The Appendix is an integral part of Certificate of Accreditation No. 568/2023 of 27/10/2023

Accredited entity according to ČSN EN ISO 15189:2013:

Fakultní nemocnice Olomouc

CAB Number 8251, Immunology Department Laboratories Hněvotínská 976/3, 775 15 Olomouc

The laboratory applies a flexible approach to the scope of accreditation.

The current "List of activities within the flexible scope" is available on the website www.fnol.cz/kliniky-ustavy-oddeleni/ustav-imunologie

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom ¹
813 - Allergology and Immunology Laboratory					
1.	Immunoglobulins	Immunonephelometry	Commercial procedure	Serum	A, B, C
2.	Specific proteins	Immunonephelometry	Commercial procedure	Serum	A, B, C
3.	Autoantibodies	Indirect immunofluorescence	Commercial procedure	Serum	A, B, C
4.	Autoantibodies	Immunoassay with photometric detection	Commercial procedure	Serum	A, B, C
5.	Autoantibodies	Immunoassay with photometric detection	Commercial procedure	Serum	A, B, C
6.	Specific IgE	Immunoassay with fluorimetric detection	Commercial procedure	Serum	A, B
7.	Immunophenotyping of cell population	Flow cytometry	In-house procedure	Blood	A, B, C
8.	HLA system examination	PCR-SSP	Commercial procedure	Biological material containing nuclear DNA	A, B, C
9.	HLA system examination	Real-Time PCR	Commercial procedure	Biological material containing nuclear DNA	A, B, C
10.	HLA system examination	NGS-MPS	Commercial procedure	Biological material containing nuclear DNA	A, B, C
11.	Examination of antiHLA antibodies	xMAP technology	Commercial procedure	Serum	A, B, C



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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.

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

