

## What's propelling Indian IVD industry

01 March 2022 | Views

The COVID-19 pandemic has brought diagnostics to centre-stage and proved its importance in the healthcare system of the country. Diagnostics is important not only for COVID but also for each and every disease. Interestingly, over the last few decades there has been a steady transformation in the testing space, from a simple blood test and manual slide review, to testing a wide range of parameters and integration of digital microscopy for better patient outcomes



Globally, the In vitro diagnostics (IVDs) market is projected to reach \$118.5 billion by 2027, growing at a CAGR of 7 per cent. On the other hand, though the domestic IVD Industry is still at a nascent stage, estimated at \$9 billion, it is expected to grow at a CAGR of ~15 per cent in the next 5 years. As a result, there have been several positive trends in the Indian IVD Industry.

**Manufacturers of IVD devices** have kept pace with the increasing demand for testing volumes with innovative diagnostic solutions that are driving the growth of the industry:

**Newer technologies:** Superior diagnostic technologies such as molecular and Nex-Gen Sequencing are witnessing fast-paced growth. Companies like Transasia are investing in research for the development of novel technologies for infectious diseases such as TB, HIV, Hepatitis, etc.

**Rapid testing:** While there will always be a demand for advanced technologies in the large-scale labs, Point-of-care testing (POCT) is proving to be a boon in resource-limited settings. Worldwide, the market is expected to grow at a 11.9 per cent CAGR upto 2023.

From diabetes and pregnancy tests to testing for infections such as Transfusion transmitted infections (TTIs), dengue, malaria and most recently COVID-19, manufacturers are expanding their product portfolio to include POCT devices. Transasia offers rapid test kits for dengue and malaria with a unique dual colour advantage for easy interpretation. Besides this Transasia has also recently introduced rapid tests for critical infections such as hepatitis, HIV, HBSAg and Syphilis and COVID-19.

**Efficient after-sales services in Tier II, III and IV cities of India:** In the last few years, manufacturers have expanded their role beyond just providing quality solutions to providing seamless service. Leading companies like Transasia Bio-Medicals operate with a well-knit network of service and applications specialists to reach out to labs in remote-settings lacking a strong infrastructure. In fact, Transasia has the largest team of sales and service personnel in the industry that caters to some locations not catered by any other company.

At Transasia, on one hand we focus on providing excellent after-sales and application support, on the other hand, we offer value-based service by identifying the customer needs and then upgrading the current technologies to meet these needs. As an example, Transasia has integrated some unique parameters in its hematology range, as preliminary indicators of cancer. Another example is of providing open systems which enable the use of reagents from any source, thereby offering convenience to lab owners.

**Automation:** With an increasing demand for tests, laboratories are looking at ways to handle the huge workload. And this is where manufacturers come into the picture, to provide solutions that meet the rising demand for speed, quality, affordability and accuracy. Labs are now inclined to switch from semi to fully automated analysers.

Another step in this direction is Total Laboratory Automation (TLA). Conveyor belts are used to connect pre-analytical specimen processing and other functions directly to an analyser. Such systems also include functions such as post-analytical storage or sorting of specimens to be transported to low-volume testing areas or to be sent to reference laboratories.

**Digitisation:** In a bid to get closer to the end user, manufacturers are leveraging data and building intelligence into their products. Integration of automated systems with Internet of things (IoT) is helping manufacturers provide the advantage of 24x7 remote access, predictive maintenance and inventory management. Further, Artificial intelligence (AI) based diagnostic devices are enhancing the lab workflow efficiencies by offering a shorter turnaround time (TAT) thereby allowing more samples to be tested. AI also aids in more accurate image analysis, thereby enhancing the accuracy. In the long run this reduces the need for repetition, leading to cost-effectiveness.

The concept of core laboratory is already picking pace in India. As a result, manufacturers too are encouraged to offer one-stop solutions to meet the needs of large chain laboratories. In addition to offering quality systems, companies like Transasia have already integrated their fully automated systems with cloud-based remote access technology and an end-to-end suite of Laboratory Information Management System (LIMS) services. Going forward, we anticipate a rise in the consolidation of chain labs with the smaller ones, and an increasing demand for manufacturers to provide 360 degree solutions.

**Industry initiatives:** In recent times, collaborative efforts of the industry and the government have led to opening up of new avenues for the IVD industry:

**Quality certifications:** For a long time, the diagnostic industry was in need of its quality assessment system. Introduced in 2018, Indian Certification for Medical Devices (ICMED) is the country's first indigenous quality assurance system for India manufactured medical devices. It is proving to be a boon for IVD manufacturers, in bringing down the substantial time and monetary investment to obtain globally accepted quality certifications and in-turn it is helping in assuring standardised products. Transasia is India's first IVD Company to receive this certification.

**Entry of pharma sector:** The entry of pharmaceutical companies and large corporate chain hospitals in the diagnostic arena as laboratory service providers, is enabling greater accessibility. Needless to say, this opens up a plethora of opportunities for IVD manufacturers as well.

**Government initiatives:** An outlay of Rs 64,000 crore towards healthcare in the current fiscal year budget is giving an impetus to this sector. Additionally, certain policy changes such as the Medical Device Regulation 2017 and the Production Linked Incentive (PLI) scheme are good start-points to engage manufacturers in high value production and incentivise domestic manufacturing.

**Make in India:** The government too has risen to the occasion and identified the medical device industry as a sunshine sector in its Make in India mission.

**Setting up of medtech parks:** The Government's collaboration with the industry has led to the setting up of medtech parks. However, most of these parks provide no other support other than land. Medtech parks should consider themselves as an integral part of the eco-system and should hand hold the industrial units to help them get all necessary Government approvals in a short time.

**Government e-Marketplace:** In the current era of e-commerce, the Government e Marketplace (GeM) is a good platform to encourage local manufacturers to reach out to government entities for public procurement.

NITI Aayog in its recent report has stated that diagnostic and pathology centers will expand in the times to come and the sector has a promising future. More and more people are opting for preventive diagnosis. Moreover, with people being aware of health concerns and importance of early detection of diseases, the onus is on manufacturers to provide technologically advanced systems for labs and home-testing.

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