The Appendix is an integral part of Certificate of Accreditation No. 284/2022 of 14/06/2022

Accredited entity according to ČSN EN ISO 15189:2013:

Fakultní nemocnice Olomouc

Immunology Department Laboratories I. P. Pavlova 185/6, 779 00 Olomouc

The Laboratory has a flexible scope of accreditation permitted as detailed in the Annex. Updated list of activities provided within the flexible scope of accreditation is available at the Laboratory from the Laboratory Manager.

Examinations:

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
	813 - Allergology an	d Immunology Laborator	y
1.	Determination of immunoglobulins IgG, IgA, IgM by nephelometry [Immunoglobulin G, Immunoglobulin A, Immunoglobulin M]	SOP-HUM-A01a	Serum, plasma
2.	Determination of immunoglobulin IgE in serum by nephelometry [Immunoglobulin E]	SOP-HUM-A01b	Serum, plasma
3.	Determination of specific IgE antibodies by high affinity FEIA method [Individual allergens and mixtures]	SOP-HUM-A02	Serum, plasma
4.	Determination of IgG antinuclear antibodies by indirect immunofluorescence [Antinuclear Ab]	SOP-HUM-A03a	Serum, plasma
5.	Determination of IgG antibodies to neutrophil cytoplasmic antigens by indirect immunofluorescence [ANCA antibodies]	SOP-HUM-A03b	Serum, plasma
6.	Determination of IgA antiendomysial antibodies by indirect immunofluorescence [EMA IgA]	SOP-HUM-A03c	Serum, plasma
7.	Quantitative determination of IgA antibodies against tissue transglutaminase by ELISA method [tTG IgA]	SOP-HUM-A04	Serum, plasma

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Ordinal number	Examination procedure name	Examination procedure identification	Examined object
8.	Quantitative determination of IgG antibodies against double-stranded DNA by ELISA method [Anti ds DNA]	SOP-HUM-A05a	Serum, plasma
9.	Quantitative determination of IgG antinucleosomal antibodies by ELISA method [Antinucleosom.Ab]	SOP-HUM-A05b	Serum, plasma
10.	Determination of CRP by nephelometry [CRP]	SOP-HUM-A06	Serum, plasma
11.	Determination of C3, C4 complement component by nephelometry [Complement C3, Complement C4]	SOP-HUM-A07	Serum, plasma
12.	Quantitative determination of anticitrulin antibodies in IgG class by ELISA method [Anti CCP]	SOP-HUM-A08	Serum, plasma
13.	Determination of lymphocyte subpopulations (relative count) by flow cytometry [CD3, CD4, CD8, CD19, CD16+56]	SOP-BUN-A01	Blood
14.	Determination of the genotype of the main human histocompatibility system – HLA and related genes by PCR-SSP method ¹⁾ [HLA I. class (DNA), HLA II. class DR, HLA II. class DQ,]	SOP-HLA-A01	Biological material containing nuclear DNA

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Ordinal number	Examination procedure name	Examination procedure identification	Examined object
15.	Determination of the genotype of the main human histocompatibility system – HLA and related genes by SBT method ¹⁾	SOP-HLA-A02	Biological material containing nuclear DNA
	[HLA I. class (DNA), HLA II. class DR, HLA II. class DQ, HLA II. class DP]	,	
16.	Determination of antiHLA antibodies of I. and II. class and antiMICA antibodies by Luminex method [AntiHLA antibodies LUMINEX]	SOP-HLA-A04	Serum
17.	Determination of the genotype of the main human histocompatibility system – HLA and related genes by REAL-TIME PCR method ¹⁾	SOP-HLA-A06	Biological material containing nuclear DNA
	[HLA I. class (DNA), HLA II. class DR, HLA II. class DQ]		
18.	Determination of the genotype of the main human histocompatibility system – HLA and related genes by NGS ¹⁾ [HLA I. class (DNA),	SOP-HLA-A07	Biological material containing nuclear DNA
	HLA II. class DR, HLA II. class DQ, HLA II. class DP]	-	

Names in parentheses [] are the names of examinations shown in the reports.



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Annex:

Flexible scope of accreditation

Examination procedure ordinal numbers:

14,15,16,17,18

The Laboratory is allowed to modify the examination procedures listed in the Annex within the specified scope of accreditation provided the measuring principle is observed.

The flexible approach to the scope of accreditation cannot be applied to the examinations not included in the Annex.

Explanatory notes:

1) Class I. HLA: loci A, B, C

Class II. HLA: loci DRB1, DQB1, DPB1

