China In Vitro Diagnostics (IVD) Marketplace

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The focus of this GEN Market & Tech Analysis Report is to frame the market landscape for *in vitro* diagnostics (IVDs) in China.

This Report is part of GEN’s continuing coverage of the international biotechnology markets and provides a glimpse into an expanding and evolving market in China for IVD products.

This Report is based on primary research wherein we collected information about qualitative and quantitative trends primarily based on conference presentations by companies in the space from Select Biosciences industry conferences focusing on the broader diagnostics domain, along with discussions with these companies at the conferences.

Overall, our goal in this GEN Report is to provide a sector snapshot of the broader diagnostics field with a country-specific perspective.
Market Overview

- Infectious Disease in China is Driving Growth of the Molecular Diagnostics (MDx) Market
- The MDx market in China is at a relatively early stage of evolution. Most of MDx systems in China are “open” with instruments supplied by multinational life science companies, such as Roche and Applied Biosystems [Life Technologies], and reagents provided by local companies, such as Fosun Diagnostics.
- Some Local companies can offer low priced MDx as they do not pay license fees
- FISH-based breast and bladder cancer testing and HPV molecular testing for cervical cancer screening forms the key element of cancer testing. China Medical Technologies, a domestic company, leads the FISH market
- FastHPV (point of care HPV offering), designed for use in low resource countries, and the acquisition of local players such as PG Biotech, QIAGEN is strengthening its presence in China
Infectious disease is the largest application for MDx in China
Many hospitals employ MDx tests for HBV, STDs, HPV, TB, and HIV, as these tests qualify for reimbursement
Even with reduced prices, many MDx tests are very profitable. For example, a PCR test for HBV has a EBIT profit margin of about 50%
Hospital acquired infections: MRSA and ventilator acquired pneumonia (VAP) are key areas of concern in Chinese hospitals. Identification is currently performed with culture methods due to high prices and a lack of awareness of rapid MDx systems, such as the GeneXpert® from Cepheid
China is beginning to adopt MDx HPV tests for cervical cancer screening. With 300 million women of screening age, China represents a large HPV opportunity
China has a vibrant domestic “CLIA sector”, with more than 13 local manufacturers that have supplied the market with roughly 8,000 instruments and the reagents they require. Of these systems, about 98% are semi-automated, but at least three local IVD companies have developed automated CLIA systems and are marketing them.

China’s molecular diagnostics market (MDx) is expanding. 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.
QIAGEN is the one exception to the local dominance of China’s molecular diagnostics market. The company is active in two very different ways:

- First, QIAGEN purchase of Digene gave it almost 100% market share of the domestic HPV market, and even though that share has been slipping due to increased competition, it is still the leader in this segment
- Second, QIAGEN acquired local PCR manufacturer PG Biotech of Shenzhen, the number-two supplier of PCR kits in China

China’s healthcare system continues to demonstrate uniformity that originates from its communist past. Historically, IVD testing has been done at hospitals where the labs served both inpatients and outpatients. The laboratory was the hospital’s second most important profit center, behind drugs and ahead of medical services, so the hospitals were unwilling to send tests out. All hospitals were owned by government bodies at various levels, state-owned enterprises, or the military. Doctors were not allowed to set up private practices, but instead worked for the hospitals

While this is still the general structure of the healthcare system and IVD testing in China, there have been some changes

- Private hospitals now exist, but they are mostly small specialty centers that account for less than 5% of the total beds in the country
- Private medical practices appear to be on the upswing, but they are still a very small component of China’s healthcare system
Breakout of MDx Applications by Infectious Disease Class in China

Source: QIAGEN Presentation.
The total number of clinical laboratories in China is estimated to be around 20,000, which corresponds to the number of hospitals in the country. Almost all of these labs have automated chemistry systems. Many other healthcare facilities in the country, including clinics in small towns and the Chinese Center for Disease Control labs, also do some IVD testing. China continues to build new hospitals, adding about 500 per year. Private labs also now exist in China, and they are becoming more important in the market. In most countries, private lab chains have emerged when a regional leader buys many smaller labs in the area and then continues to purchase other similar labs in other parts of the country. However, since there were no small private labs in China, new private companies are setting up their own labs around the country. Four major groups are building national laboratory chains in China:

- Kingmed (Guangzhou, China) is the leader with 19 labs
- Adicon (Hangzhou, China) is second with 15 labs
- They are followed by Da An (Guangzhou, China), the leading supplier of locally made PCR kits with five labs
- Lawke (Beijing)

While private laboratories have been slow to enter the marketplace and they still do only a modest proportion of China’s IVD testing, they will grow in importance in the coming years.
China Overall IVD Market Quantitative Metrics

- China IVD Total Market Size: $2.2 Billion in 2011
- China IVD Market in 2013: Forecast at $4.5 Billion
- Growing to $7.1 Billion by 2018
- China IVD Market Annual Growth Rate: 15%-30%
In Summary

- We present here a Snapshot of the China IVD Marketplace which is Expanding as Evidenced by the Growth of the Market Size
- Infectious Disease Remains the Current Mainstay of this Marketplace and Within this Segment there are Distinct Disease Classes that have More Dominance
- The Marketplace is Composed of a Mix of Local Companies as well as the Larger Multinational Diagnostics-focused Companies
  - Market Entry Points are Numerous and Include Access via Local Acquisitions
- We Believe that Oncology Testing based on Newer Technologies such as Next-Generation Sequencing (NGS), Circulating Tumor Cells (CTCs), Lab-on-a-Chip/Microfluidics-based Devices (LOAC), etc., Represents the Next Major Market Opportunity for the Growth of the MDx Space in China → This Offers a Market Entry Point