The Appendix is an integral part of
Certificate of Accreditation No. 518/2022 of 01/ 11/ 2022

Accredited entity according to ČSN EN ISO 15189:2013:

Ústav hematologie a krevní transfuze
ÚHKT Laboratories
U Nemocnice 2094/1, 128 00 Praha 2

Medical laboratory locations:

1. **Workplace No. 1** U Nemocnice 2094/1, 128 00 Praha 2
2. **Workplace No. 2** U Nemocnice 499/2, 128 00 Praha 2

1. **Workplace No. 1**

The Laboratory has a flexible scope of accreditation permitted as detailed in the Annex. Updated list of activities provided within the required flexible scope of accreditation is available from the Laboratory Quality Manager.

Examinations:

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
222 - Transfusion Medicine			
1.	Lymphocytotoxic test for the determination of HLA class I antigens and lymphocyte cross-match	233_SOP_08_01	Blood
2.	Identification of thrombocyte antibodies by PakLx	203_SOP_14_02	Serum
3.	Screening of irregular antibodies against erythrocytes by column agglutination method in DG Gel cards	203_SOP_10_04	Serum, plasma
4.	Identification of irregular antibodies against erythrocytes by column agglutination method in BioRad (DiaMed) cards	203_SOP_10_05	Serum, plasma
5.	Direct Coombs test (PAT) by column agglutination method in DG Gel cards	203_SOP_12_07	Blood
6.	Detection of HIT II antibodies (anti-heparin/PF4 IgG class) on BIO-FLASCH system	203_SOP_13_01	Blood
7.	Lymphocytotoxicity test for screening and identification of anti-HLA antibodies	203_SOP_13_02	Blood
8.	Compatibility test by LISS NAT column agglutination method in BioRad cards	203_SOP_12_09	Blood

Český institut pro akreditaci, o.p.s.
NÁRODNÍ AKREDITAČNÍ ORGÁN
-7-

Accredited entity according to ČSN EN ISO 15189:2013:

Ústav hematologie a krevní transfuze
ÚHKT Laboratories
U Nemocnice 2094/1, 128 00 Praha 2

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
9.	Examination of ABO blood group and D antigen by agglutination method, determination of Dw/v by solid phase method on NEO Iris	203_SOP_22_02	Blood
10.	Examination of erythrocyte antigens C c E e K Cw by agglutination method on NEO Iris system	203_SOP_22_03	Blood
11.	Screening of IgG irregular antibodies against erythrocytes by solid phase method on NEO Iris system	203_SOP_22_04	Blood
802 - Medical microbiology			
1.	Detection of nucleic acid of pathogenic microorganisms using the GeneXpert closed system (Cepheid) [1]	318_SOP_22_01	Nasopharyngeal swab, BAL, tracheal aspirate, sputum
2.	Qualitative detection of nucleic acid of pathogenic microorganisms by multiplex PCR method [2]	318_SOP_22_02	Nasopharyngeal swab, BAL, tracheal aspirate, sputum, cerebrospinal fluid, lesion swabs, blood, nails, exploratory biopsy
3.	Quantitative detection of nucleic acid of pathogenic microorganisms by multiplex PCR method [3]	318_SOP_22_03	Blood, plasma, cerebrospinal fluid, urine, BAL, tracheal aspirate, sputum, ascites, pleural exudate
4.	Examination of markers of blood-borne infections (HIV, HBV, HCV, CMV, Treponema pallidum) by CMIA method [4]	LPVN_SOP_19_01	Serum
813 - Allergology and Immunology Laboratory			
1.	Determination of lymphoid subpopulations by flow cytometry [5]	116_SOP_21_01	Peripheral blood
2.	Determination of CD34+ stem cells by flow cytometry – single platform protocol [6]	116_SOP_21_02	Peripheral blood, umbilical blood, blood marrow, apheresis products
3.	Determination of PNH erythrocytes neutrophils and monocytes by flow cytometry: diagnosis of paroxysmal nocturnal haemoglobinuria [7]	116_SOP_21_03	Peripheral blood

Accredited entity according to ČSN EN ISO 15189:2013:

Ústav hematologie a krevní transfuze
ÚHKT Laboratories
U Nemocnice 2094/1, 128 00 Praha 2

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
4.	Leukocyte immunophenotyping by flow cytometry [8]	116_SOP_21_04	Peripheral blood, bone marrow, lymph node, cerebrospinal fluid, malignant exudate
5.	Determination of VASP phosphorylation of thrombocytes by flow cytometry: monitoring of therapy of P2Y12 receptor ADP antagonist [9]	116_SOP_21_05	Peripheral blood
6.	Determination of measurable residual disease in chronic lymphocytic leukemia (CLL) by flow cytometry [10]	116_SOP_21_07	Peripheral blood, bone marrow, cerebrospinal fluid, malignant exudate
7.	Determination of measurable residual disease in acute B-lymphoblastic leukemia (B-ALL) by flow cytometry [11]	116_SOP_21_08	Peripheral blood, bone marrow, cerebrospinal fluid, malignant exudate
816 - Medical Genetics Laboratory			
1.	Examination of cellular chimerism after allogeneic HSCT by electrophoretic analysis of sequence polymorphisms [12]	NRL_01_SOP_14_01	Biological material containing human nuclear DNA
2.	Examination of genotype of main histocompatible system of human being – HLA by PCR-SSP method [13]	NRL_05_SOP_14_01/ procedure A	Biological material containing human nuclear DNA
3.	Examination of genotype of main histocompatible system of human being – HLA by RT PCR method [13]	NRL_05_SOP_14_01/ procedure C	Biological material containing human nuclear DNA
4.	Examination of genotype of main histocompatible system of human being – HLA by massive parallel sequencing method [13]	NRL_05_SOP_14_01/ procedure D	Biological material containing human nuclear DNA
5.	Examination of genotype of main histocompatible system of human being – HLA – quality and concentration of isolated DNA	NRL_05_SOP_14_01/ Annex 01	Biological material containing human nuclear DNA

Český institut pro akreditaci, o.p.s. NÁRODNÍ AKREDITAČNÍ ORGÁN -7-

Accredited entity according to ČSN EN ISO 15189:2013:

Ústav hematologie a krevní transfuze
ÚHKT Laboratories
U Nemocnice 2094/1, 128 00 Praha 2

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
6.	Examination of cellular chimerism after allogeneic HSCT by RT PCR analysis of sequence polymorphisms [14]	NRL_07_SOP_14_01	Biological material containing human nuclear DNA
7.	Diagnostic examination of BCR-ABL fusion gene by multiplex RT–PCR method [15]	NRL_03_SOP_14_01	Biological material containing human RNA
8.	Examination of the level of BCR-ABL1 transcript by RT PCR method [16]	NRL_04_SOP_14_01/ procedure A	Peripheral blood, bone marrow
9.	Examination of mutations in kinase domain of BCR-ABL1 by direct sequencing method	NRL_04_SOP_14_01/ procedure B	Peripheral blood, bone marrow
10.	Examination of the number of transcripts of WT1 gene by means of RT-PCR at patients with acute leukemia and MDS/MPN	NRL_02_SOP_14_01	Biological material containing human RNA
11.	Examination of mutations in HBB gene (Haemoglobin beta) by direct sequencing method	NRL_06_SOP_14_01	Biological material containing human nuclear DNA
12.	Examination of the presence of mutations in NPM1 gene by fragment analysis	NRL_09_SOP_20_01	Biological material containing human DNA
13.	Examination of the number of transcripts of mutated NPM1 gene by RT-PCR method at patients with AML	NRL_10_SOP_14_01	Biological material containing human RNA
14.	Examination of the presence of mutations in CEBPA gene by direct sequencing method	NRL_11_SOP_14_01	Biological material containing human nuclear DNA and RNA
15.	Examination of mutations in HBA1 and HBA2 genes by α-Globin StripAssay kit	NRL_12_SOP_16_01	Biological material containing human nuclear DNA
16.	Detection of JAK2 gene V617F mutation in peripheral blood and bone marrow by RT-PCR method	114_SOP_08_01	Bone marrow, peripheral blood
17.	Genotyping of erythrocyte antigens by RBC-FluoGene method [17]	203_SOP_16_01	Blood

Accredited entity according to ČSN EN ISO 15189:2013:

Ústav hematologie a krevní transfuze
ÚHKT Laboratories
U Nemocnice 2094/1, 128 00 Praha 2

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
18.	Genotyping of thrombocyte antigens by HPA FluoGene method [18]	203_SOP_16 _02	Biological material containing human nuclear DNA
19.	Examination of the presence of thrombophilic risk factors by PCR and fluorogenic target-specific hybridization	105_SOP_15_01	Blood
20.	Examination of human genome variants by massive parallel sequencing – myeloid panel [19]	NRL_13_SOP_18_01	Biological material containing human nuclear DNA
21.	Detection of mutations in kinase domain of BCR::ABL1 by next generation sequencing [20]	13100_SOP_19_01	Biological material containing human RNA
22.	Examination of BCR::ABL1 fusion gene by digital PCR method	13100_SOP_21_01	Biological material containing human DNA and RNA
23.	Examination of a panel of 28 fusion genes by real time RT PCR	13100_SOP_21_02	Biological material containing human RNA
818 - Haematology Laboratory			
1.	Activated partial thromboplastin time on STA-R analyzer using STA-PTTA kit	105_SOP_08_01	Plasma
2.	Prothrombin time by STA-R analyzer using STA-Neoplastine kit	105_SOP_08_02	Plasma
3.	Immunoturbidimetric determination of amount-of-substance concentration of D-dimer by STA-R analyzer using STA-LIATEST D-Di kit	105_SOP_08_03	Plasma
4.	Determination of fibrinogen by coagulation method with mechanical detection by STA-R analyzer	105_SOP_08_04	Plasma
5.	Determination of amount-of-substance concentration of D-Dimer by ELFIA analyzer by VIDAS kit D-Dimer Exclusion	105_SOP_08_06	Plasma
6.	Evaluation of bone marrow aspirate smear	113_SOP_21_26	Bone marrow

Accredited entity according to ČSN EN ISO 15189:2013:

Ústav hematologie a krevní transfuze
ÚHKT Laboratories
U Nemocnice 2094/1, 128 00 Praha 2

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
7.	Spectrophotometric determination of free haemoglobin	301_SOP_08_01	Plasma
8.	Determination of blood count (WBC, RBC, HGB, HCT, PLT) using Sysmex XN-10 haematology analyzer	206_SOP_22_01	Blood
9.	Peripheral blood smear analysis – leukocyte count and morphological description of cells	113_SOP_14_05	Blood
10.	Quantitative spectrophotometric determination of G-6-PDH using TRINITY BIOTECH kit, Procedure No. 345-UV, and using POINTE SCIENTIFIC kit	117_SOP_11_02	Blood
11.	Quantitative determination of A2, F and S haemoglobins by capillary electrophoresis method on MINICAP FLEX-PIERCING system	117_SOP_12_01	Blood
12.	Measurement of blood count parameters using Sysmex XN10, XN20 haematology analyzers	113_SOP_16_19	Blood
13.	Measurement of absolute number of reticulocytes on Sysmex XN20 haematology analyzer	113_SOP_16_20	Blood
14.	Determination of differential Leukocyte count on Sysmex XN10, XN20 analyzers	113_SOP_16_21	Blood

Annex:
Flexible scope of accreditation

Examination procedure ordinal numbers:
Field 816 / 1- 15,20-23

The Laboratory is allowed to modify the examination procedures listed in the Annex within the specified scope of accreditation provided the measuring principle is observed.

The flexible approach to the scope of accreditation cannot be applied to the examinations not included in the Annex.

Accredited entity according to ČSN EN ISO 15189:2013:

Ústav hematologie a krevní transfuze
ÚHKT Laboratories
U Nemocnice 2094/1, 128 00 Praha 2

Primary sample collection:

Ordinal number	Primary sample collection procedure name	Primary sample collection procedure identification	Primary sample
1.	Venous blood sampling	206_SOP_22_02	Blood

Specification of the scope of accreditation:
Superscript at the examination procedure name identifies the procedure:

[1] **318_SOP_22_01** Examined pathogens: SARS-CoV2, Influenza A, Influenza B, RSV

[2] **318_SOP_22_02** Examined pathogens: Parainfluenza virus 1-4, rhinoviruses, human enteroviruses, human adenoviruses, human metapneumoviruses and human bocaviruses, Aspergillus sp., Mucorales

[3] **318_SOP_22_03** Examined pathogens: CMV, EBV, HSV1, HSV2, Pneumocystis jirovecii

[4] **LPVN_SOP_19 _01**
Examined markers: HIV Ag/Ab, HBsAg, anti-HBs, anti-HBc, anti-Hbe, HbeAg, anti-HCV, HCV cAg, anti-CMV IgG, anti-Treponema pallidum;
Donors: HIV, HBs Ag, HCV, HCV Ag, TP

[5] **116_SOP_21_01** Examined markers: CD3, CD4, CD8, CD19, CD16, CD45, CD56 plus selected additional markers of the expanded lymphocyte immunophenotype

[6] **116_SOP_21_02** Examined markers: CD34, CD45

[7] **116_SOP_21_03** Examined markers: FLAER, CD15, CD45, CD59, CD64, CD71, CD157, CD235 plus selected additional markers of the expanded immunophenotype of erythrocytes, monocytes and neutrophils

[8] **116_SOP_21_04** Investigated markers from the list plus selected additional markers of the extended immunophenotype specific to a particular haematological malignancy

List of recommended markers for immunophenotyping in haemato-oncology as recommended by Bethesda International Conference 2006, European LeukemiaNet, International Clinical Cytometry Society (ICCS) and European Society for Clinical Cell Analysis (ESCCA).

Lineage/population	Markers
B-lymphoid lineage	CD5, CD9, CD10, CD11b, CD11c, CD19, CD20, CD22, CD23, CD24, CD25, CD37, CD31, CD34, CD38, CD39, CD43, CD44, CD45, CD49d, CD58, CD66c, CD73, CD79b, CD81, CD103, CD123, CD185, CD200, CD304, CD305, CD371, HLA-DR, TdT, TSLP, NG2, ROR1, kappa, lambda, IgM, IgD, IgG
T-lymphoid lineage	CD1a, CD2, CD3, CD4, CD5, CD7, CD8, CD16, CD26, CD27, CD30, CD45, CD56, CD57, CD99, Granzyme, Perforin, TCR-αβ, TCR-γδ, izoformy T-beta chains, TdT, TCLP, TRBC1

Accredited entity according to ČSN EN ISO 15189:2013:

Ústav hematologie a krevní transfuze
ÚHKT Laboratories
U Nemocnice 2094/1, 128 00 Praha 2

NK lineage	CD2, CD3, CD4, CD5, CD7, CD8, CD16, CD56, CD57, CD94, CD158a, CD158b, CD158e, CD159a
Plasma lineage	CD19, CD20, CD27, CD28, CD38, CD45, CD56, CD81, CD138, CD117, cyt.kappa, cyt.lambda
Eosinophils	CD11b, CD11c, CD13, CD33, CD45
Basophils	CD9, CD13, CD22, CD25, CD33, CD36, CD38, CD45, CD123, CD203
Mastocytes	CD2, CD25, CD30, CD45, CD117
Dendritic cells	CD4, CD7, CD33, CD36, CD38, CD43, CD56, CD45RA, CD123, CD303
Monocyte lineage	CD4, CD11b, CD13, CD14, CD15, CD33, CD34, CD36, CD45, CD64, CD305, HLA-DR, Lysozyme
Myeloid lineage	CD11b, CD13, CD14, CD15, CD16, CD33, CD34, CD38, CD45, CD56, CD64, CD65, CD117, CD133, CD123, HLA-DR, MPO, NG2
Erythroid lineage	CD34, CD36, CD71, CD105, CD117, CD235a
Megakaryocyte lineage	CD36, CD41, CD42, CD61
Acute myeloid leukemia (AML) stem cells	CD11b, CD22, CD33, CD34, CD38, CD44, CD45RA, CD56, CD366, CD371
Chronic myeloid leukemia (CML) stem cells	CD25, CD26, CD34, CD38, CD45

[9] **116_SOP_21_05** Examined markers: 16C2, CD61

[10] **116_SOP_21_07** Examined markers: CD3, CD5, CD19, CD20, CD43, CD79b, CD81, ROR1, Igkappa, Iglambda

[11] **116_SOP_21_08** Examined markers: CD10, CD19, CD20, CD22, CD34, CD38, CD45, CD58, CD66c, CD73, CD81, CD123, CD304, HLA-DR

[12] **NRL_01_SOP_14_01** examined polymorphisms:
VNTR: ApoB, MCT118 (D1S80), YNZ22 (D17S5), Col2A1, PAH, HVR-Ig, TPO, Amelogenin gene AMG, Y-specific sequence of DYZ1

STR: AMG, LPL, FESFPS, F13B, F13A01, D16S539, D7S820, D13S317, D5S818, D3S1358, D21S11, D18S51, Penta E, D8S1179, FGA, Penta D, Penta C, CSF1PO, TPOX, THO1, vWA, D22S1045, D2S1338, D19S433, D2S441, D10S1248, D1S1656, D12S391 and SE33.

DIP: AM X, AM Y, HLD106, HLD70, HLD84, HLD103, HLD104, HLD116, HLD112, HLD307, HLD310, HLD110, HLD133, HLD79, HLD105, HLD140, HLD163, HLD91, HLD23, HLD88, HLD101, HLD67, HLD301, HLD53, HLD97, HLD152, HLD128, HLD134, HLD305, HLD48, HLD114, HLD304, HLD131, HLD38, HLD82.

[13] **NRL_05_SOP_14_01** tested genes:
Procedure A:
Class I HLA: loci A, B, C
Class II HLA: loci DRB1, DQA, DQB1, DPB1, presence of DRB3-5
KIR genes: presence of 2DL1, 2DL2, 2DL3, 2DL4, 2DL5, 2DS1, 2DS2, 2DS3, 2DS4, 2DS5, 3DL1, 3DL2, 3DL3, 3DS1, 2DP1, 2DP2.

Accredited entity according to ČSN EN ISO 15189:2013:

Ústav hematologie a krevní transfuze
ÚHKT Laboratories
U Nemocnice 2094/1, 128 00 Praha 2

Procedure C:
HLA class I: *loci A, B, C*
HLA class II: *loci DRB1, DQA1, DQB1, DPB1, presence of DRB3-5*

Procedure D:
HLA class I: *loci A, B, C*
HLA class II: *loci DRB1, DRB3-5, DQA1, DQB1, DPB1,MICA, MICB*

[14] **NRL_07_SOP_14_01** tested specific sequence polymorphisms:
S01 (ITGA2B), S04 (DBH), S07 (UXT/ZNF81), S08 (PAPPA2/ASTN1), S10 (LTBP1), S11 (DLG2) –
each system has variants A and B, 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

[15] **NRL_03_SOP_14_01** detected alterations: b2a2 (e13a2), b3a2 (b14a2, b), e1a2, e19a2 + rare alterations

[16] **NRL_04_SOP_14_01** detected alterations: alterations b2a2 (e13a2), b3a2 (e14a2), e1a2.

[17] **203_SOP_16 _01** tested genes coding:
D, C,c,E,e,Cw erythrocyte antigens and Kell, Kidd, Duffy, MNS and Dombrock system antigens
Dweak erythrocyte antigens, D variant erythrocyte antigens, molecular basis of AB0 system antigens.

[18] **203_SOP_16 _02 tested genes coding thrombocyte antigens** *HPA-1,-2,-3,-4-, -5,-6,-9,-15*

[19] **NRL_13_SOP_18_01**
List of genes and their exons – TruSight Myeloid Sequencing Panel (Illumina)

Gene	Exon	Gene	Exon	Gene	Exon	Gene	Exon
ABL1	*4-6*	***DNMT3A***	*all*	***KDM6A***	*all*	***RAD21***	*all*
ASXL1	*12*	***ETV6/TEL***	*all*	***KIT***	*2,8-11,13,17*	***RUNX1***	*all*
ATRX	*8-10,17-31*	***EZH2***	*all*	***KRAS***	*2.3*	***SETBP1***	*Part 4*
BCOR	*all*	***FBXW7***	*9-11*	***MLL***	*5-8*	***SF3B1***	*13-16*
BCORL1	*all*	***FLT3***	*14,15,20*	***MPL***	*10*	***SMC1A***	*2,11,16.17*
BRAF	*15*	***GATA1***	*2*	***MYD88***	*3-5*	***SMC3***	*10,13,19,23,25,28*
CALR	*9*	***GATA2***	*2-6*	***NOTCH1***	*26-28.34*	***SRSF2***	*1*
CBL	*8.9*	***GNAS***	*8.9*	***NPM1***	*12*	***STAG2***	*all*

Accredited entity according to ČSN EN ISO 15189:2013:

Ústav hematologie a krevní transfuze
ÚHKT Laboratories
U Nemocnice 2094/1, 128 00 Praha 2

CBLB	*9.10*	***HRAS***	*2.3*	***NRAS***	*2.3*	***TET2***	*3-11*
CBLC	*9.10*	***IDH1***	*4*	***PDGFRA***	*12,14, 18*	***TP53***	*2-11*
CDKN2A	*all*	***IDH2***	*4*	***PHF6***	*all*	***U2AF1***	*2.6*
		IKZF1	*all*	***PTEN***	*5.7*	***WT1***	*7.9*
CSF3R	*14-17*	***JAK2***	*12.14*	***PTPN11***	*3.13*	***ZRSR2***	*all*
CUX1	*all*	***JAK3***	*13*				

[20] **13100_SOP_19_01** Examined types of BCR-ABL1 gene transcripts: major (e13a2,e14a2) and minor (e1a2) transcript

2. **Workplace No.2**

Examinations:

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
816 - Medical Genetics Laboratory			
1.	Analysis of karyotype by conventional cytogenetic method	305_SOP_20_01	Bone marrow, peripheral blood
2.	Analysis of chromosomal anomalies by fluorescent in situ hybridization (FISH)	305_SOP_20_02	Bone marrow, peripheral blood
3.	Analysis of chromosomal anomalies by multicolor fluorescent in situ hybridization (mFISH) and high resolution multicolor banding technique (mBAND)	305_SOP_20_03	Bone marrow, peripheral blood

Český institut pro akreditaci, o.p.s.
NÁRODNÍ AKREDITAČNÍ ORGÁN