



IMMUNOASSAY MARKETS

Strategies and Trends. Forecasts by Instrument Type and by Application and by Country. With Multiplex and Point of Care Market Analysis, Executive Guides and including Customized Forecasting and Analysis.

2019 to 2023



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1.1 Immunoassay Markets Definition In This Report

An immunoassay is a biochemical test that measures the presence or concentration of a macromolecule or a small molecule in a solution through the use of an antibody (usually) or an antigen. The molecule detected by the immunoassay is often referred to as an "analyte" and is in many cases a protein, although it may be other kinds of molecules, of different size and types, as long as the proper antibodies that have the adequate properties for the assay are developed. Much clinical laboratory testing is now done by immunoassay

Immunoassays come in many different formats and variations. Immunoassays may be run in multiple steps with reagents being added and washed away or separated at different points in the assay. Multi-step assays are often called separation immunoassays or heterogeneous immunoassays. Some immunoassays can be carried out simply by mixing the reagents and sample and making a physical measurement. Such assays are called homogenous immunoassays or less frequently non-separation immunoassays.

Immunoassay are often grouped based on the type of reagents or signalling method used.

1.1.1 Enzyme Based

The enzyme-linked immunosorbent assay (ELISA) is a test that uses antibodies and color change to identify the assay target. It is the most common type of immunoassay and can be considered to be a mature technology available on a wide range of instrumentation.

Performing an ELISA involves at least one antibody with specificity for a particular antigen. The sample with an unknown amount of antigen is immobilized on a solid support (usually a polystyrene microtiter plate) either non-specifically (via adsorption to the surface) or specifically (via capture by another antibody specific to the same antigen, in a "sandwich" ELISA). After the antigen is immobilized, the detection antibody is added, forming a complex with the antigen. The detection antibody can be covalently linked to an enzyme, or can itself be detected by a secondary antibody that is linked to an enzyme through bioconjugation. Between each step, the plate is typically washed with a mild detergent solution to remove any proteins or antibodies that are non-specifically bound. After the final wash step, the plate is developed by adding an enzymatic substrate to produce a visible signal, which indicates the quantity of antigen in the sample.

It is important to note that the data presented are forecasts based on available statistics and data from a wide range of sources. Nevertheless, they are just forecasts and the reader is cautioned to use the information judiciously. Forecast volumes may or may not materialize. Unfolding global events cannot necessarily be foreseen and will almost certainly cause some of these forecasts to be in error. In addition, the effect of local and regional conditions can dramatically alter the volume of tests delivered by any specific laboratory serving a specific region. Further local in-depth study should be carried out before undertaking any course of action.

The data can be used most reliably in the interpretation of *relative* testing volumes in different geographic areas and over time especially when used in conjunction with the most recent estimates of economic growth and health spending in an area.

1.3 Methodology

1.3.1 Authors

The principal author of this report holds a M.B.A. in Finance and Strategy from the University of British Columbia. He also holds a B.Sc. in Chemistry from the same university. He is a graduate of the Harvard Business School program *Finance for Senior Executives*. He is a graduate of The Burke Institute Seminar in Market Research. He has worked in clinical laboratory research and testing in a hands-on capacity. He is a co-author of the paper *The Radioimmunoassay of Angiotensinogen II by Antibody Trapping*. He has considerable experience in mergers, acquisitions and business development. The editor of this report holds a PhD in English from the University of Nevada. She is an accomplished editor with over a decade of academic experience.

1.3.2 Sources

Sources of information include the World Health Organization, the International Monetary Fund, the World Bank, several U.S. and European Union government bodies and industry associations. Considerable primary information is collected from industry associations, industry participants and executives, whose information and insight are regularly solicited.

roles. The development of diagnostic tests and instruments is often carried out by smaller specialized biotech research companies. These are purchased by larger firms once they have developed a foothold in the industry. This sector is not as dominated by large companies as one might think. Large players like ThermoFisher and BectonDickinson provide a wide range of items from complex proprietary instruments to mundane test tubes and centrifuges. But many more local or national suppliers deliver both basic and complex products. There are many small boutique labs offering specialized testing or test kits or unique instruments.

2.1.2 Independent lab specialized/esoteric

The specialist laboratory provides unique or expensive tests for which there is normally a limited demand. These laboratories generally service a national or international market providing testing services that are uneconomic for laboratories serving smaller populations. These labs may be associated, through ownership or partnership, with a larger network of laboratories servicing more routine needs. Mayo Medical Laboratories is likely the largest in the esoteric category, while it provides a complete range of routine tests its niche is esoteric testing and has maybe the largest test menu in the world. Specialist laboratories should normally be able to earn a higher rate of return for their services as they are often in a near monopoly situation.. The trade off is that these laboratories must choose their capabilities wisely as the ever-changing nature of specialized testing services can make a particular specialized test obsolete overnight. Specialized labs play an important role in the molecular diagnostics industry.

2.1.3 Independent lab national/regional

These market participants are private laboratories providing a broad range of clinical testing services to the general medical community. They may be associated with or operate specimen collection centers (bleeding stations) as well as provide specimen pickup services. Most laboratories of this kind support a network of physicians requesting service. The maintenance and care of this network, often related to geographical service area and lab capability, is a key factor in establishing and maintaining a successful referring base. Laboratories put varying degrees of emphasis on cultivating their referral network. Key to success for these labs is the establishment of a sufficiently large referring population to support a complete service offering while enjoying the economies of scale associated with high volume testing. The familiar process of laboratory merger and consolidation serves this end.

waking up to the fact that it is unacceptably expensive for everyone to wait around for a test result.

2.3.7 Lower Barriers to Entry for Instruments/Analyzers

The declining role of capital cost in the instrument purchase decision lowers the barriers to entry for new or replacement equipment. The new or replacement unit usually offers speed and efficiency gains, that, if made evident can easily justify the replacement of an instrument. Improvements in size, handling and interfaces mean that there is much lower sunk costs in training or installation. The result is that the smart shrinking instrument is lowering the barriers that kept labs loyal to particular technologies and particular suppliers.

This shifts power from the vendor to the customer. Instrument manufacturers should be vigilant of this development ensuring that they have competitive responses to protect their installed base, especially from what may be disruptive technologies.

2.3.8 Minutization and Technology Drive Acquisition

The industry will be driven over the next five years by the twin instrument aspects of miniaturization and technological change. This combined with the above mentioned lower barriers to entry. It is likely that this will lead to continued merger and acquisition activity in the industry as competitors try to build their product lines to match changing market needs.

Vendors should be aware that time to market is key in the industry. It may be a bargain to spend more on an acquisition than to build in house.

2.4.3 Arlington Scientific

1840 North Technology Drive
Springville, UT 84663
Tel: 801-489-8911

www.arlingtonscientific.com

Company Role & Description:

Arlington Scientific, Inc. (ASI) is a leading global medical technology company that develops, manufactures and sells in-vitro diagnostics, medical devices, diagnostic analyzers and blood donor lounges.

ASI remains focused on enhancing the quality and speed of diagnosing infectious diseases. ASI's flagship product, the ASI RPR Card Test for Syphilis, is a market leader in the United States. ASI manufactures over 20 million of these RPR tests annually for over 1,000 labs.

ASI is also one of the very few companies that manufactures its own carbon antigen. Other serology products include TPHA, VDRL, ASO, SLE, MONO, CRP, RF, STAPH, SICKLE CELL and RUBELLA.

ASI's blood donor lounges feature uniquely designed products that improve the safety, comfort, and ease within transfusion medicine. Current products include stationary and portable blood donor lounges, mobile coach lounges, and accessories.

Products:

ASI Serology test kits
Rapid, reliable, cost effective EIA Infectious disease kits
ASI Evolution Automated Syphilis Analyzer
Automated nontreponemal RPR testing Blood Donor Lounges
ASI Infinity Automated EIA Analyzer
Performs ELISA's from various manufacturers IVT Allergy™ Screen
ASiManager-AT
Semi-automated nontreponemal testing Nasal cytology curette

3.3.3 LISTING of CURRENT INSTRUMENT SPECIFICATIONS.

The table below lists current instrument specifications. The reader is cautioned that this list is almost certainly out of date as this data changes weekly. The role of this list is to present the range of instrumentation capability so as to understand the breadth of the instrumentation market and typical specifications.

TABLE 9 - LISTING OF CURRENT INSTRUMENT SPECIFICATIONS

MFR Model	Units in Use	Area (sq. ft.)	Tech	Simult Assays	Simult Samples	Open?	List price	Target market
Abbott Diagnostics, ARCHITECT i1000SR	—	12.3	chem	25	65	NO	—	—
Abbott Diagnostics, ARCHITECT i2000SR, i4000SR	—	20.7	chem, mag	25	135	NO	—	—
Abbott Diagnostics, ARCHITECT ci4100, ci8200, ci16200	—	43.2	chem, photo, potentio	90	367	YES	—	—
Alere, Agility	100	8.6	EIA, coat well	16	200+	YES	—	—
Alere, DS2	2300	3.8	EIA, coat well	24	100	YES	—	—
Alere, DSX	3000	7	EIA, coat well	33	98	YES	—	—
Arlington Scientific, ASI Infinity	4430	6	EIA, coat well	12	96	YES	\$25,000	20+ beds
Awareness Technology, ChemWell Fusion	10	4	ELISA, coat well	12	96	YES	\$29,000	500 tests per day

4.1 Recent Developments – Importance and How to Use This Section

4.1.1 Importance of These Developments

Many users, especially those in the financial community, have noted that this section of the report can be extremely valuable in helping to understand industry current events and the evolution of key market players. These items are not chosen at random. They have been selected by the author(s) as significant and worth reading about, i.e. important. Please keep this in mind in reviewing them.

4.1.2 How to Use This Section

These items are NOT in date order. They are in the order in which they have been added to the report. This report is updated regularly and new items are incorporated and others removed. Numbering of items may not be sequential. Generally newer items are in the lower part of this section and have the highest numbers. Please refer to the date of an item to understand its currency. Reading this entire section is recommended for those not familiar with the industry. Many of the trends and issues noted elsewhere are illustrated in these actual events,

4.2 Russian Researchers Develop Rapid Test for Heart Attack

30 January 2018

A team of researchers at the National University of Science and Technology MISiS, Russia has developed a new type of membrane test strip for the quantitative immunochromatographic rapid-test that will be able to accurately and quickly make an early diagnosis of an acute myocardial infarction. The detection is made possible through the presence of disease markers in blood. The test can also be used to identify various things such as sepsis, a pregnancy's duration, and viral & bacterial infections.

The team has managed to combine qualitative and quantitative immunochromatographic test principles in a simple and effective bioanalytical system, thus improving the quality and accuracy of their results.

6.1 Global Market by Application

Revenues are millions of 2018 US dollars.

ID = Infectious Disease

AUTO = Autoimmune & Immune System Related

ONC = Oncology

ENDO = Endocrinology

CARD = Cardiology

OTHER = All other

TABLE 11 GLOBAL MARKET BY APPLICATION

	2018	2019	2020	2021	2022	2023	CAGR
XXX	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx
XXX	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx
XXX	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx
XXX	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx
XXX	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx
XXX	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx
Total	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx