

China IVD Industry White Paper

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01 Introduction



In vitro diagnostics (IVD) is one of the fastest-growing segments in the global medical device sector, playing a critical role in disease prevention, diagnosis, monitoring, and treatment. In recent years, the global IVD market has seen continuous expansion, with China emerging as a significant growth market.

This white paper aims to provide IVD professionals in Latin America, Africa, Arab countries, and Central Asia with an in-depth analysis of the China IVD market, highlighting its current status, competitive landscape, policy environment, and future trends and opportunities.

02

Overview of the Global IVD Market

Overview of the Global IVD Market



The global IVD market has been steadily growing, with a market size of approximately USD 60 billion in 2019 and projected to reach USD 90 billion by 2025, with a compound annual growth rate (CAGR) of 7.5%.

While the US and Europe dominate the market, rapid growth in emerging markets such as China and India is becoming a key driving force for the global IVD market.

03

Current Status and Development of the China IVD Market

Current Status and Development of the China IVD Market



The China IVD market has experienced rapid growth in recent years, with market size increasing from approximately CNY 70 billion in 2016 to CNY 124.3 billion in 2021, representing a CAGR of 15.62%.

Key drivers include increased healthcare consumption, healthcare system reforms, government policy support, and the impact of the COVID-19 pandemic.



04

Analysis of Key Segments



Analysis of Key Segments



01 Immunodiagnostics



Immunodiagnostics is the largest segment of the China IVD market, accounting for 36% of the market share. Chemiluminescence technology is the mainstream, known for its high sensitivity and specificity.

In recent years, Chinese companies have made significant progress in chemiluminescence immunoassay (CLIA) technology, positioning it as a key direction for future development. From 2018 to 2021, the market size for immunodiagnostics increased from CNY 25.6 billion to CNY 44 billion, with an annual growth rate of 20%.

The growth in the immunodiagnostics market is primarily driven by continuous technological advancements and increasing market demand. Products such as New Industries' MAGLUMI X8 and Mindray's CL-8000i have performance levels that match or exceed those of international brands.

With the implementation of centralized procurement policies, Chinese companies are expected to further expand their market share and replace imported products.



Analysis of Key Segments



02 Biochemical Diagnostics



Biochemical diagnostics is the most mature segment within the IVD industry, with growth rates slowing but still presenting investment opportunities. The segment relies heavily on the combination of biochemical analyzers and corresponding reagents.

The China market has a high domestic rate, with Chinese companies demonstrating strong competitiveness in biochemical diagnostic instruments and reagents.

Centralized procurement policies have accelerated the integration and development of the biochemical diagnostics market. For instance, the centralized procurement of liver function biochemical test reagents led by Jiangxi Province achieved significant price reductions, boosting the development of China's biochemical diagnostics market.

As biochemical diagnostic technology continues to upgrade and centralized procurement policies continue to advance, the market is expected to maintain stable growth.



Analysis of Key Segments



03 POCT



POCT (Point-of-Care Testing) is the fastest-growing segment in the IVD market, with market size rapidly expanding. Molecular POCT is a key area for future development, combining the advantages of molecular diagnostics and POCT, offering broad application prospects.

POCT is known for its rapid, convenient, and cost-effective characteristics, widely used in hospitals, communities, and home testing scenarios.

Recent years have seen significant advancements in POCT due to policies promoting hierarchical diagnosis and treatment and the impact of the COVID-19 pandemic. Although the POCT market in China started relatively late, it has been growing rapidly, covering cardiovascular diseases, infectious diseases, endocrine diseases, and other fields.

With continuous innovation in POCT technology and expansion of application scenarios, the POCT market is poised for broader development.



04 Molecular Diagnostics



Molecular diagnostics has high technical barriers and has seen rapid market growth in recent years. PCR and next-generation sequencing (NGS) are the main technology platforms, widely used in early cancer screening and companion diagnostics. Molecular diagnostics is one of the most innovative and promising segments within the IVD industry.

The COVID-19 pandemic has accelerated the adoption and application of molecular diagnostics technology, driving rapid market demand growth.

Chinese companies are highly competitive in the molecular diagnostics segment, with products covering major technology platforms such as PCR and NGS. As molecular diagnostics technology continues to advance and market demand increases, the segment is expected to maintain high growth rates.



05 Coagulation Testing



The coagulation testing market benefits from the high prevalence of cardiovascular diseases, with strong market demand. Coagulation testing is mainly used for diagnosing and monitoring thrombotic and bleeding disorders.

As the population ages and cardiovascular disease incidence rises, the demand for coagulation testing continues to increase. Chinese companies have made significant progress in coagulation testing instruments and reagents, gradually replacing imported products.

With continuous technological innovation and increasing market demand, the coagulation testing market is expected to continue its rapid growth.



06 Microbial Diagnostics



Microbial diagnostics plays a crucial role in managing antibiotic misuse and diagnosing infectious diseases. PCR, mass spectrometry, and NGS technologies have broadened application scenarios, driving market demand growth.

Microbial diagnostics involves culturing, identifying, and performing susceptibility testing on microorganisms to provide essential information for diagnosing and treating infectious diseases.

Recent advancements in PCR and mass spectrometry technologies have significantly improved the sensitivity and accuracy of microbial diagnostics. Chinese companies are highly competitive in this field, offering a range of products that cover traditional microbial testing, mass spectrometry, and molecular diagnostics platforms.

With continuous technological advancements and increasing market demand, the microbial diagnostics market is expected to maintain stable growth.

05

Cooperation Opportunities and International Prospects



Cooperation Opportunities and International Prospects



Unique Advantages in Attracting Global Cooperation

The rapid development of the China IVD industry provides ample cooperation opportunities for IVD professionals in Latin America, Africa, Arab countries, and Central Asia. These regions have increasing healthcare needs, and China's technological innovations and diverse product offerings in the IVD sector can meet these market demands.





Cooperation Opportunities and International Prospects



01

Immunodiagnostics:

China's chemiluminescence technology is highly competitive globally, offering efficient and reliable diagnostic solutions for hospitals and laboratories in these regions.



02

POCT:

Point-of-care testing products are suitable for resource-limited settings and can be widely applied in communities and homes in these regions, enhancing healthcare accessibility.



03

Molecular Diagnostics:

PCR and NGS technologies are crucial for infectious disease detection and cancer screening, helping to improve diagnostic capabilities in these regions.



Cooperation Opportunities and International Prospects



By collaborating with Chinese IVD companies, IVD professionals in Latin America, Africa, Arab countries, and Central Asia can introduce high-quality IVD products and technologies, thereby improving local healthcare services and achieving mutual development.

The advanced technologies and products from Chinese IVD companies will help address practical diagnostic challenges in these regions, promoting local healthcare advancements.





Cooperation Opportunities and International Prospects



International Market Expansion and Cooperation Prospects



Chinese IVD companies are highly competitive in the international market, gradually gaining entry through continuous technological innovation and product quality improvement. IVD professionals in Latin America, Africa, Arab countries, and Central Asia can collaborate with Chinese companies to obtain cost-effective IVD products that meet local market needs.

The Chinese government actively promotes the internationalization of the healthcare industry through initiatives such as the Belt and Road Initiative, supporting IVD companies in entering global markets.

In the future, Chinese IVD companies will partner with global stakeholders to drive the development of the IVD industry worldwide, benefiting patients globally.

06

Policy Environment and Industry Chain Analysis



Policy Environment and Industry Chain Analysis

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The Chinese government actively promotes the development of the IVD industry by implementing a series of policies to support industry upgrades and innovation. Centralized procurement policies have a profound impact on the industry landscape, driving Chinese companies to enhance competitiveness and facilitate industry integration.





Policy Environment and Industry Chain Analysis

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The centralized procurement policies implemented by the government have significantly impacted the IVD market, reducing prices through centralized purchasing and price negotiations, increasing market transparency and competitiveness. By participating in centralized procurement, Chinese companies have increased their market share and brand influence, achieving rapid growth.





Policy Environment and Industry Chain Analysis

The IVD industry chain includes upstream raw material supply, midstream instrument and reagent production, and downstream end-users such as hospitals and third-party testing institutions. The upstream raw material market is primarily dominated by international brands, with a low domestic rate. In the midstream production segment, Chinese companies are gradually rising, achieving import substitution in the mid-to-low-end market. Downstream market demand remains strong, with hospitals and third-party testing institutions as the primary consumers.

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07

Future Trends and Opportunities



Future Trends and Opportunities



In the coming years, the China IVD market is expected to continue its rapid growth. Key drivers will include hierarchical diagnosis and treatment, healthcare resource allocation, new technology applications, and international market expansion.

Chinese companies must continuously enhance their technological innovation capabilities and actively expand into international markets to achieve greater market share.



Future Trends and Opportunities



As the population ages and chronic disease incidence rises, the demand for IVD products will continue to increase. Policies promoting hierarchical diagnosis and treatment and the allocation of healthcare resources will further drive the application of IVD products in primary healthcare institutions.

The adoption of new technologies, such as molecular POCT and NGS, will introduce new growth opportunities for the IVD market.



Future Trends and Opportunities



Moreover, expanding into international markets is crucial for Chinese companies to achieve rapid growth. With continuous technological advancements and improved product quality, Chinese IVD companies are highly competitive in the international market. By actively expanding into global markets, Chinese companies are poised to increase their market share further.



08 Conclusion



Conclusion



The China IVD industry is in a rapid growth phase with significant market potential. For IVD professionals in Latin America, Africa, Arab countries, and Central Asia, the China IVD market offers abundant cooperation opportunities and development prospects. By continuously enhancing technological innovation capabilities, strengthening policy support, and actively expanding into international markets, Chinese IVD companies will achieve even greater growth prospects.



Thanks for reading!

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International Market Expansion and Cooperation Prospects

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Please visit our website at www.Sinova.world. Let's work together to create a better future and contribute to global healthcare!

