



Accredited entity according to ČSN EN ISO 15189:2013:

Bioptická laboratoř s. r. o.
CAB Number 8027, Bioptická laboratoř s. r. o.
Mikulášské nám. 628/4, 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
<https://www.biopticka.cz/cz/laborator/akreditace.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, C
2.	Histological examination and diagnostics	Microscopy	Commercial procedure; published procedure	Hard tissues	A, B, C



The Appendix is an integral part of
Certificate of Accreditation No. 373/2023 ze dne: 13. 07. 2023

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/ equipment	Examined material	Degrees of freedom ¹
3.	Cytological examinations and diagnostics	Microscopy	Commercial procedure; published procedure	Cells	A, B, C
4.	Immunohistochemical examination of antigens	Microscopy	Commercial procedure; published procedure; in-house method	Tissues, cells	A, B, C

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	A, B, C, D
2.	Examination of gynecologic cytology in thin layer (LBC) by Thin Prep PAP Test method	Microscopy	Commercial procedure; published procedure	Cells	A, B, C, D



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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 followed by electrophoretic and sequencing detection	Commercial procedure, published procedure; in-house method	Clinical material	A, B, C, D
2.	Detection of nucleic acids of infectious agents	Real-Time PCR	Commercial procedure, published procedure; in-house method	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 DNA	A, B, C, D
2.	Examination of somatic genome variants	Direct sequencing	Commercial procedure; published procedure	Biological material containing DNA	A, B, C, D
3.	Examination of germline genome variants	Direct sequencing	Commercial procedure; published procedure	Biological material containing DNA	A, B, C, D
4.	Examination of somatic genome variants	PCR with fragment analysis	Commercial procedure; published 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
5.	Examination of somatic genome variants	NGS	Commercial procedure; published procedure	Biological material containing DNA	A, B, C, D
6.	Examination of germline genome variants	Real-Time PCR	Commercial procedure	Biological material containing DNA	A, B, C, D
7.	Non-invasive prenatal test (NIPT) of chromosome aneuploidies	NGS	Commercial procedure	Peripheral blood, plasma	A, B, C
8.	Examination of somatic genome variants	PCR with fragment analysis	Commercial procedure	Biological material containing DNA	A, B, C, D
817 - Clinical Cytology Laboratory					
1.	Detection and typing of human papillomavirus	Real-Time PCR	Commercial procedure	Clinical material	A, B, C, D
2.	Detection and typing of human papillomavirus	TMA	Commercial procedure	Clinical material	A, B, C, D
823 - Pathology Laboratory					
1.	Examination of histological and cytological samples	In-situ hybridization	Commercial procedure; published procedure	Biological material containing DNA/RNA	A, B, C, D
2.	Examination of somatic genome variants	PCR with fragment analysis	Commercial procedure; published procedure	Biological material containing DNA/RNA	A, B, C, D
3.	Examination of somatic genome variants	NGS	Commercial procedure; published procedure	Biological material containing 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
4.	Examination of somatic genome variants	Real-Time PCR	Commercial procedure	Biological material containing DNA/RNA	A, B, C, D
5.	Examination of somatic genome variants	Direct sequencing	Published procedure	Biological material containing DNA/RNA	A, B, C, D

4. Working Site Jilemnice

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

5. Working Site Jičín

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



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6. Working Site Strakonice

Examinations:

Ordinal Number	Analyt / parametr/diagnostika	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.

HR-HPV	high risk human papillomavirus (human papillomavirus with a high oncogenic potential)
HPV	human papillomavirus
PCR	polymerase chain reaction
NGS	next generation sequencing
TMA	transcription mediated amplification
FISH	fluorescence <i>in-situ</i> hybridization
MSI	microsatellite instability
Real-Time PCR	real-time polymerase chain reaction