

# Bioptická laboratoř

CYTOLOGY | BIOPSY | MOLECULAR GENETICS



*Jana Martínková Němcová, Ph.D., a molecular biologist from the Department of Molecular Genetics and Microbiology, with one of the highest-throughput sequencers on the market, the Illumina NovaSeq X.*

## ■ History and Expansion

Bioptická laboratoř s.r.o. was founded in 1993 and over its 33 years of existence has grown into one of the largest laboratories of its kind in Europe. From three pathologists sharing a single microscope in a small apartment, it has expanded into a laboratory with 300 employees, occupying 8,500 square meters across several buildings in Plzeň. Over the years, it has acquired significant ownership stakes in one of the largest Slovak laboratories, Cytopathos, as well as in the major Ukrainian laboratory CSD LAB in Kyiv. Both facilities continuously receive exported “know-how” developed at the Bioptická laboratoř in Plzeň.

## ■ Comprehensive Cytological, Biopsy, and Molecular Diagnostics for Clinical Facilities and Pharmaceutical Companies

Bioptická laboratoř today offers gynecological and non-gynecological cytology as well as biopsy examinations. Combined with its unrivaled breadth of immunohistochemical and molecular-genetic methods, the laboratory provides cytological, histological, and genetic diagnostics for all types of hospitals and private practices. Because the laboratory is led by highly qualified pathologists and geneticists, all analyses are performed in accordance

with the latest scientific knowledge, and the portfolio of methods is continuously expanding.

Beyond clinical facilities, many leading global pharmaceutical companies also utilize the laboratory's extensive testing capabilities in genetic analyses for their research projects. In part thanks to Biopstická laboratoř, the U.S. FDA approved the targeted anticancer drug Entrectinib for clinical use in 2018. It was the first targeted biological therapy in the history of precision medicine aimed at malignant multi-organ tumors with NTRK1/2/3 gene abnormalities. During clinical trials, Biopstická laboratoř served as the primary reference laboratory for the American company Ignyta, which developed the drug. Between 2015 and 2018, Ignyta sent tumor samples from around the world to Biopstická laboratoř for next-generation sequencing to identify patients with NTRK1/2/3 gene abnormalities suitable for treatment with this groundbreaking biological therapy.

## ■ Focus on Subspecialization and Expert Pathologist Teams

The team of 43 pathologists covers the full spectrum of diagnostic surgical pathology. The advantage of such a broad expert team is the ability to superspecialize, allowing the laboratory to have experts for each organ system (e.g., gynecopathology, dermatopathology, neuropathology, etc.) capable of handling even the most challenging cases.

"Today we process biopsies from 195,000 patients, evaluate nearly 1,000,000 cytological samples, and perform 110,000 immunohistochemical and 60,000 genetic tests annually," says Professor MUDr. Michal Michal. Of the 195,000 biopsy examinations, more than 10,000 are so-called consultation biopsies — the most diagnostically challenging cases sent from other facilities in the Czech Republic and abroad for expert opinion from Biopstická laboratoř.

## ■ World-Class Applied Research Based on Extensive Routine Experience

A significant share of financial profit is reinvested into further staff education and especially into research. Many pathologists and molecular biologists at Biopstická laboratoř participate in research projects

focused mainly on identifying new diagnostic, prognostic, and predictive tumor markers. The laboratory collaborates on these projects with laboratories of the world's most prestigious medical institutions (e.g., Memorial Sloan Kettering Cancer Center, Cleveland Clinic, Mayo Clinic) as well as numerous Czech institutions.

Each year, Biopstická laboratoř staff publish 50–70 papers in the world's top pathology journals. As a result, several of its physicians rank among the global leaders in their subspecialties, and five of them contribute to creating WHO classifications for several organ systems (skin, genitourinary system, head and neck, soft tissues, and hematopoietic system).

The strong focus on research and the enormous number of examinations — many of which are diagnostically extremely complex — led to the creation of a rare tumor registry. This registry includes all unusual tumor and non-tumor lesions from around the world, including the rarest entities in human pathology, collected over 32 years. It forms the foundation of the laboratory's academic work. Today it contains nearly 160,000 cases, many of which enabled first descriptions of dozens of new tumor types or subtypes discovered by Biopstická laboratoř physicians.

"We combine high-tech testing infrastructure with the expertise of our highly qualified pathologists, biologists, and laboratory staff to offer clinicians and their patients the highest-quality histopathological diagnostics," says Professor MUDr. Michal Michal, founder and owner of Biopstická laboratoř.

## ■ Maximum Digitalization of Operations

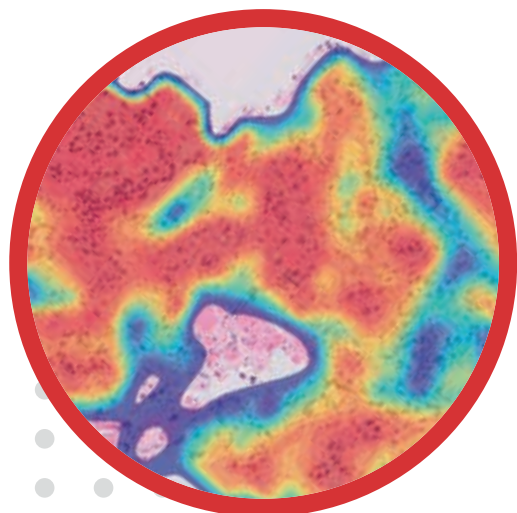
Biopstická laboratoř uses its custom automation software to streamline all manual processes from sample intake through report generation. Complementary internal analytics software further optimizes daily workflows, reduces costs, and increases efficiency. A major advantage for clients is the digitalization of results. One copy of the report is mailed to the client's address, while additional copies are quickly accessible through the laboratory's website or delivered electronically directly into the client's database — improving speed, accuracy, and operational efficiency.

## ■ Modern Methods in Cytology

In cytology, alongside traditional PAP smear evaluation, Bioptická laboratoř offers the modern Liquid-Based Cytology (LBC) method, used especially for gynecological cytology (ThinPrep PAP test) and urine cytology (ThinPrep UROCYTE). Unlike traditional PAP smears, which may be difficult to interpret and may yield false negatives or false positives, LBC allows preparation of higher-quality slides and thus more accurate cell analysis.

A major advantage is the combination of LBC with the Genius system from Hologic, which uses artificial intelligence to evaluate digitized slides, significantly increasing diagnostic accuracy and reducing false-negative results caused by human factors. LBC also enables additional molecular-genetic tests without requiring another sample collection.

Beyond classic HPV DNA and mRNA tests detecting human papillomavirus in gynecological samples, Bioptická laboratoř offers methylation-status analysis of tumor suppressor genes in patients with high-risk HPV types. This helps stratify patients by risk of progression to malignant disease — and for pregnant patients, may help defer risky surgical procedures until after childbirth.



## ■ Cutting-Edge Molecular Diagnostics for Personalized Cancer Treatment

Molecular diagnostics reveal the genetic background of tumor cells and have become a key component of precision medicine aimed at tailoring oncology treatment to each individual patient. Conventional genetic methods (such as Sanger sequencing), which assess only one or a few genes at a time, still have practical value but are insufficient for modern precision-medicine needs.

Bioptická laboratoř therefore uses the latest next-generation sequencing (NGS) systems, capable of rapidly analyzing entire genomes or selected DNA/RNA regions (thousands of genes per analysis), thus making world-class molecular diagnostics

## ■ Implementation of Artificial Intelligence in Routine Practice

The rapid development of artificial intelligence across many fields has naturally extended into medicine. Pathology is among the most progressive specialties in this regard, and Bioptická laboratoř already uses AI algorithms in routine diagnostics for certain sample types. In addition to gynecological cytology, since late 2023, all prostate biopsy evaluations have been assisted by the IBEX Galen™ AI algorithm, significantly improving diagnostic precision. The laboratory is currently preparing to deploy AI also for breast tumors and additional organ systems.

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