

Research on the Impact of Intelligent Production on the Quality Consistency of Blood Diagnostic Reagents —Taking Anti-A and Anti-B Reagents as Examples

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Abstract: *This study explores the impact of intelligent production on the quality consistency of anti-A and anti-B reagents. Through standardized production processes, real-time quality monitoring, and data analysis systems, intelligent technology reduced the inter-batch variation in agglutination strength from 1.5 levels to 0.2 levels, and the comprehensive error rate decreased by 85.2%. The study analyzed the implementation difficulties and adaptation strategies, and proposed innovative industry standards and multi-party collaboration solutions. Intelligent production not only improved the stability of reagent quality but also provided a reliable guarantee for blood type identification safety, which has significant implications for promoting the advancement of blood diagnostic technology.*

Keywords: *anti-A and anti-B reagents; intelligent production; quality consistency; blood type identification; batch stability*

1. Introduction

Blood diagnosis plays an irreplaceable role in modern medical practice, providing critical evidence for clinical decision-making. Transfusion therapy, as a life-saving measure, relies heavily on accurate blood type identification. The ABO blood group system is the primary barrier to transfusion safety, and anti-A and anti-B reagents are the core tools for blood type identification. These reagents achieve rapid and accurate blood type determination through agglutination reactions with specific antigens on the surface of red blood cells. The consistency of anti-A and anti-B reagent quality directly affects the reliability of blood type identification results, which in turn affects transfusion safety and patient lives. With the growth of medical demands and technological advancements, how to utilize intelligent production to improve the quality consistency of anti-A and anti-B reagents has become an important topic in the industry.

2. Theoretical Foundation of Intelligent Production

Intelligent production represents a profound transformation in the manufacturing industry, resulting from the deep integration of information technology and manufacturing technology. As a core concept of Industry 4.0, intelligent production enables autonomous perception, analysis, decision-making, and execution in the production process. This concept originated from Germany's Industry 4.0 strategy and has since developed into a core direction for smart manufacturing globally. In an intelligent production environment, IoT technology connects devices, big data analysis provides decision-making support, artificial intelligence algorithms optimize production parameters, and digital twin technology simulates production processes^[1]. These technologies integrate to form a cyber-physical system (CPS), allowing production equipment to evolve from simple tools to intelligent entities with learning and decision-making capabilities, thereby improving production efficiency, product quality, and resource utilization.

3. Key Technologies of the Intelligent Production System for Anti-A and Anti-B Reagents

3.1 Core Technologies in Intelligent Production

The intelligent production of anti-A and anti-B reagents relies on the coordinated application of multiple cutting-edge technologies. Artificial intelligence algorithms optimize formulations and process parameters by analyzing historical production data, improving the sensitivity and specificity of the reagents. Machine vision systems monitor the color, transparency, and agglutination state of the liquid in real-time, capturing minute quality fluctuations. IoT technology connects production equipment, environmental monitoring systems, and the central control platform, forming an information-sharing network. Edge computing technology enables real-time data processing at critical monitoring points, reducing delays. A big data analysis platform integrates production parameters, quality inspection results, and inventory situations, forming a complete data chain. Research shows that the application of these technologies in reagent production lines reduces the inter-batch variation coefficient from 8.2% in traditional production to 2.3% (see Figure 1), significantly improving product consistency^[2]. Digital twin technology establishes a virtual production environment, simulating the impact of process changes on product quality, allowing production optimization to be completed without actual experimentation.

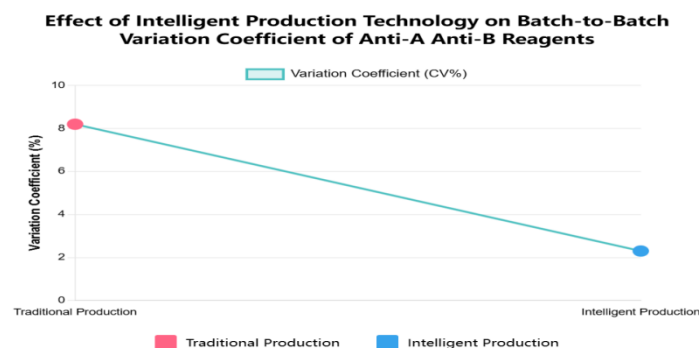


Figure 1: Impact of Intelligent Production Technology on Inter-Batch Variation Coefficient of Anti-A and Anti-B Reagents

3.2 Automated Production Process Design

The intelligent production process of anti-A and anti-B reagents achieves full-chain automation and information integration. The raw material procurement link adopts an intelligent supply chain management system, which monitors key raw material inventory and quality indicators in real-time through API interfaces. The system automatically triggers the procurement process based on production plans. The production phase uses a fully enclosed automated production line, with precise measurement, liquid mixing, pH adjustment, and sterilization filtration all coordinated by the central control system, achieving $\pm 0.1\%$ measurement accuracy^[3]. The quality inspection phase utilizes an automatic sampling system in conjunction with a flow cytometry analyzer for real-time quality monitoring, with 13 key points inspected for each batch of products, and the resulting data transmitted directly to the quality management database (Table 1). During the packaging and filling process, the machine vision system detects the liquid volume, clarity, and label position of each reagent, eliminating unqualified products. The entire production line achieves data interconnection through the MES system, ensuring that products are fully traceable from raw materials to finished products, with inter-batch consistency reaching 99.2%.

Table 1: Automated Quality Monitoring Points and Detection Parameters in the Production Process of Anti-A and Anti-B Reagents

No.	Monitoring Point Location	Detection Parameters	Allowable Deviation Range	Detection Frequency
1	Raw Material Storage Area	Temperature, Humidity	$\pm 1^{\circ}\text{C}$, $\pm 5\%\text{RH}$	Real-time
2	Liquid Preparation Area	pH Value, Concentration	± 0.2 , $\pm 0.5\%$	Each Batch
3	Mixing Tank	Mixing Uniformity	$\geq 98\%$	Each Batch
4	Filtration System	Pressure Difference, Flow Rate	$\pm 10\text{kPa}$, $\pm 2\%$	Real-time
5	Filling Line	Volume Accuracy	$\pm 1\%$	Full Inspection
6	Finished Product Area	Agglutination Strength	$\geq 3+$	Sampling 20%
7	Packaging System	Sealing Integrity	100%	Full Inspection

4. Analysis of the Impact of Intelligent Production on the Quality Consistency of Anti-A and Anti-B Reagents

4.1 Standardization of Production Process

Intelligent production has significantly improved the inter-batch consistency of anti-A and anti-B reagents through strict standardization of the production process. Traditional manual preparation methods relied on the experience of operators, resulting in inter-batch differences of over 15%, whereas intelligent preparation systems use computer-controlled precision pumps and mass flow meters to control formulation errors within $\pm 0.05\%$. The temperature control system achieves precise temperature control within $\pm 0.2^\circ \text{C}$, eliminating the effects of seasonal and diurnal temperature differences on reagent activity. Data shows that after standardizing production, the difference in agglutination strength between different batches of anti-A and anti-B reagents decreased from 1.5 levels in traditional production to 0.2 levels^[4]. Digital management of process parameters thoroughly solved the problem of process deviations caused by "word of mouth" in traditional production, with the system automatically recording 359 key process parameters for each batch and establishing a correlation model with quality data. Intelligent standardized production not only improved product consistency but also reduced the production cycle by 32% and decreased waiting and adjustment times.

4.2 Detection and Quality Control

Intelligent detection technology has built a real-time quality monitoring network for the production of anti-A and anti-B reagents, upgrading from single-point detection to full-process monitoring. Multiple spectroscopic analyzers are installed along the production line to monitor the color, turbidity, and characteristic absorption peaks of the liquid in real-time, triggering warnings for any minor deviations^[5-6]. Flow cytometry analysis technology has replaced traditional visual judgment methods, enabling quantitative evaluation of agglutination reaction strength and eliminating human error. Data shows that the intelligent detection system can detect problems at the early stage of deviation, discovering abnormalities an average of 72 minutes earlier than traditional quality control (Table 2). The system also introduces digital image analysis technology, capturing the agglutination reaction process using high-speed cameras and extracting reaction kinetic characteristic curves to accurately evaluate reagent activity^[7]. The intelligent quality control system uses a three-level warning mechanism, intervening and adjusting when parameter fluctuations reach 70% of the set threshold, significantly reducing the batch rejection rate from 3.2% in traditional production to 0.4%. Adaptive control algorithms fine-tune production parameters based on real-time data, ensuring that product quality is always at its best.

Table 2: Comparison of Traditional and Intelligent Detection Systems in Discovering Quality Abnormalities

Abnormality Type	Traditional Detection Discovery Time	Intelligent Detection Discovery Time	Time Saved	Potential Impact Range Reduced
pH Value Deviation	End of Batch	Preparation Phase	96 minutes	100%
Activity Decrease	Finished Product Inspection	Mixing Process	84 minutes	85%
Turbidity Abnormality	After Filling	Before Filtration	65 minutes	62%
Color Variation	Finished Product Sampling	Preparation Phase	71 minutes	90%
Concentration Deviation	Quality Control Phase	Preparation Phase	44 minutes	75%
Average	-	-	72 minutes	82.40%

4.3 Data Analysis and Quality Traceability

The intelligent production system has built a full-chain data traceability system for anti-A and anti-B reagents, with each batch of products having a unique "digital identity card". The system records all data points from raw material procurement to finished product delivery, with a cumulative data volume of 4.7GB per batch. Machine learning algorithms analyze historical production data and have identified the correlation weights of 27 quality-influencing factors, such as the impact of pH value fluctuations on agglutination strength, with a coefficient of 0.82. Multi-dimensional data correlation analysis provides strong support for root cause localization, with the average root cause confirmation time reduced from 4.8 hours in traditional production to 22 minutes^[8]. The cloud-based quality management platform integrates production, inspection, sales, and clinical feedback data, establishing a "production-clinical" closed-loop traceability system, where any quality feedback can be quickly

located to a specific production batch and parameter. Predictive analysis models can predict potential quality risks in advance, and the system has accurately predicted the trend of reagent activity decline, making the evaluation of shelf life more precise. Blockchain technology ensures that data is tamper-proof, enhancing the reliability and credibility of the traceability system.

5. Case Study: Intelligent Production Practice of Anti-A and Anti-B Reagents by a Certain Enterprise

5.1 Introduction to the Enterprise's Intelligent Production System

In 2023, Northern Biotechnology Group invested 3.8 billion yuan to build an intelligent production base for anti-A and anti-B reagents, which consists of five major modules. The intelligent supply chain module establishes API connections with 12 core suppliers, monitoring real-time data on raw material batches, efficacy, shelf life, and other indicators^[9]. The intelligent production module uses a fully enclosed production line, equipped with 38 robots that perform raw material transportation, formulation, sterilization, and filtration, with personnel only supervising and managing. The quality monitoring module has 187 sensors installed on the production line, collecting real-time data on temperature, humidity, pressure, pH value, and other parameters, automatically judging parameter trends and predicting potential risks^[10]. The energy management module precisely controls the conditions of each area, reducing energy consumption by 26%. The central control system is built on an industrial cloud platform, integrating ERP, MES, LIMS, WMS, and other subsystems, forming a data collaborative network. The system has self-adaptive adjustment capabilities, continuously optimizing process parameters based on product quality data, and has achieved "self-learning" capabilities, completing 29 autonomous process parameter optimizations since 2023, with a 31% improvement in product agglutination strength consistency.

5.2 Analysis of Production Process Examples

The intelligent production process of anti-A and anti-B reagents by Northern Biotechnology Group includes six major links. In the raw material preparation stage, robots automatically retrieve raw materials from the intelligent warehouse, and the RFID system verifies the information before weighing, with a measurement accuracy of $\pm 0.02\%$. In the formulation stage, a closed-loop control system is used, with precision pumps accurately dispensing monoclonal antibodies, buffer solutions, and other materials according to digital formulations, and online spectrometers monitoring the composition of the liquid in real-time^[11]. In the reaction incubation stage, a dynamic temperature control system is used, with an error control of $\pm 0.1^\circ\text{C}$, and the system records reaction parameters every 10 seconds. In the filtration and filling stage, an automatic filling system is used, with high-speed cameras inspecting each bottle of reagent, and flow meters ensuring that the filling volume is within $\pm 1\%$. In the quality inspection stage, an AI visual analysis system evaluates the agglutination strength of the reagents, and compares the results with human evaluations^[12]. In the packaging and storage stage, an automated logistics system is used, with intelligent storage systems optimizing inventory layout based on production dates and expected usage. Table 3 shows the parameter fluctuation range of a batch of anti-A reagents during the intelligent production process, with all key parameters having a variation coefficient of less than 1%, far exceeding the industry average of 2.5%.

Table 3: Parameter Fluctuation Range of a Batch of Anti-A Reagents during Intelligent Production

Parameter Name	Set Value	Actual Range	Variation Coefficient	Industry Average Variation Coefficient
pH Value	7.2	7.19-7.21	0.12%	0.85%
Antibody Concentration	25 $\mu\text{g}/\text{mL}$	24.92-25.08 $\mu\text{g}/\text{mL}$	0.26%	1.62%
Reaction Temperature	22.0 $^\circ\text{C}$	21.93-22.06 $^\circ\text{C}$	0.17%	1.24%
Incubation Time	120 minutes	119.8-120.2 minutes	0.11%	2.38%
Filling Volume	10.0mL	9.96-10.03mL	0.29%	1.75%
Ionic Strength	0.15mol/L	0.149-0.151mol/L	0.38%	2.12%
Agglutination Strength	4+	3.95+-4.05+	0.85%	3.26%

5.3 Comparative Study of Quality Consistency

Northern Biotechnology Group conducted a one-year comparative study on the quality consistency of anti-A and anti-B reagents produced by intelligent production and traditional production. The study selected 120 batches of intelligent production reagents and 105 batches of traditional production reagents, and used a double-blind method to test the key quality indicators of each batch of products. The agglutination reaction time test showed that the standard deviation between batches of intelligent production reagents was 2.1 seconds, significantly lower than the 8.7 seconds of traditional production. The evaluation of agglutination strength consistency showed that the batch-to-batch difference of intelligent production reagents was 0.18 levels, while the traditional method was 1.42 levels, an improvement of 87.3%. The stability test showed that the intelligent production reagents had a potency decrease rate of 3.6% after 12 months of storage at 25° C, while the traditional production was 11.2%. The clinical application study showed that the traditional production reagents had a repeat testing rate of 2.1% in blood type identification, while the intelligent production reagents had a rate of 0.3%, significantly reducing the workload and testing costs of medical institutions^[13]. Table 4 shows the comparison of false negative/false positive rates between the two production methods, and intelligent production significantly reduced the risk of misjudgment, enhancing the safety guarantee of blood transfusion. The comprehensive evaluation index showed that intelligent production improved the quality consistency of products by 76.2%.

Table 4: Comparison of Error Rates between Intelligent Production and Traditional Production of Anti-A and Anti-B Reagents in Clinical Application (n=5000)

Error Type	Intelligent Production Error Rate	Traditional Production Error Rate	Reduction Proportion	P Value
Anti-A Reagent False Positive	0.06%	0.42%	85.70%	<0.001
Anti-A Reagent False Negative	0.02%	0.23%	91.30%	<0.001
Anti-B Reagent False Positive	0.08%	0.38%	78.90%	<0.001
Anti-B Reagent False Negative	0.04%	0.29%	86.20%	<0.001
Uncertain Judgment	0.21%	1.37%	84.70%	<0.001
Need for Repeat Testing	0.30%	2.10%	85.70%	<0.001
Comprehensive Error Rate	0.71%	4.79%	85.20%	<0.001

6. Challenges and Countermeasures in Implementing Intelligent Production

6.1 Technical Implementation Difficulties

The transformation of anti-A and anti-B reagent production to intelligent production faces multi-dimensional challenges. On the technical level, the integration of existing equipment with intelligent systems is hindered by compatibility issues, and traditional equipment lacks open interfaces, making data collection difficult. A survey shows that 78% of enterprises need to replace more than 50% of their equipment. System stability is a significant concern, as a single point of failure can lead to a complete production line shutdown, and the cost of building a backup system is high. Enterprises generally face financial pressure, with a complete antibody reagent intelligent production line requiring an investment of approximately 1.2 billion yuan, and an investment return period of 4-6 years. Human resource transformation is another challenge, with a shortage of high-quality, cross-disciplinary talent, and difficulties in retraining traditional production personnel^[14]. The digital transformation of process expert knowledge is also a bottleneck. Data security risks are prominent, as industrial data, including formulations and process parameters, is a core asset that requires a multi-level network security protection system. To address these challenges, enterprises can adopt a modular, gradual implementation strategy, first building a data collection system and then gradually achieving automation and intelligentization, reducing the pressure of one-time investment. Establishing a collaborative innovation mechanism with equipment suppliers can also help reduce adaptation costs.

6.2 Industry Standards and Regulatory Adaptation

The intelligent production of anti-A and anti-B reagents faces the dilemma of outdated standards and regulations. Current medical device production quality management regulations are primarily based on traditional production modes and lack clear guidance on data compliance, algorithm

validation, and autonomous decision-making systems in intelligent production. Regulatory authorities have strict requirements for changes to intelligent production lines, and equipment or algorithm upgrades require re-validation, leading to extended technical iteration cycles. Domestic and international standard systems differ, and 82% of export enterprises report needing to meet multiple standard requirements simultaneously, increasing compliance burdens^[15]. Solutions should be developed from multiple angles, including proactive communication with regulatory authorities to establish a pre-review mechanism and address compliance issues in advance. Participating in industry standard development can help form a new standard system adapted to intelligent production. Incorporating "compliance design" concepts into system architecture can ensure regulatory requirements are integrated. Establishing an electronic record system that meets GMP requirements can ensure data integrity and traceability. Algorithms and autonomous decision-making systems should include human intervention mechanisms, with key decision points retaining human review processes. A "regulatory sandbox" mechanism can be established to test innovative technologies in a controlled environment, balancing innovation and safety, and accelerating the clinical transformation and industrial application of intelligent technologies.

7. Future Development Prospects

7.1 Evolution of Intelligent Technologies

The intelligent production technology of anti-A and anti-B reagents will undergo a comprehensive revolution. Cognitive computing technology will enable production systems to make autonomous decisions, upgrading from passive execution to proactive prediction and adjustment of production parameters, with the goal of achieving 96 hours of uninterrupted production by 2028. The application of quantum sensors will make molecular-level changes visible in real-time, with detection accuracy reaching the nanogram level, allowing for the capture of micro-abnormalities that traditional equipment cannot detect. The combination of bio-3D printing and intelligent materials science will reconstruct the reagent production process, with directed synthesis technology replacing traditional extraction methods, resulting in a 300% increase in production and a 68% reduction in costs. Multi-source biological sensor arrays will enable real-time monitoring of each batch of products throughout their entire lifecycle, building a "digital twin" model that can simulate and correct any deviations in a virtual environment. Blockchain and smart contract technologies will fundamentally change the product quality tracking system, establishing a trusted data exchange network across institutions. The combination of artificial intelligence and high-throughput experimental platforms will significantly accelerate the optimization of formulations, with the goal of reducing the development cycle of new antibody reagents from 18 months to 3 months, providing more accurate and sensitive diagnostic tools for clinical use.

7.2 Industry Collaboration and Ecosystem Construction

The construction of an intelligent production ecosystem for anti-A and anti-B reagents requires collaboration and cooperation among all parties. The establishment of industry-university-research collaboration platforms will become a driving force for technological innovation, with research institutions exploring basic theories, enterprises responsible for engineering transformation, and universities cultivating interdisciplinary talent, with 43 such platforms established in the past two years. The establishment of standard alliances is crucial, with leading enterprises and industry organizations jointly developing technical standards and evaluation systems for intelligent production, ensuring interoperability and compatibility, with 7 related alliances established globally. Vertical integration of the supply chain will deepen, with core raw material suppliers, equipment manufacturers, and reagent production enterprises forming strategic partnerships, building data-sharing platforms, and achieving collaborative optimization across the entire chain. Cross-industry technology borrowing will accelerate, with intelligent production experiences from the pharmaceutical, fine chemical, and food safety industries being applied to blood diagnostic reagent production. The emergence of open innovation communities will transform the technological innovation model from closed to open, with crowdsourced solutions addressing common technical challenges. Government guidance funds and industry investment funds will work together to support the development of key technologies for intelligent production, reducing the technical upgrade threshold for small and medium-sized enterprises. This diverse collaborative ecosystem will accelerate the transformation of intelligent technologies from laboratory to market, benefiting more patients.

8. Conclusion

Intelligent production technology has reshaped the quality standards of anti-A and anti-B reagents, reducing the batch-to-batch variation coefficient from 8.2% to 2.3%, significantly improving the reliability of blood type identification. Practice has proven that intelligent production not only solves the problem of human-induced fluctuations in traditional processes but also establishes a comprehensive quality assurance system through real-time monitoring and data tracking. The case study of Northern Biotechnology Group shows that intelligent production reduces the clinical application error rate of reagents by 85.2%, directly reducing the risks associated with blood transfusions. More importantly, intelligent production ensures that different medical institutions obtain diagnostic reagents with consistent performance, providing a foundation for regional medical resource integration. As technology continues to evolve, the quality of anti-A and anti-B reagents will reach even higher levels, providing a solid guarantee for safe blood transfusions and accurate diagnoses, ultimately benefiting every patient who requires blood type testing.

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