

List of activities within the flexible scope of accreditation

Accredited Body: Fakultní nemocnice Olomouc

CAB Name: Laboratories of the Department of Immunology

CAB Number: 8251

Certificate of Accreditation No.: 568/2023

Field of Accreditation: Medical Laboratory - ČSN EN ISO 15189:2013

Updated: 05/12/2024

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.	Immunoglobulins	Immunonephelometry	SOP-HUM-A01a Issue 6.; SOP-HUM-A01b Issue 6.; PI-HUM-A01.1 Issue 6.; PI-HUM-A01.2 Issue 5.; Nephelometer BN II	Serum	A, B, C
2.	Specific proteins	Immunonephelometry	SOP-HUM-A06 Issue 4.; SOP-HUM-A07 Issue 4.; PI-HUM-A01.1 Issue 6.; PI-HUM-A01.2 Issue 5.; Nephelometer BN II	Serum	A, B, C
3.	Autoantibodies	Indirect immunofluorescence	SOP-HUM-A03a Issue 4.; SOP-HUM-A03b Issue 5.; SOP-HUM-A03c Issue 4.; PI-HUM-03 Issue 5.; PI-HUM-04 Issue 2.; PP-HUM-A03a Issue 4.; PP-HUM-A03b Issue 4.; PP-HUM-A03c Issue 4.; iPRO	Serum	A, B, C
4.	Autoantibodies	Immunoassay with photometric detection	SOP-HUM-A04 Issue 4.; SOP-HUM-A08 Issue 3.; PI-HUM-01 Issue 5.;	Serum	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 ¹
			PI-HUM-02 Issue 7.; PP-HUM-A04.1 Issue 4.; PP-HUM-A08 Issue 3.		
5.	Autoantibodies	Immunoassay with photometric detection	SOP-HUM-A05a Issue 6.; SOP-HUM-A05b Issue 6.; PI-HUM-01 Issue 5.; PI-HUM-02 Issue 7.; PP-HUM-A05a Issue 6.; PP-HUM-A05b Issue 6.	Serum	A, B, C
6.	Specific IgE	Immunoassay with fluorimetric detection	SOP-HUM-A02 Issue 5.; PI-HUM-A02.1 Issue 5.; PI-HUM-A02.2 Issue 5.; PI-HUM-A02.3 Issue 4.; PP-HUM-A02.1 Issue 4.; PP-HUM-A02.2 Issue 4.; PP-HUM-A02.3 Issue 4.; PP-HUM-A02.5 Issue 4.; PP-HUM-A02.6 Issue 6.; Phadia 250	Serum	A, B
7.	Immunophenotyping of cell population	Flow cytometry	SOP-BUN-A01 Issue 5.; PI-BUN-A01.1 Issue 5.; PI-BUN-A01.2 Issue 4.; PI-BUN-A01.3 Issue 4.; PI-BUN-A01.4 Issue 4.; PI-BUN-A01.5 Issue 4.; PI-BUN-A01.6 Issue 4.; PI-BUN-A01.7 Issue 2.; BD FACSCanto; Mindray BriCyte E6	Blood	A, B, C
8.	HLA system examination	PCR-SSP	SOP-HLA-A01 Issue 5.; PI-HLA-A01.1 Issue 7.; PI-HLA-A01.3 Issue 6.;	Biological material containing nuclear DNA	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 ¹
			PP-HLA-A01.1 Issue 6.; PI-HLA-D01 Issue 3.; PI-HLA-D18 Issue 3.; PI-HLA-D20 Issue 3.; PP-HLA-D03 Issue 3.; Instruction DeNovix DS11; PI-HLA-03 Issue 5.; PI-HLA-D04 Issue 3.; PI-HLA-D05 Issue 4.; PI-HLA-05 Issue 9.; PI-HLA-06 Issue 3.; PI-HLA-04 Issue 3.; PI-HLA-D09 Issue 3.; PI-HLA-D08 Issue 6.; PI-HLA-D10 Issue 4.; PI-HLA-D11 Issue 4.; PP-HLA-D02 Issue 5.; PP-HLA-D04 Issue 3.; Biorad C1000; Biorad T100; Biometra Professional basic		
9.	HLA system examination	Real-Time PCR	SOP-HLA-A06 Issue 2.; PP-HLA-A06.1 Issue 1.; PI-HLA-D01 Issue 3.; PP-HLA-D03 Issue 3.; Instruction DeNovix DS11; PI-HLA-03 Issue 5.; PI-HLA-D04 Issue 3.; PI-HLA-D05 Issue 4.; PI-HLA-05 Issue 9.; PI-HLA-06 Issue 3.; PI-HLA-04 Issue 3.; PI-HLA-D09 Issue 3.;	Biological material containing nuclear DNA	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 ¹
			PI-HLA-D08 Issue 6.; PI-HLA-D11 Issue 4.; PP-HLA-D02 Issue 5.; Roche LightCycler 480 II		
10.	HLA system examination	NGS-MPS	SOP-HLA-A07 Issue 2.; PI-HLA-A07.1 Issue 2.; PI-HLA-D01 Issue 3.; PI-HLA-D20 Issue 3.; PI-HLA-D32 Issue 2.; PP-HLA-D03 Issue 3.; Instruction DeNovix DS11; PI-HLA-03 Issue 5.; PI-HLA-D04 Issue 3.; PI-HLA-D05 Issue 4.; PI-HLA-05 Issue 9.; PI-HLA-06 Issue 3.; PI-HLA-04 Issue 3.; PI-HLA-D09 Issue 3.; PI-HLA-D08 Issue 6.; PI-HLA-D10 Issue 4.; PI-HLA-D11 Issue 4.; PP-HLA-D02 Issue 5.; PP-HLA-D04 Issue 3.; SURFSeq 5000	Biological material containing nuclear DNA	A, B, C
11.	Examination of antiHLA antibodies	xMAP technology	SOP-HLA-A04 Issue 4.; PP-HLA-S02 Issue 2.; PI-HLA-S09 Issue 2.; LABScan3D	Serum	A, B, C

List of activities within the flexible scope of accreditation

Specification of the scope of accreditation:

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
813/1	IgG, IgA, IgM, IgE
813/2	C-reactive protein (CRP), C3 complement component, C4 complement component
813/3	ANA in IgG class, ANCA in IgG class, EMA in IgA class
813/4	tTG in IgA class, CCP in IgG class
813/5	dsDNA in IgG class, IgG antinucleosomal antibodies,
813/7	T lymphocytes CD3+, Th lymphocytes CD4+, Tc lymphocytes CD8+, B lymphocytes CD19+, NK lymphocytes CD3-CD16+CD56+
813/8	genes (loci) HLA-A, -B, -C, -DRB1, -DQB1, -DPB1
813/9	genes (loci) HLA-A, -B, -C, -DRB1, -DRB3, -DRB4, -DRB5, -DQA1, -DQB1, -DPA1, -DPB1
813/10	genes (loci) HLA-A, -B, -C, -DRB1, -DQB1, -DPB1
813/11	antiHLA-I. and II. class antibodies

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.

HLA Major histocompatibility complex of humans (*Human leukocyte antigens*)

NGS-MPS Next Generation Sequencing – Massively Parallel Sequencing

PCR-SSP Polymerase Chain Reaction with Sequence Specific Primers

Real-Time PCR Real-Time Polymerase Chain Reaction

xMAP Methodology for multiplex determination of analytes (antiHLA antibodies in this case) using diagnostic microparticles as solid phase