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. **18/2026**

Fakultní nemocnice Brno
with registered office Jihlavská 340/20, Bohunice, 625 00 Brno
Company Registration No. 65269705

for the Medical Laboratory No. **8213**
Internal Hematology and Oncology Clinic, Center of Molecular Biology and Gene Therapy

Scope of accreditation:

Examinations in the field of molecular genetics and cytogenetics 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.: 555/2025 of 31/10/2025, and/or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **31/10/2030**

Prague: 12/01/2026

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

Signed in the Czech original:
Milena Lochmanová on 12/01/2026

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 18/2026 of 12/01/2026

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

Fakultní nemocnice Brno
CAB Number 8213, Internal Hematology and Oncology Clinic, Center of Molecular Biology and Gene Therapy
Černopolní 212/9, 613 00 Brno

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 www.cmbgt.cz.

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 tumor karyotype	Conventional cytogenetic analysis	In-house method	Bone marrow, solid tumor tissue, peripheral blood, node	A, B
2.	Examination of constitutional karyotype	Conventional cytogenetic analysis	In-house method	Peripheral blood, umbilical cord blood, amniotic fluid, chorionic villi, fetal tissue	A, B
3.	Examination of acquired chromosomal aberrations	Microscopy	In-house method	Peripheral blood	A, B
4.	Examination of chromosomal aberrations	FISH	In-house method	Peripheral blood, umbilical cord blood, amniotic fluid, chorionic villi, fetal tissue, buccal smear, bone marrow, solid tumor tissue, node	A, B
5.	Examination of unbalanced chromosomal aberrations	aCGH	In-house method	Peripheral blood, umbilical cord blood, amniotic fluid, chorionic villi, fetal tissue, buccal smear, bone marrow, solid tumor tissue, node	A, B
6.	Examination of germline genome variants	PCR with electrophoretic product detection	Commercial procedure; In-house method	Biological material containing human nucleic acid	A, B, C
7.	Examination of germline genome variants	Sanger sequencing	In-house procedure	Biological material containing human nucleic acid	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]
8.	Examination of germline genome variants	NGS-MPS	In-house procedure	Biological material containing human nucleic acid	A, B, C
9.	Examination of somatic genome variants	NGS-MPS	Published procedure	Peripheral blood, bone marrow	A, B, C
10.	Examination of germline genome variants	Real-Time PCR	Commercial procedure; Published procedure	Biological material containing human nucleic acid	A, B, C
11.	Examination of somatic genome variants	Real-Time PCR	Commercial procedure; Published procedure	Peripheral blood, bone marrow	A, B, C
12.	Examination of germline genome variants	MLPA	Commercial procedure; In-house procedure	Biological material containing human nucleic acid	A, B, C
13.	Examination of chromosomal aberrations	MLPA	Commercial procedure; In-house procedure	Biological material containing human nucleic acid	A, B, C
14.	Examination of germline genome variants	Fragmentation analysis	Commercial procedure; In-house procedure; Published procedure	Biological material containing human nucleic acid	A, B, C
15.	Examination of chromosome aneuploidies	Fragmentation analysis	Commercial procedure	Peripheral blood, amniotic fluid, chorionic villi	A, B, C
16.	Examination of germline genome variants	Reverse hybridization	Commercial procedure; In-house procedure	Biological material containing human nucleic acid	A, B, C
17.	Examination of somatic genome variants	RQ-PCR	In-house procedure; Published procedure	Biological material containing human nucleic acid	A, B, C

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Černopolní 212/9, 613 00 Brno

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom[1]
18.	Examination of somatic genome variants	Fragmentation analysis	Commercial procedure	Peripheral blood, bone marrow	A, B, C

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

E – Flexibility concerning the POCT delivery points

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

aCGH	Array Comparative Genome Hybridization
FISH	Fluorescence *In-Situ* Hybridization
MLPA	Multiplex ligation-dependent probe amplification
NGS-MPS	Next Generation Sequencing – Massively Parallel Sequencing
Real-Time PCR	Polymerase Chain Reaction in real time
RQ-PCR	Quantitative Polymerase Chain Reaction

"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. "