



## 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.:** 171/2025  
**Field of Accreditation:** Medical Laboratory - ČSN EN ISO 15189 ed. 3:2023  
**Updated:** 13. 1. 2026 update of package insert sheets versions

### Examinations:

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of method procedure/equipment	Examined material	Degrees of freedom <sup>1</sup>
<b>222 - Transfusion Medicine</b>					
1.	Blood types	Gel column agglutination	SOPV KB23, verze 1.2; <b>DG Gel ABO/Rh (2DVI-)</b> <b>(2023-05 V2.0);</b> <b>DGGelNeutral (2023-07 V2.0);</b> Anti-H Mono-Type F07766/112 (09/2021); Anti-A1 Lectin F07764/111 (01/2019); DG Gel Sol (09/2021); DG Gel Anti-D – 1.0 – IFU-cs (05/2022); DG Gel Newborn – 1.0 – IFU-cs (05/2022); <b>Serigrup Diana A1B (2024-11</b> <b>V3.0);</b> ERYTRA EFLEXIS	Blood	A, B
2.	Blood types	Gel column agglutination (manual)	SOPN KB27, verze 1.2; <b>DG Gel ABO/Rh (2DVI-)</b> <b>(2023-05 V2.0);</b> <b>DGGelNeutral (2023-07 V2.0);</b> Anti-H Mono-Type F07766/112 (09/2021); Anti-A1 Lectin F07764/111 (01/2019);	Blood	A, B



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			DG Gel Sol (09/2021); DG Gel Anti-D – 1.0 – IFU-cs (05/2022); DG Gel Newborn – 1.0 – IFU-cs (05/2022); <b>Serigrup Diana A1B (2024-11 V3.0);</b> DG-Grifols (Therm/Centrifuge/Work Rack)		
3.	Screening of anti-erythrocyte antibodies	Gel column agglutination	SOPN KB25, verze 1.2; SerascanDiana 4/4P-1.0-IFU-cs (07/2021); <b>DGGelNeutral (2023-07 V2.0);</b> DG Gel Coombs -3.0-IFU-cs (07/2023); ERYTRA EFLEXIS	Blood	A, B
4.	Screening of anti-erythrocyte antibodies	Gel column agglutination (manual)	SOPN KB29, verze 1.2; SerascanDiana 4/4P-1.0-IFU-cs (07/2021); <b>DGGelNeutral (2023-07 V2.0);</b> DGGelCoombs -3.0-IFU-cs (07/2023); DG-Grifols (Therm/Centrifuge/Work Rack)	Blood	A, B
5.	Examination of compatibility	Gel column agglutination	SOPN KB24, verze 1.2; DG Gel Coombs -3.0-IFU-cs (07/2023); DG Gel Confirm (05/2022); <b>DG Gel Confirm P (2024-09 V2.0);</b> DG Gel Sol (09/2021); ERYTRA EFLEXIS	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 <sup>1</sup>
6.	Examination of compatibility	Gel column agglutination (manual)	OPN KB28, verze 1.2; DG Gel Coombs -3.0-IFU-cs (07/2023); DG Gel Confirm (05/2022); <b>DG Gel Confirm P (2024-09 V2.0);</b> DG Gel Sol (09/2021); DG-Grifols (Therm/Centrifuge/Work Rack)	Blood	A, B
7.	Direct antiglobulin test	Gel column agglutination	SOPN KB26, verze 1.2; DG Gel Coombs -3.0-IFU-cs (07/2023); DG Gel Sol (09/2021); ERYTRA EFLEXIS	Blood	A, B
8.	Direct antiglobulin test	Gel column agglutination (manual)	SOPN KB30, verze 1.2; DG Gel Coombs -3.0-IFU-cs (07/2023); DG Gel Sol (09/2021); DG-Grifols (Therm/Centrifuge/Work Rack)	Blood	A, B
<b>801 – Clinical Biochemistry</b>					
1.	Proteins	Absorption spectrophotometry	SOPV Ac01 ( <b>ALB</b> ), verze 2; IVD 4T34 <b>G9-9181/R05</b> ; SOPV Ac22 (PROT), verze 2; IVD 4U44 H1-2781/R03; ConCC 04V1501 G9-9135/R06; ARCHITECT c8000	Serum	A, B, C
2.	Enzymes	Absorption spectrophotometry	SOPV Ac03 (ALT), verze 1; IVD 8L92 H0-6156/R03; <b>C.f.a.s. 10759350 04-2025, V14.0;</b>	Serum	A, B, C



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			SOPV Ac04 (AMS), verze 2; IVD 4S89 H1-2731/R05; ConCC 04V1501 G9-9135/R06; SOPV Ac05 (AST), verze 1; IVD 8L91 H1-3630/R02; C.f.a.s. 10759350 04-2025, V14.0; SOPV Ac08 (CK), verze 1; IVD 7D63 G5-5776/R02; SOPV Ac12 (GMT), verze 2; IVD 4T00 H2-1866/R04; ConCC 04V1501 G9-9135/R06; SOPV Ac19 (LDH), verze 2; IVD 4T03 H2-6221/R03; ConCC 04V1501 G9-9135/R06; SOPV Ac34 (ALP2), verze 1; IVD 04S87 H2-5284/R01; ConCC 04V1501 G9-9135/R06; ARCHITECT c8000		
3.	Pigments	Absorption spectrophotometry	SOPV Ac06 (BILT), verze 2; IVD 4T09 H2-6265/R03; ConCC 04V1501 G9-9135/R06; SOPV Ac10 (BILD), verze 1; IVD 8G63 G5-5786/R06; BilC 1E66-05 G5-5798/R03; ARCHITECT c8000	Serum	A, B, C
4.	Minerals	Absorption spectrophotometry	SOPV Ac07 (Ca), verze 2; IVD 4S91 81-1143/R02; ConCC 04V1501 G9-9135/R06; SOPV Ac20 (P), verze 2.0;	Serum	A, B, C



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			IVD 4T07 H2-6362/R02; ConCC 04V1501 G9-9135/R06; SOPV Ac11 (Fe), verze 2; IVD 4T02 H2-5216/R02; ConCC 04V1501 G9-9135/R06; ARCHITECT c8000		
5.	Non-protein nitrogenous substances	Absorption spectrophotometry	SOPV Ac09 (KREA), verze 2; IVD 4S9520 H1-2817/R03; SOPV Ac24 (KMOC), verze 2; IVD 4T13 H1-2856/R02; SOPV Ac25 (UREA), verze 2; IVD 4T1220/4T1230 H1-2799/R04; ConCC 04V1501 G9-9135/R06; ARCHITECT c8000	Serum	A, B, C
6.	Glucose	Absorption spectrophotometry	SOPV Ac13, verze 1; IVD 3L82 G5-5789/R03; MCC 1E65-06 G5-5797/R04; ARCHITECT c8000	Serum	A, B
7.	Lipids	Absorption spectrophotometry	SOPV Ac14 (UHDL), verze 1; IVD 3K33 G5-5772/R04; Lipid MC 5P56-02 G5-5766/R04; SOPV Ac15 (CHOL), verze 2; IVD 4S92 H1-2619/R05; SOPV Ac21 (TAG), verze 2; IVD 4T10 H1-3993/R04; ConCC 04V1501 G9-9135/R06; ARCHITECT c8000	Serum	A, B, C
8.	Minerals	Potentiometry	SOPV Ac26a/b/c verze 1;	Serum	A, B, C



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			IVD 1E46-04 G5-5782/R04; IVD 1E49-20 G5-5784/R04; IVD 2P32-11 G6-6693/04; IVD 1E50-20 G6-6710/R05; ARCHITECT c8000		
9.	Apolipoproteins	Immunoturbidimetry	SOPV Ac28 (APO-A1), verze 1; IVD 9D92 H1-3503/R05; SOPV Ac29 (APO-B), verze 1; IVD 9D93 H1-3485/R06; <b>Lipid MC 5P56-02 G5-5766/R05;</b> ARCHITECT c8000	Serum	A, B, C
10.	Cardiac markers	Immunoassay with luminometric detection	SOPV Ce15 ( <b>pBNP</b> ), verze 1; IVD 09315268190 <b>2024-11, V 3.0;</b> IVD 09315292190 <b>2025-04, V 2.0;</b> SOPV Ce22 ( <b>hsTnT</b> ), verze 1; IVD 09315349190 <b>2024-11, V 3.0;</b> IVD 09315381190 <b>2025-04, V 3.0;</b> COBAS e411	Serum	A, B, C
11.	Tumor markers	Immunoassay with luminometric detection	SOPV Ai17 (CA 125), verze 1; IVD 2K45 G6-6790/R03 IVD 2K45-02 G8-1417/R03 SOPV Ai18 (C15-3), verze 1; IVD 2K44 G6-6789/R03 IVD 2K44 -02 G6-6787/R03 SOPV Ai19 ( <b>C19-9</b> ), verze 1; IVD 2K91 G6-6793/R04	Serum	A, B, C



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			IVD 2K91-03 G6-6791/R03; SOPV Ai20 (CEA), verze 1; IVD 7K68 G6-6613/R06; IVD 7K68-02 G2-4080/R03; SOPV Ai21 (PSA), verze 1; IVD 7K70 G4-6275/R07; IVD 7K70-01 G4-6382/R05; ARCHITECT i2000 SOPV BC03 (freePSA), verze 3.2; IVD 37210, C94222-D 02/2025 IVD 37215, B50160-N 03/2025 SOPV BC02 (tPSA), verze 1.0; IVD 37200 C76336-E 02/2025 IVD 37205, B50174-N 03/2025 ACCESS 2		
12.	Acid-base balance	Amperometry; Potentiometry	SOPV ABR1, verze 1 IVD: 944-126 04/2022 verze G; IVD: 944-132 04/2022 verze J; IVD: 943-906 09/2022 verze U; IVD: 906-020, 11/2023 verze A; IVD: 962-169; 962-170 (viz lahev) IVD: 944-129; 942- 060; 942-065; 942-066; 942-063; 942-064; 942-058; 945-616; 945-619; 945-612; 945-614; 945-613; 945-603; vše 15/09/2017; ABL 835 Flex	Blood	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 <sup>1</sup>
13.	Glycated haemoglobin	High-Performance Liquid Chromatography	SOPV Ar 02, verze 1; IVD 71262+71263 9/9/2024 IVD 71264 9/9/2024 IVD P313.400 24/06/2015; ADAMS A1C HA-8180V	Blood	A, B
14.	Chemical examination of urine	Reflection photometry; Refractometry; Absorption spectrophotometry	SOPV Mch 03, verze 1; IVD C36483 AD 5/2022; IVD C36485 AC 3/2019; SOPV Mch 01, verze 1; IVD 11379208 2025-09, V 7.0; IVD 11379194263 2022-04, V4.0; IRIS iChem Velocity; Urisys 1800	Urine	A, B, C
15.	Morphological examination of urine	Microscopy	SOPV Mch 03, verze 1; IVD C36365 AC 11/2021; IVD C74941 AB 08/2021; IVD C84797 AA 03/2022; IVD C84799 AA 04/2022; IVD C84798 AA 04/2022; IVD C84822 AA 04/2022; IVD C36483 AD 08/2021; IVD C36485 AC 03/2019; IRIS iChem Velocity	Urine	A, B, C



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16.	Glucose	Amperometry	SOPV Bcl01, verze 1; IVD 5206.3011 01/2024, V3.00; IVD 0201-0004-001 01/2024, V3.00; IVD 5211-3017 01/2024 V3.00; IVD 0030 343.001 13/11/2020; BIOSEN C-line	Blood	A, B
<b>813 - Allergology and Immunology Laboratory</b>					
1.	Specific proteins	Immunoturbidimetry	SOPV Ac23 (TRF), verze 1; IVD 1E04 H1-2670/R04; SP MCC 1E78-04 G9-9153/R04; SOPV Ac27 (CRP), verze 1; IVD 6K26 G6-0089/R06; IVD 6K26-10 G3-9458/R04; ARCHITECT c8000	Serum	A, B, C
2.	Immunoglobulins	Immunoturbidimetry	SOPV Ac16 (IgA), verze 1; IVD 9D9824 H1-2892/R04; SOPV Ac17 (IgG), verze 1; IVD 9D9924 H1-2874/R05; SOPV Ac18 (IgM), verze 1; IVD 1E0124 H1-2910/R04; ARCHITECT c8000	Serum	A, B, C
3.	Specific proteins	Immunonephelometry	SOPV DB 02, verze 1; IVD N AS AAG Kat.č. 10446307 08-2021/R06; SOPV DB 03, verze 1; IVD N AS AAT Kat.č. 10446312 01-2023/R07; SOPV DB 06, verze 1;	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 <sup>1</sup>
			IVD N AS C3 Kat.č. 10446291 09-2021/R07; SOPV DB 07, verze 1; IVD N AS C4 Kat.č. 10446289 09-2021/R07; N PS SL Kat.č. 10446073 07- 2025/R12; ATELLICA NEPH 630		
<b>815 - Nuclear Medicine Laboratory</b>					
1.	Myoglobin	Immunoassay with luminometric detection	SOPV Ce12, verze 1; IVD 11820788122 2024-09, V25.0; IVD 11820893122 2024-09, V16.0; COBAS e411	Serum	A, B
2.	Hormones	Immunoassay with luminometric detection	SOPV Ce04 (C-peptid), verze 1; IVD 03184897190 2025-08, V 14.0; IVD 03184919190 2025-06, V 11.0; SOPV Ai23 (TT3), verze 1; IVD 7K64 G8-1480/R09; IVD 7K64-02 G8-1400/R04; SOPV Ai24 (fT3), verze 1; IVD 7K63 G8-1469/R07; IVD 7K63-02 G6-6747/R03; SOPV Ai25 (TT4), verze 1; IVD 7K66 G8-1515/R03; IVD 7K66-02 G6-6680/R03; SOPV Ai26 (fT4), verze 1; IVD 7K65 G8-1500/R03; IVD 7K65-02 G6-0067/R02;	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 <sup>1</sup>
			<p>SOPV Ai27 (TSH), verze 1;                      IVD 7K62 G6-0153/R09;                      IVD 7K62-01 G6-0161/R06;                      SOPV Ce18 (PTH), verze 2;                      IVD 08928380190 2024-12, V 2.0;                      IVD 08928452190 2025-06, V 2.0;                      SOPV Ai29 (βHCG), verze 1;                      IVD 7K78 G6-6671/R16;                      IVD 7K78-01 G6-6670/R07;                      SOPV Ai30 (KOR), verze 1;                      IVD 8D15 G6-0108/R09;                      IVD 8D15-02 G5-4449/R04;                      SOPV Ai31 (ESTD), verze 1;                      IVD 7K72 G6-6704/R10;                      IVD 7K72-01 G6-0029/R04;                      SOPV Ai32 (FSH), verze 1;                      IVD 7K75 G6-6621/R11;                      IVD 7K75-01 G6-0146/R05;                      SOPV Ai33 (LH), verze 1;                      IVD 2P40 G6-0137/R06;                      IVD 2P40-01 G6-0136/R05;                      SOPV Ai34 (PRL), verze 1;                      IVD 7K76 G6-6620/R07;                      IVD 7K76-01 G6-0156/R05                      SOPV Ai35 (PRGS), verze 1;                      IVD 7K77 G6-6639/R09                      IVD 7K77-01 G6-0190/R08                      COBAS e411;                      ARCHITECT i2000</p>		



List of activities within the flexible scope of accreditation

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of method procedure/equipment	Examined material	Degrees of freedom <sup>1</sup>
3.	Tumor markers	Immunoassay with luminometric detection	SOPV Ai16 (AFP), verze 1; IVD 3P36 G6-0123/R06; IVD 3P36-01 G4-6207/R02; ARCHITECT i2000	Serum	A, B, C
<b>818 - Haematology Laboratory</b>					
1.	Activated partial thromboplastin time	Coagulation method with optical detection of coagulum; Calculations	SOPV KOAG 05b, verze 1; IVD 0020006300 304222-WB R02 06/2025; Kalibrační plazma 0020003700 304287-WB R00 11/2022; IL ACL TOP 350	Plasma	A, B
2.	Fibrinogen	Coagulation method with optical detection of coagulum	SOPV KOAG 06b, verze 1; IVD 0020301100 304414-WB R01 08/2023; Kalibrační plazma 0020003700 304287-WB R00 11/2022; IL ACL TOP 350	Plasma	A, B
3.	Prothrombin test	Coagulation method with optical detection of coagulum	SOPV KOAG 07b, verze 1; IVD 0020003050 304225-WB R01 09/2023; Kalibrační plazma 0020003700 304287-WB R00 11/2022; IL ACL TOP 350	Plasma	A, B
4.	D-dimers	Immunoassay with turbidimetric detection	SOPV KOAG 12, verze 1; IVD 0020007700 3800-6347-WB R02 06/2025; Kalibrační plazma 0020003700 304287-WB R00 11/2022; IL ACL TOP 350	Plasma	A, B
5.	Blood count with a five-part	Flow cytometry;	SOPV HEM 07, verze 1;	Blood	A, B, C



## List of activities within the flexible scope of accreditation

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of method procedure/equipment	Examined material	Degrees of freedom <sup>1</sup>
	differential leukocyte count	Photometry; Calculations	IVD 4R2601 25/03/2024, V5.0; IVD 7P8104 23/07/2024, V23.0; IVD 7P8004 23/07/2024, V20.0; IVD 7P7904 10/12/2025, V22.0; IVD 1R5104 06/06/2024 V6.0; ALINITY hq		
6.	Blood count with a five-part differential leukocyte count	Flow cytometry; Photometry; Calculations	SOPV HEM 04, verze 1; IVD 8H52-01 15/04/2024, V18.0; IVD 1H73-01 19/03/2024 V29.0; IVD 3H80-02 17/07/2024, V19.0; IVD 3H40-01 21/03/2024, V32.0; CD RUBY	Blood	A, B, C
7.	Peripheral blood smear analysis	Microscopy	SOPV HEM 02, verze 1; IVD 1.04699.0001 18/08/2024; IVD BLT00083 27/09/2023; Mikroskop LEICA	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

## List of activities within the flexible scope of accreditation

801/1	Albumin, total protein
801/2	Alkaline phosphatase (ALP), alanine aminotransferase (ALT), $\alpha$ -amylase (AMS), aspartate aminotransferase (AST), creatine kinase (CK), $\gamma$ -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 <sup>+</sup> , K <sup>+</sup> , Cl <sup>-</sup>
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)
801/12	pH, pO <sub>2</sub> , pCO <sub>2</sub>
801/14	pH, density, protein, glucose, ketones, urobilinogen, bilirubin, nitrites, blood, leukocytes
801/15	Erythrocytes, leukocytes, epithelia, casts, crystals, bacteria, yeasts, sperm, artifacts
813/1	Transferrin, C-reactive protein (CRP)
813/2	IgA, IgG, IgM
813/3	$\alpha$ 1-acid glycoprotein, $\alpha$ 1-antitrypsin, C3 complement component, C4 complement component
815/2	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, human chorionic gonadotropin (Total $\beta$ -HCG), cortisol
815/3	$\alpha$ -fetoprotein (AFP)
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)



## List of activities within the flexible scope of accreditation

### Primary sample collection:

Ordinal Number	Sample collection technique	Identification of sample collection procedure	Collected material	Degrees of freedom <sup>1</sup>
1.	Venepuncture	SOPV *SOP 001	Venous blood	A, B
2.	Capillary pucture	SOPV *SOP 001	Capillary blood	A, B

### Explanatory notes:

<sup>1</sup> 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

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.