

## 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:** 30/08/2024

### Examinations:

| Ordinal Number                                     | Analyte/parameter/diagnostics | Principle of examination               | Identification of method procedure/ equipment                                                                                                                                                               | Examined material | Degrees of freedom <sup>1</sup> |
|----------------------------------------------------|-------------------------------|----------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|---------------------------------|
| <b>813 - Allergology and Immunology Laboratory</b> |                               |                                        |                                                                                                                                                                                                             |                   |                                 |
| 1.                                                 | Immunoglobulins               | Immunonephelometry                     | SOP-HUM-A01a Issue 6.;<br>SOP-HUM-A01b Issue 6.;<br>PI-HUM-A01.1 Issue 6.;<br>PI-HUM-A01.2 Issue 5.;<br>Nephelometer BN II                                                                                  | Serum             | A, B, C                         |
| 2.                                                 | Specific proteins             | Immunonephelometry                     | SOP-HUM-A06 Issue 4.;<br>SOP-HUM-A07 Issue 4.;<br>PI-HUM-A01.1 Issue 6.;<br>PI-HUM-A01.2 Issue 5.;<br>Nephelometer BN II                                                                                    | Serum             | A, B, C                         |
| 3.                                                 | Autoantibodies                | Indirect immunofluorescence            | SOP-HUM-A03a Issue 4.;<br>SOP-HUM-A03b Issue 3.;<br>SOP-HUM-A03c Issue 3.;<br>PI-HUM-03 Issue 5.;<br>PI-HUM-04 Issue 2.;<br>PP-HUM-A03a Issue 3.;<br>PP-HUM-A03b Issue 3.;<br>PP-HUM-A03c Issue 3.;<br>iPRO | Serum             | A, B, C                         |
| 4.                                                 | Autoantibodies                | Immunoassay with photometric detection | SOP-HUM-A04 Issue 4.;<br>SOP-HUM-A08 Issue 3.;<br>PI-HUM-01 Issue 4.;                                                                                                                                       | Serum             | A, B, C                         |

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|----------------|-----------------------------------------|--------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|---------------------------------------|
|                |                                         |                                            | PI-HUM-02 Issue 6.;<br>PP-HUM-A04.1 Issue 4.;<br>PP-HUM-A08 Issue 3.                                                                                                                                                                                |                                                     |                                       |
| 5.             | Autoantibodies                          | Immunoassay with<br>photometric detection  | SOP-HUM-A05a Issue 6.;<br>SOP-HUM-A05b Issue 6.;<br>PI-HUM-01 Issue 4.;<br>PI-HUM-02 Issue 6.;<br>PP-HUM-A05a Issue 6.;<br>PP-HUM-A05b Issue 6.                                                                                                     | Serum                                               | A, B, C                               |
| 6.             | Specific IgE                            | Immunoassay with<br>fluorimetric detection | SOP-HUM-A02 Issue 5.;<br>PI-HUM-A02.1 Issue 5.;<br>PI-HUM-A02.2 Issue 5.;<br>PI-HUM-A02.3 Issue 4.;<br>PP-HUM-A02.1 Issue 4.;<br>PP-HUM-A02.2 Issue 4.;<br>PP-HUM-A02.3 Issue 4.;<br>PP-HUM-A02.5 Issue 4.;<br>PP-HUM-A02.6 Issue 6.;<br>Phadia 250 | Serum                                               | A, B                                  |
| 7.             | Immunophenotyping<br>of cell population | Flow cytometry                             | SOP-BUN-A01 Issue 5.;<br>PI-BUN-A01.1 Issue 5.;<br>PI-BUN-A01.2 Issue 4.;<br>PI-BUN-A01.3 Issue 4.;<br>PI-BUN-A01.4 Issue 4.;<br>PI-BUN-A01.5 Issue 4.;<br>PI-BUN-A01.6 Issue 4.;<br>PI-BUN-A01.7 Issue 2.;<br>BD FACSCanto;<br>Mindray BriCyte E6  | Blood                                               | A, B, C                               |
| 8.             | HLA system<br>examination               | PCR-SSP                                    | SOP-HLA-A01 Issue 5.;<br>PI-HLA-A01.1 Issue 7.;<br>PI-HLA-A01.3 Issue 6.;                                                                                                                                                                           | Biological<br>material<br>containing<br>nuclear DNA | A, B, C                               |

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|----------------|-----------------------------------|--------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|---------------------------------------|
|                |                                   |                          | PP-HLA-A01.1 Issue 6.;<br>PI-HLA-D01 Issue 3.;<br>PI-HLA-D18 Issue 3.;<br>PI-HLA-D20 Issue 3.;<br>PP-HLA-D03 Issue 3.;<br>Instruction DeNovix DS11;<br>PI-HLA-03 Issue 5.;<br>PI-HLA-D04 Issue 3.;<br>PI-HLA-D05 Issue 4.;<br>PI-HLA-05 Issue 8.;<br>PI-HLA-06 Issue 3.;<br>PI-HLA-04 Issue 3.;<br>PI-HLA-D09 Issue 3.;<br>PI-HLA-D08 Issue 6.;<br>PI-HLA-D10 Issue 4.;<br>PI-HLA-D11 Issue 4.;<br>PP-HLA-D02 Issue 5.;<br>PP-HLA-D04 Issue 3.;<br>Biorad C1000;<br>Biorad T100;<br>Biometra Professional basic |                                                     |                                       |
| 9.             | HLA system<br>examination         | Real-Time PCR            | SOP-HLA-A06 Issue 2.;<br>PP-HLA-A06.1 Issue 1.;<br>PI-HLA-D01 Issue 3.;<br>PP-HLA-D03 Issue 3.;<br>Instruction DeNovix DS11;<br>PI-HLA-03 Issue 5.;<br>PI-HLA-D04 Issue 3.;<br>PI-HLA-D05 Issue 4.;<br>PI-HLA-05 Issue 8.;<br>PI-HLA-06 Issue 3.;<br>PI-HLA-04 Issue 3.;<br>PI-HLA-D09 Issue 3.;                                                                                                                                                                                                                | Biological<br>material<br>containing<br>nuclear DNA | A, B, C                               |

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|----------------|--------------------------------------|--------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|---------------------------------------|
|                |                                      |                          | PI-HLA-D08 Issue 6.;<br>PI-HLA-D11 Issue 4.;<br>PP-HLA-D02 Issue 5.;<br>Roche LightCycler 480 II                                                                                                                                                                                                                                                                                                                                                                                         |                                                     |                                       |
| 10.            | HLA system<br>examination            | NGS-MPS                  | SOP-HLA-A07 Issue 2.;<br>PI-HLA-A07.1 Issue 2.;<br>PI-HLA-D01 Issue 3.;<br>PI-HLA-D20 Issue 3.;<br>PI-HLA-D32 Issue 2.;<br>PP-HLA-D03 Issue 3.;<br>Instruction DeNovix DS11;<br>PI-HLA-03 Issue 5.;<br>PI-HLA-D04 Issue 3.;<br>PI-HLA-D05 Issue 4.;<br>PI-HLA-05 Issue 8.;<br>PI-HLA-06 Issue 3.;<br>PI-HLA-04 Issue 3.;<br>PI-HLA-D09 Issue 3.;<br>PI-HLA-D08 Issue 6.;<br>PI-HLA-D10 Issue 4.;<br>PI-HLA-D11 Issue 4.;<br>PP-HLA-D02 Issue 5.;<br>PP-HLA-D04 Issue 3.;<br>SURFSeq 5000 | Biological<br>material<br>containing<br>nuclear DNA | A, B, C                               |
| 11.            | Examination of<br>antiHLA antibodies | xMAP technology          | SOP-HLA-A04 Issue 4.;<br>PP-HLA-S02 Issue 2.;<br>PI-HLA-S09 Issue 2.;<br>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:

<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.

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