



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. 635/2025

Bioptická laboratoř s. r. o.
with registered office Mikulášské náměstí 628/4, Východní Předměstí, 326 00 Plzeň
Company Registration No. 49197827

for the Medical Laboratory No. **8027**
Bioptická laboratoř s. r. o.

Scope of accreditation:

Laboratory diagnostics in the field of histopathology, including peroperational examinations, cytopathology including screening examinations of cervical carcinoma and examinations of HPV, cytogenetics, molecular genetics and medical microbiology by molecular biology methods, including shared examinations 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.: 438/2024 of 30/08/2024, and/or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **30/08/2029**

Prague: 05/12/2025



Signed in the Czech original:
Marek Vyskočil on 05/12/2025

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. 635/2025 of 05/12/2025**

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

Bioptická laboratoř s. r. o.

CAB Number 8027, Bioptická laboratoř s. r. o.

Mikulášské náměstí 628/4, Východní Předměstí, 326 00 Plzeň

Medical laboratory locations:

- | | |
|--|---|
| 1. Biopsy Section – Section B | Mikulášské nám. 628/4, 326 00 Plzeň
Mikulášské nám. 589/5, 326 00 Plzeň
Rejskova 614/8, 326 00 Plzeň
Rejskova 855/10, 326 00 Plzeň |
| 2. Cytology section – Section C | Mikulášské nám. 392/7, 326 00 Plzeň
Barrandova 392/2, 326 00 Plzeň
Barrandova 388/4, 326 00 Plzeň |
| 3. Molecular-genetics section – Section G | Rejskova 855/10, 326 00 Plzeň
Rejskova 560/12, 326 00 Plzeň |
| 4. Working Site Jilemnice | Masarykova městská nemocnice a.s.,
Nemocnice Jilemnice, Metyšova 465,
514 15 Jilemnice |
| 5. Working Site Jičín | Oblastní nemocnice Jičín a.s., Bolzanova 512,
506 43 Jičín |
| 6. Working Site Strakonice | Nemocnice Strakonice, a.s., Radomyšlská 336,
386 01 Strakonice |

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.biopicka.cz/cz/laborator/akreditace.php, <https://www.biopicka.cz/en/laboratory/accreditation.php>

1. Biopsy Section – Section B

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.	Histological examination and diagnostics	Microscopy	Published procedure	Hard tissues	A, B
3.	Cytological examinations and diagnostics	Microscopy	Published procedure	Cells from puncture of tissue, body fluids and pathological cavity content	A, B

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Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
4.	Immunohistochemical and immunocytochemical examination of antigens	Microscopy	Commercial procedure; Published procedure; In-house procedure	Tissues, cells	A, B, C
5.	Examination of histological and cytological samples	<i>In situ</i> hybridization	Commercial procedure;	Tissues, cells	A, B, C

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2. Cytology section – Section C

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	Commercial procedure; Published procedure	Cells from the cervix, vagina and vulva	A, B
2.	Examination of gynecologic cytology in thin layer (LBC)	Microscopy	Commercial procedure; Published procedure	Cells from the cervix, vagina and vulva	A, B

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3. Molecular-genetics section – Section G

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
802 – Medical Microbiology					
1.	Detection of nucleic acids of infectious agents	PCR – Direct sequencing	Commercial procedure; Published procedure; In-house procedure	Clinical material	A, B, C, D
2.	Detection of nucleic acids of infectious agents	Real-Time PCR	Commercial procedure; Published procedure; In-house procedure	Clinical material	A, B, C, D
3.	Detection of nucleic acids of infectious agents	TMA	Commercial procedure	Clinical material	A, B, C, D
816 – Medical Genetics Laboratory					
1.	Examination of chromosomal aberrations	FISH	Commercial procedure; Published procedure;	Biological material containing human DNA/ RNA	A, B, C, D
2.	Examination of somatic genome variants	Direct sequencing	Commercial procedure; Published procedure;	Biological material containing human DNA/ RNA	A, B, C, D
3.	Examination of somatic genome variants	PCR - Fragment analysis	Commercial procedure; Published procedure; In-house procedure	Biological material containing human DNA/ RNA	A, B, C, D
4.	Examination of somatic genome variants	NGS – MPS	Commercial procedure; Published procedure; In-house procedure	Biological material containing human DNA/ RNA	A, B, C, D
5.	Examination of germline genome variants	Real-Time PCR	Commercial procedure	Biological material containing human DNA/ RNA	A, B, C, D
6.	Noninvasive examination of genome	NGS – MPS	Commercial procedure	Blood, 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
7.	Examination of somatic genome variants	aCGH	Commercial procedure	Biological material containing human DNA/ RNA	A, B, C, D
8.	Examination of somatic genome variants	Real-Time PCR	Commercial procedure	Biological material containing human DNA/ RNA	A, B, C, D
9.	Examination of germline genome variants	NGS – MPS	Commercial procedure	Biological material containing human DNA/ RNA	A, B, C, D

817 - Clinical Cytology Laboratory

1.	Detection and typization of human papillomavirus	Real-Time PCR	Commercial procedure	Clinical material	A, B, C, D
2.	Detection and typization of human papillomavirus	TMA	Commercial procedure	Clinical material	A, B, C, D

823 - Pathology Laboratory

1.	Examination of chromosomal aberrations	FISH	Commercial procedure; Published procedure	Biological material containing human DNA/ RNA	A, B, C, D
2.	Examination of somatic genome variants	NGS – MPS	Commercial procedure; Published procedure	Biological material containing human DNA/ RNA	A, B, C, D
3.	Examination of somatic genome variants	Real-Time PCR	Commercial procedure	Biological material containing human DNA/ RNA	A, B, C, D
4.	Examination of somatic genome variants	Direct sequencing	Published procedure	Biological material containing human DNA/ RNA	A, B, C, D
5.	Examination of somatic genome variants	PCR - Fragment analysis	Commercial procedure	Biological material containing human DNA/ RNA	A, B, C, D

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4. Working Site Jilemnice

5. Working Site Jičín

6. Working Site Strakonice

Examinations:

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

PCR	Polymerase <i>chain reaction</i>
NGS-MPS	Next <i>generation sequencing</i> (Massively parallel sequencing)
TMA	<i>Transcription Mediated Amplification</i>
FISH	Fluorescence <i>in situ</i> hybridization
Real-Time PCR	Polymerase <i>chain reaction</i> in real time
aCGH	array comparative genomic hybridisation

"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."