

## 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.:** 325/2025  
**Field of Accreditation:** Medical Laboratory - ČSN EN ISO 15189 ed. 3:2023  
**Updated:** 02.10.2025

### 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 <sup>1</sup> |
|-----------------------------------|---------------------------------------------------------|-----------------------------------------|-----------------------------------------------|-------------------|---------------------------------|
| <b>222 - Transfusion Medicine</b> |                                                         |                                         |                                               |                   |                                 |
| 1.                                | Reserved                                                |                                         |                                               |                   |                                 |
| 2.                                | Cross-match                                             | CDC                                     | 233_SOP_08_01/VA4;<br>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;<br>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;<br>NEO Iris                | Blood             | A, B                            |
| 11.                               | Erythrocyte antigens                                    | Microplate agglutination                | 203_SOP_22_03/VA1;<br>NEO Iris                | Blood             | A, B                            |

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|-----------------------------------|----------------------------------------------------|-----------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| 12.                               | Screening of irregular anti-erythrocyte antibodies | Solid phase                       | 203_SOP_22_04 /VA1;<br>NEO Iris                                                                                                                                                                                                                                                                                   | Blood                                                                                                                                       | A, B                            |
| 13.                               | Identification of anti-erythrocyte antibodies      | Gel column agglutination (manual) | 203_SOP_23_11/VA1                                                                                                                                                                                                                                                                                                 | Blood                                                                                                                                       | A, B                            |
| <b>802 – Medical Microbiology</b> |                                                    |                                   |                                                                                                                                                                                                                                                                                                                   |                                                                                                                                             |                                 |
| 1.                                | Detection of nucleic acid of infectious agents     | Real-Time PCR                     | 318_SOP_22_01/VA1;<br>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/VA2;<br>Annex 2 A/VA2;<br>Annex 2 D/VA1;<br>Annex 2 E/VA1;<br>Annex 3 A/VA1;<br>Annex 3 B/VA1;<br>Annex 3 C/VA1;<br>Annex 3 D/VA1;<br>Annex 3 E/VA1;<br>Annex 4 A/VA1;<br>Annex 4 B/VA1;<br>Annex 4 C/VA1;<br>MagCore®plus II;<br>BIO-RAD CFX 96                                                    | Nasopharyngeal swab, bronchoalveolar lavage, 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;<br>Annex 2 A/VA2;<br>Annex 2 D/VA1;<br>Annex 2 E/VA1;<br>Annex 3 A/VA1;<br>Annex 3 B/VA1;<br>Annex 3 C/VA1;<br>Annex 3 D/VA1;<br>Annex 4 A/VA2;<br>Annex 4 B/VA2;<br>Annex 4 C/VA2;<br>Annex 4 D/VA2;<br>Annex 4E/VA1;<br>Annex 4F/VA1;<br>Annex 4G/VA1;<br>MagCore®plus II;<br>BIO-RAD CFX 96 | Blood, plasma, cerebrospinal fluid, urine, bronchoalveolar lavage, tracheal aspirate, sputum, ascites, pleural exudate                      | A, B, C, D                      |

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|----------------------------------------------------|--------------------------------------------------------|-----------------------------------------------------|-------------------------------------------------------------|-----------------------------------------------------------------------------------|---------------------------------|
| 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                         |
| <b>813 - Allergology and Immunology Laboratory</b> |                                                        |                                                     |                                                             |                                                                                   |                                 |
| 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, 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, 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                      |

Reserved

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| Ordinal Number                           | Analyte/parameter/diagnostics            | Principle of examination   | Identification of method procedure/ equipment                                                                                       | Examined material                                                                                       | Degrees of freedom <sup>1</sup> |
|------------------------------------------|------------------------------------------|----------------------------|-------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------|---------------------------------|
| 9.                                       | Determination of residual disease in AML | Flow cytometry             | 116_SOP_23_10_VA2;<br>BD FACS Canto II;<br>Cytognos Omnicyt I, II<br>Cytek Northern Lights                                          | Peripheral blood,<br>bone marrow,<br>cerebrospinal fluid,<br>malignant exudate                          | A, B, C,<br>D                   |
| 10.                                      | Examination of antiHLA antibodies        | xMAP technology            | 203_SOP_14_07_VA2;<br>203_SOP_19_03_VA2;<br>Luminex / FLEXMAP 3D                                                                    | Blood                                                                                                   | A, B                            |
| 11.                                      | Examination of HLA system                | CDC                        | 233_SOP_08_01_VA4;<br>Annex 01_VA3                                                                                                  | Blood                                                                                                   | A, B                            |
| 12.                                      | Examination of antiHLA antibodies        | CDC                        | 203_SOP_13_02_VA4                                                                                                                   | Blood                                                                                                   | A, B                            |
| <b>814 - Toxicological Laboratory</b>    |                                          |                            |                                                                                                                                     |                                                                                                         |                                 |
| 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                         |
| <b>816 – Medical Genetics Laboratory</b> |                                          |                            |                                                                                                                                     |                                                                                                         |                                 |
| 1.-2.                                    | Reserved                                 |                            |                                                                                                                                     |                                                                                                         |                                 |
| 3.                                       | Examination of somatic genome variants   | Multiplex RT-PCR           | NRL_03_SOP_14_01_VA4;<br>Annex 1_VA6<br>Annex 5_VA4;<br>Annex 6_VA4;<br>Qiaxcell Analyzer                                           | Peripheral blood,<br>bone marrow,<br>vital leukocytes<br>lyophilized cells,<br>cell lysate<br>RNA, cDNA | A, B, C,<br>D                   |
| 4.                                       | Examination of somatic genome variants   | Real-Time PCR              | NRL_04_SOP_14_01_VA7<br>postup A;<br>Annex 1_VA6;<br>Annex 2_VA3;<br>Annex 11_VA4;<br>Annex 12_VA3;<br>Annex 13_VA3;<br>RotorGene Q | Peripheral blood,<br>bone marrow,<br>vital leukocytes<br>lyophilized cells,<br>cell lysate<br>RNA, cDNA | A, B, C,<br>D                   |
| 5.                                       | Examination of somatic genome variants   | Direct sequencing (Sanger) | NRL_04_SOP_14_01_VA7<br>postup B;<br>Annex 1_VA6;<br>Annex 2_VA3;<br>Annex 9_VA5;<br>ABI3500;<br>ABI3500XL                          | Peripheral blood,<br>bone marrow,<br>vital leukocytes<br>lyophilized cells,<br>cell lysate<br>RNA, cDNA | A, B, D                         |
| 6.                                       | Examination of somatic genome variants   | Real-Time PCR              | NRL_02_SOP_14_01_VA4;<br>RotorGene Q                                                                                                | Peripheral blood,<br>bone marrow                                                                        | A, B, D                         |

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|----------------|-----------------------------------------|--------------------------------|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|---------------------------------|
| 7.             | Examination of germline genome variants | Direct sequencing (Sanger)     | NRL_06_SOP_14_01/VA3;<br>Annex 1/VA1;<br>Annex 2/VA3;<br>Annex 3/VA3;<br>ABI3500;<br>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;<br>Annex 1/VA1;<br>Annex 2/VA2;<br>Annex 3/VA1;<br>ABI3500;<br>ABI3500XL  | Bone marrow, peripheral blood                                                                         | A, B, D                         |
| 9.             | Examination of somatic genome variants  | Real-Time PCR                  | NRL_10_SOP_14_01/VA4;<br>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;<br>Annex 1/VA1;<br>Annex 2/VA1;<br>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;<br>RotorGene Q<br>Rotor-Gene 3000A                                           | Bone marrow, peripheral blood                                                                         | A, B                            |
| 13.            | Examination of germline genome variants | PCR-SSP                        | 203_SOP_16_01/VA1;<br>Annex 1/VA6;<br>Annex 2/VA6;<br>Annex 3/VA6;<br>Annex 4/VA6;<br>FluoVista | Blood                                                                                                 | A, B, C                         |
| 14.            | Examination of germline genome variants | PCR-SSP                        | 203_SOP_16_02/VA2;<br>FluoVista                                                                 | Blood                                                                                                 | A, B, C, D                      |
| 15.            | Examination of germline genome variants | Real-Time PCR                  | 105_SOP_15_01/VA2;<br>Cobas z480                                                                | Blood                                                                                                 | A, B                            |
| 16.            | Examination of somatic genome variants  | NGS-MPS                        | NRL_13_SOP_18_01/VA4;<br>Annex 4/VA4;<br>Annex 6/VA1;<br>Annex 7/VA1;<br>MiSeq<br>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;<br>MiSeq                                                                   | Peripheral blood, bone marrow, vital leukocytes lyophilized cells, cell lysate RNA                    | A, B, C, D                      |

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|-------------------------------------|------------------------------------------|------------------------------------------------------------------------|----------------------------------------------------------|------------------------------------------------------------------------------------------|---------------------------------|
| 18                                  | Examination of somatic genome variants   | Digital PCR                                                            | 13100_SOP_21_01/VA2;<br>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;<br>RotorGene Q                      | Peripheral blood, bone marrow, vital leukocytes lyophilized cells, cell lysate RNA, cDNA | A, B, C, D                      |
| <b>818 - Haematology Laboratory</b> |                                          |                                                                        |                                                          |                                                                                          |                                 |
| 1.                                  | Activated partial thromboplastin time    | Coagulation method with mechanical detection of coagulum; Calculations | 105_SOP_08_01/VA3;<br>STA-R MAX3;<br>STA-R Max           | Plasma                                                                                   | A, B                            |
| 2.                                  | Prothrombin test                         | Coagulation method with mechanical detection of coagulum; Calculations | 105_SOP_08_02/VA3;<br>STA-R MAX3;<br>STA-R Max           | Plasma                                                                                   | A, B                            |
| 3.                                  | D-dimers                                 | Immunoassay with turbidimetric detection                               | 105_SOP_08_03/VA4;<br>STA-R MAX3;<br>STA-R Max           | Plasma                                                                                   | A, B                            |
| 4.                                  | Fibrinogen                               | Coagulation method with mechanical detection of coagulum               | 105_SOP_08_04/VA4;<br>STA-R MAX3;<br>STA-R Max           | Plasma                                                                                   | A, B                            |
| 5.                                  | D-dimers                                 | Immunoassay with fluorimetric detection                                | 105_SOP_08_06/VA3;<br>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;<br>Shimadzu UV 2401                   | Plasma                                                                                   | A, B                            |
| 8.                                  | Blood count                              | Flow cytometry; Impedance method; Photometry; Calculations             | 206_SOP_22_01/VA2;<br>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;<br>Sysmex CellaVision DI60            | Blood                                                                                    | A, B                            |
| 11.                                 | Quantitative determination of G-6-PDH    | Spectrophotometry                                                      | 117_SOP_11_02/VA3;<br>DIALAB DTN-510K                    | Blood                                                                                    | A, B                            |

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|----------------|-----------------------------------------------------------|--------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|-------------------|---------------------------------|
| 12.            | Quantitative determination of haemoglobins                | Capillary electrophoresis                                          | 117_SOP_12_01/VA2;<br>MINICAP Flex piercing                                                      | Blood             | A, B, C                         |
| 13.            | Blood count with a five-part differential leukocyte count | Flow cytometry<br>Impedance method;<br>Photometry;<br>Calculations | 113_SOP_16_19/VA1;<br>113_SOP_16_21/VA1;<br>Sysmex XN10, XN20                                    | Blood             | A, B                            |
| 14.            | Reticulocytes                                             | Flow cytometry;<br>Impedance method;<br>Calculations               | 113_SOP_16_20/VA1;<br>Sysmex XN20                                                                | Blood             | A, B                            |
| 15.            | Haemocoagulation factors in the intrinsic pathway         | Coagulation method with mechanical detection of coagulum           | 105_SOP_23_01/VA2;<br>Annex 2/VA1;<br>Annex 3/VA1;<br>Annex 4/VA1;<br>Annex 5/VA1;<br>STA-R MAX3 | Plasma            | A, B, C                         |
| 16.            | Antithrombin                                              | Chromogenic method                                                 | 105_SOP_23_02/VA2;<br>Annex 2/VA1;<br>Annex 3/VA1;<br>STA-R Max;<br>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 <sup>w</sup>                                        |
| 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             |

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| Field Nr. / Ordinal Number | Detailed information on activities within the scope of accreditation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 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-<math>\alpha\beta</math>, TCR-<math>\gamma\delta</math>, isoforms of T-beta chain, TdT, TCLP, TCR C<math>\beta</math>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                      | 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 813/9                      | CD2, CD7, CD11b, CD13, CD14, CD15, CD19, CD33, CD34, CD38, CD45, CD56, CD64, CD117, CD123, CD 133, HAL-DR ,                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |



## List of activities within the flexible scope of accreditation

| Field Nr. / Ordinal Number | Detailed information on activities within the scope of accreditation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 816/8                      | Examination of mutations in <i>NPM1</i> 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 <i>JAK2</i> gene                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 816/13                     | Tested genes coding:<br>D, C,c,E,e,Cw erythrocyte antigens and Kell, Kidd, Duffy, MNS and Dombrock system antigens<br>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<br><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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |

## List of activities within the flexible scope of accreditation

| Field Nr. / Ordinal Number | Detailed information on activities within the scope of accreditation                                                  |
|----------------------------|-----------------------------------------------------------------------------------------------------------------------|
| 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 <sup>2</sup> | Sample collection technique | Identification of sample collection procedure | Collected material | Degrees of freedom <sup>1</sup> |
|-----------------------------|-----------------------------|-----------------------------------------------|--------------------|---------------------------------|
| 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/<br>parameter/diagnostics       | Principle of examination                    | Identification of method<br>procedure/ equipment | Examined material             | Degrees of freedom <sup>1</sup> |
|------------------------------------------|-----------------------------------------|---------------------------------------------|--------------------------------------------------|-------------------------------|---------------------------------|
| <b>816 – Medical Genetics Laboratory</b> |                                         |                                             |                                                  |                               |                                 |
| 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;<br>mBAND;<br>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 <sup>1</sup> |
|------------------------------------------|-----------------------------------------|--------------------------|--------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------|---------------------------------|
| <b>816 – Medical Genetics Laboratory</b> |                                         |                          |                                                                                                              |                                                                       |                                 |
| 1.                                       | Examination of HLA genotype             | PCR-SSP                  | NRL_05_SOP_14_01/VA14;<br>Annex 2/VA7;<br>Annex 9/VA6;<br>Annex 22/VA2                                       | Peripheral blood,<br>umbilical blood,<br>bone marrow,<br>buccal smear | A, B, C, D                      |
| 2.                                       | Examination of HLA genotype             | Real-Time PCR            | NRL_05_SOP_14_01/VA14;<br>Annex 20/VA5                                                                       | Peripheral blood,<br>umbilical blood,<br>bone marrow,<br>buccal smear | A, B, C, D                      |
| 3.                                       | Examination of HLA genotype             | NGS-MPS                  | NRL_05_SOP_14_01/VA14;<br>Annex 23/VA4;<br>Illumina MiSeq                                                    | Peripheral blood,<br>umbilical blood,<br>bone marrow,<br>buccal smear | A, B, C, D                      |
| 4.                                       | Examination of HLA genotype             | Spectrophotometry        | NRL_05_SOP_14_01/VA14;<br>Annex 1/VA9                                                                        | Peripheral blood,<br>umbilical blood,<br>bone marrow,<br>buccal smear | A, B, C, D                      |
| 5.                                       | Examination of germline genome variants | PCR-fragment analysis    | NRL_01_SOP_14_01/VA6;<br>Annex 19/VA5;<br>Annex 20/VA5;<br>Annex 23/VA5;<br>Annex 27/VA6;<br>ABI3500         | Peripheral blood,<br>bone marrow,<br>buccal smear                     | A, B, C, D                      |
| 6.                                       | Examination of somatic genome variants  | PCR-fragment analysis    | NRL_01_SOP_14_01/VA6;<br>Annex 20/VA5;<br>Annex 23/VA5;<br>Annex 27/VA6;<br>ABI3500                          | Peripheral blood,<br>bone marrow                                      | A, B, C, D                      |
| 7.                                       | Examination of germline genome variants | Real-Time PCR            | NRL_07_SOP_14_01/VA8;<br>Annex 8/VA6;<br>Annex 11/VA2;<br>Rotor-Gene Q;<br>Rotor-Gene 6000                   | Peripheral blood,<br>bone marrow,<br>buccal smear                     | A, B, C, D                      |
| 8.                                       | Examination of somatic genome variants  | Real-Time PCR            | NRL_07_SOP_14_01/VA8;<br>Annex 8/VA6;<br>Annex 10/VA5;<br>Annex 11/VA2;<br>Rotor-Gene Q;<br>Rotor-Gene 6000; | Peripheral blood,<br>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 <sup>1</sup> |
|----------------|--------------------------------|--------------------------|-------------------------------------------------------------------------|-------------------------------|---------------------------------|
| 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:<br>Class I HLA: loci A, B, C<br>Class II HLA: loci DRB1, DQA1, DQB1, DPB1, DRB3/4/5<br>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:<br>Class I HLA: loci A, B, C<br>Class II HLA: loci DRB1, DQA1, DQB1, DPB1, presence of DRB3-5                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 816/3                      | Tested genes:<br>Class I HLA: loci A, B, C<br>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:<br><i>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;</i><br><i>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.</i> |
| 816/6                      | Examination of cellular chimerism after allogeneic HSCT. Examined polymorphisms:<br><i>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;</i><br><i>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.</i> |
| 816/7                      | Examination of cellular chimerism after allogeneic HSCT. Tested specific sequence polymorphisms:<br><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:<br><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:<br>Class I HLA: loci A, B, C<br>Class II HLA: loci DRB1, DRB3-5, DQA1, DQB1, DPB1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |

## List of activities within the flexible scope of accreditation

### Explanatory notes:

<sup>1</sup> Established degrees of freedom according to MPA 00-09-...:

A – Flexibility concerning the documented examination / sample collection procedure

B – Flexibility concerning the technique

C – Flexibility concerning the analytes / parameters

D – Flexibility concerning the examined material

If no degree of freedom is specified, the laboratory cannot apply a flexible approach to the scope of accreditation for this examination.

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