

# Problems and perspectives of immunodiagnosics in Bulgaria

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The immunodiagnosics has made tremendous advance worldwide during the last 50 years, which has, in turn, led to the emergence of novel technologies, modern immunoassay formats and diagnostic platforms. Moreover, the global immunodiagnosics market is rapidly growing with a volume of €9 billion nowadays due to the introduction of immune diagnostic as an instrument around 60's [1]. Immunology in Bulgaria as a distinctive field of the medical science has raised at the beginning of the 80's. Since then, immunodiagnosics in the country has made a significant jump, especially for the last two decades. Now, it resembles the immunology diagnostics presented in Europe and the rest of the world. With the development of different breakthrough techniques such as labelling techniques (enzyme-based, radioactive, fluorescent labeling, etc.) or extending the measurement to other liquids (urine, liquor, saliva in addition to whole blood and serum), immunology testing has been shaped in the past, and now other trends are gaining an importance [2]. In Bulgaria, laboratories involved in immunodiagnosics are positioned mainly in university hospitals. They are funded by the government (National health insurance fund) and by the outpatient healthcare system. It is essential for the immunological laboratories to build their product portfolios including a variety of immunodiagnosics tests, consulting service, etc.) to maintain or extend their market shares [3]. Laboratories of Clinical Immunology must know also the market and to investigate the dominating trends by different market approaches. Since 1990, the immunology society in Bulgaria has started talking about Clinical Immunology, and the specialty with this name has been created in the country. The difference between Immunology and Clinical Immunology represents mainly the process of the researchers stayed in the field of Immunology, while the medical doctors and many biologists, chemists, etc., started working in the hospitals and medical centers with patients [4]. In brief, Clinical Immunology is devoted to diseases such as autoimmune diseases, immunodeficiencies, transplantation, regenerative medicine, etc. Increasing prosperity and permitting high hygiene standards, along with the increasing global average age, consequently changes the testing from "poverty" parameters to "modern" ones. Along with this, however, there is a demand for autoimmune diseases diagnostics and allergy testing, the emergence of which is connecting with the prevailing of non-lethal diseases needed early screening for prevention. Regional differences in the Bulgarian immunological laboratories are linked to the developmental status of the Bulgarian economics. We can assume and expect that the respective differences will be reduced in the future. The primary goal of the Clinical Immunology in our country is Immunodiagnosics to become more accessible, well-known, and desirable for the rest of clinical specialists, such as doctors working in the internal medicine (i.e., rheumatology, gastroenterology, oncology, infectious diseases, etc.).

Quality assessment is a crucial step in the development of the high grade and reliable immunological investigations [4]. Despite the tremendous advances in the immunodiagnosics in Bulgaria, there is still a need for rapid and cost-effective immunoassay procedures along with novel diagnostic platforms to increase the outreach of immune diagnostics to the remote settings, especially in the developing countries, like our nation. One of the most prospective developments in line with this is using Point-Of-Care apparatus or smartphones-application for immunodiagnosics. Recently, various strategies have been developed that have led to ultrasensitive immunoassays with superior analytical performance and lower limit of detection. Due to the need of higher precision of information and efficiency, immunology testing is on the increase using molecular diagnostics and other new technologies. By linking these technologies with the immunodiagnosics in integrated systems, the amount of gained information will considerably increase. This would help in balancing out the disadvantages of individual technologies used in immunology testing [2]. However, these laboratory findings need to comply not only with the stringent technology requirements but with international and national regulatory guidelines, protocols and accreditation policy could be quite challenging at the moment. Fortunately, in Bulgaria, every accredited immunological laboratory follows the standards rigorously. Nowadays, the immunology laboratories in the country are responsible for over 50000 investigations/ year [4]. Many immunological laboratories are pressing ahead with laboratory automation. One of the reasons for that is the reduction of costs for immune testing, and other - due to a lack of specialist personnel. Not only in Bulgaria, but in the USA and Europe, an increasing number of hospitals have commenced viewing their laboratories, including the immunological ones, as profit centers, whereas only about half the specialist working in the lab are trained in the specialty of Clinical Immunology. The impacts of immunological testing in medicine is beyond doubt. In Bulgaria, the perspectives for the development of Clinical Immunology prevail above the problems in the field. However, the collaboration within the immunological laboratories in the country will improve the immunodiagnosics significantly.

## REFERENCES

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