The Appendix is an integral part of
Certificate of Accreditation No. 661/2021 of 16/12/2021

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
818 - Haematology Laboratory			
1.	Activated partial thromboplastin time on STA-R analyzer using STA-PTTA kit [APTT-time, APTT-ratio]	105_SOP_08_01	Plasma
2.	Prothrombin time by STA-R analyzer using STA-Neoplastine kit [Prothrombin time, Prothrombin time-ratio]	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 [D-dimers]	105_SOP_08_03	Plasma
4.	Determination of fibrinogen by coagulation method with mechanical detection by STA-R analyzer [Fibrinogen]	105_SOP_08_04	Plasma
5.	Determination of amount-of-substance concentration of D-Dimer by ELFIA analyzer by VIDAS kit D-Dimer Exclusion [D-Dim (ELISA) (VIDAS)]	105_SOP_08_06	Plasma
6.	Reserved		

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Ordinal number	Examination procedure name	Examination procedure identification	Examined object
7.	Spectrophotometric determination of free haemoglobin [Free haemoglobin in plasma]	301_SOP_08 _01	Plasma
8.	Reserved		
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 [HbA2, HbF, HbS]	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
15.-99.	Reserved		

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Ordinal number	Examination procedure name	Examination procedure identification	Examined object
222 - Transfusion Medicine			
100.	Lymphocytotoxic test for the determination of HLA class I antigens and lymphocyte cross-match [HLA serotyping, Lymphocytotoxic crossmatch (between unseparated donor T and B lymphocytes and recipient serum)]	233_SOP_08_01	Blood
101.-104.	Reserved		
105.	Identification of thrombocyte antibodies by PakLx [Identification of thrombocyte antibodies by Pak Luminex]	203_SOP_14_02	Serum
106.	Screening of irregular antibodies against erythrocytes by column agglutination method in DG Gel cards [Scr prot DG Gel]	203_SOP_10 _04	Serum, plasma
107.	Identification of irregular antibodies against erythrocytes by column agglutination method in BioRad (DiaMed) cards [Id prot DiaMed]	203_SOP_10 _05	Serum, plasma
108.	Examination of AB0 Rh D blood group by agglutination method on Galileo system [KS]	203_SOP_11 _01	Blood
109.	Examination of erythrocyte antigens C c E e K Cw by agglutination method on Galileo system [Phenotype Rh, K]	203_SOP_11 _02	Blood
110.	Screening of IgG irregular antibodies against erythrocytes by solid phase method on Galileo system [Scr prot donor]	203_SOP_11 _04	Blood
111.	Direct Coombs test (PAT) by column agglutination method in DG Gel cards [PAT]	203_SOP_12 _07	Blood

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Ordinal number	Examination procedure name	Examination procedure identification	Examined object
112.	Compatibility test by LISS NAT column agglutination method in BioRad cards [DiaMed]"LISS/Coombs" [zkgDM]	203_SOP_12 _09	Blood
113.	Detection of HIT II antibodies (anti-heparin/PF4 IgG class) on BIO-FLASCH system [BioFlash_IgG]	203_SOP_13 _01	Blood
114.	Lymphocytotoxicity test for screening and identification of anti-HLA antibodies [HLA antibodies – Screening: Lymphocytotoxicity test, LCT PRA, LCT reaction score, HLA antibodies – Identification: LCT identification test]	203_SOP_13 _02	Blood
115.	Genotyping of HPA antigens by BLOODchip IDHPAXT method [HPA BLOODchip ID]	203_SOP_14 _06	Blood
116.-199.	Reserved		
816 - Medical Genetics Laboratory			
200.	Examination of cellular chimerism after allogeneic HSCT by electrophoretic analysis of sequence polymorphisms[8] [Examination of cellular chimerism after allogeneic HSCT – elpho]	NRL_01_SOP_14_01	Biological material containing human nuclear DNA
201.	Examination of genotype of main histocompatible system of human being – HLA by PCR-SSP method [9] [Examination of HLA-PCR-SSP method]	NRL_05_SOP_14_01/ procedure A	Biological material containing human nuclear DNA

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Ordinal number	Examination procedure name	Examination procedure identification	Examined object
202.	Examination of genotype of main histocompatible system of human being – HLA by direct sequencing method [9] [Examination of HLA-SBT method]	NRL_05_SOP_14_01/ procedure B	Biological material containing human nuclear DNA
203.	Examination of genotype of main histocompatible system of human being – HLA by real-time PCR[9] method [Examination of HLA – qPCR method]	NRL_05_SOP_14_01 procedure C	Biological material containing human nuclear DNA
204.	Examination of genotype of main histocompatible system of human being – HLA by massive parallel sequencing method [9] [Examination of HLA – NGS method]	NRL_05_SOP_14_01/ Procedure D	Biological material containing human nuclear DNA
205.	Examination of genotype of main histocompatible system of human being – HLA – quality and concentration of isolated DNA [Examination of HLA – DNA isolation]	NRL_05_SOP_14_01/ Annex 01	Biological material containing human nuclear DNA
206.	Examination of cellular chimerism after allogeneic HSCT by real-time PCR analysis of sequence polymorphisms [10] [Examination of cellular chimerism after allogeneic HSCT qPCR]	NRL_07_SOP_14_01	Biological material containing human nuclear DNA
207.	Diagnostic examination of BCR-ABL fusion gene by multiplex RT–PCR method [11] [Diagnostic examination of BCR-ABL]	NRL_03_SOP_14_01	Biological material containing human RNA
208.	Examination of the level of BCR-ABL1 transcript by real-time RT PCR method [12] [Monitoring of BCR-ABL]	NRL_04_SOP_14_01/ procedure A	Peripheral blood, bone marrow

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Ordinal number	Examination procedure name	Examination procedure identification	Examined object
209.	Examination of mutations in kinase domain of BCR-ABL1 by direct sequencing method [Mutations in kinase domain of BCR-ABL1]	NRL_04_SOP_14_01/ procedure B	Peripheral blood, bone marrow
210.	Examination of the number of transcripts of WT1 gene by means of real-time RT-PCR at patients with acute leukemia and MDS/MPN [Examination of WT1 gene expression by real-time RT-PCR]	NRL_02_SOP_14_01	Biological material containing human RNA
211.	Examination of mutations in HBB gene (Haemoglobin beta) by direct sequencing method [Examination of mutations in HBB gene by direct sequencing method]	NRL_06_SOP_14_01	Biological material containing human nuclear DNA
212.	Examination of the presence of mutations in NPM1 gene by fragment analysis [Examinations: Prognostic factors for AML and MDS]	NRL_09_SOP_20_01	Biological material containing human DNA
213.	Examination of the number of transcripts of mutated NPM1 gene by real-time RT-PCR method at patients with AML [Examination of NPM1 gene expression by real-time RT-PCR]	NRL_10_SOP_14_01	Biological material containing human RNA
214.	Examination of the presence of mutations in CEBPA gene by direct sequencing method [Examinations: Prognostic factors for AML and MDS]	NRL_11_SOP_14_01	Biological material containing human nuclear DNA and RNA
215.	Examination of mutations in HBA1 and HBA2 genes by α-Globin StripAssay kit	NRL_12_SOP_16_01	Biological material containing human nuclear DNA

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Ordinal number	Examination procedure name	Examination procedure identification	Examined object
216.	Detection of JAK2 gene V617F mutation in peripheral blood and bone marrow by RT-PCR method [Result of RT-PCR examination of JAK2 V617F mutation]	114_SOP_08_01	Bone marrow, peripheral blood
217.	Genotyping of erythrocyte antigens by RBC-FluoGene method [13] [ERB_FG]	203_SOP_16 _01	Blood
218.	Genotyping of thrombocyte antigens by HPA FluoGene method [14]	203_SOP_16 _02	Blood
219.	Examination of the presence of thrombophilic risk factors by PCR and fluorogenic target-specific hybridization [Thrombophilia]	105_SOP_15_01	Blood
223.	Examination of human genome variants by massive parallel sequencing – myeloid panel[17] [Examinations: Mutations by NGS method – myeloid panel]	NRL_13_SOP_18_01	Biological material containing human nuclear DNA
224.	Detection of mutations in kinase domain of BCR-ABL1 by next generation sequencing (NGS) [18]	13100_SOP_19_01	Biological material containing human RNA
225.	Examination of BCR-ABL1 fusion gene by digital PCR method	13100_SOP_21_01	Biological material containing human DNA and RNA
226	Examination of a panel of 28 fusion genes by real time RT PCR	13100_SOP_21_02	Biological material containing human RNA
227.-299.	Reserved		
802 - Medical microbiology			
300.	Detection of human papillomavirus (HPV) by Hybrid Capture 2 method (HC2) [Hybrid Capture]	318_SOP_08 _01	Smears

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Ordinal number	Examination procedure name	Examination procedure identification	Examined object
301.	Detection of human papillomavirus by reverse hybridization method (RLB)[1] [PCR]	318_SOP_08 _02	Smears, oral cavity lavage, bronchoalveolar lavage, aspirate, exploratory biopsy, paraffin fixed tissue
302.	Examination of markers of blood-borne infections (HIV, HBV, HCV, CMV, Treponema pallidum) by CMIA method [for HIV LABORATORY Ag/Ab, HBsAg, anti-HBs, anti-HBc, anti-HBe, HBeAg, anti-HCV, HCV cAg, anti-CMV IgG, anti-Treponema pallidum; for AMADEUS HIV, HBs Ag, HCV, HCV Ag, TP]	LPVN_SOP_19 _01	Serum
303.-499.	Reserved		
813 - Allergology and Immunology Laboratory			
500.	Determination of lymphoid subpopulations by flow cytometry [2]	116_SOP_21_01	Peripheral blood
501.	Determination of CD34+ stem cells by flow cytometry – single platform protocol [3]	116_SOP_21_02	Peripheral blood, umbilical blood, blood marrow, apheresis products
502.	Determination of PNH erythrocytes neutrophils and monocytes by flow cytometry: diagnosis of paroxysmal nocturnal haemoglobinuria [4]	116_SOP_21_03	Peripheral blood
503.	Leukocyte immunophenotyping by flow cytometry [5]	116_SOP_21_04	Peripheral blood, bone marrow, lymph node, cerebrospinal fluid, malignant exudate
504.	Determination of VASP phosphorylation of thrombocytes by flow cytometry: monitoring of therapy of P2Y12 receptor ADP antagonist [6]	116_SOP_21_05	Peripheral blood
505.	Reserved		

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Ordinal number	Examination procedure name	Examination procedure identification	Examined object
506.	Determination of measurable residual disease in chronic lymphocytic leukemia (CLL) by flow cytometry [15]	116_SOP_21_07	Peripheral blood, bone marrow, cerebrospinal fluid, malignant exudate
507.	Determination of measurable residual disease in acute B-lymphoblastic leukemia (B-ALL) by flow cytometry [16]	116_SOP_21_08	Peripheral blood, bone marrow, cerebrospinal fluid, malignant exudate

Annex:
Flexible scope of accreditation

Examination procedure ordinal numbers:
200-215,223-226

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.

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

[1] **318_SOP_08 _02:** (type HPV 6, 11, 16, 18, 26, 31, 33, 34, 35, 39, 40, 42, 43, 44, 45, 51, 52, 53, 54, 55, 56, 57, 58, 59, 61, 66, 68, 70, 71, 72, 73, 81, 82, 83, 84, 71, 89).

[2] **116_SOP_21_01**: Examined markers: CD3, CD4, CD8, CD19, CD16, CD45, CD56 plus selected additional markers of the expanded lymphocyte immunophenotype

[3] **116_SOP_21_02**: Examined markers: CD34, CD45.

[4] **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.

[5] **116_SOP_21_04:** Investigated markers from the list plus selected additional markers of the extended immunophenotype specific to a particular haematological malignancy.

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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-□□, TCR-□□, isoforms T-beta chains, TdT, TCLP, TRBC1
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

[6] **116_SOP_21_05**: Examined markers: 16C2, CD61.

[7] **Reserved**

[8] **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,

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HLD67, HLD301, HLD53, HLD97, HLD152, HLD128, HLD134, HLD305, HLD48, HLD114, HLD304, HLD131, HLD38, HLD82.

[9] **NRL_05_SOP_14_01 tested genes:**
Procedure A and B:
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.
Procedure C
Presence of *HLA-B*57.*
Procedure D:
HLA class I: *loci A, B, C*
HLA class II: *loci DRB1, DQA, DQB1, DPB1*
NGS = next-generation sequencing.

[10] **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.

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

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

[13)] **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.

[14] **203_SOP_16 _02 tested genes coding thrombocyte antigens** *HPA-1,-2,-3,-4-, -5,-6,-9,-15.*

[15] **116_SOP_21_07:**CD3, CD5, CD19, CD20, CD43, CD79b, CD81, ROR1, Igkappa, Iglambda.

[16] **116_SOP_21_08:**CD10, CD19, CD20, CD22, CD34, CD38, CD45, CD58, CD66c, CD73, CD81, CD123, CD304, HLA-DR.

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[17] **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*
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*
CEBPA	*all*	***IKZF1***	*all*	***PTEN***	*5,7*	***WT1***	*7,9*
CSF3R	*14-17*	***JAK2***	*12,14*	***PTPN11***	*3,13*	***ZRSR2***	*all*
CUX1	*all*	***JAK3***	*13*				

[18] **13100_SOP_19_01** Examined types of BCR-ABL1 gene transcripts: major (e13a2,e14a2) and minor (e1a2) transcript.

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2. **Workplace No.2**

Examinations:

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
816 - Medical Genetics Laboratory			
220.	Analysis of karyotype by conventional cytogenetic method [Conventional cytogenetic analysis]	305_SOP_20_01	Bone marrow, peripheral blood
221.	Analysis of chromosomal anomalies by fluorescent in situ hybridization (FISH) [Analysis of chromosomal anomalies by FISH method]	305_SOP_20_02	Bone marrow, peripheral blood
222.	Analysis of chromosomal anomalies by multicolor fluorescent in situ hybridization (mFISH) and high resolution multicolor banding technique (mBAND) [Analysis of chromosomal deviations by mFISH/mBAND method]	305_SOP_20_03	Bone marrow, peripheral blood

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