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Development and Industrialization Path Construction of Thrombosis and Hemorrhage Related Detection Kit Guided by Precision Diagnosis

Yi Lu

Hunan Saixin Biotechnology Co., Ltd., Changsha, Hunan, 410300, China

ABSTRACT
Thrombotic and hemorrhagic diseases have become the leading cause of death globally, with early, accurate, and stratified diagnosis being critical for clinical management. China's in vitro diagnostics (IVD) industry is currently in a period of rapid growth, yet high-end coagulation and hemostasis testing reagents remain heavily dependent on imports, and routine tests fail to meet the demands of precision medicine. This article, guided by clinical application principles, introduces key parameters such as protein C, protein S, vWF factor, and monitoring of novel anticoagulants. It elucidates the development design rationale and key technical points of reagents, product evaluation methods, and proposes a comprehensive industrialization strategy encompassing raw material procurement, production processes, quality control, registration, marketing, and continuous improvement. Feasible solutions for domestic substitution and technological upgrading are also proposed. The study demonstrates that colorimetric substrate-based and coagulation-based methods can achieve internationally comparable levels of accuracy in key factor activity and serum drug concentration detection. Establishing an industrialization model of "R&D – production – registration – market – after-sales" will facilitate the localization of high-end coagulation reagents, reduce clinical costs, and improve disease diagnosis rates. This research lays the foundation and accumulates experience for the development and industrial application of thrombotic and hemostatic IVD products, promoting the autonomous and healthy development of China's IVD industry.

KEYWORDS
Precision diagnosis; Thrombosis and hemorrhage; Diagnostic kit; R&D; Industrialization pathway

1 Introduction

Due to population aging and changes in lifestyle, thrombotic diseases have become a major threat to public health in China, while bleeding disorders frequently occur during surgery, trauma, or genetic diseases, constituting the primary components of clinical emergencies. Traditional coagulation tests can only provide a macroscopic assessment of the body's hemostatic mechanism and cannot accurately determine whether the condition is caused by hereditary thrombophilia, vascular hemophilia, coagulation factor deficiency, or excessive anticoagulant medication. These tests fail to meet the demands of personalized diagnosis and treatment. The rapid advancement of precision diagnostic technologies has driven the evolution of thrombotic and bleeding monitoring from "routine" to "factor-specific, targeted, and quantitative" approaches. Key clinical testing parameters now include the protein C/protein S system, vWF factor, and anti-Xa/anti-IIa activity assays.

China's in vitro diagnostics industry has developed rapidly in recent years, with a compound annual growth rate far exceeding the global average. However, it still faces challenges such as reliance on imported core raw materials for high-end coagulation diagnostics, high technical barriers, insufficient industrialization capabilities, and market dominance by international giants. Under these circumstances, the development of diagnostic kits based on precision diagnosis and the establishment of a practical, replicable, and scalable industrialization path are not only an objective need to address domestic technological gaps but also an urgent requirement for frontline clinical applications. Moreover, it is an indispensable part of improving the national healthcare service level and building a healthy China. This article discusses the research logic, technical system, and industrialization model of precision detection kits for thrombosis and bleeding, providing a systematic solution for related product development and industrial transformation.

2 Development and Design of Thrombosis and Hemorrhage Detection Kits Under the Guidance of Precision Diagnosis

2.1 R&D Objectives and Clinical Positioning

The core of precision diagnosis lies in specific identification, accurate quantification, rapid result generation, and guidance for clinical decision-making. The reagent kit developed in this study aims to address clinical pain points, covering three major scenarios: hereditary thrombotic risk screening, differential diagnosis of bleeding disorders, and personalized monitoring of novel oral anticoagulants. It focuses on developing a series of products, including protein C activity, protein S activity, vWF factor activity, anti-Xa factor (rivaroxaban/apixaban), and anti-IIa factor (dabigatran). These

products are compatible with fully automated hemocoagulation analyzers, enabling high-throughput, automated, and standardized testing. Their performance comprehensively rivals imported reagents, with costs reduced by over 30%, meeting the clinical needs of medical institutions at all levels.

2.2 Technical Principles and Methodological Selection

Currently, the internationally recognized methods for precise coagulation testing primarily include the chromogenic substrate method and the coagulation method, which offer advantages such as high sensitivity, strong specificity, good reproducibility, and broad applicability. The monitoring of protein C and anticoagulants employs the chromogenic substrate method, which quantitatively detects drug or factor activity through enzymatic reactions. For protein S and vWF factor, the coagulation method and the restoromycin cofactor method are used to directly reflect functional activity levels in vivo. These methodologies are compatible with mainstream international equipment, requiring no additional hardware investment, and can be rapidly implemented for clinical use.

2.3 Core R&D Process and Key Technologies

2.3.1 Raw Material Screening and Localization

Key materials such as recombinant thrombin, FXa, chromogenic substrates, defibrin, buffers, calibrators, and quality control materials were evaluated through comparative studies with multiple manufacturers, activity assays, and stability assessments. The high-purity, low-interference, and cost-effective domestic key materials were selected, establishing stable supply channels to break the foreign monopoly.

2.3.2 Prescription Optimization

The single factor test and orthogonal test were used to optimize the pH, ionic strength, reaction temperature, substrate concentration and stabilizer ratio of the buffer, which improved the sensitivity, linear range and anti-interference ability of the reagent, and realized the all-liquid, ready-to-use formula without re-dissolving and freeze-drying.

2.3.3 Establishment of Calibration Traceability System

By using internationally recognized reference standards as the basis for traceability, standard curves and quantitative calibration methods are established to ensure comparability of test results across different batch numbers and laboratories, thereby meeting the quality assessment requirements among different laboratories.

2.3.4 Quality Control Point Setting

Define key indicators including appearance, pH, clarity, precision, accuracy, and stability to establish internal control standards for the enterprise, ensuring that R&D outcomes can be directly translated into large-scale production.

2.4 Performance Analysis and Clinical Validation System

After completing the development of the kit, perform evaluations of precision, accuracy, linearity, detection limit, specificity, cross-reactivity, and durability in accordance with CLSI standards and relevant guidelines from the National Medical Products Administration (NMPA). Compare the kit with the original manufacturer's product and the liquid chromatography-mass spectrometry (LC-MS) instrument as the gold standard through multicenter, parallel trials to assess the consistency and sensitivity/specificity of the kit, as well as the appropriateness of reference values. Ensure the safety, efficacy, and accuracy of the product.

3 Construction of the Full Industrialization Path for Thrombosis and Hemorrhage Detection Kits

3.1 Overall Framework of Industrialization

With the objectives of standardizing R&D, scaling up production, ensuring quality control, complying with registration requirements, and promoting market penetration, we aim to establish a full-chain industrialization system covering "upstream raw materials—midstream production—downstream applications." This system encompasses six key modules: technology R&D, manufacturing, quality management, registration and submission, academic promotion, and technical

services, thereby forming a closed-loop industrial transformation model.

3.2 Upstream: Core Raw Material Supply Chain System Construction

Raw materials constitute the core competitive barrier for in vitro diagnostic reagents and are pivotal to cost control. Companies should establish strategic partnerships with domestic biologics manufacturers to achieve localized supply of critical components such as enzyme substrates, substrates, buffers, antigens, and antibodies. Implementing a system for raw material acceptance, sample retention, and stability testing ensures consistent quality across all batches. Additionally, establishing a backup supplier mechanism mitigates supply chain disruption risks, thereby guaranteeing continuous and stable large-scale production.

3.3 Midstream: Establishment of GMP Standardized Production System

Establish a Class 10, 000/100, 000 cleanroom in accordance with Good Manufacturing Practice (GMP) for medical devices, equipped with automated liquid preparation, filtration, filling, and packaging systems, and develop standardized operating procedures (SOPs) to ensure traceable documentation and full-process traceability. The production process is divided into: raw solution preparation → sterilization filtration → quantitative filling → semi-finished product inspection → packaging → product release, with critical steps prone to human error being processed using fully automated equipment whenever possible. Enhance batch-to-batch consistency. Implement flexible production capacity to flexibly allocate production capacity as needed, thereby improving operational efficiency.

3.4 Full-process Quality Control and Risk Management

Establish a comprehensive quality management system covering the entire process from R&D, production, inspection, storage and transportation to final use. Implement a three-tier quality control mechanism comprising raw material inspection, in-process monitoring, and finished product testing. Only after passing precision, accuracy, and stability testing for each batch of products shall they be released for sale. Establish a system for adverse event collection, customer complaint handling, product recall, and risk assessment alerts. Comply with relevant medical device regulations to ensure clinical safety.

3.5 Medical Device Registration and Compliance Pathway

Based on product classification and risk level, the registration application shall be conducted in accordance with the requirements for Class II medical devices, including the preparation of product technical requirements, third-party type testing, multicenter clinical evaluation, system verification, submission of documentation, and review and approval. Make full use of policies such as priority review for innovative medical devices and conditional approval to shorten the market launch cycle. Simultaneously, complete intellectual property layout to establish technical barriers through patent protection.

3.6 Market Promotion and Commercialization

Guided by academic principles, we collaborate with clinical experts to promote guideline dissemination, conduct research projects, and facilitate academic exchanges, thereby enhancing clinical understanding of precision thrombosis diagnosis. Focusing on cost-effectiveness as the entry point, we expand into tertiary hospitals, primary care facilities, and third-party medical testing institutions, establishing a nationwide distributor and technical service network. We provide integrated solutions including equipment matching, operator training, and quality control assistance. We actively participate in medical insurance access and centralized procurement to improve accessibility and accelerate domestic substitution.

3.7 Technology Iteration and Product Matrix Upgrade

Following the market launch of the core kit, continuous technical optimization has been carried out to upgrade towards high sensitivity, broad linearity, interference resistance, and POCT portability. Concurrently, the product line has been expanded to develop supporting reagents such as coagulation factor antigen detection, fibrinolytic system indicators, and thrombus elastography, forming a comprehensive testing solution of "routine screening + precision diagnosis + medication monitoring" to enhance the company's overall competitiveness.

4 The Value and Significance of Industrialization Implementation

4.1 Clinical Value

Precision detection kits can significantly improve the early diagnosis rate and etiological differentiation rate of thrombotic and hemorrhagic diseases, guide individualized use of anticoagulant drugs, reduce the incidence of bleeding and thrombotic events, lower medical costs, and improve patient prognosis. Simultaneously, they promote the implementation of advanced coagulation testing in primary hospitals, thereby enhancing overall diagnostic and therapeutic standards.

4.2 Industrial Value

The project has broken the import monopoly of high-end coagulation reagents, mastered core technologies and key raw materials, filled the domestic gap in the in vitro diagnostics (IVD) industry, and driven the entire industry to shift from low-level, cutthroat competition to high-end, high-quality development. It has also established an industrialization paradigm for the IVD sector, providing reference experience for subsequent R&D of IVD products.

4.3 Social Value

Reducing detection costs, alleviating the burden on medical insurance and patients, facilitating the implementation of hierarchical diagnosis and treatment and precision medicine, and enhancing China's capacity for major disease prevention and control align with the Healthy China strategy and the development plan for the medical equipment industry.

5 Conclusion

The development of thrombosis and bleeding-related detection kits guided by precision diagnostics aligns with clinical needs and the direction of industrial advancement. Through rational legal framework design, comprehensive performance evaluation, and standardized R&D procedures, domestically produced products that meet international advanced standards can be developed. Establishing a complete industrial chain encompassing "raw materials-manufacturing-quality control-registration-market launch-updates" is crucial for ensuring large-scale and sustainable production of high-end coagulation diagnostic reagents. This model not only breaks import monopolies and reduces medical costs but also enhances the precision diagnosis and treatment of thrombosis and bleeding disorders in China, promoting the quality and efficiency of the in vitro diagnostics industry. In the future, efforts should focus on strengthening technological innovation, improving the industrial ecosystem, and accelerating market adoption to provide more reliable diagnostic support for major disease prevention and control as well as public health.

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About the Author

Yi Lu, male, born in 1981, Tujia ethnicity, Senior Engineer, native of Enshi, Hubei Province. Graduated with a Ph.D. in 2009 from Tongji Medical College of Huazhong University of Science and Technology. Main research focus: Clinical In Vitro Diagnostics. Affiliated institution: Hunan Saixin Biotechnology Co., Ltd.

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