EA MLA Signatory
Český institut pro akreditaci, o.p.s.
(Czech Accreditation Institute)
Hájkova 2747/22, Žižkov, 130 00 Praha 3

issues

according to section 16 of Act No. 22/1997 Coll., on technical requirements for products and on changes and amendments to some Acts, as amended

CERTIFICATE OF ACCREDITATION

No. **325/2025**

Ústav hematologie a krevní transfuze
with registered office U Nemocnice 2094/1, 128 00 Praha 2
Company Registration No. 00023736

for the Medical Laboratory No. **8081**
Komplement laboratoří ÚHKT

Scope of accreditation:

Laboratory diagnostics in clinical biochemistry, haematology (including flow cytometry methods), immunohaematology and transfusion service, cytogenetics, molecular genetics and medical microbiology, including shared examination procedures to the extent as specified in the appendix to this Certificate.

This Certificate of Accreditation is a proof of accreditation issued on the basis of assessment of fulfillment of the accreditation criteria in accordance with

ČSN EN ISO 15189 ed. 3:2023

In its activities performed within the scope and for the period of validity of this Certificate, the abovementioned Accredited Body is entitled to refer to this Certificate, provided that the accreditation is not suspended and the Accredited Body meets the specified accreditation requirements in accordance with the relevant regulations applicable to the activity of an accredited conformity assessment body.

This Certificate of Accreditation replaces, to the full extent, Certificate No.: 670/2024 of 10/12/2024, and/or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **01/11/2027**

Prague: 30/06/2025

Český institut pro akreditaci, o.p.s.
«CAI»

Signed in the Czech original:
Milena Lochmanová on 30/06/2025

Milena Lochmanová
Director of the Department
of Medical Laboratories
Czech Accreditation Institute

This translation of the Czech original has been issued by: Jana Chvalovská

The Appendix is an integral part of
Certificate of Accreditation No. 325/2025 of 30/06/2025

Accredited entity according to ČSN EN ISO 15189 ed. 3:2023:

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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	Serum	A, B
4.	Screening of irregular anti-erythrocyte antibodies	Gel column agglutination (manual)	Commercial procedure	Serum, plasma	A, B
5.	Identification of irregular anti-erythrocyte antibodies	Gel column agglutination (manual)	Commercial procedure	Serum, plasma	A, B
6.	Direct antiglobulin test	Gel column agglutination (manual)	Commercial procedure	Blood	A, B
7.	Detection of HIT-associated antibodies	Immunoassay with luminometric detection	Commercial procedure	Blood	A, B
8.	Reserved				
9.	Examination of compatibility	Gel column agglutination (manual)	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
13.	Identification of anti-erythrocyte antibodies	Gel column agglutination (manual)	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 (automated)	Commercial procedure	Serum, plasma	A, B, C
5.	HIV markers	Immunoassay with luminometric detection (automated)	Commercial procedure	Serum, plasma	A, B, C
6.	Antigens of infectious agents	Immunoassay with luminometric detection (automated)	Commercial procedure	Serum, plasma	A, B, C
7.	Reserved				
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

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom[1]
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 antiHLA antibodies	CDC	In-house procedure	Blood	A, B
814 - Toxicological Laboratory					
1.	Determination of antifungal drugs	LC-MS/MS	Commercial procedure	Blood	A, B, C
2.	Determination of immunosuppressants	LC-MS/MS	Commercial procedure	Blood	A, B, C
816 – Medical Genetics Laboratory					
1.-2.	Reserved				
3.	Examination of somatic genome variants	Multiplex RT-PCR	In-house procedure	Biological material containing human nucleic acid	A, B, C, D
4.	Examination of somatic genome variants	Real-Time PCR	In-house procedure	Biological material containing human nucleic acid	A, B, C, D
5.	Examination of somatic genome variants	Direct sequencing (Sanger)	In-house procedure	Biological material containing human nucleic acid	A, B, D
6.	Examination of somatic genome variants	Real-Time PCR	Commercial procedure	Biological material containing human nucleic acid	A, B, D
7.	Examination of germline genome variants	Direct sequencing (Sanger)	In-house procedure	Biological material containing human nucleic acid	A, B, D
8.	Examination of somatic genome variants	PCR with fragment analysis	In-house procedure	Biological material containing human 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]
9.	Examination of somatic genome variants	Real-Time PCR	Commercial procedure	Biological material containing human nucleic acid	A, B, D
10.	Reserved				
11.	Examination of germline genome variants	PCR with reverse hybridization	Commercial procedure	Biological material containing human 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 human 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 human nucleic acid	A, B, C, D
17.	Examination of somatic genome variants	NGS-MPS	In-house procedure	Biological material containing human nucleic acid	A, B, C, D
18	Examination of somatic genome variants	Digital PCR	In-house procedure	Biological material containing human nucleic acid	A, B, D
19.	Examination of somatic genome variants	Real-Time PCR	Commercial procedure	Biological material containing human nucleic acid	A, B, C, D
818 - Haematology Laboratory					
1.	Activated partial thromboplastin time	Coagulation method with mechanical detection of coagulum; Calculations	Commercial procedure	Plasma	A, B
2.	Prothrombin test	Coagulation method with mechanical detection of coagulum; Calculations	Commercial 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]
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
12.	Quantitative determination of haemoglobins	Capillary electrophoresis	Commercial procedure	Blood	A, B, C
13.	Blood count 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

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Primary sample collection:

Ordinal Number[2]	Sample collection technique	Identification of sample collection procedure	Collected material	Degrees od freedom[1]
1.	Venepuncture	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 human nucleic acid	A, B, C, D
2.	Examination of HLA genotype	Real-Time PCR	Commercial procedure	Biological material containing human nucleic acid	A, B, C, D
3.	Examination of HLA genotype	NGS-MPS	Commercial procedure	Biological material containing human nucleic acid	A, B, C, D
4.	Examination of HLA genotype	Spectrophotometry	Commercial procedure	Biological material containing human nucleic acid	A, B, C, D
5.	Examination of germline genome variants	PCR-fragment analysis	In-house procedure; Commercial procedure	Biological material containing human nucleic acid	A, B, C, D
6.	Examination of somatic genome variants	PCR-fragment analysis	In-house procedure; Commercial procedure	Biological material containing human nucleic acid	A, B, C, D
7.	Examination of germline genome variants	Real-Time PCR	In-house procedure; Commercial procedure	Biological material containing human nucleic acid	A, B, C, D
8.	Examination of somatic genome variants	Real-Time PCR	In-house procedure; Commercial procedure	Biological material containing human nucleic acid	A, B, C, D
9.	Examination of HLA genotype	NGS-MPS (2nd generation)	Commercial procedure	Biological material containing human 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	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

"This document is an appendix to the certificate of accreditation. In case of any discrepancies between the English and Czech versions, the Czech version shall prevail, both for the certificate appendix and the certificate itself. "