



List of activities within the flexible scope of accreditation

Accredited Body: Zdravotní ústav se sídlem v Ústí nad Labem
CAB Name: Department of Laboratory Immunology of the Centre for Immunology and Microbiology
CAB Number: 8065
Certificate of Accreditation No.: 291/2024
Field of Accreditation: Medical Laboratory - ČSN EN ISO 15189 ed. 2:2013
Updated: 13. 6. 2024

1. Workplace Ústí nad Labem

Na Kabátě 229, 400 11 Ústí nad Labem

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom ¹
801 – Clinical Biochemistry					
1.	Albumin	Absorption spectrophotometry	ŠOPv-6a-ALB, version 2; AU480	Serum, plasma	A, B
2.	Total protein	Absorption spectrophotometry	SOPv-6b-CB, version 2; AU480	Serum, plasma	A, B, D
3.	Albumin	Immunonephelometry	SOPv-4-SP2a, version 1; BNII	Cerebrospinal fluid	A, B
802 – Medical Microbiology					
1.	Antibodies against infectious agents	Immunoassay with luminometric detection	SOPv-20-HEP, version 5; SOPv-22-IA, version 2; SOPv-26-IAG, version 3; Architect i1000	Serum, plasma	A, B, C
2.	Antigens of infectious agents	Immunoassay with luminometric detection	SOPv-20-HEPb, version 5; Architect i1000	Serum, plasma	A, B, C
3.	HIV markers	Immunoassay with luminometric detection	SOPv-20-HEPd, version 5; Architect i1000	Serum, plasma	A, B
4.	Antigens of infectious agents	Immunoassay with luminometric detection	SOPv-20-HEPb, version 5; Liaison	Serum, plasma	A, B, C
5.	Post-vaccination antibodies	Immunoassay with photometric detection	SOPv-28- OA, version 5	Serum, plasma	A, B, C
6.	Antibodies against <i>Borrelia burgdorferi s.l.</i>	Immunoassay with photometric detection	SOPv-24aBBE, version 2	Serum, plasma	A, B
7.	Antibodies against <i>Treponema pallidum</i>	Immunoassay with photometric detection	SOPv-24bTPE, version 1	Serum, plasma	A, B

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8.	Antibodies against <i>Treponema pallidum</i>	Indirect immunofluorescence	SOPv-25-IAF, version 4	Serum, plasma	A, B
9.	Antibodies against Tick-borne Encephalitis virus	Immunoassay with photometric detection	SOPv-47-KE, version 2; Vidimat	Serum, plasma	A, B
10.	Antibodies against pertussis toxin	Immunoassay with photometric detection	SOPv-45-PT, version 2	Serum, plasma	A, B
11.	Antibodies against infectious agents	Immunoblotting	SOPv-27-IWB, version 2	Serum, plasma	A, B, C
12.	Intrathecal antibody synthesis against infectious agents	Immunoassay with photometric detection	SOPv-50-BBI, version 2	Serum, plasma, cerebrospinal fluid	A, B, C
813 - Allergology and Immunology Laboratory					
1.	Immunoglobulins	Immunoturbidimetry	SOPv-1-SPa, version 4 AU480	Serum, plasma	A, B, C
2.	Specific proteins	Immunoturbidimetry	SOPv-1-SPb, version 4; SOPv-2-LPa, version 1; AU480	Serum, plasma	A, B, C
3.	Rheumatoid factor	Immunoturbidimetry	SOPv-2-LPb, version 1 AU480	Serum, plasma	A, B
4.	Antistreptolysin O (ASLO)	Immunonephelometry	SOPv-2-LPc, version 1 BNII	Serum, plasma	A, B
5.	IgG subclasses	Immunonephelometry	SOPv-3-IgG1-4, version 3 BNII	Serum, plasma	A, B
6.	Immunoglobulins	Immunonephelometry	SOPv-4-SP2b, version 1; BNII	Cerebrospinal fluid	A, B
7.	Albumin quotient and intrathecal synthesis of total immunoglobulins	Calculation	SOPv-76-VYP, version 1	Serum, plasma, cerebrospinal fluid	A, B
8.	Detection and typing of paraprotein	Electrophoresis and immunofixation	SOPv-30-EL, version 2; SOPv-31-FIX, version 2; Hydrasys	Serum, plasma, urine	A, B
9.	Oligoclonal IgG	Isoelectric focusing	SOPv-33-OLI, version 4; Hydrasys	Serum, cerebrospinal fluid	A, B
10.	Total IgE	Fluorescence immunoassay	SOPv-11-IgE, version 3; Phadia 250	Serum, plasma	A, B

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11.	Specific IgE	Fluorescence immunoassay	SOPv-12-sIgE, version 2; Phadia 250	Serum, plasma	A, B
12.	Immunophenotyping of cell populations	Flow cytometry	SOPv-13-IFT, version 8; FACScalibur	Blood	A, B, C
13.	INF γ after T cells stimulation by <i>Mycobacterium tuberculosis</i> antigens	Immunoassay with photometric detection	SOPv-51-QF, version 2	Plasma	A, B
14.	Autoantibodies	Indirect immunofluorescence	SOPv-14-ANAC, version 10; SOPv-15a-AMA, version 5; SOPv-15b-EMA, version 5; SOPv-15d-EBM, version 2; SOPv-15c-GBM, version 2; SOPv-38-ASCA, version 3	Serum, plasma	A, B, C
15.	Neuronal autoantibodies	Indirect immunofluorescence	SOPv-72-NEUa, version 2	Serum, plasma, cerebrospinal fluid	A, B, C
16.	Autoimmune encephalitis-associated antibodies	Indirect immunofluorescence	SOPv-72-NEUb, version 2	Serum, plasma, cerebrospinal fluid	A, B, C
17.	Autoantibodies	Fluorescence immunoassay	SOPv-16-AP, version 4; SOPv-17b-ENA, version 5; Phadia 250	Serum, plasma	A, B, C
18.	Autoantibodies	Immunoassay with luminometric detection	SOPv-17c-tTGA, version 4; Bioflash	Serum, plasma	A, B, C
19.	Autoantibodies	Immunoassay with luminometric detection	SOPv-18-ATH, version 3; SOPv-39-CCP, version 1; Architect 1000i	Serum, plasma	A, B, C
20.	Autoantibodies	Immunoassay with photometric detection	SOPv-17a-ANCAE, version 5; SOPv-73-DM, version 1; SOPv-75-PA, version 1	Serum, plasma	A, B, C
21.	Autoantibodies	Immunoblotting	SOPv-19-AWB, version 2	Serum, plasma	A, B, C
22.	Neuronal autoantibodies	Immunoblotting	SOPv-74-NEB, version 3	Serum, plasma	A, B, C

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815 - Nuclear Medicine Laboratory					
1.	Prostate-specific antigen - total (PSA)	Immunoassay with luminometric detection	SOPv-8-TM1, version 6; Architect 1000i	Serum, plasma	A, B

Specification of the scope of accreditation:

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
802/1	Antibodies against HAV in class IgG, antibodies against HBs, HBc, HCV, total antibodies against <i>Treponema pallidum</i>
802/2	HBsAg
802/3	Antibodies against HIV 1+2, Ag p24
802/4	Antibodies against EBV VCA, EBNA-1 EBV-EA(D) in class IgG and VCA in class IgM
802/5	Antibodies against toxins of <i>Clostridium tetanii</i> , <i>Corynebacterium diptheriae</i> and <i>Haemophilus influenzae</i> B in class IgG
802/6	Antibodies against <i>Borrelia species</i> in class IgM and <i>Borrelia species</i> + VlsE in class IgG
802/7	Antibodies against <i>Treponema pallidum</i> in classes IgM and IgG
802/8	Antibodies against <i>Treponema pallidum</i> FTA-Abs
802/10	Antibodies against <i>Bordetella pertusiss</i> toxin in classes IgA, IgG
802/11	Antibodies against <i>Treponema pallidum</i> and <i>Borrelia burgdorferi s.l.</i> in classes IgM and IgG
802/12	Antibodies against <i>Borrelia burgdorferi s.l.</i> in class IgG
813/1	IgG, IgM, IgA
813/2	C-reactive protein (CRP), Complement component 3, Complement component 4, Transferrin, Orosomuroid, Prealbumin, Ceruloplasmin, Alpha-1 antitrypsin, Haptoglobin
813/5	IgG1, IgG2, IgG3, IgG4
813/6	IgG, IgA, IgM
813/7	IgG, IgA, IgM
813/12	T-cells (CD3+), Th-cells (CD3+CD4+), Tc-cells (CD3+CD8+), B-cells (CD19+), NK-cells (CD3-CD56+)
813/14	ANA IgG, anti-dsDNA IgG, ANCA IgG, AMA IgG, ASMA IgG, LKM IgG, ASCA IgA, ASCA IgG, EMA IgA,



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Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
	IgG antibodies against parietal cells, EBM IgG, ICS IgG, GBM IgG
813/15	IgG against Hu (ANNA-1), Ri (ANNA-2), Yo (PCA-1)
813/16	IgG against aquaporin 4 and NMO
813/17	IgG against SS-A/Ro SS-B/La, Sm, U1-RNP, Jo-1, Scl-70, ACLA IgM, ACLA IgG, anti-B2GPI IgM, anti-B2GPI IgG
813/18	IgA against tissue transglutaminase
813/19	IgG against TG, TPO, CCP
813/20	IgG against ANCA MPO, ANCA PR3, GAD, IA2, proton pump and inner factor
813/21	IgG against nRNP/Sm, Sm, SS-A, Ro-52, SS-B, Scl-70, PM-Scl, Jo-1, CENP B, PCNA, dsDNA, nukleosomes, histones, ribo-P, AMA-M2, Sp100, gp210, LKM-1, LC-1, SLA/LP, Ro 52 kDa IgG
813/22	IgG against ANNA-1 (Hu), ANNA-2 (Ri), PCA-1 (Yo), amphiphysin, PNMA2 (Ma2/Ta, CV2); IgM and IgG against gangliosides anti-GM1, anti-GM2, anti-GM3, anti-GD1a, anti-GD1b, anti-GQ1b, anti-GT1b



List of activities within the flexible scope of accreditation

2. Workplace Praha

Dittrichova 329/17, 12000 Praha 2

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom ¹
802 – Medical Microbiology					
1.	Antibodies against infectious agents	Immunoassay with luminometric detection	SOPv-20-HEP/LI, version 3; Architect i1000	Serum, plasma	A, B, C
2.	HIV markers	Immunoassay with luminometric detection	SOPv-20-HEP/LI, version 3; Architect i1000	Serum, plasma	A, B
813 - Allergology and Immunology Laboratory					
1.	Immunoglobulins	Immunonephelometry	SOPv-1-SP/LI, version 3; BN ProSpec	Serum, plasma	A, B, C
2.	C-reactive protein (CRP)	Immunonephelometry	SOPv-2-LP/LI, version 3; BN ProSpec	Serum, plasma	A, B
3.	Total IgE	Fluorescence immunoassay	SOPv-11-IgE/LI, version 2; Phadia 250	Serum, plasma	A, B
4.	Specific IgE	Fluorescence immunoassay	SOPv-12-sIgE/LI, version 2; Phadia 250	Serum, plasma	A, B
5.	Autoantibodies	Indirect immunofluorescence	SOPv-14-ANAC/LI, version 2; SOPv-15a-AMA/LI, version 2; SOPv-15b-EMA/LI, version 2	Serum, plasma	A, B, C
6.	Calprotectin	Fluorescence immunoassay	SOPv-3-Calp/LI, version 1 Phadia 250	Stool	A, B

Specification of the scope of accreditation:

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
802/1	Antibodies against HBs and HCV
802/2	Antibodies against HIV 1+2, Ag p24
813/1	IgG, IgM, IgA
813/5	ANA IgG, AMA IgG, IgA, IgM, ASMA IgG, IgA, IgM, LKM IgG, IgA, IgM, EMA IgA



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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

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