The in vitro diagnostics industry in China

Haibo Song | Yaoyi Zhu

China Association of In Vitro Diagnostics, National Association of Health Industry and Enterprise Management, Shanghai, China
China Association for Medical Devices Industry IVD Branch, Shanghai, China

Correspondence
Haibo Song, China Association of In Vitro Diagnostics, Shanghai, China.
Email: songhaibo@caivd.org

Abstract
In vitro diagnosis refers to the diagnosis of diseases or other condition of the human body through the collection, preparation, and testing of human samples with reagents, instruments, and systems. The purpose of in vitro diagnostics is to provide information for the alleviation, treatment, and prevention of diseases and their complications. Enterprises engaged in the production, development, marketing, service, and application of in vitro diagnostic instruments, reagents, standards, consumables, and quality control products constitute the in vitro diagnostic industry. China’s in vitro diagnostic industry began in the 1980s and has developed rapidly, from simple products to large systems and from single products to complete industrial chains. In vitro diagnostics has become the world’s second-largest sales market and second-largest production base. Looking to the future, China’s in vitro diagnostics industry is projected to maintain a growth rate more than double that of the global market and contribute to the development of Chinese and the global industry.

KEYWORDS
China, in vitro diagnostics, industry, market

The Food and Drug Administration (FDA)’s definition of in vitro diagnostics (IVD) refers to the use of reagents, instruments, and systems for the collection, preparation, and testing of human samples to diagnose diseases or other conditions of the human body. IVD provide information that can prevent diseases and their complications. Companies engaged in the production, research and development, marketing, service, and application of IVD instruments, reagents, standards, consumables, and quality control products constitute the IVD industry.1

China’s in vitro diagnosis industry began in the 1980s, and has been in existence for only 40 years. From the perspective of industrial-scale and market-capacity development analysis, China’s IVDs industry history is divided into three development stages. The initial stage, in the 1980s, was characterized by the production of manual reagents and by low capacity in a small market. The next development stage, in the 1990s, was about studying the industry in developed countries primarily. Except for the production of some conventional and hepatitis reagents, most biochemical reagent packages were imported. In this second stage, only semi-automatic microplate readers, semi-automatic chemical analyzers, and some fully automatic instruments, such as blood cell analyzers and urine analyzers, could be produced in China. The new century brought about a period of rapid development in China, where all reagents and instruments in various subdivisions came to be produced in-house. Exports have increased year by year and domestic demand has been met. China’s IVD industry has developed from the single and simple reagent-and-instrument production to a more complete industrial chain, from a
reagent-instrument system to raw materials, and from the domestic market to the global market. Chinese products now cover various industry segments. China has become a country with one of the most complete product lines in the global IVD industry; it is also the country with the strongest market demand.\(^2,3\)

Approximately 1000 IVD reagents are in active use in large-scale comprehensive medical institutions in China, of which approximately 500 are used in laboratories; 250-300 are used in pathology (including flow-cytometer reagents) and other specialty laboratories, such as rheumatology, skin diseases, organ transplants, tissue matching, and more—nearly 100 kinds.\(^4\) It should be noted that China’s LDT project has not yet been incorporated into project management.

Based on the ex-factory prices of Chinese domestic manufacturers and ex-factory prices of multinational companies’ products in China, the market size of China’s IVD industry was 80 billion yuan (about 11 billion US dollars) in 2018, the largest segment of the Chinese medical-device industry. In the field, imported products account for approximately 60% of the 80 billion yuan market share, primarily from Roche, Abbott, Beckman Coulter, Siemens, Thermo Fisher, BD, BioMérieux, Tecan, Sysmex, Hitachi, Ortho, Illumina, PE, Werfen, etc. In the past 5 years, the average annual growth rate of China’s IVDs market has exceeded 15%; among the various product segments in 2018, the biochemical market share accounted for 25% with a growth rate of 7%; the immune share accounted for 35% with a growth rate of 20%; the molecule diagnostic share was 10% with a growth rate of more than 20%; the blood and body fluids share was 10% with a growth rate of 10%; the microbiologic share was 5% with a growth rate of 10%; POCT share was 10% with a growth rate of more than 20%. The pathological market share accounted for less than 5%, with a growth rate of more than 15%. In 2018, the export value of IVD products in China was about 1 billion US dollars, of which 760 million US dollars was the value of instrument exports.\(^5\)

According to preliminary statistics from the members of the China Association of In Vitro Diagnostics, China currently has more than 1400 manufacturers of IVD products, including 113 urine-analyzer manufacturers, 216 POCT (point-of-care testing) manufacturers, 41 blood coagulation analyzers companies, 289 biochemical analyzer and reagent manufacturers, 39 mass spectrometer manufacturers, 41 microbiological detector manufacturers, 80 immunoassay products manufacturers, 38 electrolyte manufacturers, and 15 flow cytometer manufacturers. There are 96 Vacuum vessel production enterprises, 171 glycated hemoglobin manufacturers, 43 specialized protein-meter manufacturers (as shown in Table 1), and more than 350 million distributors. These manufacturers serve 12 109 public hospitals, 20 011 private hospitals, 3469 CDCs, 14 168 reproductive technology service institutions, and 1390 blood banks.

By the end of 2018, the total market value of IVDs manufacturing was more than 300 billion yuan (approximately 42 billion US dollars). With the development of China’s economy, living standards have improved and people’s demand for health care has continued to grow. According to China’s hygiene and health development statistics, in 2017 China’s per capita health expenditure was 3712 yuan, a yearly increase of 10.76%; in 2018, it was 4148.1 yuan, a yearly increase of 9.6%. In 2017, the total number of reported diagnosis and treatment in medical institutions reached 8.18 billion, an increase of 3.2%; in 2018, the total was 83.1 billion, an increase of 1.6%. Medical inspection revenue also increased, which in turn led to increased demand for IVD products.

The Chinese government has various administrative departments involved in the IVDs industry. The National Medical Products Administration (NMPA) is responsible for product registration and supervision, the National Health Commission is responsible for the management of medical institutions and inspection services, the National Healthcare Security Administration (NHSA) is responsible for inspection-service pricing and medical insurance, the National Ministry of Science and Technology provides IVD product research and development support, and the Ministry of Industry and Information Technology (MIIT) and the National Development and Reform Commission provide IVD product industrialization support. The Chinese Academy of Sciences and the Chinese Academy of Engineering also have scientific research developments projects.

NMPA operates special medical clinical testing laboratories. The Clinical Laboratory Testing and In vitro Diagnostic Test Systems (SAC/TC 136) is responsible for the formulation of IVD product standards. In vitro diagnostic products sold in China must be based on standards formulated by

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**Table 1** The number of manufacturers of in vitro diagnostic products in China

| In vitro diagnostic products                                      | Number of manufacturers |
|------------------------------------------------------------------|------------------------|
| Urine-analyzer manufacturers                                     | 113                    |
| POCT manufacturers                                               | 216                    |
| Blood-coagulation analyzers companies                            | 41                     |
| Biochemical analyzer and reagent manufacturers                   | 289                    |
| Mass spectrometer manufacturers                                  | 39                     |
| Microbe manufacturers                                            | 41                     |
| Immuno-immunoassay products manufacturers                        | 80                     |
| Glycated hemoglobin manufacturers                                | 171                    |
| Specialized protein-meter manufacturers                          | 43                     |

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There is a solid clinical demand for the continuous development of IVD enterprises. Currently, the maximum number of testing projects being carried out by Chinese clinical laboratories is approximately 1500, far behind than the 4500 projects in most developed countries. However, new diagnostic requirements are constantly emerging that require clinical laboratories to carry out new testing projects continuously and IVD enterprises to develop new technologies and new products.

- In recent years, the government has introduced policies to reduce taxes and fees related to in vitro development, for example, reducing the value-added tax from 17% to 13%. The high-tech enterprise income tax is 15% (corporate income tax is usually 25%). Most in-vitro diagnostic manufacturing companies apply for and are approved to receive high-tech enterprise designations and can enjoy this preferential income tax. In 2019, the government also reduced the proportion of enterprise employee pension payments by 20%. In addition, various government research and development, industrialization, and other project funding sources have reduced the burden on enterprises, actively encouraged enterprises to invest in research and development innovation, and actively promoted the commercialization of products.
- Currently, in vitro diagnosis is a field to which various investment funds pay attention and in which they invest actively. There are many kinds of active investments. At each stage, there are corresponding investment funds involved, including angel, venture capital (VC), private equity (PE), and mergers and acquisitions. By the end of September 2019, there were 24 IVD companies listed on domestic A-shares, 2 listed on the Hong Kong Exchanges and Clearing Limited (HKEX), and 70 listed on the New Third Board. Companies listed on the main board accounted for 40% of the total medical device companies listed, and more than 10 companies were actively applying for listing.
- With the improved living standards of the Chinese people and the aging speed of the Chinese population, the demand for family health management is increasing. Household diagnosis is an important base for and means of family health management. Currently, there are not enough products suitable for household diagnosis; demand is far from being satisfied. Manufacturers of in vitro diagnosis products have not developed a series of in vitro diagnosis products suitable for home use; this avenue will become an important growth point for in vitro diagnosis enterprises.

China has already become the world’s largest manufacturing base, largest trading nation, and largest exporter, but has less than 2% of export volume for IVD products into the global market. With full-chain industry in IVD field, as long as China’s IVD enterprises continue to innovate, improve product quality and services, the global market must be enlarged.

In 2018, the newly established NHSA pooled the functions of medicine and medical services pricing, bidding and procurement, and cost payment, and introduced a series of new policies. Those policies included lowering drug prices, various high-value consumable prices, overall inspection fees, and
piloting diagnosis-related group (DRG) fees. These changes have brought new requirements and challenges to medical-product providers, including those in the in vitro diagnosis industry, that need to be addressed and responded to by enterprises.

Also in 2018, the newly established NMPA and local-administrations introduced a series of policies and regulations to control the management of enterprises and industries, implement product life-cycle management, and run through all aspects of product development, production, distribution, transportation, and application. At the same time, product registration time was extended. In the past 3 years, the number of newly approved IVD products of three different classes and the number of imported product registration certificates have dropped by more than 20% each year. Enterprise operating costs have also increased accordingly.

Due to the large number of IVD manufacturing companies in China and the continuous emergence of in vitro products, more intense product competition now exists. Coupled with the bidding and procurement policies of medical institutions, competition has led to continuous decline in product sales prices.

China is the main market for US IVD companies, with billions of dollars in imports each year. Chinese domestic manufacturers must also import US-made raw materials and parts every year. At the same time, Chinese companies are actively exporting to the US market. Therefore, the impact of tariffs and trade policies on the industry is becoming clearer, which brings uncertainty to many business activities.

After nearly 40 years of development, China’s in vitro diagnosis industry has grown rapidly, from simple products to large-scale systems, from single products to complete industrial chains. China has become the world’s second largest sales market for this industry and the second-largest production base. In the future, China’s IVDs industry is projected to grow more than twice as fast as the global market, contributing to the development of China and the global industry.

CONFLICT OF INTEREST
There is no conflict of interest to declare.

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