List of activities within the flexible scope of accreditation

Accredited Body: Ústav hematologie a krevní transfuze
Název objektu: Komplement laboratoří ÚHKT
CAB Number: 8081
Certificate of Accreditation No.: 457/2026
Field of Accreditation: Medical Laboratory - ČSN EN ISO 15189 ed. 3:2023
Updated: 07.10.2026

1. **Workplace No. 1** U Nemocnice 2094/1, 128 00 Praha 2

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom[1]
222 - Transfusion Medicine					
1.	Reserved				
2.	Cross-match	CDC	233_SOP_08_01/VA4; Annex 02/VA4	Blood	A, B
3.	Identification of thrombocyte antibodies	Multiplex bead method	203_SOP_14_02/VA1	Serum	A, B
4.	Screening of irregular anti-erythrocyte antibodies	Gel column agglutination (manual)	203_SOP_10 _04/VA4	Serum, plasma	A, B
5.	Identification of irregular anti-erythrocyte antibodies	Gel column agglutination (manual)	203_SOP_10 _05/VA3	Serum, plasma	A, B
6.	Direct antiglobulin test	Gel column agglutination (manual)	203_SOP_12 _07/VA3	Blood	A, B
7.	Detection of HIT-associated antibodies	Immunoassay with luminometric detection	203_SOP_13 _01/VA2; ACL BIO-FLASH	Blood	A, B
8.	Reserved				
9.	Examination of compatibility	Gel column agglutination (manual)	203_SOP_12 _09/VA2	Blood	A, B
10.	Blood type	Microplate agglutination	203_SOP_22 _02/VA1; NEO Iris	Blood	A, B
11.	Erythrocyte antigens	Microplate agglutination	203_SOP_22 _03/VA1; NEO Iris	Blood	A, B

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom[1]
12.	Screening of irregular anti-erythrocyte antibodies	Solid phase	203_SOP_22 _04 /VA1; NEO Iris	Blood	A, B
13.	Identification of anti-erythrocyte antibodies	Gel column agglutination (manual)	203_SOP_23_11/VA1	Blood	A, B
802 – Medical Microbiology					
1.	Detection of nucleic acid of infectious agents	Real-Time PCR	318_SOP_22_01/VA1; GeneXpert	Nasopharyngeal swab, bronchoalveolar lavage, tracheal aspirate, sputum	A, B, C, D
2.	Detection of nucleic acid of infectious agents	Real-Time PCR	318_SOP_22_02/VA3; Annex 2 A/VA3; Annex 2 D/VA1; Annex 2 E/VA1; Annex 3 A/VA1; Annex 3 B/VA1; Annex 3 C/VA1; Annex 3 D/VA1; Annex 3 E/VA1; Annex 4 A/VA1; Annex 4 B/VA1; Annex 4 C/VA1; Annex 4 D/VA1; MagCore®plus II; croBEE NA16 BIO-RAD CFX 96	Nasopharyngeal swab, bronchoalveolar lavage, tracheal aspirate, sputum, cerebrospinal fluid, lesion swabs, blood, nails, exploratory biopsy	A, B, C, D

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom[1]
3.	Detection of nucleic acid of infectious agents	Real-Time PCR	318_SOP_22_03/VA2; Annex 2 A/VA3; Annex 2 D/VA1; Annex 2 E/VA1; Annex 3 A/VA1; Annex 3 B/VA1; Annex 3 C/VA1; Annex 3 D/VA1; Annex 4 A/VA3; Annex 4 B/VA3; Annex 4 C/VA3; Annex 4 D/VA2; Annex 4E/VA2; Annex 4F/VA2; Annex 4G/VA2; MagCore®plus II; croBEE NA16 BIO-RAD CFX 96	Blood, plasma, cerebrospinal fluid, urine, bronchoalveolar lavage, tracheal aspirate, sputum, ascites, pleural exudate	A, B, C, D
4.	Antibodies to infectious agents	Immunoassay with luminometric detection (automated)	LPVN_SOP_19 _01/VA2; Architect i2000SR	Serum, plasma	A, B, C
5.	HIV markers	Immunoassay with luminometric detection (automated)	LPVN_SOP_19 _01/VA2; Architect i2000SR	Serum, plasma	A, B, C
6.	Antigens of infectious agents	Immunoassay with luminometric detection (automated)	LPVN_SOP_19 _01/VA2; Architect i2000SR	Serum, plasma	A, B, C
7.	Reserved				
813 - Allergology and Immunology Laboratory					
1.	Immunophenotyping of lymphoid subpopulations	Flow cytometry	116_SOP_21_01/VA1; BD FACS Canto II; Cytognos Omnicyt I, II	Peripheral blood	A, B, C, D
2.	Determination of stem cells	Flow cytometry	116_SOP_21_02/VA1; BD FACS Canto II; Cytognos Omnicyt I, II	Peripheral blood, umbilical blood, blood marrow, apheresis products	A, B, C, D

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom[1]
3.	Determination of PNH clones	Flow cytometry	116_SOP_21_03/VA1; BD FACS Canto II; Cytognos Omnicyt I, II	Peripheral blood	A, B, C, D
4.	Immunophenotyping of leukocytes	Flow cytometry	116_SOP_21_04/VA1; BD FACS Canto II; Cytognos Omnicyt I, II	Peripheral blood, bone marrow, lymph node, cerebrospinal fluid, malignant exudate	A, B, C, D
5.	Examination of VASP phosphorylation in blood platelets	Flow cytometry	116_SOP_21_05/VA1; BD FACS Canto II; Cytognos Omnicyt I, II	Peripheral blood	A, B, C, D
6.	Determination of residual disease in CLL	Flow cytometry	116_SOP_21_07/VA1; BD FACS Canto II; Cytognos Omnicyt I, II	Peripheral blood, bone marrow, cerebrospinal fluid, malignant exudate	A, B, C, D
7.	Determination of residual disease in B-ALL	Flow cytometry	116_SOP_21_08/VA2; BD FACS Canto II; Cytognos Omnicyt I, II Northern Lights	Peripheral blood, bone marrow, cerebrospinal fluid, malignant exudate	A, B, C, D
8.	Determination of residual disease in MM	Flow cytometry	116_SOP_23_09/VA1; BD FACS Canto II; Cytognos Omnicyt I, II	Peripheral blood, bone marrow, cerebrospinal fluid, malignant exudate	A, B, C, D
9.	Determination of residual disease in AML	Flow cytometry	116_SOP_23_10_VA2; BD FACS Canto II; Cytognos Omnicyt I, II Cytek Northern Lights	Peripheral blood, bone marrow, cerebrospinal fluid, malignant exudate	A, B, C, D
10.	Examination of antiHLA antibodies	xMAP technology	203_SOP_14 _07/VA2; 203_SOP_19 _03/VA2; Luminex / FLEXMAP 3D	Blood	A, B
11.	Examination of HLA system	CDC	233_SOP_08_01/VA4; Annex 01/VA3	Blood	A, B
12.	Examination of antiHLA antibodies	CDC	203_SOP_13 _02/VA4	Blood	A, B
814 - Toxicological Laboratory					
1.	Determination of antifungal drugs	LC-MS/MS	301_SOP_21_04/VA1	Blood	A, B, C
2.	Determination of immunosuppressants	LC-MS/MS	301_SOP_23_01/VA1	Blood	A, B, C
816 – Medical Genetics Laboratory					
1.-2.	Reserved				

List of activities within the flexible scope of accreditation

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom[1]
3.	Examination of somatic genome variants	Multiplex RT-PCR	NRL_03_SOP_14_01/VA4; Annex 1/VA6 Annex 5/VA4; Annex 6/VA4; Qiaxcell Analyzer	Peripheral blood, bone marrow, vital leukocytes lyophilized cells, cell lysate RNA, cDNA	A, B, C, D
4.	Examination of somatic genome variants	Real-Time PCR	NRL_04_SOP_14_01/VA7 postup A; Annex 1/VA6; Annex 2/VA3; Annex 11/VA4; Annex 12/VA3; Annex 13/VA3; RotorGene Q	Peripheral blood, bone marrow, vital leukocytes lyophilized cells, cell lysate RNA, cDNA	A, B, C, D
5.	Examination of somatic genome variants	Direct sequencing (Sanger)	NRL_04_SOP_14_01/VA7 postup B; Annex 1/VA6; Annex 2/VA3; Annex 9/VA5; ABI3500; ABI3500XL	Peripheral blood, bone marrow, vital leukocytes lyophilized cells, cell lysate RNA, cDNA	A, B, D
6.	Examination of somatic genome variants	Real-Time PCR	NRL_02_SOP_14_01/VA4; RotorGene Q	Peripheral blood, bone marrow	A, B, D
7.	Examination of germline genome variants	Direct sequencing (Sanger)	NRL_06_SOP_14_01/VA4; Annex 1/VA1; Annex 2/VA3; Annex 3/VA4; ABI3500; ABI3500XL	Peripheral blood, bone marrow, smear from buccal mucosa, umbilical cord blood	A, B, D
8.	Examination of somatic genome variants	PCR with fragment analysis	NRL_09_SOP_20_01/VA3; Annex 1/VA1; Annex 2/VA3; Annex 3/VA2; ABI3500; ABI3500XL	Bone marrow, peripheral blood	A, B, D
9.	Examination of somatic genome variants	Real-Time PCR	NRL_10_SOP_14_01/VA4; RotorGene Q	Bone marrow, peripheral blood	A, B, D
10.	Reserved				
11.	Examination of germline genome variants	PCR with reverse hybridization	NRL_12_SOP_16_01/VA1; Annex 1/VA1; Annex 2/VA1; Annex 3/VA1	Peripheral blood, bone marrow, smear from buccal mucosa, umbilical cord blood	A, B, D
12.	Examination of somatic genome variants	Real-Time PCR	114_SOP_08_01/VA3; RotorGene Q Rotor-Gene 3000A	Bone marrow, peripheral blood	A, B

List of activities within the flexible scope of accreditation

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom[1]
13.	Examination of germline genome variants	PCR-SSP	203_SOP_16 _01/VA1; Annex 1/VA6; Annex 2/VA6; Annex 3/VA6; Annex 4/VA6; FluoVista	Blood	A, B, C
14.	Examination of germline genome variants	PCR-SSP	203_SOP_16 _02/VA2; FluoVista	Blood	A, B, C, D
15.	Examination of germline genome variants	Real-Time PCR	105_SOP_15_01/VA2; Cobas z480	Blood	A, B
16.	Examination of somatic genome variants	NGS-MPS	NRL_13_SOP_18_01/VA5; Annex 4/VA5; Annex 6/VA1; Annex 7/VA1; MiSeq SURFSeq 5000	Peripheral blood, bone marrow, smear from buccal mucosa, umbilical cord blood, lyophilized leukocytes	A, B, C, D
17.	Examination of somatic genome variants	NGS-MPS	13100_SOP_19_01/VA6; MiSeq	Peripheral blood, bone marrow, vital leukocytes lyophilized cells, cell lysate RNA	A, B, C, D
18	Examination of somatic genome variants	Digital PCR	13100_SOP_21_01/VA2; QX200 Droplet Digital PCR System	Peripheral blood, bone marrow, vital leukocytes lyophilized cells, cell lysate RNA, cDNA	A, B, D
19.	Examination of somatic genome variants	Real-Time PCR	13100_SOP_21_02/VA1; RotorGene Q	Peripheral blood, bone marrow, vital leukocytes lyophilized cells, cell lysate RNA, cDNA	A, B, C, D
20.	Examination of germline genome variants	NGS-MPS	13500_SOP_26_14/VA1 Procedure A: Annex 3/VA1 Annex 6/VA1 Annex 7/VA1, Procedure B: Annex 2/VA1 Annex 5/VA1 Annex 7/VA1; MiSeq SURFSeq 5000	Peripheral blood, bone marrow, buccal mucosa, cDNA	A, B, C, D

List of activities within the flexible scope of accreditation

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom[1]
818 - Haematology Laboratory					
1.	Activated partial thromboplastin time	Coagulation method with mechanical detection of coagulum; Calculations	105_SOP_08_01/VA4; STA-R MAX3; STA-R Max	Plasma	A, B
2.	Prothrombin test	Coagulation method with mechanical detection of coagulum; Calculations	105_SOP_08_02/VA4; STA-R MAX3; STA-R Max	Plasma	A, B
3.	D-dimers	Immunoassay with turbidimetric detection	105_SOP_08_03/VA5; STA-R MAX3; STA-R Max	Plasma	A, B
4.	Fibrinogen	Coagulation method with mechanical detection of coagulum	105_SOP_08_04/VA5; STA-R MAX3; STA-R Max	Plasma	A, B
5.	Reserved				
6.	Evaluation of bone marrow aspirate smear	Microscopy	113_SOP_21_26/VA2	Bone marrow	A, B
7.	Determination of free haemoglobin	Spectrophotometry	301_SOP_08 _01/VA2; Shimadzu UV 2401	Plasma	A, B
8.	Blood count	Flow cytometry; Impedance method; Photometry; Calculations	206_SOP_22_01/VA2; Sysmex XN-10	Blood	A, B
9.	Peripheral blood smear analysis	Microscopy	113_SOP_14_05/VA1	Blood	A, B
10.	Peripheral blood smear analysis	Digital microscopy	113_SOP_14_05/VA2; Sysmex CellaVision DI60 DC-1	Blood	A, B
11.	Quantitative determination of G-6-PDH	Spectrophotometry	117_SOP_11_02/VA3; DIALAB DTN-510K	Blood	A, B
12.	Quantitative determination of haemoglobins	Capillary electrophoresis	117_SOP_12 _01/VA2; MINICAP Flex piercing	Blood	A, B, C
13.	Blood count with a five-part differential leukocyte count	Flow cytometry Impedance method; Photometry; Calculations	113_SOP_16_19/VA2; 113_SOP_16_21/VA2; Sysmex XR10, XR20	Blood	A, B

List of activities within the flexible scope of accreditation

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom[1]
14.	Reticulocytes	Flow cytometry; Impedance method; Calculations	113_SOP_16_20/VA2; Sysmex XR20	Blood	A, B
15.	Haemocoagulation factors in the intrinsic pathway	Coagulation method with mechanical detection of coagulum	105_SOP_23_01/VA3; Annex 2/VA1; Annex 3/VA1; Annex 4/VA2; Annex 5/VA2; STA-R MAX3	Plasma	A, B, C
16.	Antithrombin	Chromogenic method	105_SOP_23_02/VA3; Annex 2/VA1; Annex 3/VA1; STA-R Max; STA-R MAX3	Plasma	A, B

Specification of the scope of accreditation:

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
222/3	In the IgG class
222/4	NAT, Enzym
222/5	NAT, Enzym
222/6	Senzibilization of erytrocytes IgG and/or C3d
222/7	anti-heparin/PF4 in the class IgG
222/9	Compatibility of donor erythrocytes with recipient plasma in NAT
222/10	AB0, RhD
222/11	C, c, E, e, K, C^w
222/12	In the IgG class in blood donors
222/13	NAT, Enzym
802/1	RNA SARS-CoV2, RNA Influenza A, RNA Influenza B, RNA RSV
802/2	RNA multiplex Parainfluenza virus 1-4, rhinoviruses, human enteroviruses, human adenoviruses, human metapneumoviruses and human bocaviruses, *Aspergillus* sp., *Mucorales.* Pathogens of atypical pneumonia *Chlamydophila pneumoniae, Mycoplasma pneumoniae, Legionella pneumophila*
802/3	RNA multiplex CMV, EBV, HSV1, HSV2, *Pneumocystis jirovecii*, BKV, VZV, HHV6
802/4	CMV in the class IgG, hepatitis C (Anti HCV), Syphilis (anti-*Treponema pallidum*), hepatitis B (anti HBs, anti HBc)
802/5	Ab anti HIV 1,2 (Ig total) and Ag HIV p24

List of activities within the flexible scope of accreditation

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
802/6	Hepatitis B (HBsAg), hepatitis C (HCV cAg)
813/1	CD3, CD4, CD8, CD19, CD16, CD45, CD56 plus selected additional markers of the expanded lymphocyte immunophenotype
813/2	CD34, CD45
813/3	FLAER, CD15, CD45, CD59, CD64, CD71, CD157, CD235a, plus selected additional markers of the expanded erythrocyte, monocyte immunophenotype
813/4	B-lymfoid lineage: CD5, CD9, CD10, CD11b, CD11c, CD19, CD20, CD22, CD23, CD24, CD25, CD37, CD31, CD34, CD38, CD39, CD43, CD44, CD45, CD49d, CD58, CD66c, CD73, CD79b, CD81, CD103, CD123, CD185, CD200, CD304, CD305, CD371, HLA-DR, TdT, TSLP, NG2, ROR1, kappa, lambda, IgM, IgD, IgG T-lymfoid lineage: CD1a, CD2, CD3, CD4, CD5, CD7, CD8, CD16, CD26, CD27, CD30, CD45, CD56, CD57, CD99, Granzyme, Perforin, TCR-αβ, TCR-γδ, isoforms of T-beta chain, TdT, TCLP, TCR Cβ1 NK lineage: CD2, CD3, CD4, CD5, CD7, CD8, CD16, CD56, CD57, CD94, CD158a, CD158b, CD158e, CD159a Plasma lineage: CD19, CD20, CD27, CD28, CD38, CD45, CD56, CD81, CD138, CD117, cyt.kappa, cyt.lambda Eozinofils**:** CD11b, CD11c, CD13, CD33, CD45 Bazofils : CD9, CD13, CD22, CD25, CD33, CD36, CD38, CD45, CD123, CD203 Mastocyes: CD2, CD25, CD30, CD45, CD117 Dendritic cells: CD4, CD7, CD33, CD36, CD38, CD43, CD56, CD45RA, CD123, CD303 Monocyte lineage: CD4, CD11b, CD13, CD14, CD15, CD33, CD34, CD36, CD45, CD64, CD305, HLA-DR, Lysozym Myeloid lineage: CD11b, CD13, CD14, CD15, CD16, CD33, CD34, CD38, CD45, CD56, CD64, CD65, CD117, CD133, CD123, HLA-DR, MPO, NG2 Erythroid lineage: CD34, CD36, CD71, CD105, CD117, CD235a Megakaryocyte lineage: CD36, CD41, CD42, CD61 Acute myeloid leukemia (AML) stem cells: CD11b, CD22, CD33, CD34, CD38, CD44, CD45RA, CD56, CD366, CD371 Chronic myeloid leukemia (CML) stem cells: CD25, CD26, CD34, CD38, CD45
813/5	16C2, CD61
813/6	CD3, CD5, CD19, CD20, CD43, CD79b, CD81, RORJ
813/7	CD9, CD10, CD13, CD19, CD20, CD22, CD33, CD34, CD38, CD45, CD58, CD66b, CD66c, CD73, CD81, CD86, CD123, CD304, HLA-DR
813/8	CD19, CD27, CD28, CD38, CD45, CD56, CD81, CD138, kappa, lambda
813/9	CD2, CD7, CD11b, CD13, CD14, CD15, CD19, CD33, CD34, CD38, CD45, CD56, CD64, CD117, CD123, CD 133, HAL-DR ,
813/10	Antibodies antiHLA-I. and II. classes
813/11	HLA-A, B, Bw, Cw
813/12	In the class IgG and IgM
814/1	Voriconazole, Posaconazole, Isavuconazole
814/2	Ciclosporin A, Tacrolimus, Sirolimus

List of activities within the flexible scope of accreditation

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
816/3	Detected rearrangements**:** b2a2 (e13a2), b3a2 (b14a2, b), e1a2, e19a2 + rare rearrangements
816/4	Detected rearrangements: b2a2 (e13a2), b3a2 (b14a2, b), e1a2, e19a2 + rare rearrangements
816/5	Examination of mutations in kinase domain of BCR::ABL1
816/6	Examination of the number of transcripts in *WT1* gene
816/7	Examination of mutations in *HBB* gene
816/8	Examination of mutations in *NPM1* gene
816/9	Examination of the number of transcripts of mutated NPM1 gene
816/11	Examination of mutations in HBA1 and HBA2 genes
816/12	Examination of V617F mutation in *JAK2* gene
816/13	Tested genes coding: D, C,c,E,e,Cw erythrocyte antigens and Kell, Kidd, Duffy, MNS and Dombrock system antigens Dweak erythrocyte antigens, D variant erythrocyte antigens, molecular basis of AB0 system antigens
816/14	Tested genes coding thrombocyte antigens HPA-1, -2, -3, -4, -5, -6, -9, -15
816/15	Investigated pathogenic polymorphisms: FV Leiden (c.1601G>A), FIIG20210A (c.*97G>A)
816/16	List of genes and their exons SureSelect Custom Panel (Agilent) Procedure B *ABL1* exon 4-6, *ANKRD26, ASXL1* exon 11, 12, *ATRX* exon 8-10, 17-31*, BCOR, BCORL1, BRAF* exon 15, *CALR* exon 9, *CBL, CBLB* exon 9, 10, *CDKN2A, CEBPA, CSF3R* exon 14-17, *CUX1, DDX41, DNMT3A, ETNK1* exon 3, *ETV6/TEL, EZH2, FLT3* exon 12, 14, 15, 16, 20, 22, *GATA1* exon 2-*4, GATA2* exon 2-6*, GNAS* exon 8, 9*, GNB1* exon 5-7, *IDH1* exon 4, *IDH2* exon 4, *IKZF1, JAK2* exon 12, 14, 23, 24, *JAK3* exon 13-15, *KDM6A* exon 4, 7, 23-27, *KIT* exon 2, 8-11, 13, 17, KRAS exon 2-4*, MLL* exon 1-12, 27, 34, *MPL* exon 3, 5, 7-12, *NF1* exon 3-5, 9, 10, 12, 13, 17, 18, 40-42, 44-46, 49 -51, 55-57, *NOTCH1* exon 26-28, 34, *NPM1* exon 11, *NRAS* exon 2-4, *PDGFRA* exon 12, 14, 18, *PHF6, PIGA, PPM1D* exon 6, *PRPF8* exon 30, 31, 36, *PTEN* exon 5, 7, *PTPN11* exon 2-4, 8, 12-14, *RAD21, RUNX1, SETBP1 exon 4, SF3B1* exon 13-18, *SMC1A* exon 2, 11, 16, 17, *SMC3* exon 10, 13, 19, 23, 25, 28*, SRSF2* exon 1, 2, *STAG2, TET2* exon 3-11, *TP53* exon 2-11, *U2AF1* exon 2, 6-8, *UBA1, WT1, ZRSR2.*
816/17	Investigated types of BCR-ABL1 gene transcripts: *major (e13a2,e14a2)* and *minor (e1a2) transcript.*
816/18	Quantitative examination of fuse gene *major BCR::ABL1* transcript level
816/19	Examination in the scope of HemaVision®-28Q kit
816/20	Genes and non-coding regions analyzed within the target regions of the SSELXT HS Human All Exon V8+NCV probes – Procedure A SureSelect Custom Panel KOAIPD Gene List-Procedure B *A2M, ABO, ABCC4, ABCG5, ABCG8, ACE, ACTB, ACTN1, ACBD5, ADAMTS13, ADRA2A, ADRA2B, ANKRD26, ANO6, ANXA2, AP3B1, AP3D1, ARPC1B, ARSA, ASGR1, AVPR2, BLOC1S3, BLOC1S5, BLOC1S6, C2CD4B, C3, C4BPB, CD36, CDC42, CFI, CFH, CFHR1, CFHR3, CLEC1B, CLEC4M, CPB2, CYCS, DAB2IP, DIAPH1, DTNBP1, ENG, EPHB2, ETV6, F2, F3, F5, F7, F8, F9, F10, F11, F12, F13, F2R, F2RL3, FCHO2, FERMT3, FGA, FGB, FGG, FLI1, FLNA, FUT1, FYB1, GALE, GATA1, GATA2, GBA1, GFI1B, GGCX, GIMAP7, GNE, GP1BA, GP1BB, GP5, GP6, GP9, HLA-DQA1, ITGB1, ITGB3, HOXA11, HPS1, HPS3, HPS4, HPS5, HPS6, HRG, IKZF5, ITGA2, ITGA2B, LMAN1, MCFD2, MYH9, KDSR, MPL, KLKB1, KMT2D, KNG1, LRP1, LYST, MAST2, MASTL, MCP, MECOM, MLPH, MPIG6B, MYO5A, NBEA, NBEAL2, NFE2, NOS3, OR13C5, ORAI1, P2RY12, PDHB, PIGA, PLA2G4A, PLAT, PLAU, PLAUR, PLG, PRKACG, PROC, PROCR, PROS1, PTGS1, PTPRJ, TBXA2R, RAB27A, RAB5C, RAP1B, RASGRP2, RBM8A, RGS2, RNU4ATAC, RUNX1, SCARA5, SERPINA1, SERPINA10, SERPINB2, SERPINC1, SERPIND1, SERPINE1, SERPINF2, SERPING1, SLC44A2, SLFN14, SRC, STIM1, ST3GAL4, STAB2, STX2, STXBP1, STXBP2, STXBP5, TC2N, TBXAS1, THBD, THPO, TPM4, TRPM7, TSPAN15, TSPAN17, TUBA8, TUBB1, UFM1, VIPAS39, VKORC1, VPS33B, VTN, vWF, WAS, WIPF1.*

List of activities within the flexible scope of accreditation

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
818/1	APTT-time, APTT-ratio
818/2	PT-time, PT-INR, PT-ratio
818/8	Examined parameters: WBC, RBC, Hgb, Hct, MCV, RDW, Plt, PDW, MPV
818/12	A2, F and S
818/13	Examined parameters: WBC, RBC, Hgb, Hct, MCV, RDW, Plt, PDW, MPV, NEUT, LY, MO, EO, BASO, #NEUT, #LY, #MO, #EO, #BASO
818/15	FVIII, FIX, FXI, FXII
818/16	AT(IIa); AT(Xa)

Primary sample collection:

Ordinal Number[2]	Sample collection technique	Identification of sample collection procedure	Collected material	Degrees od freedom[1]
1.	Venepuncture	206_SOP_22 _02/VA1	Venous blood	A, B

List of activities within the flexible scope of accreditation

2. **Workplace No. 2** U Nemocnice 499/2, 128 00 Praha 2

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom[1]
816 – Medical Genetics Laboratory					
1.	Examination of constitutional karyotype	Conventional cytogenetic analysis	305_SOP_20_01/VA4	Bone marrow, peripheral blood	A, B
2.	Examination of chromosomal aberrations	FISH	305_SOP_20_02/VA3	Bone marrow, peripheral blood	A, B
3.	Examination of chromosomal aberrations	mFISH; mBAND; Fluorescence microscopy	305_SOP_20_03/VA3	Bone marrow, peripheral blood	A, B

List of activities within the flexible scope of accreditation

3. **Workplace No. 3** Kateřinská 521/19, 128 00 Praha 2

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom[1]
816 – Medical Genetics Laboratory					
1.	Examination of HLA genotype	PCR-SSP	NRL_05_SOP_14_01/VA15; Annex 2/VA7; Annex 9/VA6; Annex 22/VA2	Peripheral blood, umbilical blood, bone marrow, buccal smear	A, B, C, D
2.	Examination of HLA genotype	Real-Time PCR	NRL_05_SOP_14_01/VA15; Annex 20/VA5	Peripheral blood, umbilical blood, bone marrow, buccal smear	A, B, C, D
3.	Examination of HLA genotype	NGS-MPS	NRL_05_SOP_14_01/ VA15; Annex 23/VA5; Ilumina MiSeq MisqTM i100 Serie	Peripheral blood, umbilical blood, bone marrow, buccal smear	A, B, C, D
4.	Examination of HLA genotype	Spectrophotometry	NRL_05_SOP_14_01/ VA15; Annex 1/VA10	Peripheral blood, umbilical blood, bone marrow, buccal smear	A, B, C, D
5.	Examination of germline genome variants	PCR-fragment analysis	NRL_01_SOP_14_01/VA6; Annex 19/VA5; Annex 20/VA5; Annex 23/VA5; Annex 27/VA6; ABI3500	Peripheral blood, bone marrow, buccal smear	A, B, C, D
6.	Examination of somatic genome variants	PCR-fragment analysis	NRL_01_SOP_14_01/VA6; Annex 20/VA5; Annex 23/VA5; Annex 27/VA6; ABI3500	Peripheral blood, bone marrow	A, B, C, D
7.	Examination of germline genome variants	Real-Time PCR	NRL_07_SOP_14_01/VA8; Annex 8/VA6; Annex 11/VA2; Rotor-Gene Q; Rotor-Gene 6000	Peripheral blood, bone marrow, buccal smear	A, B, C, D
8.	Examination of somatic genome variants	Real-Time PCR	NRL_07_SOP_14_01/VA8; Annex 8/VA6; Annex 10/VA5; Annex 11/VA2; Rotor-Gene Q; Rotor-Gene 6000;	Peripheral blood, bone marrow	A, B, C, D

List of activities within the flexible scope of accreditation

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom[1]
9.	Examination of HLA genotype	NGS-MPS (2nd generation)	NRL_05_SOP_14_01/ VA15; Annex 24/VA2; Oxford Nanopore Technology MinION	Peripheral blood, bone marrow	A, B, C, D

Specification of the scope of accreditation:

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
816/1	Tested genes: Class I HLA: loci A, B, C Class II HLA: loci DRB1, DQA1, DQB1, DPB1, DRB3/4/5 KIR genes: presence of 2DL1, 2DL2, 2DL3, 2DL4, 2DL5, 2DS1, 2DS2, 2DS3, 2DS 4, 2DS5, 3DL1, 3DL2, 3DL3, 3DS1, 2DP1, 2DP2
816/2	Tested genes: Class I HLA: loci A, B, C Class II HLA: loci DRB1, DQA1, DQB1, DPB1, presence of DRB3-5
816/3	Tested genes: Class I HLA: loci A, B, C Class II HLA: loci DRB1, DRB3-5, DQA1 , DQB1, DPB1 ,MICA, MICB
816/4	Quality and concentration of isolated DNA
816/5	Examination of cellular chimerism after allogeneic HSCT. Examined polymorphisms: STR: *AMG, LPL, FESFPS, F13B, F13A01, D16S539, D7S820, D13S317, D5S818, D3S1358, D21S11, D18S51, Penta E, D8S1179, FGA, Penta D, Penta C, CSF1PO, TPOX, TH01, vWA, D22S1045, D2S1338, D19S433, D2S441, D10S1248, D1S1656, D12S391 a SE33;* DIP: *AM X, AM Y, HLD106, HLD70, HLD84, HLD103, HLD104, HLD116, HLD112, HLD307, HLD310, HLD110, HLD133, HLD79, HLD105, HLD140, HLD163, HLD91, HLD23, HLD88, HLD101, HLD67, HLD301, HLD53, HLD97, HLD152, HLD128, HLD134, HLD305, HLD48, HLD114, HLD304, HLD131, HLD38, HLD82.*
816/6	Examination of cellular chimerism after allogeneic HSCT. Examined polymorphisms: STR: *AMG, LPL, FESFPS, F13B, F13A01, D16S539, D7S820, D13S317, D5S818, D3S1358, D21S11, D18S51, Penta E, D8S1179, FGA, Penta D, Penta C, CSF1PO, TPOX, TH01, vWA, D22S1045, D2S1338, D19S433, D2S441, D10S1248, D1S1656, D12S391 a SE33;* DIP: *AM X, AM Y, HLD106, HLD70, HLD84, HLD103, HLD104, HLD116, HLD112, HLD307, HLD310, HLD110, HLD133, HLD79, HLD105, HLD140, HLD163, HLD91, HLD23, HLD88, HLD101, HLD67, HLD301, HLD53, HLD97, HLD152, HLD128, HLD134, HLD305, HLD48, HLD114, HLD304, HLD131, HLD38, HLD82.*
816/7	Examination of cellular chimerism after allogeneic HSCT. Tested specific sequence polymorphisms: *S08 (PAPPA2/ASTN1), S11 (DLG2) – – each system has A and B variant, GAPDH, KMR501-A, KMR502-A, KMR504-A, KMR505-A, KMR506-A, KMR511-C, KMR512-C, KMR520-DPB1, KMR521-DPB1, KMR522-DPB1, REF 901.*
816/8	Examination of cellular chimerism after allogeneic HSCT. Tested specific sequence polymorphisms: *S01 (ITGA2B), S04 (DBH), S07 (UXT/ZNF81), S08 (PAPPA2/ASTN1), S10 (LTBP1), S11 (DLG2)* – each system has *A* and *B* variant*, S05B (EIF2S2), GAPDH, SMCY (AF273841),* HLD polymorphisms (see NRL_01_SOP_14_01) in variant *D* (deletion) and *I* (insertion) for quantification, β-Globin, *KMR501-A, KMR502-A, KMR504-A, KMR505-A, KMR506-A, KMR511-C, KMR512-C, KMR520-DPB1, KMR521-DPB1, KMR522-DPB1, REF 901.*
816/9	Tested genes: Class I HLA: loci A, B, C Class II HLA: loci DRB1, DRB3-5, DQA1 , DQB1, DPB1

List of activities within the flexible scope of accreditation

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.

FISH	Fluorescence *in situ* Hybridization
mBAND	High resolution multicolor banding
NGS-MPS	New Generation Sequencing - Massively Parallel Sequencing
PCR	Polymerase Chain Reaction
Real-Time PCR	Polymerase Chain Reaction in real time
PCR-SSP	Polymerase Chain Reaction with Sequence Specific Primers
CDC	Microlymphocytotoxic test
HIT	Heparin-Induced Thrombocytopenia
PNH	Paroxysmal nocturnal hemoglobinuria
Multiplex RT-PCR	Reverse transcription-multiplex Polymerase Chain Reaction
CLL	Chronic lymphocytic leukemia
B-ALL	B-cell acute lymphoblastic leukemia
MM	Multiple myeloma
AML	Acute myeloid leukemia
LC-MS/MS	Liquid chromatography with mass spectrometry
G-6-PDH	Glucose-6-phosphate dehydrogenase