

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 |

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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 |





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 |
|----------------|--|-----------------------------|---|--|---------------------------------------|
| 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 *in-situ* hybridization

MSI microsatellite instability

Real-Time PCR real-time polymerase chain reaction

