Introduction

The range of diagnostic tools available to the clinician has been steadily expanding since the advent of modern medicine. We are, however, at the threshold of seeing an exponential rise in this area, akin to the rapid developments in the field of digital technology that occurred over the last decade. The driving force behind the rapid expansion of the diagnostic market can be attributed to developments in biomolecular and genomic technologies.

The popular press regularly provides tantalizing stories of how all disease diagnosis and therapy will soon become tailored to an individual’s genetic makeup (often referred to as personalized medicine). Although the emerging field of pharmacogenomics (targeted drug therapy by taking account of an individual’s genetic makeup) is expected to make rapid progress in the years ahead, there have been some setbacks and disappointments. Gene therapy is one of the more notable areas where the early enthusiasm has been tempered by difficulties in obtaining successful outcomes. Similarly, the discovery of the brca gene family and its putative link to breast cancer was followed by the realization that genetic testing may not be highly predictive, especially for the Indian genetic makeup.

Molecular diagnostics has, however, been extremely successful in the area of infectious diseases where viral and bacterial genotyping has made rapid progress. Similarly, cancer diagnostics through mutational analysis and gene expression profiling, though still at an embryonic stage, is likely to be the next major breakthrough area in clinical practice. Although clinicians require a large range and high efficacy of tests to undertake correct diagnosis, laboratory testing currently accounts for only 1% of total health costs worldwide, according to the World Health Organization (Figure 1).

The current in vitro diagnostic segment is composed of various well-established tests that clinicians have come to depend on, including clinical chemistry, immunoassay, and others. Indeed, infectious disease and blood screening tests together are responsible for over 70% of all diagnostic tests. The United States provides the major driving force, accounting for more than 50% of sales. In this context, the overall market share of molecular diagnostics currently holds a modest position (Figure 2). The leading players in the industry are Roche Diagnostics, which currently holds close to 40% market share, with other major players such as Abbot, Chiron, and Bayer making significant inroads.
Although molecular diagnostics currently occupies a modest position in comparison to other segments, it is also clear that in many respects this is where the future is, as evidenced by its growth rate. Although estimates vary depending on the reporting methodology, there is general consensus that the current growth rate is in excess of 25% (Figure 3). These estimates do not take into account many cutting-edge tests that are making their way into the marketplace, the so-called esoteric tests. This segment is increasing at a rapid rate for two reasons. First, a number of innovative companies are introducing early-stage, often fledgling new technologies, into clinical labs. And second, the rapid development of automated systems and point-of-care platforms is adding to the throughput of molecular testing. Together, these factors augur well for the future growth of molecular diagnostics with the accompanying prospect of greater affordability down the road.

Prospects for India

The emergence of ultra high-end tests is in general accompanied by consumer concerns of high cost. The initial introduction of such tests therefore must often be targeted to the economic sector that can afford such tests. In this regard, there are three demographic factors in India that provide for an encouraging outlook in terms of market prospects. First, the economic boom in India has led to a striking increase in purchasing power among the middle- to upper-tier economic groups. Along with the increasing wealth of Indians is the emergence of a more Westernized attitude. Thus, although esoteric testing and disease-screening programs are largely at an embryonic stage compared to the West, the shift in economics and attitude provides for a more encouraging outlook in terms of the success of such efforts in the future.

The second encouraging demographic factor also relates to the economic boom. The arrival of multinational corporations in large numbers to the Indian scene has been accompanied by a similar growth in indigenous corporate entities, especially those catering to information technology (IT), business process outsourcing (BPO), and other related sectors. As a result, a new corporate mentality is emerging in India, one in which employee health issues, especially those of managers and executives, are of increasing importance. A parallel development has been the progressive expansion of health insurance programs that cover curative, diagnostic, and health screening programs. The continuing rapid expansion of the Indian economy suggests that this trend will only accelerate, and with it, state-of-the-art diagnostic technologies should have a bright future in this marketplace. And finally, the economic boom continues to bring people from many different nationalities into India who are accustomed to the Westernized practice of routine medical checkups, early disease screening, and application of the latest technologies for disease identification.

The third encouraging facet of the demographic shift in India concerns the increasingly large numbers of returning Indians from abroad. Non-resident Indians (NRIs) have spent much of their lifetime in the West as immigrants. After retirement, many NRIs find it more fulfilling to return to their homeland to spend their retirement and live in comparative luxury with their life-savings. The numbers of returning NRIs is growing rapidly and with it represents a significant market for high-end products and services. Indeed, throughout India there is a boom in residential properties and services that are specifically tailored to meet the needs of NRIs. Medical services in particular have flourished with the establishment of “NRI hospitals”. Returning NRIs are accustomed to having regular medical checkups and know well the value of preventive medicine.
from their stay in the West. These facts combined with the age and purchasing power of NRIs represent a significant and growing market for cutting-edge tests.

Given the above demographic facts and trends, the future market potential for molecular diagnostics is widely believed to be extremely positive in terms of sales growth. The number of high- and ultra-high net worth people in India is growing at a very impressive rate, with one recent report showing the rate to be greater than that of China. These overall trends have made the manufacturers and distributors of premium-priced products and services very bullish on the Indian market. The benefit to the overall medical community in India is that once market penetration has been achieved, the combined factors of financial return from investment coupled with advancing technology are likely to lead to cost reduction, allowing greater economic segments of the Indian society to afford these tests.

**Summary**

The current trends and future outlook for molecular diagnostics are excellent for the worldwide market. India is a very cost-conscious market. However, the rapid advancement of the Indian economy has dramatically increased the purchasing power of a growing segment of the populace which, coupled with an emerging mindset toward wellness, preventive medicine, and access to cutting-edge products and services, makes the future outlook extremely positive for this very exciting new field in clinical care. In terms of clinical importance, the rapid diagnosis of infectious disease in saving lives cannot be overstated in acute cases. The detection of predisposition to lifestyle disorders and underlying genetic factors that may contribute to eventual disease onset are correspondingly important factors in long-term (chronic) health care management.

The initial market for emergent diagnostic technologies is the upper-tier economic group, as was the case with arrival of new technologies in the past (e.g., colour TVs, computers, mobile phones, etc.). In a similar way, the provision of new and cutting-edge molecular tests in India will surely be followed by greater affordability as prices come down due to return on investment, competition, and technology advancement. The 21st century has arrived with a bang for India. It is clear that India must now be ready to provide cutting-edge molecular diagnostic tests that are becoming available in other markets, and which Indians will demand access to in increasingly greater numbers.