



## List of activities within the flexible scope of accreditation

**Accredited Body:** Fakultní nemocnice v Motole

**CAB Name:** Laboratory Centre of the Department of Paediatric Haematology and Oncology  
Second Faculty of Medicine, Charles University and University Hospital Motol  
CLIP Laboratory Centre

**CAB Number:** 8276

**Certificate of Accreditation No.:** 69/2024

**Field of Accreditation:** Medical Laboratory - ČSN EN ISO 15189 ed. 2:2013

**Updated:** 21.05.2024

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.	Determination of lymphocyte subpopulations	Flow cytometry	SOPm_012/V12 (procedure A); BD FACSLytic	Peripheral blood	A, B, C, D
2.	Determination of lymphocyte subpopulations	Flow cytometry	SOPm_012/V12 (procedure B); BD FACSLytic	Peripheral blood	A, B, C, D
3.	Immunophenotyping of leukemias	Flow cytometry	SOPm_013/V11; (procedure A); BD FACSLytic SOPm_013/V11; (procedure B); BD FACSLytic	Bone marrow, peripheral blood, effusion, and cerebrospinal fluid	A, B, C, D
4.	Determination of hematopoietic stem and progenitor cells	Flow cytometry	SOPm_016/V10; BD FACSLytic	Bone marrow, peripheral blood, umbilical cord blood, apheresis products	A, B, C, D
5.	Determination of minimal residual disease in B precursor ALL	Flow cytometry	SOPm_006/V3; BD FACSLytic	Bone marrow, peripheral blood, effusion, and cerebrospinal fluid	A, B, C, D



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<b>816 – Medical Genetics Laboratory</b>					
1.	Examination of somatic genome variants	NGS-MPS	SOPm_01/V3; Annex 1 (1. 5. 2014); Annex 2 (2. 3. 2020); Annex 3 (1. 5. 2014); Annex 4 (11. 7. 2018); Annex 5 (1. 6. 2020); Annex 6 (1. 5. 2014); MiSeq	Biological material containing nucleic acid	A, B, C
2.	Examination of somatic genome variants	Real-Time PCR	SOPm_01/V3; Annex 4 (11. 7. 2018); Annex 8 (1. 12. 2016); Annex 9 (1. 5. 2014); TaqMan 7500 Fast Real-Time PCR; QuantStudio™5 real time PCR	Biological material containing nucleic acid	A, B, C
3.	Examination of fusion genes	Real-Time PCR	SOPm_02/V1; Annex (1. 7. 2022); TaqMan 7500 Fast Real-Time PCR; QuantStudio™5 real time PCR	Biological material containing nucleic acid	A, B, C
4.	Examination of somatic genome variants	NGS-MPS	SOPm_03/V1; Annex 1 (1. 9. 2022); Annex 3 (1. 9. 2022); MiSeq	Biological material containing nucleic acid	A, B, C
5.	Examination of somatic genome variants	Real-Time PCR	SOPm_03/V1; Annex 2 (1. 9. 2022); TaqMan 7500 Fast Real-Time PCR; QuantStudio™5 real time PCR	Biological material containing nucleic acid	A, B, C

#### Specification of the scope of accreditation:

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
813/1	Tested antigens: CD3, CD4 (CD3+CD4+), CD8 (CD3+CD8+), CD19, CD3-16,56+ including additional markers for extended immunophenotyping of lymphocytes
813/2	Tested antigens: CD3, CD4 (CD3+CD4+), CD8 (CD3+CD8+), CD19, CD3-16,56+ including additional markers for extended immunophenotyping of lymphocytes



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Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
813/3	<p>Procedure A: „BD OneFlow™ ALOT“ : Tested antigens: CD45, CD3, CD7, CD19, CD34, intra-CD3, intra-CD79a, intra-MPO.</p> <p>Procedure B: Tested antigens: CD45, CD3, CD4, CD8, CD5, CD7, CD99, intra-lysozyme, CD15, CD117, CD11b, CD11c, CD14, CD33, CD19, CD10, CD20, CD34, CD38, CD81, CD56, CD66c, HLA-DR, intra-CD22, intra-TdT including additional markers specific for leukemia of B-lymphoid, T-lymphoid, or myeloid origin.</p>
813/4	„CD34 QuantiFlowEx Kit“: Tested antigens: CD34, CD45, CD3, CD4, CD8 according to ISHAGE guidance for CD34+.
813/5	Tested antigens: CD10, CD19, CD20, CD34, CD38, CD45, CD81 including additional markers of immunophenotype of leukemia blasts examined in the diagnosis according to SOPm_013
816/1	Screening of IG/TCR rearrangements in systems IGH-VJ, IGH-DJ, IGK-VJ-Kde, Intron-Kde, TRB-VJ, TRB-DJ, TRD, TRG
816/2	Quantitative determination of minimal residual disease by IG/TCR rearrangements
816/3	HemaVision ®-28Q kit
816/4	<p>Detection of fusion genes and mutations (AML-MDS_v2 – mark 1B): <i>ASXL1, BCOR, BCORL1, BRAF, CBL, CEBPA, CSF3R, DNMT3A, EZH2, FLT3, GATA1, GATA2, IDH1, IDH2, JAK2, JAK3, KIT, KRAS, NF1, NOTCH1, NPM1, NRAS, PHF6, PIGA, PPM1D, PTPN11, RAD21, RRS, RUNX1, SAMD9, SAMD9L, SETBP1, SMARCA2, STAG2, TET2, TP53, U2AF1, WT1, UBTF</i></p> <p>Detection of fusion genes (CommonFusions - mark 2): <i>ABL1, BCR, CFBF, CSF1R, ETV6, IGH, KMT2A, MYH11, PDGFRB, PML, RARA, RUNX1, RUNX1T1, ZC3HAV1</i></p> <p>Detection of fusion genes (RareFusions - mark 3): <i>CBFA2T3, DEK, ETV6, FUS, HOXA10, HOXA11, HOXA13, HOXA7, HOXA9, HOXB7, HOXB8, HOXB9, KAT6A, KAT6B, NUP214, NUP98, PICALM, RARB, RARG, RBM15, XPO1, ZEB2, ZNF384</i></p>
816/5	Quantitative determination of minimal residual disease by mutation or fusion genes

#### 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.

ALL	Acute lymphoblastic Leukemia
NGS	Next Generation Sequencing – Massively Parallel Sequencing (MPS)
PCR	Polymerase Chain Reaction
Real-Time PCR	Real-Time Polymerase Chain Reaction