



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 |



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| | | | 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 |



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| | | | 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 |



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| | | | 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