

New Age Diagnostics

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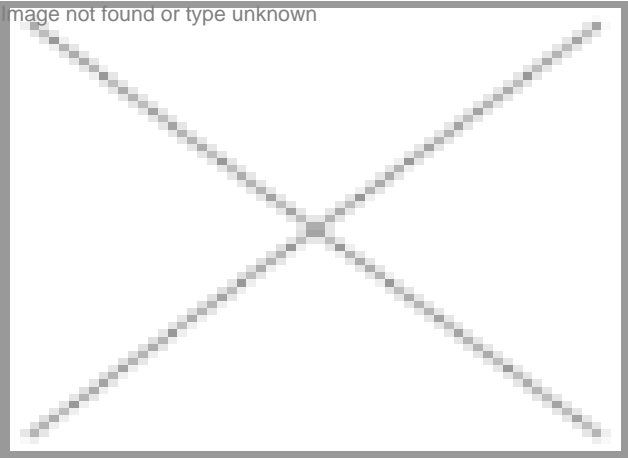
Believing in the mantra of different strokes for different folks, new age diagnostic companies can perhaps change the face of an industry that reels under slackened growth.

Aslight change in the tactics can pave the way for a radical breakthrough, this is applicable to the Indian diagnostic market. Growing at a rate of 15-20 percent, the market had been facing myriad bottlenecks in its progress route and was slammed by critics and market analysts as a highly segmented market that sans regulation and parliamentary pathways. Now that can be passé as the industry is heading for a complete makeover. Backed by the spirit of entrepreneurship, rising awareness among the Indian populace about the concept of modern healthcare coupled with India being recognized as a genetically heterogeneous country, the diagnostic market is now witnessing the flourishing of new age diagnostic companies.

So what are these new age diagnostic companies and what distinguishes them from the companies who had been dominating the scenario till date? The terminology coined is 'New Age' because these companies have taken the plunge to explore new territories and divert their focus from the usual business models pursued by most of the Indian companies till date. So today we have companies looking at core businesses like diagnostic testing of patients at the genetic level in order to prescribe medicines and drugs suited to the patient's metabolism rate and single-nucleotide polymorphism (SNP), tests looking at gene mutations, manufacture of antigens from natural and cell derived sources. The cost-effective quotient of these methodologies are the icing on the cake. Though at an initial stage of growth, these methodologies can fuel the growth for an industry reeling under clogged growth.

BioSpectrum, has kept a close watch on market trends across the country and has managed to bring those companies, who have adopted unique business models to explore the untrodden path, to the limelight.

Yashraj Biotechnology, Mumbai



Yashraj Biotechnology Ltd (YBL) is established in 1999. It is the

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diagnosis, reagent,
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diagnostic kits are indigenously produced. We were always looking at methods which could be affordable to the people.”

with the hospital as a reagent for the biomedical waste is subsequently transported to
laboratory. This is mainly due to the fact that diagnostic kits are affordable because the reagents for the

“Currently, the manufacturing of reagents is mainly done either at standard laboratories
various assays are being done in laboratory-based research and development, and

Puri. The monoclonal antibody products will soon be available for use as reagent in diagnostic kits.

As the primary disease is tuberculosis, sexually transmitted diseases (STDs), HIV/AIDS.
YBL is the process of mining with HIV antigen for diagnosis of the monoclonal antibody under
evaluation of HIV/AIDS serology antigen extracted from human saliva. It has brought

products into the market and nine products are in the R&D phase.

The research is conducted in safety of the product. All reagents are tested for
HbsAg, anti-hepatitis-B-Virus (HBsAg), anti-HCV, anti-HCC, non-reactive, and
processing. The non-reactive reagents are tested for HBsAg, HCV, and CRBV

is not tested in HBsAg.

Yashraj is a contract manufacturing company, so custom supplied materials
case, projects of antigens is taken up either through joint R&D venture or exclusive technology transfer for buy back.

Tagman, Dr. S. B. Patil, Director and member of the Board, Manabha, Chairman
the scientific advisory committee of Yashraj Biotechnology. He is responsible for identifying
ideas about manufacturing according to the health care industry and for

biomedical fluids (especially saliva).

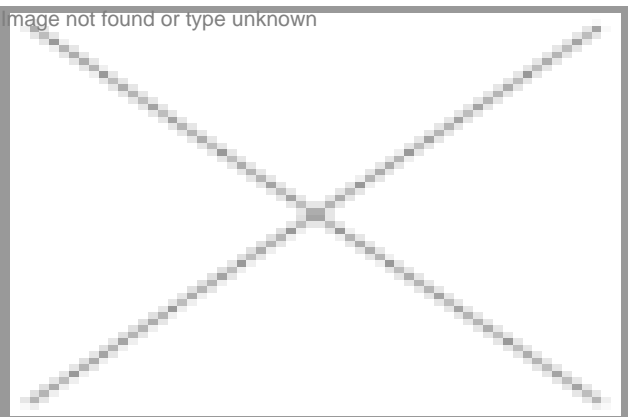
YBL has facilities for antigen, antibody, cell culture, quality control, R&D, experimental animal
facility. New business opportunities like cell-derived antigens and antibodies, monoclonal
antibodies, and diagnostic technology, cyclosporin, cell culture, and pressurized
(diagnostic and therapeutic) experimental animal facility development. It is equipped

a 1,50,000 sq m facility, either for contract manufacturing or as a joint venture set up.

Having achieved milestones in the indigenous production of reagents and antibodies, YBL is
diagnostic manufacturing and contract manufacturing. The company has identified technology in financial

are four buildings already allotted for it. Also they are in talks with scientists from all over the world.

Acton Biotech, Pune



The tagline of the company, 'celebrating genetics', best describes Acton's business model in a nutshell. Pune-based, Acton Biotech, was founded on the scientific contention that different people react differently to drugs because of their genetic structure. This idea is well explained as four people represented in red, blue, yellow and green. The person in red represents 60 percent of the population, who respond positively to a drug; about 25 percent of the population are fast metabolisers of the drug that means the drug will get washed out of their body before it can have any positive effect, this population is represented by the blue person; another 10 percent of the population are slow metabolisers, they are represented by the yellow person, people in this population will have minor or major side effects because of accumulation of the drug, as the drug gets washed out very slowly and finally the green

person represents the remaining five percent of the population, which shows undetectable or no enzyme activity and so all the drug taken in by the person keep accumulating and this can cause severe side effects.

Throwing light on Acton's business model Sandeep Saxena, founder and CEO of the company said, "Nowadays, choosing a drug for any complex disease like cancer is very difficult because of the difference in the rates of efficacy of these drugs amongst the Indian populace, as cancer drugs are inherently toxic to some of them. This difference in efficacy is because of the variation in metabolic rates of enzymes from person to person. Acton focuses on the basic DNA code, checks for the enzymes that are responsible for the metabolism, mutations in the genes and suggests drugs according to the genetic structure of the person. This saves both cost and time."

Acton, an angel-funded company, has its genesis way back when founder and chairman, Saxena was graduating with an MBA degree from Nirma Labs affiliated with the Nirma University based in Gujarat. "At the end of the course we are supposed to write a business plan for our start-up company. If that plan would be accepted then they would give us seed fund to initiate that start-up. Our business plan finally got accepted for incubation," recollected Sandeep Saxena.

"We did a detailed study and got all the research articles on pharmacogenomics and zeroed in on the important genes and expressions and its functions. At that time we had no focus. We looked into diseases like cancer, central nervous system (CNS) and depression. Then we decided to focus on oncology as it is the most widely read and researched field that boasts a huge market in India," pointed out Saxena.

While commenting on the modus operandi of the company Sandeep Saxena said, "We have a laboratory in Pune with the basic set of equipments. We collect blood samples from all across the country, we extract the genes while focusing on single points called single nucleotide polymorphism (SNP). From our background research we got a clear idea about the drug response in different patients. Acton's sales force educates doctors, update them on the different drugs and the type of SNP they will positively react."

Acton now follows one gene-one drug correlation. Take for instance the somatic KRAS gene mutation, which is responsible for therapy resistance to tyrosine kinase inhibitors such as cetuximab, in the metastatic colorectal cancer tissue. Around 40 percent of the population does not show any response to the drug because of mutations in the KRAS gene. Acton offers this KRAS gene mutation testing, which should be done immediately after the diagnosis. According to the National Comprehensive Cancer Network (NCCN), only patients with tumors of the abnormal type of KRAS gene should receive treatment with the epidermal growth factor receptor inhibitor cetuximab. For this type of genetic testing already 30 patient samples have been analyzed by Acton and tests have been repeated. Turnaround time for this test is 10 days and tests are done after optimizing the DNA extraction from formalin fixed paraffin embedded (FFPE) blocks and the polymerase chain reaction (PCR).

"From January onwards we ramped up everything right from the number of people, lab equipment and research by recruiting sales managers and executives, we started opening up blood collection centers in Mumbai, Hyderabad, Chennai, Baroda, Ahmedabad and Surat. We also have tie-ups with hospitals in Delhi, Hyderabad, Bangalore and Kolkata," pointed out Saxena.

Acton intends to focus on areas like cardiology and diabetes. "We are talking to cardiologists. This is a recent initiative taken by the company. We believe that genetic tests will avoid severe complications," concluded Saxena.

Ch Srinivas Rao along with Nayantara Som