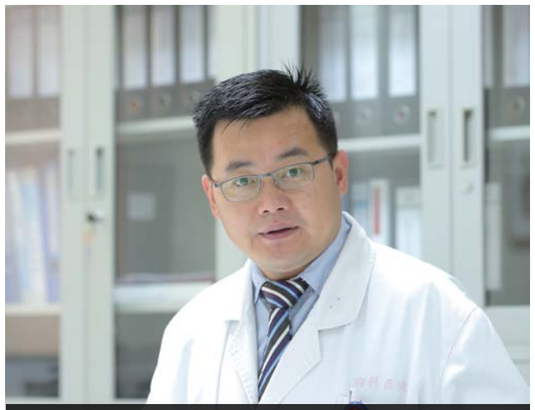
A close look at in vitro diagnosis

Advancement of in vitro diagnostics is PROVIDING NEW TOOLS TO SUPPORT DISEASE DIAGNOSIS AND TREATMENT. In China, researchers encourage university-industry collaboration to promote technological innovation.

QIAN KUN: Principal Investigator, School of Biomedical Engineering at SJTU



LOU JIATAO: Director, Department of Laboratory Medicine, Shanghai Chest Hospital affiliated with SJTU

The growing prevalence of chronic and infectious diseases has spurred development of the in vitro diagnostics (IVD) market. It is estimated that the global IVD market will reach US$73.9 billion by 2020 from US$61.9 billion in 2016. And the Chinese IVD market, estimated at 60 billion RMB (approximately US$10 billion) in 2017, is the fastest growing.

Discoveries in microbiology and immunochemistry have provided cost-effective diagnostic tools for faster and more accurate results. To explore advanced IVD technologies to improve disease detection and treatment, Shanghai Jiao Tong University (SJTU), China Association of In-Vitro Diagnostics, and the Experimental Medicine Professional Committee (EMPC) have partnered with *Nature Biomedical Engineering* to present a Nature Conference on IVD in March 2019. Here, two of the conference organizers, Qian Kun, and Lou Jiatao from SJTU, share their outlook on the future of IVD technologies in China and around the world.

QIAN: The development of IVD aims to provide faster, smaller, and more cost-effective tools that enable more precise diagnosis and point-of-care testing or self-testing. Artificial intelligence and cloud services also provide low-cost solutions for limited-resource settings. Today's cutting-edge technologies in laboratory medicine, including genetic sequencing, liquid biopsy, microfluidics and mass spectrometry technologies, reflect such trends. Sequencing technologies and multi-omic analysis provide a more comprehensive picture for personalised disease diagnosis. Liquid biopsy enables a non-invasive, real-time tool for early diagnosis of cancers. Microfluidics and other micro/nano devices provide a solution to system integration and make instruments smaller. And mass spectrometry helps achieve fast, high-throughput and high-sensitivity testing.

Our ultimate aim is to improve global health. We hope by discussing the current trends of IVD, we can guide its development and achieve our goals faster.

LOU: One area of increasing application of IVD technologies is cancer diagnosis and treatment, of which an exciting breakthrough is liquid biopsy. High-throughput sequencing techniques offer a non-invasive approach that enable disease diagnosis based on blood or urine samples. Researchers typically evaluate circulating tumour DNA (ctDNA) or circulating tumour cells (CTCs) to identify cancer biomarkers, the results of which can be used for cancer screening, to guide treatment plans and to monitor responses to treatment.

At SJTU, we are developing sequencing technologies to meet clinical needs for multi-gene testing and digital polymerase chain reaction (PCR) technology, which are undergoing trials. Together with microfluidic device and mass spectrometry techniques, these developments are allowing personalised disease management.

QIAN: Among my personal interests is developing mass spectrometry techniques for large-scale clinical use. Mass spectrometry is a common method used in omics analysis and is considered the future of diagnostics. It allows testing hundreds of thousands of indicators in a single test, shortening testing time to a couple of minutes. The technology offers high-throughput, femtomolar sensitivity and fast testing, taking analysis from molecular to cellular levels. I have no doubt that it will revolutionize IVD.

LOU: In China, the IVD market is growing fast and has great potential. However, our IVD market is still relatively small and is generally dominated by big multinational companies. We need core products, and have lots of overlapping production. There is also a gap in our research capacity, compared with the world's science powerhouses. As IVD products have long R&D cycles and high technological thresholds, it is important for academia and industry to join forces.

QIAN: Developing IVD technologies requires collaboration across academia, the health sector, enterprises and governments. Academics propose novel research questions, explore the questions and publish the results in high impact journals. They are the source of innovation capacity and responsible for cultivating talented professionals. The industry has engineering capacity and provides funding support to research. As it connects to the end-users, it provides clinical application solutions. Governments also provide essential funding support and by enhancing market monitoring and speeding up product approval, facilitate commercialization of IVD technologies.

LOU: SJTU is very keen on this great endeavour. We are equipped with advanced research platforms, including national major science and technology infrastructure facilities, state key laboratories, such as those focusing on cancer genetics and medical omics studies, as well as various national research centres, laboratories and international collaboration centres. Our capacity is also demonstrated by our strong publication record, with the number of papers published in SCI journals leading in China. We are also national leaders in the number and value of natural science research grants won. More importantly, we have integrated, strong biomedical and engineering programmes. Our clinical medicine programme is the best in the country and the laboratory medicine department has a good academic standing. With our affiliated hospitals, we can also facilitate close collaboration with the clinical sector, making IVD technologies more accessible. ■

CONFERENCE ORGANIZERS

SONG HAIBO
Chairman,
China Association of In-Vitro Diagnostics

As an experienced IVD technician, Song has served as deputy director of Anhui Provincial Center for Clinical Laboratories, deputy chairman of Anhui Micro-Improvement Society, and vice chairman of National Association of Health Industry and Enterprises Management. He has supported standardization of IVD systems and provided technical support to boosting the IVD industry. Song also holds several academic positions and serves on editorial boards of several journals in laboratory medicine. He is the founder of China Association of Clinical Laboratory Practice Expo (CACLP), China's largest professional exhibition in IVD industry.

WANG HUALIANG
Director,
Experimental Medicine Professional Committee (EMPC, China)

Wang is the director of Shanghai Clinical Laboratory Center, editor-in-chief of the journal of *Laboratory Medicine*, vice director of the Laboratory Medicine Management Committee of Chinese Hospital Association, and the vice director of Genetic Diagnosis Branch of Genetics Society of China. As an expert receiving special allowance from the State Council, Wang has led or participated in more than 20 major research projects, funded by the national or Shanghai municipal government, winning multiple science and technology awards. He has also published in top academic journals, such as *Science*, and *Clinical Biochemistry*.

+86 (0)21 64760765
zhaobing@caivd.org
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