Analysis of Innovation and Development of China's IVD Industry in the Age of Big Data

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Abstract. At present, about two-thirds of global medical decision-making was based on diagnosis, and in vitro diagnosis (IVD) was an important part of the process of preventing diagnosis and treatment of diseases. According to a report by Markets in December 2016, the total global IVD market in 2016 reached US$60.22 billion. It was expected to grow rapidly at a compound annual growth rate of 5.5% from 2016 to 2021. By 2021, it will reach US$78.74 billion, of which China is the fastest growing market in the world. This paper summarized the problems encountered in the IVD core technology system and the development status of IVD industry in China, and proposes feasible countermeasures for the innovation development of IVD industry in China.

Keywords: big data, in vitro diagnosis, signal and measurement

1. Introduction

In vitro diagnosis (IVD) is a product and service that obtains biological information of human body through the detection of human samples (blood, body fluids, tissues, etc.), including reagents, instruments, standards, and detection systems. As the country gradually implements the “Healthy China 2030” strategy, the concept of “early diagnosis, early treatment, early rehabilitation, and achieving universal health” will continue to strengthen and will continue to raise people's demand for diagnosis. IVD is not only the cornerstone of medical and health activities, 70% of health care decisions rely on IVD, and it is the most cost-effective health care factor, accounting for only 1% of total health care spending.

2. Modern IVD core technology system

IVD industry technology is king, high-end immune import substitution, molecular diagnostic technology upgrade and POCT convenience are the three major directions for future development. IVD belongs to high-tech industry. The core of the industry lies in the technical platform and reaction system of diagnostic testing. The core competitiveness of the enterprise lies mainly in its technical level.

Modern IVD technology mainly includes three core systems: identification and reaction, signal and measurement, analysis and control. The identification and reaction unit mainly includes the identification product and the reaction carrier, and the integrated product of the liquid-collecting electromechanical calculation. The signal and measurement unit mainly includes the integration of probe, signal and measurement technology products such as electromechanical calculation. The analysis and control unit mainly includes intelligent technology such as artificial intelligence, signal processing and information fusion. Modern technologies such as digital PCR, liquid biopsy, single-molecule detection, molecular imaging, intelligent sensing, flexible wearing, handheld sequencing and flow analysis are increasingly emerging. As shown in Figure 1.
3. China's IVD industry technology development status

China's IVD industry started in the 1980s. After 30 years of development and growth, it now has the conditions for industrial scale development and is in a critical period of rapid development. China's population accounts for one-fifth of the world's total population, but China's IVD industry accounts for less than 15% of the global market share, and the market space is broad. At present, the annual usage of in vitro products in China is only 2.75 US dollars per capita, far lower than the per capita usage of 25-30 US dollars in developed countries. According to the "China Medical Health Blue Book" statistics, in 2014, the market size of China's IVD products reached 30.6 billion yuan. It is estimated that the market size will reach 72.3 billion yuan in 2019, with an average annual compound growth rate of 18.7%. The IVD industry will be in the next 3 years. Will continue to maintain 16%-20% express growth.

3.1 The core technology research and development has achieved important results, and the segmentation field has formed certain comparative advantages

Using Web of Science, Derwent and other database searches, through literature measurement and patent analysis, China's SCI articles published in the field of biosensing and nanofluids are ranked 2nd in the world, and the number of invention patent applications is ranked 3rd; The SCI article published in the field of materials technology ranks 1st, and the invention patent application ranks 2nd; The SCI article published in the field of biological targets and 3D printing technology ranks 4th, which is sufficient to show that China has a solid research foundation in the field of IVD technology.

3.2 Import substitution of products has made important breakthroughs, and the quality of low-end and mid-end products has improved significantly

China's biochemical instrument closure trend is conducive to companies with strong equipment research and development capabilities to break through the industry, the industry may be differentiated; The immune domestic chemiluminescence technology has broken through in the segmentation of infectious diseases, the door to import substitution has been opened. In the field of
microbiology, with the listing of new technology products for domestic mass spectrometry is expected to break the import monopoly; in the field of molecular diagnosis, the cost of sequencing is rapidly decreasing, the NIPT market and new clinical requirements have become the focus of attention; in the field of POCT, the newly emerged gold magnetic particle technology, quantum dot technology and other new types Technology have also strongly promoted the innovative development of POCT at the technical level.

At present, the IVD products and instruments developed in China have a low-end market share of 90% in the fields of immune diagnosis and molecular diagnostics, of which the biochemical fully automatic low-end market share of under 200 is less than 85% and the low-end market share of three classification blood ball instrument is 90%.

3.3 Rapid industrial development has led to the establishment of a more comprehensive industrial technology system

There are more than 1,000 IVD enterprises in China, with an annual growth rate of 17% higher than the global growth rate of 5%. At present, The high-end products such as 1200 high-throughput automatic biochemical analyzers, fully automatic chemiluminescence, real-time PCR, and five-class blood cell analyzers have begun to be localized; the technical level of major IVD products such as smart POCT is close to the international mainstream product level.

4. Current status and bottlenecks of China's IVD industry

The competition in the IVD industry is ultimately the competition of technology. At present, the two hotspots of IVD competition are two units of instruments and menus. The ecological environment of China's IVD industry has unhealthy status such as poor research technology, disjointed supply and demand of research products, and poor product sales. It is mainly reflected in the following three aspects:

4.1 Small scale of enterprises and low industrial concentration

The number of IVD companies in China accounts for the first in the world, with annual sales generally concentrated on the scale of 10 to 50 million, but less than 20 with annual sales exceeding 100 million yuan. Due to the relatively high gross profit margin of the IVD industry, which is about 40%-70%, capital has entered a big profit. However, due to the limited technical content of most enterprises, the single scope of operation, and the serious development of scale benefits, domestic enterprises are small and scattered. A highly competitive situation. In 2015, the domestic market share of China's five representative in-vitro diagnostic listed companies was 14 %, and customers were mainly concentrated in secondary hospitals and basic hospitals, as well as clinical biochemical markets where the market space became saturated. The concentration of the domestic market needs to be further enhanced.

Figure 2. China's IVD market share
4.2 Misalignment of research orientation with market demand

Using Web of Science, Derwent and other database searches, through literature measurement and patent analysis and market research, it is found that the number of full-time R&D personnel in China ranks first in the world, and the number of invention patent applications ranks first in the world. However, the idle rate of technology and products also ranks among the top in the world, showing that the scientific research results of scientific research units are not actively transformed, that there is nowhere to use technology, that enterprises have no ability to innovate and that there is no need for technology. The disconnection between research and application, the disconnection between products and demand; ultimately led to the sub-ecological environment that the new technology products and instrument testing departments are unwilling to use and the clinical departments cannot use.

4.3 The four core technical elements of optics, fluids, computing and omics are backward

Throughout the development of IVDs, it is precisely because of the major discoveries and inventions such as physics, chemistry, immunology, molecular biology and other disciplines that make the IVD keep pace with the times. Rich, development and perfection. The rapid development of biotechnology represented by IVDs has led to the development of IVDs in a more convenient, faster and more informational direction.

With the rapid growth of China's economy, IVD technology is constantly developing and innovating. However, there are still some gaps in the core technical elements of the country and abroad. Mainly in the four core technologies of optics, fluids, computing, and omics, all of which are modeled after foreign countries. The key targets are also foreign, the core components are all imported, and 90% of the key raw materials are imported, resulting in 90% of high-end products being occupied by foreign countries. 90% of high-end hospitals are occupied by foreign countries. In addition, the biological target discovery and transformation ability is low, the technology platform innovation and transformation ability is low, precision manufacturing and scale production capacity are low.

5. China's IVD industry innovation development countermeasures

5.1 Promote disruptive technological innovation and strengthen platform technology research

Enhance four core technologies innovation research of micro-droplet technology, single molecular detection technology, non-invasive biochemical detection technology and intracellular Metabolism Detection for promotion the original ability of IVD technology; Focus on breaking through the development of four key devices: molecular devices, electronic skin, intelligent biological probes, and silicon-based photon sensors, breaking the monopoly of foreign markets, and domestic research and development instead of imports; Establish four innovative technology platforms for microfluidic engineering, liquid biopsy, intelligent biosensor, and BIOMEMS, and perfects the innovation system for IVD technology; The four types of important decision-making models of chronic disease early warning model, health identification model, tumor early diagnosis target system and microbiological diagnosis model are studied to meet the urgent needs of medical health.

5.2 Focus on innovative product development to meet new health care needs

5.2.1 Reinventing POCT technology system with nanotechnology, artificial intelligence and internet to develop innovative wisdom inspection equipment

Wisdom test refers to the intelligent inspection system with self-inspection, self-study, self-diagnosis and self-reporting. It integrates detection, decision-making, interaction and learning. It can realize IVD in-depth community, enter the family, support active health and graded diagnosis and treatment, so that the people are less sick, less likely to see a doctor, and convenient to see a doctor.

China should make full use of nanotechnology, Internet, artificial intelligence to reshape the POCT technology system, and develop smart wearable devices such as wearable biochemistry, implantable wearable devices, biological diagnostic skin and swallowable capsule laboratories; realize mobile...
phone laboratory, smart home Checkboxes, digital table/tableware and digital furniture/environmental smart home inspections; and micro-laboratory lines, in the body weight monitoring system, precision microbial field diagnostics and smart field inspection of handheld sequencers.

5.2.2 Reinventing IVD technology system with nanotechnology, artificial intelligence, inspection and calculation, and developing full-flow pipeline and high-end digital inspection equipment

Integrating nanotechnology, artificial intelligence, Computational inspection technique to reshape the IVD technology system, breaking through the six bottlenecks of automation, intelligence, integration, serialization, standardization and desktopization, developing automatic medical mass spectrometer, next-generation sequencer, multi-modal Flow analyzer, automatic high-resolution microscope four digital inspection equipment; construction of laboratory robots, automatic pathology analysis system, automatic microbiome analysis system three new automatic inspection systems; and automatic assembly line, full laboratory automation line, automatic microbial assembly line three integrated inspection systems. To achieve high-end equipment import substitution, support efficient diagnosis and treatment and precision medicine, and ease the chaos of large hospitals.

5.3 Strengthen related software development, give IVD decision-making ability, and return IVD to original

In the era of big data, comprehensively use the whole process, multi-dimensional, multi-angle production data and information data, develop identification diagnostic software and diagnosis and treatment equipment, realize the transformation and upgrade from in vitro test to IVD, give IVD decision-making ability, realize wisdom test function. As shown in Figure 3.

**Figure 3.** Transformational structure from in vitro testing to IVD

5.4 Promote “Four Energy Technology” and “Five-Services” to help build a smart grading diagnosis and treatment system

In response to the low level of skills of basic hospital personnel, mismatches in diagnosis and treatment techniques, facilities and equipment are not suitable, doctors can not see the disease, and
patients can not stay. We will build a smart graded diagnosis and treatment system for “four energy technologies” and “five services” to improve health service capabilities.

5.5 Construction of intelligent stratification management system based on iPOCT

Instant detection (POCT) is a new branch in the field of clinical diagnosis. Compared with traditional detection methods, it has the advantages of quick and sensitive, easy operation, small sample size, no site limitation, significantly shortened reporting time, and quick results. It has been rapidly developed and widely used. With the development of intelligent medicine, POCT has become a part of the medical system and an important complement to medical emergency testing.

The classification diagnosis and treatment system requires the implementation of the mechanism of “first diagnosis at the grassroots level, graded diagnosis and treatment, and two-way referral”. At present, the operation mode of the laboratory of the primary hospital cannot meet this change, and the POCT highly satisfies the reform of this system and the development of the medical market. Secondly, the reform of the medical system requires the development of POCT. The Chinese government clearly pointed out in the report of the 17th National Congress that it should build a public health medical service system covering urban and rural residents. The reform of these policies and measures requires that large medical institutions, in addition to large-scale equipment and more advanced inspection projects, should also go out of the hospital, facing the grassroots, family-oriented, and rural areas, which requires improvements in testing instruments and testing methods. It is extremely urgent to build a smart layered management system based on iPOCT chronic disease.
China has more than 30,000 scientific and technological achievements at the provincial and ministerial level each year, but only 10% to 15% can promote large-scale benefits. The annual patent technology is more than 70,000, but the patent implementation rate is only about 10%. Due to various ills such as the disconnection of scientific research and production and the imperfect transformation of results in China, a large number of scientific research results are lying in the archives, or scattered in the hands of researchers, and the conversion rate is seriously lower than that of developed countries. In order to solve the phenomenon that “the research results of scientific research units are not actively transformed, there is nowhere to use technology, and enterprises have no ability to innovate and need technology to find nowhere”. Relying on strategic alliances such as science associations, enterprise alliances and industry associations, we will create research platforms, results transformation platforms and product demonstration platforms for reshaping a good innovative ecological environment of “requirements for scientific research services”, and “good demand from the market” and “product service market”.

**Figure 5.** iPOCT chronic disease wisdom layered management system

**Figure 6.** Innovative platform architecture
6. Summary

China's IVD industry has sufficient long-term growth momentum, and all of the demand-side population is aging, urbanization, health awareness, supply-side technology upgrades, new project listings, raw material self-sufficiency and industrial support policies will encourage the domestic IVD industry to continue to maintain rapid growth in the next 3-5 years.

At present, the proportion of medicines and diagnoses in China is very high. The ratio of medicines and diagnosis in foreign countries is about 1:0.8, while the proportion in China is about 1:0.19, and the space for diagnosis is four times that of medicine. Coupled with the current pressure of medical insurance control fees, the diagnostic department is likely to become a new profit growth point for hospitals.

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