



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. 441/2025

EUC Laboratoře CGB a.s.
with registered office Kořenského 1210/10, Vítkovice, 703 00 Ostrava
Company Registration No. 25386735

for the Medical Laboratory No. **8025**
CGB laboratory

Scope of accreditation:

Examinations in the field of pathology (histopathology, cytopathology, molecular pathology) and medical genetics (cytogenetics, molecular genetics) 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.: 27/2025 of 23/01/2025, and/or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **28/05/2029**

Prague: 29/08/2025



Signed in the Czech original:
Marek Vyskočil on 29/08/2025

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. 441/2025 of 29/08/2025**

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

EUC Laboratoře CGB a.s.
CAB Number 8025, CGB laboratory
Kořenského 1210/10, Vítkovice, 703 00 Ostrava

Medical laboratory locations:

- | | | |
|----|--------------------------------------|---|
| 1. | Pathology Laboratory | Kořenského 1210/10, Vítkovice, 703 00 Ostrava |
| 2. | Cytogenetics Laboratory | Kořenského 1317/12, Vítkovice, 703 00 Ostrava |
| 3. | Molecular Genetics Laboratory | Kořenského 1331/6, Vítkovice, 703 00 Ostrava |
| 4. | Pathology Laboratory | třída Tomáše Bati 5135, 760 01 Zlín |
| 5. | Molecular Genetics Laboratory | Opavská 962/39, 708 00 Ostrava |
| 6. | Pathology Laboratory | Vydmuchov 399/5, 734 01 Karviná, Ráj |
| 7. | Pathology Laboratory | Zakladatelská 975/22, 735 06 Karviná – Nové Město |
| 8. | Pathology Laboratory | Sušilova 1835/21, Přerov I-Město, 750 02 Přerov |
| 9. | Pathology Laboratory | Škrobárenská 511/5, 617 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
<https://www.euclaboratore.cz/o-nas/akreditace-a-certifikaty/>.*

1. Pathology Laboratory

Examinations:

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
817 - Clinical Cytology Laboratory					
1.	Cervicovaginal cytological examination and diagnostics (screening)	Microscopy	Published procedure	Cells from the cervix, vagina and vulva	A, B
823 - Pathology Laboratory					
1.	Histological examination and diagnostics	Microscopy	Published procedure	Tissues	A, B
2.	Intraoperative histological and cytological examination and diagnostics	Microscopy	Published procedure	Tissues, cells	A, B

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom¹
3.	Cytological examination and diagnostics	Microscopy	Published procedure	Cells	A, B
4.	Histochemical and cytochemical examination and diagnostics	Microscopy	Published procedure	Tissues, cells	A, B
5.	Immunohistochemical and immunocytochemical examination of antigens	Microscopy	Published procedure; Commercial procedure	Tissues, cells	A, B, C

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2. Cytogenetics Laboratory

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	Published procedure	Peripheral blood, amniotic fluid, chorionic villi, fetal tissue	A, B
2.	Examination of tumor karyotype	Conventional cytogenetic analysis	Published procedure	Bone marrow, peripheral blood	A, B
3.	Examination of chromosomal aberrations	FISH	Commercial procedure	Peripheral blood, amniotic fluid, bone marrow, chorionic villi, tissue (fetal, tumor)	A, B
4.	Examination of unbalanced chromosomal aberrations	aCGH	Commercial procedure	Biological material containing nuclear DNA	A, B, D

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3. Molecular Genetics Laboratory

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 germline genome variants	PCR with electrophoretic detection	Published procedure	Biological material containing DNA	A, B, C, D
2.	Examination of somatic genome variants	PCR with electrophoretic detection	Published procedure	Biological material containing tumor DNA	A, B, C, D
3.	Examination of germline genome variants	PCR – RFLP	Published procedure	Biological material containing DNA	A, B, C, D
4.	Examination of somatic genome variants	Real-Time PCR with electrophoretic detection	Published procedure	Biological material containing nucleic acids	A, B, C, D
5.	Examination of somatic genome variants	Real-Time PCR	Commercial procedure	Biological material containing tumor DNA	A, B, C, D
6.	Examination of germline genome variants	Real-Time PCR	Published procedure; Commercial procedure	Biological material containing DNA	A, B, C, D
7.	Examination of germline genome variants	Capillary electrophoresis	Commercial procedure	Biological material containing DNA	A, B, C, D
8.	Chromosome aneuploidy testing	Capillary electrophoresis	Commercial procedure	Biological material containing DNA	A, B, C, D
9.	Examination of somatic genome variants	SNaPshot	Published procedure	Biological material containing tumor DNA	A, B, C, D
10.	Examination of germline genome variants	MLPA	Commercial procedure	Biological material containing DNA	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
11.	Examination of germline genome variants	Direct sequencing	Published procedure	Biological material containing DNA	A, B, C, D
12.	Examination of somatic genome variants	Direct sequencing	Published procedure	Biological material containing tumor DNA	A, B, C, D
13.	Examination of germline genome variants	NGS - MPS	Commercial procedure	Biological material containing DNA	A, B, C, D
14.	Examination of somatic genome variants	NGS - MPS	Commercial procedure	Biological material containing tumor DNA	A, B, C, D
817 - Clinical Cytology Laboratory					
1.	Detection and typization of HPV	Real-Time PCR	Commercial procedure	Cells	A, B, C
823 - Pathology Laboratory					
1.	Examination of somatic genome variants	NGS - MPS	Commercial procedure	Biological material containing tumor DNA	A, B, C, D
2.	Examination of somatic genome variants	Capillary electrophoresis	Commercial procedure	Biological material containing tumor DNA	A, B, C, D

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4. Pathology Laboratory

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
823 - Pathology Laboratory					
1.	Histological examination and diagnostics	Microscopy	Published procedure	Tissues	A, B
2.	Intraoperative histological and cytological examination and diagnostics	Microscopy	Published procedure	Tissues, cells	A, B
3.	Cytological examination and diagnostics	Microscopy	Published procedure	Cells	A, B
4.	Immunohistochemical and immunocytochemical examination of antigens	Microscopy	Published procedure; Commercial procedure	Tissues, cells	A, B, C

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5. Molecular Genetics Laboratory

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 germline genome variants	PCR with electrophoretic detection	Published procedure; Commercial procedure	Peripheral blood	A, B, C D
2.	Examination of germline genome variants	PCR with reverse hybridization	Commercial procedure	Biological material containing DNA	A, B, C D
3.	Examination of somatic genome variants	PCR with reverse hybridization	Commercial procedure	Biological material containing tumor DNA	A, B, C, D
4.	Examination of germline genome variants	PCR – RFLP	Published procedure	Biological material containing DNA	A, B, C, D
5.	Examination of germline genome variants	Real-Time PCR	Commercial procedure	Biological material containing DNA	A, B, C D
817 - Clinical Cytology Laboratory					
1.	Detection and typization of HPV	Real-Time PCR	Commercial procedure	Cells	A, B, C

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6. Pathology Laboratory

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
823 - Pathology Laboratory					
1.	Intraoperative histological and cytological examination and diagnostics	Microscopy	Published procedure	Tissues, cells	A, B

7. Pathology Laboratory

Examinatons:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
823 - Pathology Laboratory					
1.	Intraoperative histological and cytological examination and diagnostics	Microscopy	Published procedure	Tissues, cells	A, B

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8. Pathology Laboratory

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
817 - Clinical Cytology Laboratory					
1.	Cervicovaginal cytological examination and diagnostics (screening)	Microscopy	Published procedure	Cells from the cervix, vagina and vulva	A, B
823 - Pathology Laboratory					
1.	Histological examination and diagnostics	Microscopy	Published procedure	Tissues	A, B
2.	Cytological examination and diagnostics	Microscopy	Published procedure	Cells	A, B
3.	Immunohistochemical and immunocytochemical examination of antigens	Microscopy	Published procedure; Commercial procedure	Tissues, cells	A, B, C

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9. Pathology Laboratory

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
823 - Pathology Laboratory					
1.	Histological examination and diagnostics	Microscopy	Published procedure	Tissues	A, B
2.	Cytological examination and diagnostics	Microscopy	Published procedure	Cells	A, B

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.

FISH	Fluorescence <i>in situ</i> hybridization
aCGH	Oligonucleotide array comparative genomic hybridization
PCR	Polymerase chain reaction
RFLP	Restriction fragment length polymorphism
NGS-MPS	Massive parallel sequencing
MLPA	Multiplex Ligation-Dependent Probe Amplification
Real-Time PCR	PCR in real time
SNaPshot assay	Primer extension method

"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."