



List of activities within the flexible scope of accreditation

Accredited Body: Revmatologický ústav
CAB Name: Clinical Immunology Department (CID)
CAB Number: 8176
Certificate of Accreditation No.: 72/2024
Field of Accreditation: Medical Laboratory - ČSN EN ISO 15189 ed. 2:2013
Updated: 1.11.2024

1. Clinical Immunology Laboratory Na Slupi 450/4, 128 50 Nové Město, Praha 2

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom ¹
813 - Allergology and Immunology Laboratory					
1.	Rheumatoid factor (RF)	Immunoassay with photometric detection (manual)	I-SOPA-3, version 03; I-PI-50, version 01; I-SOPA-4, version 03; I-PI-53, version 01; I-SOPA-5, version 03; I-PI-54, version 01; I-SOPA-103, version 01; I-PI-140, version 01; I-PM-27, version 01; I-PI-36, version 01; SUNRISE BASIC- TECAN	Serum	A, B, C, D
2.	Rheumatoid factor (RF)	Immunoassay with photometric detection (automatic)	I-SOPA-6, version 03; I-PI-51, version 01; I-SOPA-7, version 03; I-PI-53, version 01; I-SOPA-8, version 03; I-PI-55, version 01; I-SOPA-109, version 01; I-PI-153, version 01; I-SOPA-110, version 01; I-PI-154, version 01;	Serum	A, B, C, D



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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom ¹
			<p>I-SOPA-111, version 01; I-PI-155, version 01; I-SOPT- 6, version 01; I-SOPT-16, version 01; I-SOPT-17, version 01; I-PM-38, version 01; DSX II; DSX I; ANALYZER</p>		
3.	Autoantibodies	Indirect immunofluorescence (manual)	<p>I-SOPA-26, version 03; I-PI-79, version 02; I-SOPA-101, version 01; I-PI-134, version 01; I-SOPA-28, version 03; I-PI-82, version 03; I-SOPA-55, version 03; I-PI-83, version 03; I-SOPA-100, version 01; I-PI-133, version 01; I-SOPA-98, version 01; I-PI-146, version 01; I-PM-8, version 01; I-PI-17, version 01; I-PI-135, version 01; I-PI-165, version 01; Olympus BH2-FL Olympus BX53</p>	Serum	A, B, C, D
4.	Autoantibodies	Indirect immunofluorescence (automatic)	<p>I-SOPA-54, version 03; I-PI-80, version 02; I-PM-2, version 01; I-PI-28, version 01; I-PI-135, version 01;</p>	Serum	A, B, C, D



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			I-PI-165, version 01; BELLINE AFT 2000; Olympus BH2-FL Olympus BX53		
5.	Autoantibodies	Immunoassay with photometric detection (manual)	I-SOPA-22, version 02; I-PI-72, version 01; I-SOPA-12, version 02; I-PI-66, version 02; I-SOPA-14, version 02; I-PI-70, version 02; I-SOPA-16, version 02; I-PI-71, version 02; I-SOPA-18, version 02; I-PI-73, version 02; I-SOPA-20, version 02; I-PI-74, version 02; I-PM-27, version 01; I-PI-36, version 01; SUNRISE BASIC- TECAN	Serum	A, B, C, D
6.	Autoantibodies	Immunoassay with photometric detection (automatic)	I-SOPA-15, version 02; I-PI-90, version 02; I-SOPA-17, version 02; I-PI-91, version 02; I-SOPA-19, version 02; I-PI-75, version 02; I-SOPA-21, version 02; I-PI-76, version 02; I-SOPA-13, version 02; I-PI-67, version 01; I-SOPA-114, version 01; I-PI-158, version 01; I-SOPA-115, version 01;	Serum	A, B, C, D



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			<p>I-PI-159, version 01; I-SOPA-116, version 01; I-PI-160, version 01; I-SOPA-117, version 01; I-PI-161, version 01; I-SOPA-118, version 01; I-PI-163, version 01; I-SOPA-122, version 01; I-PI-156, version 01; I-SOPT-6, version 06; I-SOPT-16, version 01; I-SOPT-17, version 01; I-PM-32, version 01; I-PM-4, version 01; I-PM-38, version 01; DSX II; DSX I; ANALYZER</p>		
7.	Antibodies	Immunoassay with photometric detection (manual)	<p>I-SOPA-9, version 03; I-PI-56, version 02; I-SOPA-62, version 02; I-PI-105, version 02; I-SOPA-97, version 01; I-PI-136, version 01; I-SOPA-61, version 02; I-PI-128, version 01; I-PM-27, version 01; I-PI-36, version 01; SUNRISE BASIC- TECAN</p>	Serum	A, B, C, D
8.	Antibodies	Immunoassay with photometric detection (automatic)	<p>I-SOPA-10, version 03; I-PI-57, version 02; I-SOPA-113, version 01;</p>	Serum	A, B, C, D



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Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom ¹
			I-PI-157, version 01; I-SOPT-6, version 06; I-SOPT-16, version 01; I-PM-32, version 01; I-PM-4, version 01; DSX II; DSX I		
9.	Antibodies	Immunoassay with photometric detection (automatic)	I-SOPA-65, version 03; I-PI-104, version 01; I-SOPA-67, version 03; PI-106, version 03; I-SOPT-10, version 01; Alegria	Serum	A, B, C, D
10.	Autoantibodies	Immunoassay with luminometric detection (automatic)	I-SOPA-104, version 01; I-PI-141, version 01; I-SOPA-105, version 01; I-PI-142, version 01; I-SOPT-15, version 01; I-PI-143, version 01; BioFlash	Serum	A, B, C, D
11.	Autoantibodies	Immunoblotting (manual)	I-SOPA-29, version 03; I-PI-77, version 02	Serum	A, B, C, D
12.	Autoantibodies	Immunoblotting (automatic)	I-SOPA-53, version 03; I-PI-78, version 02; I-PM-11, version 01; Profiblot 48	Serum	A, B, C, D
802 – Medical Microbiology					
1.	Antibodies against infectious agents	Immunoassay with photometric detection (manual)	I-SOPA-39, version 03; I-PI-84, version 02; I-SOPA-40 version 03; I-PI-85, version 02; I-SOPA-48, version 03;	Serum	A, B, C, D



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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom ¹
			I-PI-88, version 02; I-SOPA-47, version 03; I-PI-89, version 02; I-SOPA-44, version 03; I-PI-87, version 02; I-SOPA-43, version 03; I-PI-86, version 02; I-SOPA-85, version 03; I-PI-122, version 02; I-SOPA-86, version 03; I-PI-123, version 02; I-SOPA-87, version 03; I-PI-124, version 02; I-SOPA-88, version 03; I-PI-125, version 02; I-SOPA-89, version 03; I-PI-126, version 02; I-SOPA-90, version 03; I-PI-127, version 02; I-SOPA-106, version 01; I-PI-150, version 01 I-SOPA-107, version 01; I-PI-151, version 01; I-PM-27, version 01; I-PI-36, version 01; SUNRISE BASIC- TECAN		
2.	Antibodies against infectious agents	Immunoassay with photometric detection (automatic)	I-SOPA-95, version 01; I-PI-120, version 01; I-SOPA-96, version 01; I-PI-121, version 01; I-PM-28, version 01; CHORUS	Serum	A, B, C, D



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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom ¹
3.	Antibodies against infectious agents	Immunoblotting (automatic)	I-SOPA-49, version 02; I-PI-97, version 01; I-SOPA-50, version 02; I-PI-99, version 01; I-SOPA-51, version 02; I-PI-98, version 01; I-SOPA-52, version 02; I-PI-100, version 01; I-SOPA-91, version 02; I-PI-118, version 02; I-SOPA-92, version 02; I-PI-119, version 02; I-PM-4, version 01; Dynablot	Serum	A, B, C, D
4.	Determination of gamma interferon	Immunoassay with photometric detection (manual)	I-SOPA-25, version 04; I-PI-65, version 04; I-PM-27, version 01; I-PI-36, version 01; SUNRISE BASIC- TECAN	Plasma	A, B, C

Specification of the scope of accreditation:

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
813/1	RF screen, RF IgG, RF IgA, RF IgM
813/2	RF IgG, RF IgA, RF IgM
813/3	ANA IgG, anti dsDNA IgG, ANCA IgG (ethanol), ANCA IgG (formaldehyde), anti EMA IgA, anti GBM IgG
813/4	ANA IgG
813/5	anti nucleosome antibodies IgG, anti ds DNA IgG, anti ACLA IgG, anti ACLA IgM, anti beta-2-GPI IgG, anti-beta-2GPI IgM



List of activities within the flexible scope of accreditation

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
813/6	anti nucleosome antibodies IgG, anti ds DNA IgG, anti ACLA IgG, anti ACLA IgM, anti beta-2-GPI IgG, anti-beta-2GPI IgM
813/7	anti CCP IgG, anti MCV, CIK bond C1q, anti C1q
813/8	anti CCP IgG, anti MCV
813/9	DGP IgA, DGP IgG, TGA IgA, TGA IgG
813/10	anti MPO IgG, anti PR3 IgG
813/11	Antibodies against extractable nuclear antigens: Sm D1 IgG, PCNA IgG, P protein IgG, Ro-60 IgG, Ro-52 IgG, La IgG, CENP B IgG, Scl-70 IgG, U1-snRNP IgG, AMA M2 IgG, Jo-1 IgG, PM-Scl 100 IgG, Mi-2 IgG, Ku70/80 IgG, DFS 70 IgG
813/12	Antibodies against extractable nuclear antigens: Sm D1 IgG, PCNA IgG, P protein IgG, Ro-60 IgG, Ro-52 IgG, La IgG, CENP B IgG, Scl-70 IgG, U1-snRNP IgG, AMA M2 IgG, Jo-1 IgG, PM-Scl 100 IgG, Mi-2 IgG, Ku70/80 IgG, DFS 70 IgG
802/1	Antibodies against <i>Borrelia</i> species IgG, <i>Borrelia</i> species IgM, <i>Borrelia garinii</i> IgG, <i>Borrelia garinii</i> IgM, <i>Borrelia afzelii</i> IgG, <i>Borrelia afzelii</i> IgM, <i>Chlamydia</i> species IgA, <i>Chlamydia</i> species IgG, <i>Chlamydia pneumoniae</i> IgA, <i>Chlamydia pneumoniae</i> IgG, <i>Chlamydia trachomatis</i> IgA, <i>Chlamydia trachomatis</i> IgG
802/2	CMV IgM, CMV IgG, EBV – VCA IgM, EBV-VCA IgG, EBV-EBNA IgG, EBV-EA IgM, EBV-EA-IgG
802/3	Antibodies against <i>Borrelia</i> species IgG, <i>Borrelia</i> species IgM, <i>Borrelia garinii</i> IgG, <i>Borrelia garinii</i> IgM, <i>Borrelia afzelii</i> IgG, <i>Borrelia afzelii</i> IgM, <i>Chlamydia</i> species IgA, <i>Chlamydia</i> species IgG,
802/4	QFN TB Gold



List of activities within the flexible scope of accreditation

2. **Flow Cytometry Laboratory** Na Slupi 450/4, 128 50 Nové Město, Praha 2

Examinations:

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom ¹
813 - Allergology and Immunology Laboratory					
1.	Immunophenotyping of lymphocyte subpopulations	Flow cytometry	I-SOPA-93, version 07; I-PI-49, version 07; I-SOPT-12, version 04; I-PI-45, version 04; CyAn ADP TM	Blood	A, B, C
2.	Immunophenotyping of leukocyte subpopulations	Flow cytometry	I-SOPA-94, version 06 I-PI-93, version 05 I-SOPT-12, version 04 I-PI-45, version 04 CyAn ADP TM	Blood	A, B, C

Specification of the scope of accreditation:

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
813/1	T lymphocyte (CD3+), Tly auxiliary (CD3+CD4+), Tly cytotoxic (CD3+CD8+), NK cells (CD3-CD16,56+), B lymphocyte (CD19+)
813/2	HLA-B27, HLA-B7

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.