



List of activities within the flexible scope of accreditation

Accredited Body: Ústav hematologie a krevní transfuze

CAB Name: Komplement laboratoří ÚHKT

CAB Number: 8081

Certificate of Accreditation No.: 573/2023

Field of Accreditation: Medical Laboratory - ČSN EN ISO 15189:2013

Updated: 31. 10. 2023

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.	HLA system examination	CDC	233_SOP_08_01/VA4; Annex 01/VA3	Blood	A, B
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	203_SOP_10_04/VA3	Serum, plasma	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	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.	Examination of antiHLA antibodies	CDC	203_SOP_13_02/VA4	Blood	A, B
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
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/VA1; Annex 2 A/VA1; Annex 2 B/VA1; 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	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/VA1; Annex 2 A/VA1; Annex 2 B/VA1; 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/VA1; Annex 4 B/VA1; Annex 4 C/VA1; Annex 4 D/VA1	Blood, plasma, cerebrospinal fluid, urine, BAL, tracheal aspirate, sputum, ascites, pleural exudate	A, B, C, D
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

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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	Peripheral blood	A, B, C, D
2.	Determination of stem cells	Flow cytometry	116_SOP_21_02/VA1	Peripheral blood, umbilical blood, blood marrow, apheresis products	A, B, C, D
3.	Determination of PNH clones	Flow cytometry	116_SOP_21_03/VA1	Peripheral blood	A, B, C, D
4.	Immunophenotyping of leukocytes	Flow cytometry	116_SOP_21_04/VA1	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	Peripheral blood	A, B, C, D
6.	Determination of residual disease in CLL	Flow cytometry	116_SOP_21_07/VA1	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/VA1	Peripheral blood, bone marrow, cerebrospinal fluid, malignant exudate	A, B, C, D
816 – Medical Genetics Laboratory					
1.	Examination of cellular chimerism after allogeneic HSCT	PCR-fragment analysis	NRL_01_SOP_14_01/VA5; Annex 19/VA5; Annex 20/VA5; Annex 23/VA5; Annex 27/VA6	Peripheral blood, bone marrow, smear from buccal mucosa	A, B, C, D
2.	Examination of cellular chimerism after allogeneic HSCT	Real-Time PCR	NRL_07_SOP_14_01/VA7; Annex 8/VA6; Annex 10/VA5; Annex 11/VA2	Peripheral blood, bone marrow, smear from buccal mucosa	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.	Examination of BCR::ABL1 fusion gene	Multiplex RT PCR	NRL_03_SOP_14_01/VA3; Annex 1/VA4; Annex 5/VA5; Annex 6/VA4	Peripheral blood, bone marrow, vital leukocytes lyophilized cells, cell lysate RNA, cDNA	A, B, C, D
4.	Examination of level of BCR::ABL1 transcript	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	Peripheral blood, bone marrow, vital leukocytes lyophilized cells, cell lysate RNA, cDNA	A, B, C, D
5.	Examination of mutations in kinase domain of BCR::ABL1	Direct sequencing (Sanger)	NRL_04_SOP_14_01/VA6 procedure B; Annex 1/VA4; Annex 2/VA3; Annex 9/VA4	Peripheral blood, bone marrow, vital leukocytes lyophilized cells, cell lysate RNA, cDNA	A, B, D
6.	Examination of the number of transcripts in <i>WT1</i> gene	Real-Time PCR	NRL_02_SOP_14_01/VA4	Peripheral blood, bone marrow	A, B, D
7.	Examination of mutations in <i>HBB</i> gene	Direct sequencing (Sanger)	NRL_06_SOP_14_01/VA3; Annex 1/VA1; Annex 2/VA3; Annex 3/VA3	Peripheral blood, bone marrow, smear from buccal mucosa, umbilical cord blood	A, B, D
8.	Examination of mutations in <i>NPM1</i> gene	PCR-fragment analysis	NRL_09_SOP_20_01/VA2; Annex 1/VA1; Annex 2/VA2; Annex 3/VA1	Peripheral blood, bone marrow,	A, B, D
9.	Examination of the number of transcripts of mutated <i>NPM1</i> gene	Real-Time PCR	NRL_10_SOP_14_01/VA4	Peripheral blood, bone marrow	A, B, D
10.	Examination of mutations in <i>CEBPA</i> gene	Direct sequencing (Sanger)	NRL_11_SOP_14_01/VA4; Annex 1/VA1; Annex 2/VA1	Peripheral blood, bone marrow	A, B, D
11.	Examination of mutations in <i>HBA1</i> and <i>HBA2</i> genes	PCR 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 V617F mutation in <i>JAK2</i> gene	Real-Time PCR	114_SOP_08_01/VA2	Bone marrow, peripheral blood	A, B
13.	Genotyping of erythrocyte antigens	Real-Time PCR	203_SOP_16_01/VA1; Annex 1/VA6; Annex 2/VA6; Annex 3/VA6; Annex 4/VA6	Blood	A, B, C



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14.	Genotyping of HPA antigens	Real-Time PCR	203_SOP_16_02/VA1	Blood	A, B, C, D
15.	Detection of thrombophilic risk factors	Real-Time PCR	105_SOP_15_01/VA2; Cobas z480	Blood	A, B
16.	Examination of human somatic genome variants – myeloid panel	NGS-MPS	NRL_13_SOP_18_01/VA2; Annex 2/VA1; Annex 3/VA1; Annex 4/VA3; Annex 6/VA1	Peripheral blood, bone marrow, smear from buccal mucosa, umbilical cord blood, lyophilized leukocytes	A, B, C, D
17.	Examination of BCR::ABL1 mutation	NGS-MPS	13100_SOP_19_01/VA5	Peripheral blood, bone marrow, vital leukocytes lyophilized cells, cell lysate RNA	A, B, C, D
18.	Examination of BCR::ABL1 fusion gene	Digital PCR	13100_SOP_21_01/VA1	Peripheral blood, bone marrow, vital leukocytes lyophilized cells, cell lysate RNA, cDNA	A, B, D
19.	Examination of fusion genes	Real-Time PCR	13100_SOP_21_02/VA1	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	Plasma	A, B
2.	Prothrombin test	Coagulation method with mechanical detection of coagulum; Calculation	105_SOP_08_02/VA3; STA-R MAX3	Plasma	A, B
3.	D-dimers	Immunoassay with turbidimetric detection	105_SOP_08_03/VA4; STA-R MAX3	Plasma	A, B

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4.	Fibrinogen	Coagulation method with mechanical detection of coagulum	105_SOP_08_04/VA4; STA-R MAX3	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
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

Specification of the scope of accreditation:

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
222/1	HLA-A, B, Bw, Cw
222/4	Basic screening in NAT and papain enzyme assay
222/5	Identification in NAT and papain enzyme assay
222/6	IgG and/or C3d erythrocyte sensitization

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222/7	anti-heparin/PF4 in IgG class
222/8	In IgG and IgM class
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
802/1	RNA SARS-CoV2, RNA Influenza A, RNA Influenza B, RNARSV
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
802/4	CMV in IgG class, 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) and 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-lymphoid 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-lymphoid lineage: CD1a, CD2, CD3, CD4, CD5, CD7, CD8, CD16, CD26, CD27, CD30, CD45, CD56, CD57, CD99, Granzyme, Perforin, TCR-$\alpha\beta$, TCR-$\gamma\delta$, isoforms 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>Eosinophils: CD11b, CD11c, CD13, CD33, CD45</p> <p>Basophils: 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, Lysozyme</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>

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813/5	Examined markers: 16C2, CD61.
813/6	Examined markers: CD3, CD5, CD19, CD20, CD43, CD79b, CD81, RORJ
813/7	Examined markers: CD10, CD19, CD20, CD22, CD34, CD38, CD45, CD58, CD66c, CD73, CD81, CD123, CD304, HLA-DR
816/1	Examined polymorphisms: VNTR: <i>ApoB</i> , <i>MCT118 (D1S80)</i> , <i>YNZ22 (D17S5)</i> , <i>Col2A1</i> , <i>PAH</i> , <i>HVR-Ig</i> , <i>TPO</i> , <i>Amelogenin gene AMG</i> , <i>Y-specific sequence of DYZI</i> ; STR: <i>AMG</i> , <i>LPL</i> , <i>FESFPS</i> , <i>F13B</i> , <i>F13A01</i> , <i>D16S539</i> , <i>D7S820</i> , <i>D13S317</i> , <i>D5S818</i> , <i>D3S1358</i> , <i>D21S11</i> , <i>D18S51</i> , <i>Penta E</i> , <i>D8S1179</i> , <i>FGA</i> , <i>Penta D</i> , <i>Penta C</i> , <i>CSF1PO</i> , <i>TPOX</i> , <i>THO1</i> , <i>vWA</i> , <i>D22S1045</i> , <i>D2S1338</i> , <i>D19S433</i> , <i>D2S441</i> , <i>D10S1248</i> , <i>D1S1656</i> , <i>D12S391</i> and <i>SE33</i> ; DIP: <i>AM X</i> , <i>AM Y</i> , <i>HLD106</i> , <i>HLD70</i> , <i>HLD84</i> , <i>HLD103</i> , <i>HLD104</i> , <i>HLD116</i> , <i>HLD112</i> , <i>HLD307</i> , <i>HLD310</i> , <i>HLD110</i> , <i>HLD133</i> , <i>HLD79</i> , <i>HLD105</i> , <i>HLD140</i> , <i>HLD163</i> , <i>HLD91</i> , <i>HLD23</i> , <i>HLD88</i> , <i>HLD101</i> , <i>HLD67</i> , <i>HLD301</i> , <i>HLD53</i> , <i>HLD97</i> , <i>HLD152</i> , <i>HLD128</i> , <i>HLD134</i> , <i>HLD305</i> , <i>HLD48</i> , <i>HLD114</i> , <i>HLD304</i> , <i>HLD131</i> , <i>HLD38</i> , <i>HLD82</i> .
816/2	Tested specific sequence polymorphisms: <i>S01 (ITGA2B)</i> , <i>S04 (DBH)</i> , <i>S07 (UXT/ZNF81)</i> , <i>S08 (PAPPA2/ASTN1)</i> , <i>S10 (LTBP1)</i> , <i>S11 (DLG2)</i> – each system has A and B variant, <i>S05B (EIF2S2)</i> , <i>GAPDH</i> , <i>SMCY (AF273841)</i> , <i>HLD polymorphisms (see NRL_01_SOP_14_01) in variant D (deletion) and I (insertion) for quantification</i> , <i>β-Globin</i> , <i>KMR501-A</i> , <i>KMR502-A</i> , <i>KMR504-A</i> , <i>KMR505-A</i> , <i>KMR506-A</i> , <i>KMR511-C</i> , <i>KMR512-C</i> , <i>KMR520-DPB1</i> , <i>KMR521-DPB1</i> , <i>KMR522-DPB1</i> , <i>REF 901</i> .
816/3	Detected rearrangements: <i>b2a2 (e13a2)</i> , <i>b3a2 (b14a2, b)</i> , <i>e1a2</i> , <i>e19a2</i> + rare rearrangements.
816/4	Detected rearrangements: <i>b2a2 (e13a2)</i> , <i>b3a2 (b14a2, b)</i> , <i>e1a2</i> , <i>e19a2</i> + rare rearrangements.
816/13	Tested genes coding: <i>D</i> , <i>C</i> , <i>c</i> , <i>E</i> , <i>e</i> , <i>Cw</i> erythrocyte antigens and <i>Kell</i> , <i>Kidd</i> , <i>Duffy</i> , <i>MNS</i> and <i>Dombrock</i> system antigens <i>Dweak</i> erythrocyte antigens, <i>D</i> variant erythrocyte antigens, molecular basis of <i>ABO</i> system antigens.
816/14	Tested genes coding thrombocyte antigens <i>HPA-1</i> , <i>-2</i> , <i>-3</i> , <i>-4</i> , <i>-5</i> , <i>-6</i> , <i>-9</i> , <i>-15</i> .
816/15	Investigated pathogenic polymorphisms: <i>FV Leiden (c.1601G>A)</i> , <i>FIIG20210A (c.*97G>A)</i> .



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816/16	<p>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 part of exon 4</i>, <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>.</p> <p>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>NFI</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 exon 4</i>, <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>.</p>
816/17	Investigated types of BCR-ABL1 gene transcripts: <i>major (e13a2,e14a2)</i> and <i>minor (e1a2) transcript</i> .
816/19	HemaVision®-28Q kit
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

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 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/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 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/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, blood marrow, buccal smear	A, B, 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

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



List of activities within the flexible scope of accreditation

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
HBB	Haemoglobin beta
mBAND	High resolution multicolor banding
MPS	Massively Parallel Sequencing
NAT	Indirect Antiglobulin Test
NGS	Next Generation Sequencing – Massively Parallel Sequencing
PCR	Polymerase Chain Reaction
Real-Time PCR	Real-Time Polymerase Chain Reaction
PCR-SSP	Polymerase Chain Reaction with Sequence Specific Primers
CDC	Microlymphocytotoxic test
Cross-match	Cross-match test
HIT	Heparin-Induced Thrombocytopenia
PNH	Paroxysmal Nocturnal Hemoglobinuria
HSCT	Hematopoietic Stem Cell Transplantation
Multiplex RT PCR	Multiplex Reverse Transcription Polymerase Chain Reaction
CLL	Chronic Lymphocytic Leukemia
B-ALL	acute B-lymphoblastic Leukemia