

**The Appendix is an integral part of
Certificate of Accreditation No 573/2023 of 31/10/2023**

Accredited entity according to ČSN EN ISO 15189:2013:

**Ústav hematologie a krevní transfuze
CAB Number 8081, Komplement laboratoří ÚHKT
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 |
| 3. Workplace No. 3 | Kateřinská 521/19, 128 00 Praha 2 |

The laboratory applies a flexible approach to the scope of accreditation.

The current "List of activities within the flexible scope" is available on the website <https://www.uhkt.cz/laboratore/komplement-laboratori>.

1. Workplace No. 1

Examinations:

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom ¹
222 - Transfusion Medicine					
1.	HLA system examination	CDC	In-house procedure	Blood	A, B
2.	Cross-match	CDC	In-house procedure	Blood	A, B
3.	Identification of thrombocyte antibodies	Multiplex bead method	Commercial procedure	Serum	A, B
4.	Screening of irregular anti-erythrocyte antibodies	Gel column agglutination	Commercial procedure	Serum, plasma	A, B
5.	Identification of irregular anti-erythrocyte antibodies	Gel column agglutination	Commercial procedure	Serum, plasma	A, B
6.	Direct antiglobulin test	Gel column agglutination	Commercial procedure	Blood	A, B
7.	Detection of HIT-associated antibodies	Immunoassay with luminometric detection	Commercial procedure	Blood	A, B
8.	Examination of antiHLA antibodies	CDC	In-house procedure	Blood	A, B
9.	Examination of compatibility	Gel column agglutination	Commercial procedure	Blood	A, B
10.	Blood type	Microplate agglutination	Commercial procedure	Blood	A, B
11.	Erythrocyte antigens	Microplate agglutination	Commercial procedure	Blood	A, B

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Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom ¹
12.	Screening of irregular anti-erythrocyte antibodies	Solid phase	Commercial procedure	Blood	A, B
802 – Medical Microbiology					
1.	Detection of nucleic acid of infectious agents	Real-Time PCR	Commercial procedure	Clinical material	A, B, C, D
2.	Detection of nucleic acid of infectious agents	Real-Time PCR	Commercial procedure	Clinical material	A, B, C, D
3.	Detection of nucleic acid of infectious agents	Real-Time PCR	Commercial procedure	Clinical material	A, B, C, D
4.	Antibodies to infectious agents	Immunoassay with luminometric detection (automatic)	Commercial procedure	Serum, plasma	A, B, C
5.	HIV markers	Immunoassay with luminometric detection (automatic)	Commercial procedure	Serum, plasma	A, B, C
6.	Antigens of infectious agents	Immunoassay with luminometric detection (automatic)	Commercial procedure	Serum, plasma	A, B, C
7.	Hepatitis B markers	Immunoassay with luminometric detection (automatic)	Commercial procedure	Serum, plasma	A, B, C
813 - Allergology and Immunology Laboratory					
1.	Immunophenotyping of lymphoid subpopulations	Flow cytometry	Commercial procedure	Clinical material	A, B, C, D
2.	Determination of stem cells	Flow cytometry	Commercial procedure	Clinical material	A, B, C, D
3.	Determination of PNH clones	Flow cytometry	In-house procedure	Clinical material	A, B, C, D
4.	Immunophenotyping of leukocytes	Flow cytometry	In-house procedure	Clinical material	A, B, C, D
5.	Examination of VASP phosphorylation in blood platelets	Flow cytometry	Commercial procedure	Clinical material	A, B, C, D

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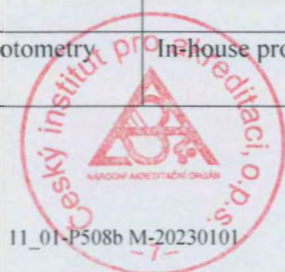
Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom ¹
6.	Determination of residual disease in CLL	Flow cytometry	In-house procedure	Clinical material	A, B, C, D
7.	Determination of residual disease in B-ALL	Flow cytometry	In-house procedure	Clinical material	A, B, C, D
816 – Medical Genetics Laboratory					
1.	Examination of cellular chimerism after allogeneic HSCT	PCR-fragment analysis	In-house procedure, Commercial procedure	Biological material containing nucleic acid	A, B, C, D
2.	Examination of cellular chimerism after allogeneic HSCT	Real-Time PCR	In-house procedure, Commercial procedure	Biological material containing nucleic acid	A, B, C, D
3.	Examination of BCR::ABL1 fusion gene	Multiplex RT PCR	In-house procedure	Biological material containing nucleic acid	A, B, C, D
4.	Examination of level of BCR::ABL1 transcript	Real-Time PCR	In-house procedure	Biological material containing nucleic acid	A, B, C, D
5.	Examination of mutations in kinase domain of BCR::ABL1	Direct sequencing (Sanger)	In-house procedure	Biological material containing nucleic acid	A, B, D
6.	Examination of the number of transcripts in <i>WT1</i> gene	Real-Time PCR	Commercial procedure	Biological material containing nucleic acid	A, B, D
7.	Examination of mutations in <i>HBB</i> gene	Direct sequencing (Sanger)	In-house procedure	Biological material containing nucleic acid	A, B, D
8.	Examination of mutations in <i>NPM1</i> gene	PCR-fragment analysis	In-house procedure	Biological material containing nucleic acid	A, B, D
9.	Examination of the number of transcripts of mutated <i>NPM1</i> gene	Real-Time PCR	Commercial procedure	Biological material containing nucleic acid	A, B, D
10.	Examination of mutations in <i>CEBPA</i> gene	Direct sequencing (Sanger)	In-house procedure	Biological material containing nucleic acid	A, B, D
11.	Examination of mutations in <i>HBA1</i> and <i>HBA2</i> genes	PCR Reverse hybridization	Commercial procedure	Biological material containing nucleic acid	A, B, D
12.	Examination of V617F mutation in <i>JAK2</i> gene	Real-Time PCR	Published procedure	Bone marrow, peripheral blood	A, B
13.	Genotyping of erythrocyte antigens	Real-Time PCR	Commercial procedure	Blood	A, B, C

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Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom ¹
14.	Genotyping of HPA antigens	Real-Time PCR	Commercial procedure	Biological material containing nucleic acid	A, B, C, D
15.	Detection of thrombophilic risk factors	Real-Time PCR	Commercial procedure	Blood	A, B
16.	Examination of human somatic genome variants – myeloid panel	NGS-MPS	Commercial procedure	Biological material containing nucleic acid	A, B, C, D
17.	Examination of BCR::ABL1 mutation	NGS-MPS	In-house procedure	Biological material containing nucleic acid	A, B, C, D
18.	Examination of BCR::ABL1 fusion gene	Digital PCR	In-house procedure	Biological material containing nucleic acid	A, B, D
19.	Examination of fusion genes	Real-Time PCR	Commercial procedure	Biological material containing nucleic acid	A, B, C, D
818 - Haematology Laboratory					
1.	Activated partial thromboplastin time	Coagulation method with mechanical detection of coagulum; Calculation	Commercial procedure	Plasma	A, B
2.	Prothrombin test	Coagulation method with mechanical detection of coagulum; Calculation	Commercial procedure	Plasma	A, B
3.	D-dimers	Immunoassay with turbidimetric detection	Commercial procedure	Plasma	A, B
4.	Fibrinogen	Coagulation method with mechanical detection of coagulum	Commercial procedure	Plasma	A, B
5.	D-dimers	Immunoassay with fluorimetric detection	Commercial procedure	Plasma	A, B
6.	Evaluation of bone marrow aspirate smear	Microscopy	Published procedure	Bone marrow	A, B
7.	Determination of free haemoglobin	Spectrophotometry	In-house procedure	Plasma	A, B



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Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom ¹
8.	Blood count	Flow cytometry; Impedance method; Photometry; Calculations	Commercial procedure	Blood	A, B
9.	Peripheral blood smear analysis	Microscopy	Published procedure	Blood	A, B
10.	Peripheral blood smear analysis	Digital microscopy	Published procedure	Blood	A, B
11.	Quantitative determination of G-6-PDH	Spectrophotometry	Commercial procedure	Blood	A, B
12.	Quantitative determination of haemoglobin	Capillary electrophoresis	Commercial procedure	Blood	A, B, C
13.	Blood count with a with a five-part differential Leukocyte count	Flow cytometry Impedance method; Photometry; Calculations	Commercial procedure	Blood	A, B
14.	Reticulocytes	Flow cytometry; Impedance method; Calculations	Commercial procedure	Blood	A, B

Primary sample collection:

Ordinal Number	Sample collection technique	Identification of sample collection procedure	Collected material	Degrees of freedom ¹
1.	Venipuncture	Published procedure	Venous blood	A, B



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2. Workplace No. 2

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom¹
816 – Medical Genetics Laboratory					
1.	Examination of constitutional karyotype	Conventional cytogenetic analysis	Commercial procedure	Bone marrow, peripheral blood	A, B
2.	Examination of chromosomal aberrations	FISH	Commercial procedure	Bone marrow, peripheral blood	A, B
3.	Examination of chromosomal aberrations	mFISH; mBAND; fluorescence microscopy	Commercial procedure	Bone marrow, peripheral blood	A, B



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3. Workplace No. 3

Vyšetření:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom ¹
816 – Medical Genetics Laboratory					
1.	Examination of HLA genotype	PCR-SSP	Commercial procedure	Biological material containing nucleic acid	A, B, C, D
2.	Examination of HLA genotype	Real-Time PCR	Commercial procedure	Biological material containing nucleic acid	A, B, C, D
3.	Examination of HLA genotype	NGS-MPS	Commercial procedure	Biological material containing nucleic acid	A, B, C, D
4.	Examination of HLA genotype	Spectrophotometry	Commercial procedure	Biological material containing nucleic acid	A, B, D

Explanatory notes:

¹ Established degrees of freedom according to MPA 00-09-...:

A – Flexibility concerning the documented examination/ sample collection procedure

B – Flexibility concerning the technique

C – Flexibility concerning the analytes / parameters

D – Flexibility concerning the examined material

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

FISH	Fluorescence In Situ Hybridization
HBB	Haemoglobin beta
mBAND	High resolution multicolor banding
MPS	Massively Parallel Sequencing
NAT	Indirect Antiglobulin Test
NGS	Next Generation Sequencing – Massively Parallel Sequencing
PCR	Polymerase Chain Reaction
Real-Time PCR	Real-Time Polymerase Chain Reaction
PCR-SSP	Polymerase Chain Reaction with Sequence Specific Primers
CDC	Microlymphocytotoxic test
Cross-match	Cross-match test
HIT	Heparin-Induced Thrombocytopenia
PNH	Paroxysmal Nocturnal Hemoglobinuria

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HSCT
Multiplex RT PCR
CLL
B-ALL

Hematopoietic Stem Cell Transplantation
Multiplex Reverse Transcription Polymerase Chain Reaction
Chronic Lymphocytic Leukemia
acute B-lymphoblastic Leukemia

