

List of activities within the flexible scope of accreditation

Accredited Body: Ústav hematologie a krevní transfuze
Název objektu: Komplement laboratoří ÚHK
CAB Number: 8081
Certificate of Accreditation No.: 325/2025
Field of Accreditation: Medical Laboratory - ČSN EN ISO 15189 ed. 3:2023
Updated: 23.03.2026

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/VA3 | Serum, plasma | A, B |
| 5. | Identification of irregular anti-erythrocyte antibodies | Gel column agglutination (manual) | 203_SOP_10_05/VA2 | Serum, plasma | A, B |
| 6. | Direct antiglobulin test | Gel column agglutination (manual) | 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. | Reserved | | | | |
| 9. | Examination of compatibility | Gel column agglutination (manual) | 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 (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/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; Annex 4 D/VA1; MagCore®plus II; 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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|--|--|---|---|--|---------------------------------|
| 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, 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 |
| 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 |

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 |
|--|--|--------------------------|--|---|---------------------------------|
| 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 | | | | |

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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 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/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 with 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 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 |

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| Ordinal Number | Analyte/parameter/diagnostics | Principle of examination | Identification of method procedure/ equipment | Examined material | Degrees of freedom ¹ |
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| 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/VA4; Annex 4/VA4; 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 |
| 818 - Haematology Laboratory | | | | | |
| 1. | Activated partial thromboplastin time | Coagulation method with mechanical detection of coagulum; Calculations | 105_SOP_08_01/VA3; STA-R MAX3; STA-R Max | Plasma | A, B |
| 2. | Prothrombin test | Coagulation method with mechanical detection of coagulum; Calculations | 105_SOP_08_02/VA3; STA-R MAX3; STA-R Max | Plasma | A, B |

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|----------------|---|---|--|-------------------|---------------------------------|
| 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; 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 |
| 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/VA2; Annex 2/VA1; Annex 3/VA1; Annex 4/VA1; Annex 5/VA1; STA-R MAX3 | Plasma | A, B, C |

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| 16. | Antithrombin | Chromogenic method | 105_SOP_23_02/VA2; 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 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 |
| 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, <i>Aspergillus</i> sp., <i>Mucorales</i> . Pathogens of atypical pneumonia <i>Chlamydomphila pneumoniae</i> , <i>Mycoplasma pneumoniae</i> , <i>Legionella pneumophila</i> |
| 802/3 | RNA multiplex CMV, EBV, HSV1, HSV2, <i>Pneumocystis jirovecii</i> , BKV, VZV, HHV6 |
| 802/4 | CMV in the class IgG, hepatitis C (Anti HCV), Syphilis (anti- <i>Treponema pallidum</i>), hepatitis B (anti HBs, anti HBc) |
| 802/5 | Ab anti HIV 1,2 (Ig total) and Ag HIV p24 |
| 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 |

List of activities within the flexible scope of accreditation

| Field Nr. / Ordinal Number | Detailed information on activities within the scope of accreditation |
|----------------------------------|--|
| 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-$\gamma\delta$, isoforms of T-beta chain, TdT, TCLP, TCR $\text{C}\beta$1</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 | 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 |
| 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 <i>WT1</i> gene |
| 816/7 | Examination of mutations in <i>HBB</i> gene |

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|----------------------------|--|
| 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: 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 <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)</i> and <i>minor (e1a2) transcript</i> . |
| 816/18 | Quantitative examination of fuse gene <i>major BCR::ABL1</i> transcript level |
| 816/19 | Examination in the scope of 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 |
| 818/15 | FVIII, FIX, FXI, FXII |

Primary sample collection:

| Ordinal Number ² | Sample collection technique | Identification of sample collection procedure | Collected material | Degrees of 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/VA14; 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/VA14; 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/VA14; Annex 23/VA4; 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/VA14; Annex 1/VA9 | 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/ VA14; Annex 24/VA1; 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: <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> |
| 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 <i>in situ</i> 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 |