



List of activities within the flexible scope of accreditation

Accredited Body: Ústav hematologie a krevní transfuze
CAB Name: Komplement laboratoří ÚHKKT Genetics
CAB Number: 8081
Certificate of Accreditation No.: 178/20243
Field of Accreditation: Medical laboratory - ČSN EN ISO 15189 ed. 2:2013
Updated: 18. 4. 2024

1. Workplace No. 1

U Nemocnice 2094/1, 128 00 Praha 2

Examinations:

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of 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	Blood	A, B
4.	Screening of irregular anti-erythrocyte antibodies	Gel column agglutination	203_SOP_10_04/VA3	Serum	A, B
5.	Identification of irregular anti-erythrocyte antibodies	Gel column agglutination	203_SOP_10_05/VA2	Serum, plasma	A, B
6.	Direct antiglobulin test	Gel column agglutination	203_SOP_12_07/VA2	Serum, plasma	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			Blood	
9.	Examination of compatibility	Gel column agglutination	203_SOP_12_09/VA1	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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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	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, BAL, tracheal aspirate, sputum	A, B, C, D
2.	Detection of nucleic acid of infectious agents	Real-Time PCR	318_SOP_22_02/VA2; Annex 2 A/VA2; 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; MagCore®plus II; BIO-RAD CFX 96	Nasopharyngeal swab, BAL, tracheal aspirate, sputum, cerebrospinal fluid, lesion swabs, blood, nails, exploratory biopsy	A, B, C, D
3.	Detection of nucleic acid of infectious agents	Real-Time PCR	318_SOP_22_03/VA2; Annex 2 A/VA2; 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/VA2; Annex 4 B/VA2; Annex 4 C/VA2; Annex 4 D/VA2; Annex 4E/VA1; Annex 4F/VA1; Annex 4G/VA1; MagCore®plus II; BIO-RAD CFX 96	Blood, plasma, cerebrospinal fluid, urine, BAL, tracheal aspirate, sputum, ascites, pleural exudate	A, B, C, D

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Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
4.	Antibodies to infectious agents	Immunoassay with luminometric detection (automatic)	LPVN_SOP_19_01/VA2; Architect i2000SR	Serum, plasma	A, B, C
5.	HIV markers	Immunoassay with luminometric detection (automatic)	LPVN_SOP_19_01/VA2; Architect i2000SR	Serum, plasma	A, B, C
6.	Antigens of infectious agents	Immunoassay with luminometric detection (automatic)	LPVN_SOP_19_01/VA2; Architect i2000SR	Serum, plasma	A, B, C
7.	Hepatitis B markers	Immunoassay with luminometric detection (automatic)	LPVN_SOP_19_01/VA2; Architect i2000SR	Serum, plasma	A, B, C
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
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, lymph node, cerebrospinal fluid, malignant exudate	A, B, C, D
7.	Determination of residual disease in B-ALL	Flow cytometry	116_SOP_21_08/VA1; BD FACS Canto II; Cytognos Omnicyt I, II	Peripheral blood, bone marrow, lymph node, cerebrospinal fluid, malignant exudate	A, B, C, D

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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, lymph node, cerebrospinal fluid, malignant exudate	A, B, C, D
9.	Determination of residual disease in AML	Flow cytometry	116_SOP_23_10_VA1; BD FACS Canto II; Cytognos Omnicyt I, II	Peripheral blood, bone marrow, lymph node, cerebrospinal fluid, malignant exudate	A, B, C, D
10.	Examination of antiHLA antibodies	xMAP technology	203_SOP_14_07/VA1; 203_SOP_19_03/VA1; Luminex	Blood	A, B
11.	Examination of HLA system	CDC	233_SOP_08_01/VA4; Annex 01/VA3	Blood	A, B
12.	Examination of HLA antibodies	CDC	203_SOP_13_02/VA4	Blood	A, B
816 – Medical Genetics Laboratory					
1.-2.	Reserved				
3.	Examination of somatic genome variants	Multiplex RT-PCR	NRL_03_SOP_14_01/VA3; Annex 1/VA4; Annex 5/VA5; 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/VA6 procedure A; Annex 1/VA4; Annex 2/VA3; Annex 11/VA3; 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/VA6 postup B; Annex 1/VA4; Annex 2/VA3; Annex 9/VA4; 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

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Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
7.	Examination of germline genome variants	Direct sequencing (Sanger)	NRL_06_SOP_14_01/VA3; Annex 1/VA1; Annex 2/VA3; Annex 3/VA3; ABI3500; ABI3500XL	Peripheral blood, bone marrow, smear from buccal mucosa, umbilical cord blood	A, B, D
8.	Examination of somatic genome variants	PCR-fragment analysis	NRL_09_SOP_20_01/VA2; Annex 1/VA1; Annex 2/VA2; Annex 3/VA1; 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 Reverse hybridization	NRL_12_SOP_16_01/VA1; Annex 1/VA1; Annex 2/VA1; Annex 3/VA1; Termocycler; Thermo-Shaker Biosan	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/VA2; Rotor-Gene 3000A	Bone marrow, peripheral blood	A, B
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/VA2; Annex 2/VA1; Annex 3/VA1; Annex 4/VA3; Annex 6/VA1; MiSeq	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/VA5; MiSeq	Peripheral blood, bone marrow, vital leukocytes lyophilized cells, cell lysate RNA, cDNA	A, B, C, D

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Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
18	Examination of somatic genome variants	Digital PCR	13100_SOP_21_01/VA1; 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
818 - Haematology Laboratory					
1.	Activated partial thromboplastin time	Coagulation method with mechanical detection of coagulum; Calculation	105_SOP_08_01/VA3; STA-R MAX3; STA-R Max	Plasma	A, B
2.	Prothrombin test	Coagulation method with mechanical detection of coagulum; Calculation	105_SOP_08_02/VA3; STA-R MAX3; STA-R Max	Plasma	A, B
3.	D-dimers	Immunoassay with turbidimetric detection	105_SOP_08_03/VA4; STA-R MAX3; STA-R Max	Plasma	A, B
4.	Fibrinogen	Coagulation method with mechanical detection of coagulum	105_SOP_08_04/VA4; STA-R MAX3; STA-R Max	Plasma	A, B
5.	D-dimers	Immunoassay with fluorimetric detection	105_SOP_08_06/VA3; VIDAS 3	Plasma	A, B
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	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/VA1	Blood	A, B

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Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
11.	Quantitative determination of G-6-PDH	Spectrophotometry	117_SOP_11_02/VA2	Blood	A, B
12.	Quantitative determination of haemoglobin	Capillary electrophoresis	117_SOP_12_01/VA2; MINICAP Flex piercing	Blood	A, B, C
13.	Blood count with a with a five-part differential Leukocyte count	Flow cytometry Impedance method; Photometry; Calculations	113_SOP_16_19/VA1; 113_SOP_16_21/VA1; Sysmex XN10, XN20	Blood	A, B
14.	Reticulocytes	Flow cytometry; Impedance method; Calculations	113_SOP_16_20/VA1; Sysmex XN20	Blood	A, B
15.	Haemocoagulation factors in the intrinsic pathway	Coagulation method with mechanical detection of coagulum	105_SOP_23_01/VA1; Annex 2/VA1; Annex 3/VA1; Annex 4/VA1; Annex 5/VA1; STA-R Max	Plasma	A, B, C
16.	Antithrombin	Chromogenic method	105_SOP_23_02/VA1; Annex 2/VA1; Annex 3/VA1; STA-R Max; STA-R MAX3	Plasma	A, B

Specification of the scope of accreditation:

Field Nr./ Ord. 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 erythrocytes 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

List of activities within the flexible scope of accreditation

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
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 (<i>anti-Treponema Pallidum</i>), hepatitis B (<i>anti HBs, anti HBc</i>)
802/5	Ab anti HIV 1,2 (Ig total) a Ag HIV p24
802/6	<i>Hepatitis B (HBsAg), hepatitis C (HCV cAg)</i>
802/7	<i>Hepatitis B (HbeAg, anti HbeAg)</i>
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	<p>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</p> <p>T-lymfoid lineage: CD1a, CD2, CD3, CD4, CD5, CD7, CD8, CD16, CD26, CD27, CD30, CD45, CD56, CD57, CD99, Granzyme, Perforin, TCR-$\alpha\beta$, TCR-$\gamma\delta$, izoformy T-beta chains, TdT, TCLP, TCR Cβ1</p> <p>NK lineage: CD2, CD3, CD4, CD5, CD7, CD8, CD16, CD56, CD57, CD94, CD158a, CD158b, CD158e, CD159a</p> <p>Plasma lineage: CD19, CD20, CD27, CD28, CD38, CD45, CD56, CD81, CD138, CD117, cyt.kappa, cyt.lambda</p> <p>Eozinofils: CD11b, CD11c, CD13, CD33, CD45</p> <p>Bazofils : CD9, CD13, CD22, CD25, CD33, CD36, CD38, CD45, CD123, CD203</p> <p>Mastocytes: CD2, CD25, CD30, CD45, CD117</p> <p>Dendritic cells: CD4, CD7, CD33, CD36, CD38, CD43, CD56, CD45RA, CD123, CD303</p> <p>Monocyte lineage: CD4, CD11b, CD13, CD14, CD15, CD33, CD34, CD36, CD45, CD64, CD305, HLA-DR, Lysozym</p> <p>Myeloid lineage: CD11b, CD13, CD14, CD15, CD16, CD33, CD34, CD38, CD45, CD56, CD64, CD65, CD117, CD133, CD123, HLA-DR, MPO, NG2</p> <p>Erythroid lineage: CD34, CD36, CD71, CD105, CD117, CD235a</p> <p>Megakaryocyte lineage: CD36, CD41, CD42, CD61</p> <p>Acute myeloid leukemia (AML) stem cells: CD11b, CD22, CD33, CD34, CD38, CD44, CD45RA, CD56, CD366, CD371</p> <p>Chronic myeloid leukemia (CML) stem cells: CD25, CD26, CD34, CD38, CD45</p>
813/5	16C2, CD61
813/6	CD3, CD5, CD19, CD20, CD43, CD79b, CD81, RORJ
813/7	CD10, CD19, CD20, CD22, CD34, CD38, CD45, CD58, CD66c, CD73, CD81, CD123, CD304, HLA-DR
813/8	CD19, CD27, CD28, CD38, CD45, CD56, CD81, CD138, kappa, lambda

List of activities within the flexible scope of accreditation

813/9	CD2, CD7, CD11b, CD13, CD14, CD15, CD19, CD33, CD34, CD38, CD45, CD56, CD64, CD117, CD123, HAL-DR
813/10	Antibodies antiHLA-I. and II. classes
813/11	HLA-A, B, Bw, Cw
813/12	In the class IgG a IgM
816/3	Detected rearrangements: <i>b2a2 (e13a2), b3a2 (b14a2, b), e1a2, e19a2 + rare rearrangements</i>
816/4	Detected rearrangements: <i>b2a2 (e13a2), b3a2 (b14a2, b), e1a2, e19a2 + rare rearrangements</i>
816/5	Examination of mutations in kinase domain of BCR::ABL1
816/6	Examination of the number of transcripts in <i>WT1</i> gene
816/7	Examination of mutations in <i>HBB</i> gene
816/8	Examination of mutations in <i>NPM1</i> gene
816/9	Examination of the number of transcripts of mutated <i>NPM1</i> gene
816/11	Examination of mutations in <i>HBA1</i> and <i>HBA2</i> genes
816/12	Examination of V617F mutation in <i>JAK2</i> gene
816/13	Tested genes coding: <i>D, C,c,E,e,Cw erythrocyte antigens and Kell, Kidd, Duffy, MNS and Dombrock system antigens</i> <i>Dweak erythrocyte antigens, D variant erythrocyte antigens, molecular basis of ABO system antigens</i>
816/14	Tested genes coding thrombocyte antigens <i>HPA-1,-2,-3,-4-, -5,-6,-9,-1</i>
816/15	Investigated pathogenic polymorphisms: FV Leiden (c.1601G>A), FIIG20210A (c.*97G>A)
816/16	List of genes and their exons – TruSight Myeloid Sequencing Panel (Illumina) Procedure A. <i>ABL1</i> exon 4-6, <i>ASXL1</i> exon 12, <i>ATRX</i> exon 8-10, 17-31, <i>BCOR</i> , <i>BCORL1</i> , <i>BRAF</i> exon 15, <i>CALR</i> exon 9, <i>CBL</i> exon 8, 9, <i>CBLB</i> exon 9, 10, <i>CBLC</i> exon 9, 10, <i>CDKN2A</i> , <i>CSF3R</i> exon 14-17, <i>CUX1</i> , <i>DNMT3A</i> , <i>ETV6/TEL</i> , <i>EZH2</i> , <i>FBXW7</i> exon 9-11, <i>FLT3</i> exon 14, 15, 20, <i>GATA1</i> exon 2, <i>GATA2</i> exon 2-6, <i>GNAS</i> exon 8-9, <i>HRAS</i> exon 2, 3, <i>IDH1</i> exon 4, <i>IDH2</i> exon 4, <i>IKZF1</i> , <i>JAK2</i> exon 12, 14, <i>JAK3</i> exon 13, <i>KDM6A</i> , <i>KIT</i> exon 2, 8-11, 13, 17, <i>KRAS</i> exon 2, 3, <i>MLL</i> exon 5-8, <i>MPL</i> exon 10, <i>MYD88</i> exon 3-5, <i>NOTCH1</i> exon 26-28, 34, <i>NPM1</i> exon 12, <i>NRAS</i> exon 2, 3, <i>PDGFRA</i> exon 12, 14, 18, <i>PHF6</i> , <i>PTEN</i> exon 5, 7, <i>PTPN11</i> exon 3, 13, <i>RAD21</i> , <i>RUNX1</i> , <i>SETBP1</i> part of exon 4, <i>SF3B1</i> exon 13-16, <i>SMC1A</i> exon 2, 11, 16, 17, <i>SMC3</i> exon 10, 13, 19, 23, 25, 28, <i>SRSF2</i> exon 1, <i>STAG2</i> , <i>TET2</i> exon 3-11, <i>TP53</i> exon 2-11, <i>U2AF1</i> exon 2, 6, <i>WT1</i> exon 7, 9, <i>ZRSR2</i> . List of genes and their exons SureSelect Custom Panel (Agilent) Procedure B <i>ABL1</i> exon 4-6, <i>ANKRD26</i> , <i>ASXL1</i> exon 11, 12, <i>ATRX</i> exon 8-10, 17-31, <i>BCOR</i> , <i>BCORL1</i> , <i>BRAF</i> exon 15, <i>CALR</i> exon 9, <i>CBL</i> , <i>CBLB</i> exon 9, 10, <i>CDKN2A</i> , <i>CEBPA</i> , <i>CSF3R</i> exon 14-17, <i>CUX1</i> , <i>DDX41</i> , <i>DNMT3A</i> , <i>ETNK1</i> exon 3, <i>ETV6/TEL</i> , <i>EZH2</i> , <i>FLT3</i> exon 12, 14, 15, 16, 20, 22, <i>GATA1</i> exon 2-4, <i>GATA2</i> exon 2-6, <i>GNAS</i> exon 8, 9, <i>GNB1</i> exon 5-7, <i>IDH1</i> exon 4, <i>IDH2</i> exon 4, <i>IKZF1</i> , <i>JAK2</i> exon 12, 14, 23, 24, <i>JAK3</i> exon 13-15, <i>KDM6A</i> exon 4, 7, 23-27, <i>KIT</i> exon 2, 8-11, 13, 17, <i>KRAS</i> exon 2-4, <i>MLL</i> exon 1-12, 27, 34, <i>MPL</i> exon 3, 5, 7-12, <i>NF1</i> exon 3-5, 9, 10, 12, 13, 17, 18, 40-42, 44-46, 49 -51, 55-57, <i>NOTCH1</i> exon 26-28, 34, <i>NPM1</i> exon 11, <i>NRAS</i> exon 2-4, <i>PDGFRA</i> exon 12, 14, 18, <i>PHF6</i> , <i>PIGA</i> , <i>PPM1D</i> exon 6, <i>PRPF8</i> exon 30, 31, 36, <i>PTEN</i> exon 5, 7, <i>PTPN11</i> exon 2-4, 8, 12-14, <i>RAD21</i> , <i>RUNX1</i> , <i>SETBP1</i> exon 4, <i>SF3B1</i> exon 13-18, <i>SMC1A</i> exon 2, 11, 16, 17, <i>SMC3</i> exon 10, 13, 19, 23, 25, 28, <i>SRSF2</i> exon 1, 2, <i>STAG2</i> , <i>TET2</i> exon 3-11, <i>TP53</i> exon 2-11, <i>U2AF1</i> exon 2, 6-8, <i>UBA1</i> , <i>WT1</i> , <i>ZRSR2</i> .
816/17	Investigated types of BCR-ABL1 gene transcripts: <i>major (e13a2,e14a2) and minor (e1a2) transcript</i> .
816/18	Examination of level of BCR::ABL1 transcript
816/19	Examination in the scope of HemaVision®-28Q kit



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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

Primary sample collection:

Ordinal Number	Sample collection technique	Identification of sample collection procedure	Collected material	Degrees of freedom ¹
1.	Venipuncture	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 procedure/equipment	Examined material	Degrees of freedom ¹
816 – Medical Genetics Laboratory					
1.	Examination of constitutional karyotype	Conventional cytogenetic analysis	305_SOP_20_01/VA3	Bone marrow, peripheral blood	A, B
2.	Examination of chromosomal aberrations	FISH	305_SOP_20_02/VA2	Bone marrow, peripheral blood	A, B
3.	Examination of chromosomal aberrations	mFISH; mBAND; fluorescence microscopy	305_SOP_20_03/VA2	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 procedure/equipment	Examined material	Degrees of freedom ¹
816 – Medical Genetics Laboratory					
1.	Examination of HLA genotype	PCR-SSP	NRL_05_SOP_14_01/VA12; 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/VA12; Annex 20/VA3	Peripheral blood, umbilical blood, bone marrow, buccal smear	A, B, C, D
3.	Examination of HLA genotype	NGS-MPS	NRL_05_SOP_14_01/VA12; Annex 23/VA3; Illumina MiSeq	Peripheral blood, umbilical blood, bone marrow, buccal smear	A, B, C, D
4.	Examination of HLA genotype	Spectrophotometry	NRL_05_SOP_14_01/VA12; Annex 1/VA7	Peripheral blood, umbilical blood, bone marrow, buccal smear	A, B, D
5.	Examination of germline genome variants	PCR-fragment analysis	NRL_01_SOP_14_01/VA5; 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/VA5; 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/VA7; 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/VA7; 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

Specification of the scope of accreditation:

Field Nr./ Ord. 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: <i>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</i> ; DIP: <i>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.</i>
816/6	Examination of cellular chimerism after allogeneic HSCT. Examined polymorphisms: STR: <i>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</i> ; DIP: <i>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.</i>
816/7	Examination of cellular chimerism after allogeneic HSCT. Tested specific sequence polymorphisms: <i>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.</i>
816/8	Examination of cellular chimerism after allogeneic HSCT. Tested specific sequence polymorphisms: <i>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.</i>

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.



List of activities within the flexible scope of accreditation

FISH	Fluorescence In Situ Hybridization
mBAND	Fluorescence In Situ Hybridization
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	Heparin-Induced Thrombocytopenia
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