunoassay with luminometric detection	SOPV Ce 012, version 2; COBAS e411	Serum	A, B
18.	Hormones	Immunoassay with luminometric detection	SOPV Ce 004 (C-peptide), version 2; SOPV Ce 018 (PTH), version 2; COBAS e411 SOPV Ai 023 (TT3), version 2; SOPV Ai 024 (fT3), version 2; SOPV Ai 025 (TT4), version 2; SOPV Ai 026 (fT4), version 2; SOPV Ai 027 (TSH), version 2; SOPV Ai 030 (KOR), version 2; SOPV Ai 031 (ESTD), version 2; SOPV Ai 032 (FSH), version 2; SOPV Ai 033 (LH), version 2; SOPV Ai 034 (PRL), version 2; SOPV Ai 035 (PRGS), version 2; ARCHITECT i2000	Serum	A, B, C
813 - Allergology and Immunology Laboratory					
1.	Specific proteins	Immunoturbidimetry	SOPV Ac 023 (TRF), version 2; ARCHITECT c8000	Serum	A, B, C

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom[1]
2.	Immunoglobulins	Immunoturbidimetry	SOPV Ac 016 (IgA), version 2; SOPV Ac 017 (IgG), version 2; SOPV Ac 018 (IgM), version 2; ARCHITECT c8000	Serum	A, B, C
3.	Specific proteins	Immunonephelometry	SOPV DB 002 (alfa1-AG), version 2; SOPV DB 003 (alfa1-AT), version 2; SOPV DB 006 (C3c), version 2; SOPV DB 007 (C4), version 2; ATELLICA NEPH 630	Serum	A, B, C
815 - Nuclear Medicine Laboratory					
1.	Tumor markers	Immunoassay with luminometric detection	SOPV Ai 029 (βHCG), version 2; ARCHITECT i2000	Serum	A, B, C
818 - Haematology Laboratory					
1.	Activated partial thromboplastin time	Coagulation method with optical detection of coagulum; Calculations	SOPV KOAG 005b, version 2; IL ACL TOP 350	Plasma	A, B
2.	Fibrinogen	Coagulation method with optical detection of coagulum	~~SOPV KOAG 006b, version 2;~~ SOPV KOAG 016, version 1; IL ACL TOP 350	Plasma	A, B
3.	Prothrombin test	Coagulation method with optical detection of coagulum	SOPV KOAG 007b, version 2; IL ACL TOP 350	Plasma	A, B
4.	D-dimers	Immunoassay with turbidimetric detection	SOPV KOAG 012, version 2; IL ACL TOP 350	Plasma	A, B
5.	Blood count with a five-part differential leukocyte count	Flow cytometry; Photometry; Calculations	SOPV HEM 007, version 2; ALINITY hq	Blood	A, B
6.	Blood count with a five-part differential leukocyte count	Flow cytometry; Photometry; Calculations	SOPV HEM 004, version 2; CD RUBY	Blood	A, B

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom[1]
7.	Blood count with a five-part differential leukocyte count	Fluorescence flow cytometry; Photometry; Impedance method; Calculations	SOPV HEM 008, version 1; XR-1000	Blood	A, B, C
8.	Peripheral blood smear analysis	Microscopy	SOPV HEM 002, version 2; Microscope LEICA	Blood	A, B
9.	Peripheral blood smear analysis	Digital microscopy	SOPV HEM 002, version 2; DC-1 CELLAVISION	Blood	A, B

Specification of the scope of accreditation:

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
222/1	AB0, RhD
222/2	AB0, RhD
222/3	NAT, Enzyme
222/4	NAT, Enzyme
801/1	Albumin, total protein
801/2	Alkaline phosphatase (ALP), alanine aminotransferase (ALT), α-amylase (AMS), aspartate aminotransferase (AST), creatine kinase (CK), γ-glutamyltransferase (GGT), lactatedehydrogenase (LDH)
801/3	Total bilirubin, conjugated bilirubin
801/4	Total calcium, inorganic phosphate, total iron
801/5	Creatinine, uric acid, urea
801/7	HDL-cholesterol, total cholesterol, triacylglycerols
801/8	Na^+, K^+, Cl^-
801/9	Apolipoprotein A1, apolipoprotein B
801/10	Pro-natriuretic peptide (proBNP), troponin T hs
801/11	Carbohydrate tumor antigens CA 125, CA 15-3, CA 19-9, carcinoembryonic antigen (CEA), free prostate specific antigen (fPSA), total prostate-specific antigen (Total PSA), α-fetoprotein (AFP)

List of activities within the flexible scope of accreditation

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
801/12	pH, pO2, pCO2
801/14	pH, density, protein, glucose, ketones, urobilinogen, bilirubin, nitrites, blood, leukocytes
801/15	Erythrocytes, leukocytes, epithelia, casts, crystals, bacteria, yeasts, sperm, artifacts
801/18	Total triiodothyronine (T3), free triiodothyronine (fT3), total thyroxine (T4), free thyroxine (fT4), thyroid-stimulating hormone (TSH), estradiol, follicle-stimulating hormone (FSH), luteinizing hormone (LH), prolactin, progesterone, parathormone, cortisol
813/1	Transferrin, C-reactive protein (CRP)
813/2	IgA, IgG, IgM
813/3	α1-acid glycoprotein (alfa1-AG), α1-antitrypsin (alfa1-AT), C3 complement component (C3c), C4 complement component (C4)
815/1	Human chorionic gonadotropin (Total β-HCG),
818/1	APTT-time, APTT-ratio
818/3	PT-time, PT-INR, PT-ratio
818/5	Leukocytes (WBC), erythrocytes (RBC), haemoglobin (HGB), mean corpuscular volume (MCV), haematocrit (HCT), platelets (PLT), neutrophils (NSEG), eosinophils (ESEG), basophils (BSEG), lymphocytes (LY), monocytes (MO)
818/6	Leukocytes (WBC), erythrocytes (RBC), haemoglobin (HGB), mean corpuscular volume (MCV), haematocrit (HCT), platelets (PLT), neutrophils (NSEG), eosinophils (ESEG), basophils (BSEG), lymphocytes (LY), monocytes (MO)
818/7	Leukocytes (WBC), erythrocytes (RBC), haemoglobin (HGB), mean corpuscular volume (MCV), haematocrit (HCT), platelets (PLT), neutrophils (NSEG), eosinophils (ESEG), basophils (BSEG), lymphocytes (LY), monocytes (MO)
818/8	Myeloblast (MB), parablast (PBL), blast (BLAST), promyelocyte (PMC), neutrophilic myelocyte (NMC), neutrophilic metamyelocyte (NMMC), neutrophilic band (NTYC), neutrophilic segmented neutrophil (NSEGM), eosinophils – immature forms (IEO), eosinophilic segmented granulocyte (ESEGM), basophilic segmented granulocyte (BSEGM), lymphocyte (LYM), monocyte (MOM), plasma cell (PLB), megakaryocyte (MEKC), normoblasts (NRBCM), schistocytes (SCH)
818/9	Myeloblast (MB), parablast (PBL), blast (BLAST), promyelocyte (PMC), neutrophilic myelocyte (NMC), neutrophilic metamyelocyte (NMMC), neutrophilic band (NTYC), neutrophilic segmented neutrophil (NSEGM), eosinophils – immature forms (IEO), eosinophilic segmented granulocyte (ESEGM), basophilic segmented granulocyte (BSEGM), lymphocyte (LYM), monocyte (MOM), plasma cell (PLB), megakaryocyte (MEKC), normoblasts (NRBCM), schistocytes (SCH)

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Primary sample collection:

Ordinal Number	Sample collection technique	Identification of sample collection procedure	Collected material	Degrees od freedom[1]
1.	Venepuncture	SOPV *SOP 001	Venous blood	A, B
2.	Capillary puncture	SOPV *SOP 001	Capillary blood	A, B

Explanatory notes:

[1] Established degrees of freedom according to MPA 00-09-..:

A – Flexibility concerning the documented examination/ sample collection procedure

B – Flexibility concerning the technique

C – Flexibility concerning the analytes / parameters

D – Flexibility concerning the examined material

E – Flexibility concerning the POCT delivery points

If no degree of freedom is specified, the laboratory cannot apply a flexible approach to the scope of accreditation for this examination.

Changes are highlighted in red.