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China and India are fastest growing IVD markets worldwide

It is likely that China will become the world's largest economy sometime during the next decade and the growth of the IVD markets in India and China, two countries that account for approximately one-third of the world's population, have been growing at a rate of 18% and 25% respectively over the past 15 years which makes them the fastest growing large IVD markets in the world.

According to official figures, China's economy has grown at an average rate of 9.1% during the last decade and increasing prosperity is one of the main drivers of IVD market growth in China. The other main driver is urbanization. Factory workers and office employees are more likely to be customers for diagnostic products than farmers in the countryside.

India's economy has grown at an average annual rate of 6.1% during the last decade, and Goldman Sachs has predicted that India will be the world's third largest economy by 2050. During the last 15 years, India's IVD market has, like China's, grown continuously. While the annual growth rate was around 10% a decade ago, it has increased and is currently at approximately 18%. The same two key drivers (increasing prosperity and urbanization) that are propelling China's market have also contributed to India's impressive growth in IVD spending.

China's IVD market is estimated to be \$2.1 billion with a growth rate of about 25% while India's IVD market is estimated to be \$531 million and growing at approximately 18%. There are differences in the two markets however that IVD developers should pay careful attention to. While both countries are buying and using large numbers of automated IVD systems, China is a better market for instrumentation, particularly automated chemistry systems. While the total IVD market in China is roughly four times as large as India's, its total number of automated chemistry systems is more than six times as high. China and India have substantial differences in their molecular testing markets. At \$112 million, China's molecular market is more than ten times the size of India's. This is due to the large volume of PCR testing for infectious diseases done in China using domestically produced kits. These tests account for about three-fourths of China's molecular market, which sell at prices that no foreign IVD company is willing to match. As a result, the multinational companies are mostly selling instruments. However, emerging disease areas such as oncology will start to give international firms a greater presence in the molecular reagent market since there is no significant local competition.

IVD product registration is an area in which the two countries differ greatly. Product registration is going to get more difficult in India, but it still remains relatively inexpensive and rapid. India's government is making changes in the regulations for medical devices and IVD products. According to industry contacts and Ministry of Health officials, a notification is expected that would bring a group of medical devices and IVDs under the regulatory framework. The authority regulating medical devices and IVDs will be the Central Drug Standard Control Organization (CDSCO) in the Ministry of Health. In China, the situation is very different. The State Food and Drug Administration (SFDA) is responsible for regulating drugs and medical devices. Both IVD instruments and reagents must be registered, and all products must be re-registered every four years.

Both China and India are inspiring success stories, lifting millions of their citizens out of poverty, providing better healthcare, and positioning themselves to play major roles in the global IVD market in the future. The growth rates of the IVD markets in each country have been very impressive during the last 15 years. It is sometimes asked if this growth will slow down in the future. As long as the two main market drivers—increasing prosperity and urbanization—continue, strong growth in the Chinese and Indian IVD markets is expected for many years. Even after 15 years of growth, the two countries combined are spending only about one dollar per person per year on diagnostics. Compared to the \$25-30 per person per year spent on diagnostics in developed countries, it is clear that the IVD markets in China and India are nowhere near market saturation.