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IN VITRO
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COMPANY
OF THE YEAR

Diagnostic BioSystems



*The annual listing of 10 companies that are at the forefront of providing
In Vitro Diagnostic solutions and impacting the industry*

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Diagnostic BioSystems

Providing Innovative Anatomic Pathology Reagents and Systems



On a global scale, cancer is considered one of the leading causes of death. According to WHO, it accounted for at least ten million deaths last year alone. To stop this increasing incidence and prevalence of cancer, scientists are continuously striving to introduce novel treatment and testing options. To this end, Immunohistochemistry (IHC), or the utilization of monoclonal and polyclonal antibodies for the detection of specific antigens in tissue sections, promises a feasible way forward. That's why recent years have witnessed tremendous growth of this specific market segment. In fact, many reports suggest that the global IHC market will reach \$2.7 billion by 2025 from \$1.9 billion in 2020,

at a CAGR of 6.6 percent. However, this growth has invited several predicaments. Clinical and academia labs pathologists and researchers are often found struggling to find appropriate quality reagents for their tests.

This is where Diagnostic BioSystems—a cutting-edge in-vitro diagnostics provider to the anatomic pathology and histology market—makes a world of difference.

A History of Dynamic Perseverance

Back in 1994, Diagnostic BioSystems was founded by Dr. Bipin Gupta, PhD, MBA to provide high-quality innovative anatomic pathology reagents to improve the practice of pathology. Over the years, the company has earned many accolades. It achieved ISO 9001:2008 certification to sell CE-marked medical device products in 2003. After four more years, Diagnostic BioSystems became FDA certified cGMP-compliant facility, which enabled the company to produce and sell IVD labelled products into the clinical U.S. market. And this was just the beginning of a spectacular journey! In 2016, Diagnostic BioSystems launched the first semi-automated IHC multiplex platform for anatomic pathology and placed the first Montage 360 Autostainer in the US Market. Two years later, they also became ISO 13485:2016 certified and expanded into the international market with its newest Latin

America Chapter in Mexico City, Mexico, and its first Asia office in Hyderabad, India, followed by an office in Germany (in 2020) to cater to its European customers.



Dr. Olga Petruskene

Today, Diagnostic BioSystems is well-recognized as the provider of a large variety of high-quality antibodies and ancillaries, which help both clinical and academia research and test development. "We are extremely well positioned to meet IHC Testing market demands. The company is prepared to scale up its production of large variety high quality antibodies, other reagents and system," mentions Dr. Gupta, who is currently donning the hat CEO and CSO at Diagnostic BioSystems.

Diagnostic BioSystems offers its clients complete systems for IHC testing, including a fully automated stainer, HighLighter®, and semi-automated staining platforms, complemented with IVD and RUO reagents and ancillaries. A recent addition to the company's product portfolio is the rapid SITVue™ detection system, which brings unmet speed and specificity to IHC testing. It is an enzyme-mediated reaction that utilizes horseradish peroxidase (HRP) to catalyze the deposition of two separate Linkers applied sequentially onto tissue sections or cell preparation. The deposited Linkers can be detected with a streptavidin-peroxidase conjugate

followed by a reaction with a peroxidase substrate/chromogen solution such as diaminobenzidine (DAB). This system supports more than 70 distributors/OEM partners in more than 60 countries. Often, each distributor brings requests for unique solutions from their customers. "Diagnostic BioSystems, with its innovative approach and flexible manufacturing, constantly helps clients to overcome challenges and meet their business goals," says Dr. Olga Petruskene, MBA, GM, VP Business Development at Diagnostic BioSystems.



Dr. Bipin Gupta

A Strong Focus on Innovation

What always keeps Diagnostic BioSystems a notch above the rest is its focus on customer needs. Dr. Gupta and the highly dedicated team of professionals have the deepest knowledge of the IHC technologies, gaps, markets, and competitors. "This allows the company R&D and business Development move fast in a right direction. High quality manufacturing is always flexible to support product customization and constantly rising expectations of our OEM partners," Dr. Olga mentions.

The fast pace of Diagnostic BioSystems' development has always been accompanied by a strong focus on innovation and as a result, the company has a solid IP portfolio and collection of

proprietary solutions. This, as Dr. Gupta mentions, will serve as a solid basis for Diagnostic BioSystems' future offerings. The company's family of more than 70 global distributors (currently in more than 60 countries) is being constantly enriched by new members, with recent additions in Lithuania (EU, Baltic region), Morocco, Ireland, and Peru.

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In a nutshell, established in a garage, Diagnostic BioSystems has indeed come a long way to emerge as a leader in the IHC space. With the global launch of the HighLighter, Fully Automated Staining System, and Mohs line of products in August 2020, only sky's the limit for Diagnostic BioSystems going forward. "We are always focused on R&D. Currently, we have several dozens of proprietary products and six patents in the pipeline. So, we are all set for the future," Dr. Gupta concludes. 

