

**The Appendix is an integral part of
Certificate of Accreditation No. 178/2024 of 18/04/2024**

Accredited entity according to ČSN EN ISO 15189 ed. 2:2013:

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.	Reserved				
2.	Cross-match	CDC	In-house procedure	Blood	A, B
3.	Identification of thrombocyte antibodies	Multiplex bead method	Commercial procedure	Blood	A, B
4.	Screening of irregular anti-erythrocyte antibodies	Gel column agglutination	Commercial procedure	Serum	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	Serum, plasma	A, B
7.	Detection of HIT-associated antibodies	Immunoassay with luminometric detection	Commercial procedure	Blood	A, B
8.	Reserved			Blood	
9.	Examination of compatibility	Gel column 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
10.	Blood type	Microplate agglutination	Commercial procedure	Blood	A, B
11.	Erythrocyte antigens	Microplate agglutination	Commercial procedure	Blood	A, B
12.	Screening of irregular anti-erythrocyte antibodies	Solid phase	Commercial procedure	Blood	A, B
13.	Identification of anti-erythrocyte antibodies	Gel column agglutination	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

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Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
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
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
8.	Determination of residual disease in MM	Flow cytometry	In-house procedure	Clinical material	A, B, C, D
9.	Determination of residual disease in AML	Flow cytometry	In-house procedure	Clinical material	A, B, C, D
10.	Examination of antiHLA antibodies	xMAP technology	Commercial procedure	Blood	A, B
11.	Examination of HLA system	CDC	In-house procedure	Blood	A, B
12.	Examination of HLA antibodies	CDC	In-house procedure	Blood	A, B
816 – Medical Genetics Laboratory					
1.-2.	Reserved				
3.	Examination of somatic genome variants	Multiplex RT-PCR	In-house procedure	Biological material containing nucleic acid	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
4.	Examination of somatic genome variants	Real-Time PCR	In-house procedure	Biological material containing nucleic acid	A, B, C, D
5.	Examination of somatic genome variants	Direct sequencing (Sanger)	In-house procedure	Biological material containing nucleic acid	A, B, D
6.	Examination of somatic genome variants	Real-Time PCR	Commercial procedure	Biological material containing nucleic acid	A, B, D
7.	Examination of germline genome variants	Direct sequencing (Sanger)	In-house procedure	Biological material containing nucleic acid	A, B, D
8.	Examination of somatic genome variants	PCR-fragment analysis	In-house procedure	Biological material containing nucleic acid	A, B, D
9.	Examination of somatic genome variants	Real-Time PCR	Commercial procedure	Biological material containing nucleic acid	A, B, D
10.	Reserved				
11.	Examination of germline genome variants	PCR Reverse hybridization	Commercial procedure	Biological material containing nucleic acid	A, B, D
12.	Examination of somatic genome variants	Real-Time PCR	Published procedure	Bone marrow, peripheral blood	A, B
13.	Examination of germline genome variants	PCR-SSP	Commercial procedure	Blood	A, B, C
14.	Examination of germline genome variants	PCR-SSP	Commercial procedure	Biological material containing nucleic acid	A, B, C, D
15.	Examination of germline genome variants	Real-Time PCR	Commercial procedure	Blood	A, B
16.	Examination of somatic genome variants	NGS-MPS	Commercial procedure	Biological material containing nucleic acid	A, B, C, D
17.	Examination of somatic genome variants	NGS-MPS	In-house procedure	Biological material containing nucleic acid	A, B, C, D
18.	Examination of somatic genome variants	Digital PCR	In-house procedure	Biological material containing nucleic acid	A, B, D

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Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
19.	Examination of somatic genome variants	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
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

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Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom¹
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
15.	Haemocoagulation factors in the intrinsic pathway	Coagulation method with mechanical detection of coagulum	Commercial procedure	Plasma	A, B, C
16.	Antithrombin	Chromogenic method	Commercial procedure	Plasma	A, B

Primary sample collection:

Ordinal Number	Sample collection technique	Identification of sample collection procedure	Collected material	Degrees of freedom¹
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 freedom ¹
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

Examinations:

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
5.	Examination of germline genome variants	PCR-fragment analysis	In-house procedure; Commercial procedure	Biological material containing nucleic acid	A, B, C, D
6.	Examination of somatic genome variants	PCR-fragment analysis	In-house procedure; Commercial procedure	Biological material containing nucleic acid	A, B, C, D
7.	Examination of germline genome variants	Real-Time PCR	In-house procedure; Commercial procedure	Biological material containing nucleic acid	A, B, C, D
8.	Examination of somatic genome variants	Real-Time PCR	In-house procedure; Commercial procedure	Biological material containing nucleic acid	A, B, C, 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.

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FISH	Fluorescence In Situ Hybridization
mBAND	Fluorescence In Situ Hybridization
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	Heparin-Induced Thrombocytopenia
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