

China makes its mark on global IVD stage

China has been a lucrative market for global manufacturers of in vitro diagnostics for some time. However, the country's homegrown IVD companies are increasingly giving multinational rivals a run for their money with their own innovations. Greg Stutman and Jonathan Chen of Boston Biomedical Consultants reports from last month's AACC meeting

The American Association for Clinical Chemistry Annual Meeting (AACC) & Clinical Lab Expo (CLE) is a key global conference for the *in vitro* diagnostic industry. Given the importance of the meeting, it comes as no surprise that over the past decade the presence of China-based IVD companies has increased at the annual event. This year's AACC & CLE, which took place on 28 July-1 August in Houston, Texas, featured approximately 80 China-based companies, up from less than 20 just 10 years earlier. Not only has the number of China exhibitors increased, but the product breadth and quality on display has evolved. Early on, China exhibitors presented limited product offerings targeting lower-range segments, including ELISA reagents, rapid test kits, and semi-automated or lowthroughput clinical chemistry and hematology analyzers. In Houston, the breadth and scope of product lines included fully-automated systems across a wide range of market segments including clinical chemistry, Chemiluminescence Immunoassay (CLIA), hematology, coagulation, urinalysis, microbiology, and molecular diagnostics, among others.

China's IVD landscape

The China IVD market is home to more than 400 local manufacturers, many of which only cater to their domestic market, with a noteworthy number also selling to other emerging regions, primarily through distributors. While a select number of China companies have achieved US FDA approval, China companies exhibit at the AACC & CLE primarily to seek distribution and OEM partners, along with promoting their products to a global audience. Long-term, many China companies have aspirations of expanding beyond the emerging markets and penetrating the two largest geographic regions, the US and Western Europe, which together represented a \$30bn market opportunity in 2012, or approximately 60% of the global IVD industry. As part of their strategy, China manufacturers will look to leverage their low-cost position to penetrate the more developed regions.

Despite the advancements made by China IVD manufacturers, widespread penetration in the more developed regions will remain a challenge. This is due in large part to the established presence of multinational companies, high demand for product quality and customer service, and the importance of established and reputable distributors, among other barriers to entry in the US and Western Europe. For example, many China companies continue to invest heavily in CLIA platforms, yet menu development remains a key hurdle, especially in light of the decades of expertise among the multinational companies, which continue to enhance their own product offerings through next-generation assays,

biomarker discovery, and higher-capacity platforms (channels and throughput). While the quality of China-made CLIA platforms has improved, the level of sophistication and automation is still below that of the immunoassay systems offered by the multinational corporations.

China grows presence at AACC

The largest presence from a China-based company at the AACC conference once again belonged to Mindray Medical International, which featured its broad and expanding portfolio throughout the exhibition. The company has witnessed rapid organic and inorganic growth in recent years, with several acquisitions including Beijing Precil in October 2012 (coagulation) and Hunan Changsha Tiandiren Biotech in late 2011 (microbiology). Overall, the company achieved 2012 global IVD sales of nearly \$300m, making it the largest China-based IVD company. The centerpiece of Mindray's AACC booth was the OmniLab, the company's first integrated chemistry/CLIA system featuring the BS-2000M chemistry platform (launched in 2012) and the new CL-2000i CLIA system, with the integrated platform expected to launch in China later in 2013. The company also displayed its other chemistry, hematology, coagulation, and urinalysis solutions.

Dirui was second only to Mindray in absolute booth size among China companies; founded in 1992 and originally established as a leading player in the urinalysis segment, Dirui's portfolio has since expanded to include fully-automated clinical chemistry, hematology, and urinalysis products, with the company also developing its first ever CLIA system. The centerpiece of its AACC 2013 display was the CS6400 (launched in China in 2012), a modular clinical chemistry system offering a throughput ranging from 1,600 to 6,400 photometric tests per hour, making it the fastest platform among China manufactures. Furthermore, the company unveiled the CS-4000, a scaled-down version of the CS-6400, with a total throughput of 4,960 tests per hour. Dirui remains committed to expanding its domestic and international presence and driving product line expansion, and is currently pursuing an IPO in order to raise capital to fund its initiatives.

A leader among domestic CLIA companies, Shenzhen New Industries Biomedical Engineering (SNIBE) hosted a medium-size booth at the AACC meeting. SNIBE launched the first China-made fully-automated CLIA analyzer in 2010 and is currently the leader among domestic companies in the China CLIA market in absolute installed base. The company's position is aided by its broad menu, which spans >100 parameters, including 2013 additions of Ddimer, 25-hydroxy vitamin D, TORCH, Epstein Barr virus, and prostatic acid

phosphatase. In Houston, the company displayed two new MAGLUMI CLIA models, the MAGLUMI 4000 with a throughput of 280 tests per hour and the benchtop MAGLUMI 600, with a throughput up to 180 tests per hour. SNIBE is also developing its first ever integrated chemistry/CLIA platform, the IBE 6000. The system was not displayed in Houston last month, but has been showcased at numerous China conferences and made its debut at the 67th China International Medical Equipment Fair in April 2012. The IBE 6000 features an integrated BC 1200 chemistry system and the MAGLUMI 2000 Plus CLIA system, along with an ISE module, and is currently pending China FDA (CFDA) approval.

Other notable companies on display, among others, included URIT, which showcased its five-part differential hematology analyzer, the URIT-5500. The system, which debuted at last year's AACC show, and Mindray's BC-6800 are the only two reticulocyte count-ready hematology systems commercialized by Chinabased companies. Rapid-test products leader InTec's AACC display featured the company's new ABO and RhD test cards, signaling its entrance into the blood grouping and typing market. Among point-of-care testing companies, Edan Diagnostics unveiled its new i15, a POC, cartridge-based blood gas/chemistry analyzer, while Upper Biotech previewed three POC systems for hsCRP, Cystatin C, and D-Dimer, among others. Succeeder and Rayto both featured fully automated coagulation platforms, while Maker, a major clinical chemistry reagent supplier and the largest IVD manufacturer in southeast China, promoted its clinical chemistry reagent line and first-ever CLIA platform, the IS 1200.

Move towards global standards

Recognizing the growing role of the China clinical laboratory service sector in the global market, BD Diagnostics and

the College of American Pathologists (CAP) announced the BD/CAP Strategic Alliance during the AACC meeting. The partnership is focused on improving access to external quality assurance/proficiency testing (PT) in China, with BD managing PT distribution and assisting CAP in promoting awareness of global practice standards. Currently, a majority of clinical laboratories in China participate in national external quality assessment programs and are pursuing certification from the China National Accreditation Service for Conformity Assessment (CNAS). In order to expand their quality certification beyond China, a small, yet growing number of large China hospital and commercial laboratories are pursuing international "gold standard" accreditation, such as CAP and the American Society for Clinical Pathology. These events speak to the overall focus to improve both IVD product quality and laboratory services in China.

What remains evident is the focus of both domestic and multinational companies on the China market, especially given the weak growth outlook for the developed regions due to ongoing austerity measures and economic uncertainty. Historically, the China market has been defined by the presence of multinationals in the Level III (high-level) hospitals, with the domestic players better suited for the lower-level and rural sites. However, investment in higher-capacity platforms and menu offering – as evident by the products Chinese players were showcasing at AACC in Houston – represents a clear signal that domestic companies are eager to play in the higher profile sites in China, while expanding their footprint globally.

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