

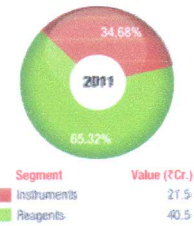
## COAGULATION INSTRUMENTS AND REAGENTS: Mature and Competitive Market

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Coagulation testing is more standardized, offering opportunities for quality control products and services. The contraction of the gap between the hospital system and technological advances may facilitate decentralization of hemostasis testing closer to the patient, creating additional opportunities and challenges for suppliers.

Laboratory coagulation testing is estimated to be the fifth largest market in professional diagnostics worldwide, representing approximately Rs. 7124 crore in sales in 2011 and having a projected annual growth rate of 5.1 percent over the next four years. Biotechnology companies and manufacturers are investing heavily into developing hi-tech solutions for the future.

Indian Coagulation Instruments and Reagents Market Value-Wise Total (₹ Cr.)



### Indian Market Dynamics

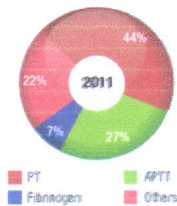
The total Indian coagulation market is valued at Rs. 62 crore in 2011. The reagents are estimated at Rs. 40.5 crore and instruments at Rs. 21.5 crore.

The market is dominated by Suyog Diagnostics and Transasia Bio-Medicals, having a combined market share of 71 percent. Instrumentation Laboratory is an aggressive player.

The major customers for Suyog Diagnostics in 2011 included Dr. Lal PathLabs; SRL, Mumbai; and Metropolis Lab, Mumbai. The major customers for Transasia Bio-Medicals in 2011 included Medanta Medicity, Gurgaon; and CMC, Vellore.

Other players include Accurex, Agappe Diagnostics, Alere Medical, Ark Diagnostics, BD Biosciences, Bio-Rad Laboratories, Compact Diagnostics, CPC Diagnostics, Horiba, Iris Healthcare, J Mitra, Medsource Ozone Biomedicals, Monash International, Monozyme, MP Biomedicals, Rapid Diagnostics, Roche Diagnostics, Siemens Healthcare Diagnostics, Span Diagnostics, Spark Meditech, Sysmex, Triviron, Tulip Diagnostics, UR Diagnostics, and Wheecon Instruments among others.

Indian Coagulation (Reagents) Market Test Contribution



Coagulation testing faces a serious concern of standardization. Coagulation test results can be influenced easily by biological, pre-analytical, and analytical factors due to the peculiar sensitivity of the assay methodology and the potentially adverse clinical consequences of spurious test results. The collection and transportation conditions also affect the test results. Delay in processing the samples can make the sample deficient. Using a roller mixer improves the reliability of coagulation testing. Such standardization in pre-analytical phase may be helpful in preventing laboratory errors and obtaining correct test results in coagulation tests. Robotic mechanisms for sending the tubes away from the roller exactly after 1 min can probably be helpful in avoiding platelet activation.

### Technology Leap

Coagulation analyzers have come a long way from measuring the optical density of a clot in a cuvette. Initial coagulation analyzers were operated using a hook to detect a clot in the cuvette. This has now been replaced by simultaneous detection of clotting factors via clotting, colorimetric, and immuno principles. Current technologies use automated platelet function analyzers, flow cytometers, PCRs, and microarrays. Combination of all these technologies eliminates preanalytical and postanalytical handling, yielding accuracy and increased productivity.

Standardized tests allow hospitals to provide timely medical care, and the tests monitored in real time are accurate, and recorded via data warehoused in networks with easy access for physicians. This field is now moving toward integrated analyzing software, increasing the robustness of the test and the precision while reducing the analysis time.

Based on the liquid resonance principle, a novel sensing technology for detecting blood coagulation was proposed. The course of blood coagulation can alter its inherent properties, such as viscosity and density. Liquid resonance frequency of blood will change with blood agglomeration. A gold-plated interdigital electrode (IDE) was fabricated and a detection system was designed for the acquisition of frequency. The APTT was measured using IDE and the detection system.

In addition to routine testing needs, coagulation laboratories continue to add special coagulation assays to their testing menus. This is being driven by a general increase in the number of patients needing these tests and the ability of the vendors to supply testing kits and analyzers at a lower cost than the cost of sending the test out. Coagulation analyzers perform chromogenic and immunoturbidimetric assays so that the laboratories have the capability to perform all coagulation tests available in the market.

Portability, connectivity, and ease of use continue to be the chief demands for point-of-care (POC) coagulation test system users and the market is starting to see some fibrillation of its own as pharmaceutical manufacturers start to crank out esoteric anticoagulants. Rapid coagulation testing provides critical information on a patient's clotting time.

### Challenges and Opportunities

A major issue in the coagulation market in India is lack of awareness. When one traces the developmental history of technologies used in coagulation analyzers, there have not been many major changes in the principles used for measurement of the end-point in most of the coagulation assays in the past two decades or more. Looking ahead, the situation is unlikely to change drastically in the next decade.

POC and near patient tests devices in coagulation are competing with coagulometers and analyzers traditionally used in laboratories. Both have specific roles in management of patients and should complement each other.

Unlike biochemistry and hematology analyzer markets, coagulation market in India is significantly smaller. There are several international players already operating in this field and have largely captured the existing market. Replacing them in the near future can be a major challenge for Indian manufacturers. Being a rapidly growing market, new entrants may still find it difficult to succeed quickly. Starting a JV with established manufacturers could be an option the aspiring Indian manufacturers could consider. Representing international manufacturers in India would remain an attractive proposition.

### The Road Ahead

Most coagulation analyzers are heading toward accuracy, ease of use, and timely results and focus has shifted to better bioinformatics and integrated software across multiple platforms and analyzers. Informatics is an area of growing interest for clinical laboratories. Customers are looking for IT solutions that will help them leverage data management, improve process flow in their lab, and monitor instrument events - error flags and service events to yield enhanced diagnostics value.

Government and private sectors provide healthcare in India, but patients increasingly turn to private hospitals and clinics for quality treatment and better facilities. According to estimates provided by industry sources, there are approximately 35,000 laboratories that service 1.25-1.50 million patients per day. This includes specialized laboratories, laboratory facilities in hospitals and nursing homes, and small testing centers with basic facilities. The quality of services and facilities provided by these laboratories varies widely. Coagulation market is growing with 15-16 percent per annum and hematologists are getting more exposure on new special parameters like vWF, Protein C, Protein S, APC-R, antithrombin III, Factor Xa, heparin induced thrombocytopenia (HIT), lupus anticoagulant, and so on. Fully automated high-end floor models have been installed in India and are expected to grow very fast. The Indian market is facing challenges from low quality products by Chinese manufacturers and from few other countries.



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