

**The Appendix is an integral part of
Certificate of Accreditation No. 438/2024 of 30/08/2024**

Accredited entity according to 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

<https://www.biopticka.cz/cz/laborator/akreditace.php>

<https://www.biopticka.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	Commercial procedure ; Published procedure	Tissues	A, B
2.	Histological examination and diagnostics	Microscopy	Commercial procedure ; Published procedure	Hard tissues	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 examinations and diagnostics	Microscopy	Commercial procedure ; Published procedure	Cells from puncture of tissue, body fluids and pathological cavity content	A, B
4.	Immunohistochemical and immunocytochemical examination of antigens	Microscopy	Commercial procedure ; Published procedure; In-house 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.	Cerviko-vaginal 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;	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

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
6.	Noninvasive prenatal testing (NIPT)	NGS – MPS	Commercial procedure	Blood, plasma	A, B, C
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
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

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

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

"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. "