Sciences in Nursing and Health
ISSN: 3078-7408
DOI: https://doi.org/10.61784/snh3023

DEVELOPMENT OF THE IN VITRO DIAGNOSTICS SUB-INDUSTRY WITHIN CHINA'S BIG HEALTH ECONOMY: EVIDENCE FROM A NATIONAL STATISTICAL SURVEY

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Abstract: In vitro diagnostics (IVD) is a core segment of China's big health economy, and it supports disease screening, chronic disease management, and infectious disease control. This paper measures the operating state of the Chinese IVD industry in 2025. Four statistical sources are merged. They are a national enterprise survey with 206 valid responses, the financial record of 59 listed IVD companies, the public registration database of the National Medical Products Administration, and a record of primary-market investment events. Four dimensions are measured, namely aggregate scale, segment structure, innovation supply, and capital allocation. The results show that the finished IVD market fell by 10.0% in 2025 to CNY 108.0 billion. Revenue of listed firms fell by 12.22% and net profit fell by 28.49%. Molecular diagnostics, point-of-care testing, and pathology remained resilient, while biochemistry and immunoassay were weak. Domestic Class III approvals rose by 12.95% and imported approvals fell by 18.60%. A rank-order centroid model converts the survey ranking of operating difficulties into cardinal weights. Reimbursement pricing carries the largest weight of 0.408, and disordered competition follows at 0.242. The paper then proposes a three-level upgrading path for regulators, firms, and the supply chain. A moderate recovery between 0 and 5% is expected in 2026.
Keywords: Big health industry; In vitro diagnostics; Industry survey; Rank-order centroid; Volume-based procurement

1 INTRODUCTION

The big health economy covers prevention, diagnosis, treatment, rehabilitation, and long-term care. In vitro diagnostics sits at the front of this chain. Laboratory results support a large share of clinical decisions, so the sector carries weight far beyond its revenue share [1,2]. China has built a complete IVD supply chain over the past two decades. The chain now runs from antibodies and enzymes to reagents, instruments, and independent clinical laboratories.

The policy environment changed sharply after 2021. Volume-based procurement was extended from drugs to diagnostic reagents [3,4]. Provincial alliances began to bid for biochemistry and chemiluminescence assays. Payment reform based on diagnosis-related groups and the diagnosis-intervention packet then spread to almost every prefecture [5,6]. Hospitals now treat laboratory testing as a cost centre rather than as a revenue source. Test volume still grows, but unit prices fall faster. The industry therefore entered a period of shrinking revenue with rising physical output.

Existing work on this shift is limited in two ways. Most policy studies examine drugs and high-value consumables, and they rarely separate diagnostics [4,7,8]. Most market reports give aggregate size figures without firm-level evidence [9]. Neither approach explains how the pressure is distributed across technology segments. Neither approach shows which constraints firms themselves rank as the most severe.

This paper addresses that gap. It merges four statistical sources for 2025 and builds a four-dimension measurement frame. The contribution is threefold. First, the paper quantifies the gap between reported market contraction and firm-level financial contraction. Second, it maps the spread of sentiment across five technology segments and links that spread to specific policy instruments. Third, it converts an ordinal survey ranking of operating difficulties into cardinal weights through a rank-order centroid model, so that the constraints can be compared on a single scale.

The rest of the paper is organised as follows. Section 2 describes the data and the method. Section 3 reports aggregate performance. Section 4 analyses segment structure. Section 5 covers registration, the supply chain, and capital. Section 6 ranks the constraints. Section 7 discusses growth drivers. Section 8 gives recommendations. Section 9 concludes.

2 DATA AND METHOD

2.1 Statistical Sources

Four sources are used. Table 1 lists their scope, size, and period. Figure 1 shows how they feed the analysis.

The enterprise survey was distributed by a national health industry association during 2025 [10]. It reached firms across the whole chain, including raw material suppliers, reagent makers, instrument makers, and independent laboratories. In total 206 valid responses were returned. The questionnaire used closed items on revenue growth, segment outlook, operating difficulty, and policy demand. Respondents ranked operating difficulties rather than scoring them.

The second source is the reported financial record of 59 IVD companies listed on the A-share market. Revenue, net profit attributable to the parent, and market value were collected for 2021 to 2025. A wider set of 100 listed entities was used for the half-year comparison, because several firms report diagnostics inside a larger medical device business.

The third source is the public approval record of the National Medical Products Administration [11]. First-time registrations were separated into domestic Class III products and imported products. The provincial location of each registrant was also recorded.
The fourth source is a record of primary-market investment events. Event count, disclosed amount, and financing round were collected for the period from 2022 to 2025.

Table 1 Composition and Coverage of the Statistical Sources

Source and provider	*Sample and period*	*Variables used in this paper*
Enterprise survey by a national health industry association, whole chain from raw materials to laboratories	206 valid responses, 2025	Growth expectation, segment outlook, ranked operating difficulty, policy demand
Reported accounts of A-share listed IVD companies, with 100 listed entities used for the half-year test	59 companies, 2021 to 2025	Revenue, net profit attributable to the parent, aggregate market value
Public approval database of the National Medical Products Administration	707 approvals in 2025, 2022 to 2025	First-time registrations, domestic and imported split, province of registrant
Disclosed primary-market transactions in the IVD sector	83 events in 2025, 2022 to 2025	Event count, disclosed amount, financing round

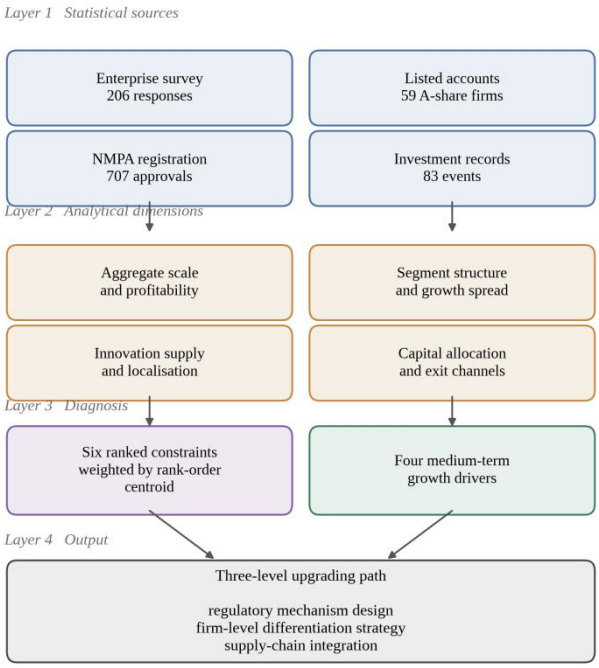

Figure 1 Four-layer Analytical Frame

Note: Layer 1 lists the statistical sources. Layer 2 lists the measured dimensions. Layer 3 gives the diagnosis. Layer 4 gives the policy and strategy output.

2.2 Treatment of the Data

All monetary values are converted to CNY billion. Values for 2024 that were not published directly were recovered from the reported year-on-year rate, and they are marked in the tables. Growth brackets that the survey did not publish separately were interpolated so that the shares in each year sum to 100%.

2.3 Weighting of the Constraints

The survey reports operating difficulties as a rank order. A rank order alone cannot show how much more severe the first item is than the second. The rank-order centroid method solves this problem. It assumes that the true weights are spread uniformly over the set of weight vectors that respect the given order, and it takes the centroid of that set [12]. For n ranked items the weight of item i is

$$w\,i = (1/n)\,\Sigma\,j=i..n\,(1/j) \tag{1}$$

The weights sum to one and they decline smoothly. The method is stable when small ranking errors occur, so it suits survey data in which respondents are confident about order but not about distance [13].
All monetary values are converted to CNY billion. Values that were derived from a reported growth rate rather than published directly are marked in Table 2.

3 AGGREGATE PERFORMANCE

3.1 Market Scale

Table 2 and Fig. 2 report the aggregate picture. The finished IVD market in China reached CNY 108.0 billion in 2025. This is a fall of 10.0% from CNY 120.0 billion in 2024. The whole industry chain, which adds raw materials, instruments, and exports, reached CNY 160.0 billion after a fall of 6.0%. The chain fell more slowly than the finished market. Export sales and upstream localisation offset part of the domestic price cut.

The pattern is best described as growing volume with falling value. Hospitals ran more tests in 2025, yet the average price of a routine test dropped. Total revenue therefore declined even though clinical demand did not.

Table 2 Industry Scale and Listed-Company Performance

Indicator	*Base year*	*2025*	*Change (%)*
Finished IVD market, CNY billion	120.0	108.0	-10.00
Whole industry chain, CNY billion	170.2 *	160.0	-6.00
Upstream raw material market, CNY billion	below 21 *	below 20	-5.00
Revenue of 59 listed firms, first three quarters, CNY billion	82.76 *	72.64	-12.22
Net profit of 59 listed firms, first three quarters, CNY billion	10.55 *	7.54	-28.49
Revenue of 100 listed entities, first half, CNY billion	68.06 *	58.06	-14.69
Net profit of 100 listed entities, first half	n.d.	n.d.	-44.01
Third-party clinical laboratory market	n.d.	n.d.	-10.00
Aggregate market value, CNY billion, 2022 against 2025	1,088.5	716.0	-34.20

Note: Values marked with an asterisk were recovered from the published year-on-year rate and were not reported directly. The base year is 2024 for every row except the last one, where the base year is 2022.

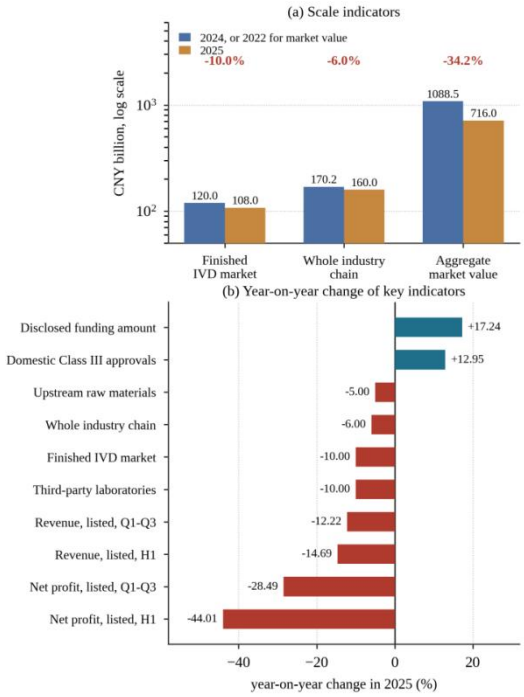

Figure 2 Aggregate Indicators of the Chinese IVD Industry. Panel (a) shows scale on a logarithmic axis. Panel (b) ranks the year-on-year change of eleven indicators in 2025

Note: Only registration of domestic Class III products and disclosed funding rose during the year.

3.2 Listed-Company Performance

Financial data show a deeper contraction than the market aggregate. Revenue of the 59 listed firms over the first three quarters of 2025 was CNY 72.64 billion, which is 12.22% lower than a year earlier. Net profit attributable to the parent was CNY 7.54 billion, which is 28.49% lower. The half-year figures are worse. Revenue of the 100 listed entities fell by 14.69% and net profit fell by 44.01%.

Profit falls about twice as fast as revenue. This gap has a clear mechanism. Reagent price cuts reduce gross margin at once, while selling, research, and depreciation costs are fixed in the short run. Many firms placed instruments in hospitals under reagent-linked contracts. The depreciation on those instruments cannot be reduced when reagent prices fall.

Market value tells the same story over a longer window. The aggregate market value of listed IVD firms was CNY 1,088.5 billion at the end of 2022 and CNY 716.0 billion at the end of 2025. The three-year loss is 34.2%. Investors have therefore

repriced the sector rather than treating 2025 as a single weak year.

3.3 Survey Expectations

Fig. 3(a) compares expectations for 2025 and 2026. Among the 206 respondents, 37% expected the industry to contract in 2025. Only 2% expected growth between 15% and 20%, and no firm expected growth above 20%. Expectations for 2026 improve. The share expecting contraction falls to 25%, and 32% expect growth between 0 and 5%. Half of the respondents place the five-year average growth rate near 5%.

The survey and the financial record agree on direction and disagree on depth. Firms report a milder decline than the listed accounts show. Two reasons are likely. Listed firms are larger and depend more on hospital tenders, which were repriced first. Smaller respondents also serve primary care and export markets, and those channels held up better.

4 SEGMENT STRUCTURE

Table 3 and Fig. 3(b) show the spread across segments. The spread is wide, and it maps closely onto policy exposure.

Table 3 Segment Structure and Survey Signals in 2025

Segment	*Market share (%)*	*Firms expecting contraction (%)*	*Growth expectation*	*Main source of pressure*
Molecular	n.d.	13	48% expect 5% or more	No compliant payment route for high-end assays
POCT	n.d.	13	33% expect 10% or more	Limited reimbursement outside hospitals
Pathology	n.d.	11	n.d.	High equipment cost and slow validation
Immunoassay	33	27	n.d.	Provincial procurement, average price cut above 50%
Biochemistry	15 to 20	38	n.d.	National procurement, value down about 10%

Note: The survey covers seven segments. The five segments above are the ones for which quantitative results were published. The abbreviation n.d. means not disclosed. The whole-industry contraction expectation was 37%, which is shown as a reference line in Fig. 3(b).

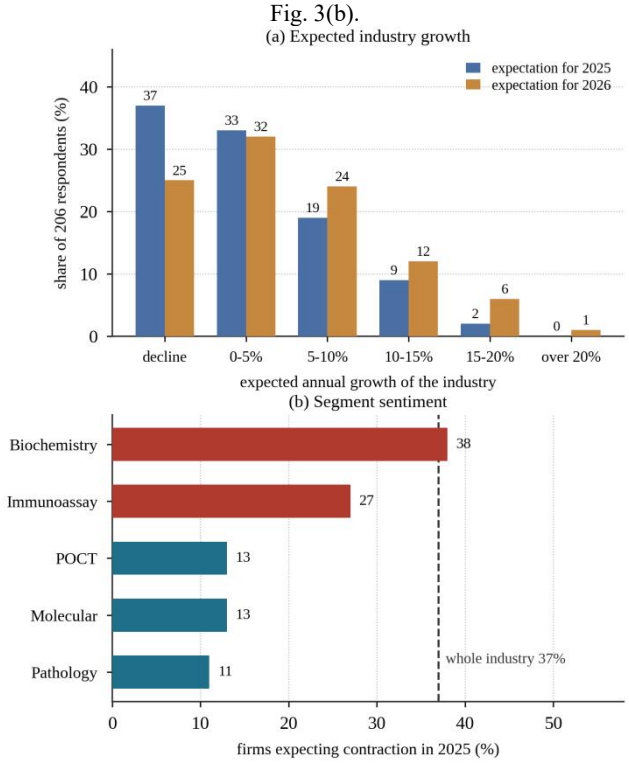

Figure 3 Survey Results from 206 Respondents. Panel (a) compares expected industry growth for 2025 and 2026. Panel (b) shows the share of firms expecting contraction in each segment against the whole-industry level of 37%

Note: Middle brackets in panel (a) were interpolated so that each year sums to 100%.

4.1 Resilient Segments

Molecular diagnostics recorded the strongest sentiment among the large segments. Only 13% of firms expected contraction, and 48% expected growth of at least 5%. Companion diagnostics, next-generation sequencing, and multiplex respiratory panels drove the demand. The domestic share of molecular products passed 50% during the year. Molecular

assays have escaped broad procurement so far, because the assays are heterogeneous and hard to standardise into a single bid.

Point-of-care testing showed a similar sentiment level. Contraction was expected by 13% of firms, and 33% expected growth above 10%. The growth comes from primary care and from home testing. Microfluidic cartridges and small chemiluminescence analysers are the main platforms [14,15]. These products are sold outside the tertiary hospital tender system, so they face weaker price pressure.

Pathology was the most stable segment, and only 11% of firms expected contraction. Whole-slide scanners and artificial intelligence reading tools create new demand [16-18]. The segment is small. It is protected by a shortage of trained pathologists rather than by policy.

4.2 Segments under Pressure

Biochemistry recorded the weakest sentiment, and 38% of firms expected contraction. This is the seventh year in a row in which biochemistry ranked last. National procurement of biochemistry reagents has pushed terminal prices down repeatedly. The segment holds 15% to 20% of the market and lost about 10% of its value in 2025.

Immunoassay is the largest segment at 33% of the market, and 27% of firms expected it to contract. Provincial procurement of thyroid function assays and tumour marker assays cut prices by more than 50% on average. Routine chemiluminescence reagents once carried the highest margins in the industry. The effect on sector profit was therefore large.

The pattern is consistent across the seven segments covered by the survey. Segments with standard analytes and many suppliers are procured first, and they lose the most value. Segments with heterogeneous methods and few suppliers keep pricing power. Technical differentiation therefore acts as the main defence against procurement pressure.

5 INNOVATION SUPPLY, SUPPLY CHAIN, AND CAPITAL

5.1 Registration Statistics

Table 4 and Fig. 4(a) report registration. The regulator approved 707 first-time IVD registrations in 2025. Domestic Class III products accounted for 602 of them, which is a rise of 12.95%. Imported products accounted for 105, which is a fall of 18.60%. The domestic share rose from 80.5% to 85.1%.

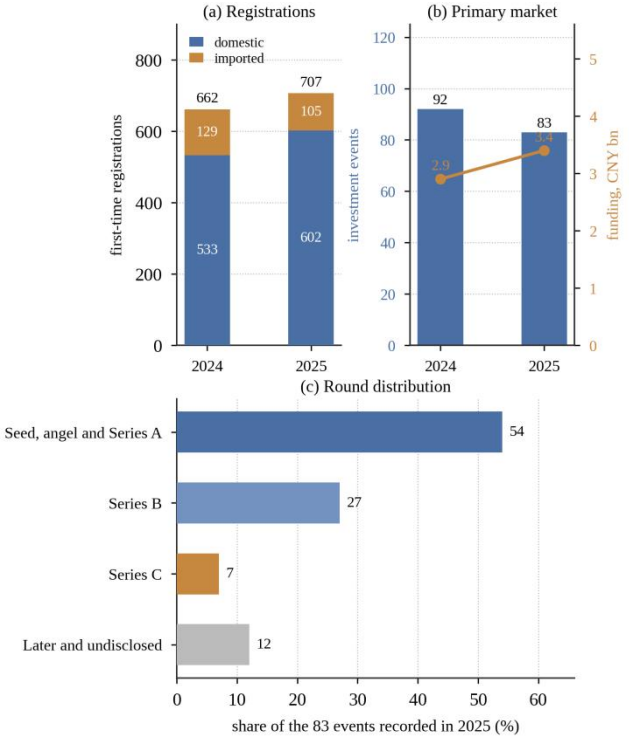

Figure 4 Innovation Supply and Capital Allocation. Panel (a) shows first-time registrations by origin. Panel (b) shows investment events against disclosed funding. Panel (c) shows the round distribution of the 83 events recorded in 2025

Two forces explain the change. Domestic firms have moved into high-barrier categories that were once dominated by foreign suppliers. Foreign suppliers have also slowed new launches in China, because procurement has lowered the expected return on a local registration. Registrants cluster in Guangdong, Jiangsu, Zhejiang, and Shanghai, which confirms a strong coastal cluster effect.

5.2 Upstream and Downstream

The upstream raw material market is worth less than CNY 20 billion, and it fell by about 5% in 2025. The domestic share of raw materials nevertheless passed 30%. Nanobodies and freeze-dried nucleic acid reagents are the clearest cases of substitution. Upstream localisation lowers the cost base of the whole chain, and it partly explains why the chain fell more slowly than the finished market.

Downstream independent clinical laboratories shrank by about 10%. The two largest operators each lost more than 18% of revenue. Smaller laboratories continued to exit. Concentration in this layer is therefore rising while the layer as a whole contracts.

5.3 Capital Allocation

Fig. 4(b) and Fig. 4(c) show the primary market. There were 83 investment events in 2025, which is 9.78% fewer than the 92 events of 2024. Disclosed funding rose by 17.24% to CNY 3.4 billion. The average deal size therefore rose by about 30%. Fewer companies raised money, and those that did raise money raised more.

The round distribution confirms a shift toward technology risk. Seed, angel, and Series A rounds accounted for 54% of events. Series B accounted for 27% and Series C for 7%. Investors are backing early platform technology, and they are avoiding late-stage consumable businesses that face procurement.

Exit channels also changed. Two firms completed listings during the year, one on the Beijing Stock Exchange and one in Hong Kong. Six more filed prospectuses in Hong Kong. One listed company was removed from the market after a financial violation. Hong Kong has become the main venue for IVD listings, and compliance review has tightened at the same time.

Table 4 Registration and Primary-Market Statistics

Indicator	*2024*	*2025*	*Change*
First-time IVD registrations, total	662 *	707	+6.80%
Domestic Class III registrations	533 *	602	+12.95%
Imported registrations	129 *	105	-18.60%
Domestic share of registrations	80.5% *	85.1%	+4.6 points
Primary-market investment events	92	83	-9.78%
Disclosed funding, CNY billion	2.9	3.4	+17.24%
Average disclosed deal size, CNY million	31.5 *	41.0 *	+30.1%
Share of seed, angel, and Series A events	n.d.	54%	n.d.
Share of Series B events	n.d.	27%	n.d.
Share of Series C events	n.d.	7%	n.d.

Note: Values marked with an asterisk were derived from published totals or from published growth rates. The average deal size is the disclosed amount divided by the event count, so it understates the true mean when an amount is not disclosed.

6 DEVELOPMENT CONSTRAINTS

Table 5 reports the six constraints in survey rank order together with the weights obtained from (1).

Table 5 Ranked Constraints, Rank-Order Centroid Weights, and Proposed Responses

Rank	*Constraint*	*ROC weight*	*Proposed response*
1	Reimbursement and pricing adjustment	0.408	Tiered service pricing, a technical labour price for high-end assays, and reimbursement pilots
2	Disordered market competition	0.242	Abnormally low price review and combined scoring on quality, capacity, and price
3	Funding pressure	0.158	Instant medical insurance settlement across all pooling regions by the end of 2026
4	Research and development cost	0.103	Shared public research and registration platforms
5	Product registration cycle	0.061	Wider clinical exemption catalogue and priority review for innovative devices
6	Talent shortage	0.028	Joint programmes between industry and universities

Note: Weights are computed from (1) using the survey rank order. The sum of the six weights is 1.000. The first two constraints together carry 65.0% of the total weight.

6.1 Reimbursement and Pricing

Reimbursement pricing ranks first with a weight of 0.408. It has held first place for two years in a row. Three instruments act together. Payment by diagnosis-related group and by diagnosis-intervention packet gives the hospital a fixed budget for each case, so any test that is not required is removed [5,6]. Panel clean-up removes bundled orders. Medical service

price adjustment lowers the listed price of each item. Procurement then cuts the reagent price on top of these three effects. Volume growth cannot offset a price cut of this size.

6.2 Disordered Competition

Competition ranks second with a weight of 0.242. Many small firms crowd into biochemistry and colloidal gold, where products are close substitutes. Public tenders often award on lowest price without a floor. Respondents reported bids at prices far below any reasonable cost. Low-quality products then win share, and firms that invest in research cannot recover the investment through price. This weakens the incentive to innovate at the exact moment when innovation is the only escape from procurement [7,8].

6.3 Funding, Research Cost, and Registration

Funding pressure ranks third at 0.158. Hospital receivable cycles are long, and primary institutions pay more slowly than tertiary hospitals. Research cost ranks fourth at 0.103. The registration cycle ranks fifth at 0.061. The clinical trial requirement for Class III molecular products and companion diagnostic products is heavy, even though the exemption catalogue has been widened. Small firms therefore wait several years before revenue returns. Faster registration was the third most requested policy change in the survey.

6.4 Talent and the Commercialisation Channel

Talent shortage ranks sixth at 0.028. The binding problem is not headcount but the mix of skills. Firms need staff who understand assay chemistry, software, and regulation at the same time.

A further constraint sits outside the ranked list. Only 29 institutions hold pilot status for laboratory developed tests nationwide [19,20]. High-end sequencing assays and mass spectrometry assays therefore have no compliant route to charge patients in most hospitals. Innovation reaches the laboratory bench but not the payment system. Similar debates over the oversight of laboratory developed tests are under way in the United States and in the European Union, so the design problem is not unique to China [21,22].

7 GROWTH DRIVERS AND OUTLOOK

Survey respondents ranked policy support, clinical demand, and population ageing as the three main growth drivers. Four medium-term drivers follow from the statistics.

7.1 Expansion of Primary Care

The national programme to strengthen primary health facilities continues to release funds. Advance medical insurance subsidies of CNY 3.5 billion were allocated for 2026. Chronic disease management centres are being built at county level. In the survey, 36% of firms expect demand for primary-care point-of-care testing, glycated haemoglobin testing, and basic biochemistry equipment. Instant medical insurance settlement will cover all pooling regions by the end of 2026, which should shorten receivable cycles and ease the third-ranked constraint.

7.2 Population Ageing

China now has more than 310 million residents aged 60 and above [23]. Demand for chronic disease monitoring, neurodegenerative testing, and cancer screening grows with this group. Respondents chose elderly chronic disease as the largest segment opportunity for the next three to five years. Glycated haemoglobin and blood-based markers for Alzheimer disease are specific examples [24]. Home testing grows alongside, and internet-based care drives glucose and respiratory self-tests.

7.3 Technology Renewal

Five technology lines have entered industrialisation. They are molecular point-of-care testing, fully automated track systems, single-molecule immunoassay, digital pathology with artificial intelligence, and clinical mass spectrometry. Priority review for innovative devices and a wider clinical exemption catalogue shorten the path to market. Progress in upstream raw materials lowers cost across the chain and improves export competitiveness.

7.4 Export Markets

Exports of reagents and instruments grew slightly in 2025. A new rule on export sales certificates allows products without domestic registration to be sold abroad. Mutual recognition agreements with Malaysia and Thailand have taken effect. Emerging markets are building laboratory capacity, so exports can offset part of the domestic price pressure. Firms still report high registration cost and long certification times, especially under the European regulation on in vitro diagnostic medical devices [22].

Taken together, the four drivers support a moderate recovery. The market is expected to stabilise in 2026 with growth

between 0 and 5%. This matches both the survey consensus and the five-year expectation of about 5%.

8 RECOMMENDATIONS

8.1 Regulatory Level

Procurement rules should include a review of abnormally low prices with published cost reference points. Award scoring should combine quality, supply capacity, and price rather than price alone. Testing service prices should be set in tiers, so that sequencing and mass spectrometry receive a technical labour price that reflects their cost. The pilot for laboratory developed tests should be widened, and high-value assays should enter reimbursement pilots. These three measures address the first, second, and fifth constraints directly.

8.2 Firm Level

Large firms should invest in high-end instruments and core raw materials. Track systems, companion diagnostics, and overseas channels justify their scale. Acquisition can complete a product line and spread research cost across a larger revenue base. Small and medium firms should avoid biochemistry and routine chemiluminescence. They should focus on point-of-care testing, microbiology, and pathology, and they should serve primary care and home testing. Domestic raw materials help them lower cost. All firms should invest in automation and software, because a differentiated product is the only stable defence against price-based competition.

8.3 Supply Chain Level

Raw material suppliers and reagent makers should form long-term supply agreements. Localisation reduces both cost and supply risk. State capital and industrial funds should support consolidation, so that weak capacity leaves the market in an orderly way. A shared public platform for research and registration would lower the fixed cost that small firms cannot carry alone. Public services for overseas registration and regulatory advice would also help firms use the new mutual recognition agreements.

9 CONCLUSION

The Chinese IVD industry is in a policy-driven adjustment rather than in structural decline. Scale fell in 2025 because prices fell faster than volume rose. Listed accounts show a sharper contraction than the market aggregate, and profit fell about twice as fast as revenue. Sentiment varies widely across segments, and the variation follows exposure to procurement rather than differences in clinical demand. Registration and investment data show that innovation supply is still expanding, because domestic Class III approvals rose by 12.95% and average deal size rose by about 30%.

The rank-order centroid analysis shows that reimbursement pricing and disordered competition together carry 65% of the total constraint weight. Policy design should therefore address price formation and bidding rules first. The four growth drivers remain intact, so a moderate recovery between 0 and 5% in 2026 is the most likely outcome. The core task of the industry has moved from scale expansion to high-quality innovation.

Future work should extend the panel beyond a single year. A difference-in-differences design could then test the effect of each procurement round on each segment, and it could separate the price effect from the volume effect with greater confidence.

COMPETING INTERESTS

The authors have no relevant financial or non-financial interests to disclose.

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