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Research Report on IVD Industry

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1 Economic Outlook

1.1 Global Economy

Global Economic Growth Expected to Sustain at ~3% in Near Term

Global economic growth is projected to moderate to around 3.1% in 2026, reflecting the impact of geopolitical tensions in energy and trade flows. The ongoing Middle East conflict poses downside risks, with prolonged disruptions potentially reducing growth further to 2.5%, or lower. However, supportive factors such as continued investment momentum and policy support are helping offset some of these pressures.

Chart 1: Global Growth Outlook Projections (Real GDP, Y-o-Y change in %)

	CY21	CY22	CY23	CY24	CY25E	CY26P	CY27P	CY28P	CY29P	CY30P	CY31P
World	6.7%	3.8%	3.3%	3.4%	3.4%	3.1%	3.2%	3.2%	3.2%	3.1%	3.1%
Advanced Economies	6.1%	3.1%	1.7%	1.8%	1.9%	1.8%	1.7%	1.7%	1.6%	1.5%	1.5%
Emerging Market and Developing Economies	7.0%	4.3%	4.4%	4.5%	4.4%	3.9%	4.2%	4.2%	4.1%	4.0%	4.0%

Source: IMF – World Economic Outlook, April 2026; Notes: E-Estimate, P-Projections

Table 1: GDP growth trend comparison - India v/s Other Economies (Real GDP, Y-o-Y change in %)

	Real GDP (Y-o-Y Change in %)										
	CY21	CY22	CY23	CY24	CY25E	CY26P	CY27P	CY28P	CY29P	CY30P	CY31P
India	9.7	7.6	7.2	7.1	7.6	6.5	6.5	6.5	6.5	6.5	6.5
China	8.6	3.1	5.4	5.0	5.0	4.4	4.0	4.0	3.7	3.3	3.3
Indonesia	3.7	5.3	5.0	5.0	5.1	5.0	5.1	5.2	5.2	5.2	5.2
Saudi Arabia	6.5	12.0	0.5	2.6	4.5	3.1	4.5	3.6	3.5	3.5	3.6
Middle East and Central Asia	4.7	6.4	2.6	2.8	3.6	1.9	4.6	4.0	4.0	3.8	3.8
Latin America	7.5	4.3	2.3	2.4	2.4	2.3	2.7	2.9	2.9	2.7	2.6
Brazil	4.8	3.0	3.2	3.4	2.3	1.9	2.0	2.4	2.5	2.5	2.5
Euro Area	6.4	3.6	0.4	0.9	1.4	1.1	1.2	1.4	1.2	1.1	1.1
United States	3.7	5.3	5.0	5.0	5.1	5.0	5.1	5.2	5.2	5.2	5.2

Source: IMF- World Economic Outlook Database (April 2026)

Note: E-Estimate, P- Projections; India's fiscal year (FY) aligns with the IMF's calendar year (CY). For instance, FY24 corresponds to CY23.

1.1.1 Iran Conflict Impacts Energy Intensive Sectors

The current geopolitical tensions surrounding Iran conflict in West Asia, are having a direct quantifiable impact on the Indian consumer industry due to its high dependence on energy imports routed through the Strait of Hormuz (presently the zone of conflict). India imports around 60% its LPG demand and nearly 90% of the imports transit through the Strait of Hormuz route. Since LPG is a primary cooking fuel for over 300 million Indian households, any disruption in supply chains, or increase in freight and insurance costs has an immediate effect on household consumption expenditure and urban demand patterns in the country.

This impact is further amplified by India's crude oil dependence, with over 85% of total crude demand being imported, a large share of which travels from West Asia and eventually moves through the Strait of Hormuz route. A significant share of India's energy cargo, approximately 40–50% of crude oil imports and most LPG imports is routed through the Strait of Hormuz too, making it a critical chokepoint for India's energy security.

This creates a structural vulnerability, where even moderate disruptions or price shocks translate into higher fuel costs. Since fuel constitutes a key component of logistics, particularly in a distribution-heavy economy like India, rising crude prices increase transportation and supply chain costs across sectors such as FMCG, retail, e-commerce, and consumer durables. This leads to cost transmission across the value chain, affecting both producers' margins and end-consumer prices.

Additionally, a significant share of India's natural gas imports is also linked to this route, impacting energy-intensive sectors such as fertilizers, packaging, and manufacturing inputs. These sectors are closely integrated with consumer industries, creating second-order effects through higher input costs and supply-side pressures. As a result, the consumer industry faces broad-based cost escalation, with companies either absorbing margin pressures or passing on selective price increases, potentially moderating demand in price-sensitive segments.

Overall, the magnitude of exposure is substantial, with a large share of India's critical energy imports concentrated through a single geopolitical chokepoint. While short-term pressures on costs and supply chains remain elevated, ongoing efforts toward diversification of energy sourcing and strengthening of supply resilience are expected to partially mitigate risks, supporting the sector's medium- to long-term stability.

1.2 Indian Economic Outlook

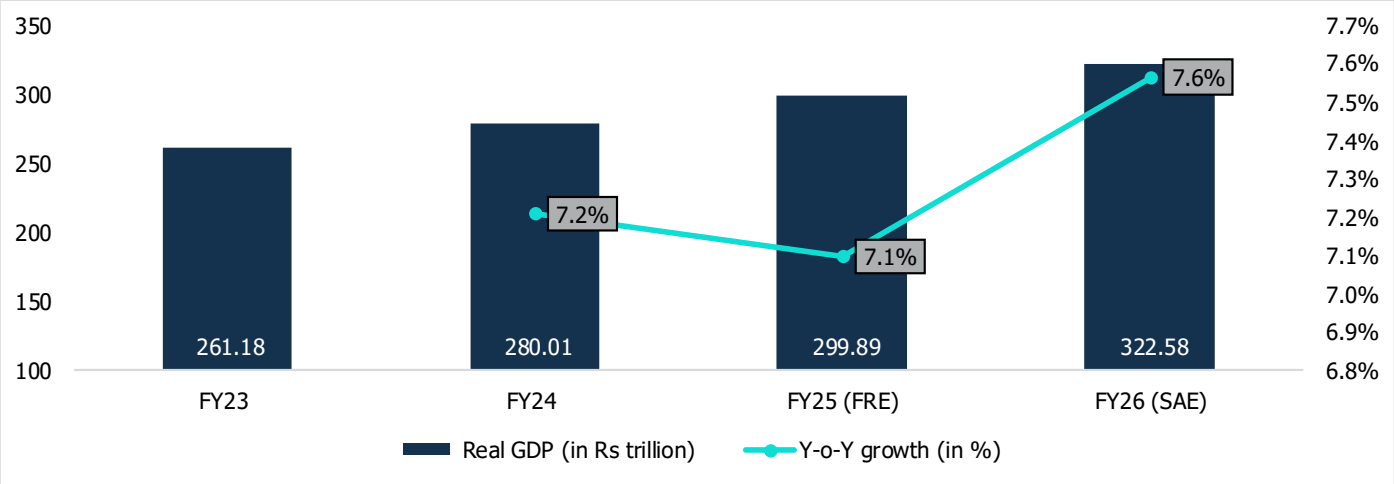
1.2.1 GDP Growth and Outlook

Resilience to External Shocks Remains Critical for Near-term Outlook

The Indian economy continues to show rapid growth. For FY26, GDP is expected to grow by 7.6%, supported by rising rural demand, better job opportunities, and favourable business conditions.

In FY25, provisional estimates show a growth of 7.1% (Rs 299.89 trillion), led by robust performance in manufacturing, construction, and financial services. Consumer spending rose by 7.6%, and government spending increased by 3.8%, both contributing to the overall growth of the economy. In FY23, the real GDP stood at Rs 261.18 trillion and registered Y-o-Y growth of 7.2% in FY24 (Rs 280.01 trillion).

Chart 2: Trend in Real Indian GDP growth rate



Source: MOSPI, RBI;
Note: FRE- First Revised Estimates, SAE- Second Advanced Estimates;
The trend for FY23-FY26 is based on new series base year 2022-23.

GDP Growth Outlook (April 2026)

FY27 GDP Outlook: The Reserve Bank of Indi (RBI) projects real GDP growth at 6.9% for 2026–27, supported by sustained momentum in the services sector, strong reservoir levels aiding the agricultural sector, and private consumption expected to remain uplifted by discretionary spending. The Indian government is also working towards minimising supply chain disruptions in critical sectors to ensure limited interruptions.

However, elevated energy and other commodity prices, as well as the travel disruptions in the Strait of Hormuz are likely to affect the growth this year. However, the government is working towards minimising the impact of the supply chain disruptions towards critical sectors to ensure limited interruptions.

Table 2: RBI's GDP Growth Outlook (Y-o-Y %)

FY27P (Complete Year)	Q1FY27P	Q2FY27P	Q3FY27P	Q4FY27P
6.9%	6.8%	6.7%	7.0%	7.2%

Source: RBI; Note: P-Projected
The trend for FY23-FY26 is based on new series base year 2022-23

1.2.2 Gross Value Added (GVA)

GVA is the measure of the value of goods and services produced in an economy. GVA gives a picture of the supply side, whereas GDP represents consumption. GVA in FY25 was powered by a broad-based rebound across sectors. The gap between GDP and GVA growth stood at 0.1 percentage point in FY25, with GDP growing at 7.2% and GVA at 7.3%, as per MoSPI's provisional estimates released in March 2026.

In FY26 (FAE), real GVA growth of 7.7% is primarily led by manufacturing, Trade, Hotels, Transport, Communication & Services related to Broadcasting, Storage. Industry is estimated at 8.8%, supported by a pickup in manufacturing and construction (11.5% and 7.1% respectively).

Table 3: Sectoral Growth (Y-o-Y % Growth) – at Constant Prices

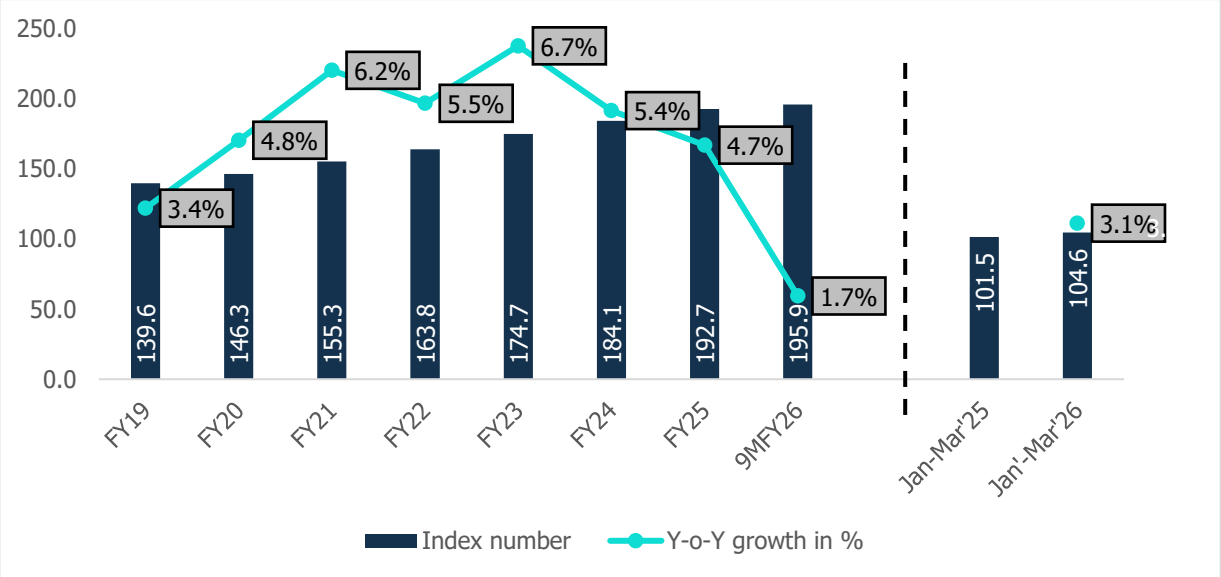
At Constant Prices	FY24 (FRE)	FY25 (PE)	FY26 (SAE)
Agriculture, Forestry & Fishing	**2.6**	**4.2**	**2.4**
Industry	**10.9**	**8.3**	**8.8**
Mining & Quarrying	2.4	11.7	4.1
Manufacturing	12.7	9.3	11.5
Electricity, Gas, Water Supply & Other Utility Services	10.7	2.9	1.5
Construction	9.9	7.3	7.1
Services	**7.0**	**7.9**	**9.0**
Trade, Hotels, Transport, Communication & Broadcasting	10.1	6.6	10.1
Financial, Real Estate & Professional Services	5.5	10.0	9.9
Public Administration, Defence and Other Services	6.8	5.0	5.8
GVA at Basic Price	**7.2**	**7.3**	**7.7**

Source: MOSPI; Note: SAE – Second Advance Estimates, FE – Final Estimates, PE- Provisional Estimates

1.2.3 Consumer Price Index (CPI) Records Combined Inflation Rate of 3.4% in March 2026

CPI inflation for March 2026 stood at 3.4%, reflecting a 3.2% increase compared to March 2025. Corresponding inflation rates for the rural and urban areas are 3.63% and 3.11% respectively.

Chart 3: Retail Price Inflation in Terms of Index and Y-o-Y Growth in % (Base: 2011-12=100, 2023-24=100)



Source: MOSPI; Note: year for FY26 YTD has been revised to 2024, while prior years remain on the 2012 base; the January-March 2025 and 2026 figures are also reported on the 2024 base.

The CPI is primarily factored in by RBI while preparing their bi-monthly monetary policy. At the bi-monthly meeting held in April 2026, RBI projected inflation at 4.6% for FY27 with inflation during Q1FY27 at 4.0%, Q2FY27 at 4.2%, Q3FY27 at 5.2% and Q4FY27 at 4.7%.

Considering the current inflation situation, RBI has maintained the repo rate at 5.25% in the April 2026 meeting of the Monetary Policy Committee (MPC).

1.2.4 Trends in Per capita Domestic Product (SDP)

SDP is the total value of goods and services produced during any financial year, within the geographical boundaries of a state. The top performing states on per capita SDP include Delhi, Gujarat, Karnataka, and Tamil Nadu, due to their strong industrial and services base, higher urbanisation, better infrastructure and greater investment inflows, leading to higher income generation.

As of FY25, major states having a per capita SDP below national average include Andhra Pradesh, Rajasthan, Madhya Pradesh and Uttar Pradesh growing Y-o-Y by 8.0%, 6.9%, 4.7% and 7.9% respectively. Bihar is the poorest performing state with a per capita SDP of Rs 33,996. It has consistently been performing the poorest since FY18, growing merely at a CAGR of 4.5% from FY18 to FY25. Bihar's poor performance is due to factors such as a high population base, lower levels of industrialisation, infrastructure gaps, lower human capital development and higher dependence on agriculture, which together limit productivity and income growth

Table 4: Per Capita SDP for Key States (at constant prices, in Rs.)

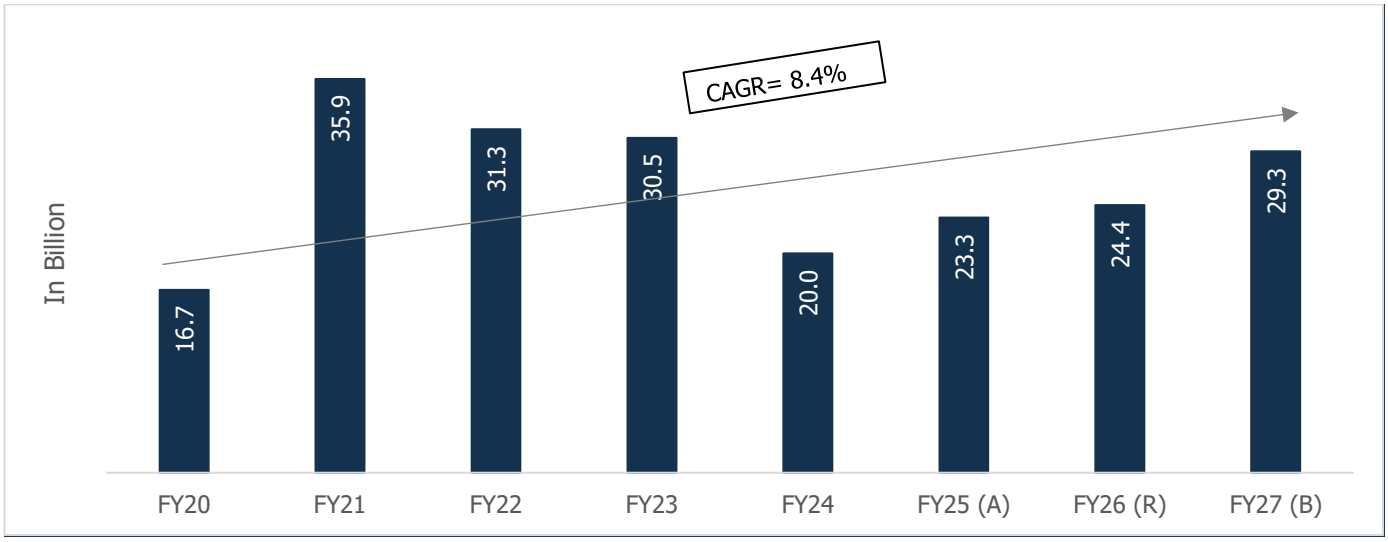
State\UT	FY18	FY19	FY20	FY21	FY22	FY23	FY24	FY25
Andhra Pradesh	1,03,177	1,08,853	1,10,587	1,10,971	1,18,349	1,23,853	1,31,083	1,41,609
Bihar	26,719	29,092	29,798	26,839	27,674	30,678	33,966	36,342
Gujarat	1,43,604	1,54,887	1,64,060	1,56,285	1,70,519	1,81,963	NA	NA
Karnataka	1,40,747	1,49,024	1,56,478	1,49,673	1,65,517	1,82,371	1,91,970	2,04,605
Madhya Pradesh	54,824	59,005	60,452	56,086	61,011	63,681	67,301	70,434
Maharashtra	1,37,808	1,40,782	1,45,626	1,27,550	1,41,651	1,54,979	1,66,013	1,76,678
Rajasthan	73,529	73,975	76,840	73,447	79,490	84,585	90,414	96,638
Tamil Nadu	1,33,029	1,41,844	1,44,845	1,43,482	1,54,269	163,205	1,78,496	1,97,747
Uttar Pradesh	41,771	42,333	43,061	39,866	45,294	48,014	51,898	55,990
Delhi	2,52,960	2,57,597	2,60,559	2,28,162	2,39,821	2,52,768	2,71,490	2,83,093

Source: MOSPI

1.2.5 The Capex for Health Sector Demonstrates Substantial Rise in FY25

The trend in health capital expenditure (Capex) in India demonstrates a substantial increase from FY20 to FY21, followed by a decline in FY22 and FY23, with a rise in FY25. The significant increase in FY21 can be attributed to the government's heightened focus on strengthening healthcare infrastructure in response to the COVID-19 pandemic, which necessitated large-scale investments in medical facilities, equipment and pandemic-related initiatives. The decrease in FY22 and FY23 likely reflect a phase of stabilisation post-pandemic, with reduced emergency spending. However, the anticipated increase in FY25, followed by FY26 indicates a renewed emphasis on healthcare sector development, driven by rising healthcare demands and ongoing government efforts toward long-term healthcare reforms.

Chart 4: Capital expenditure towards the health sector (in crores)



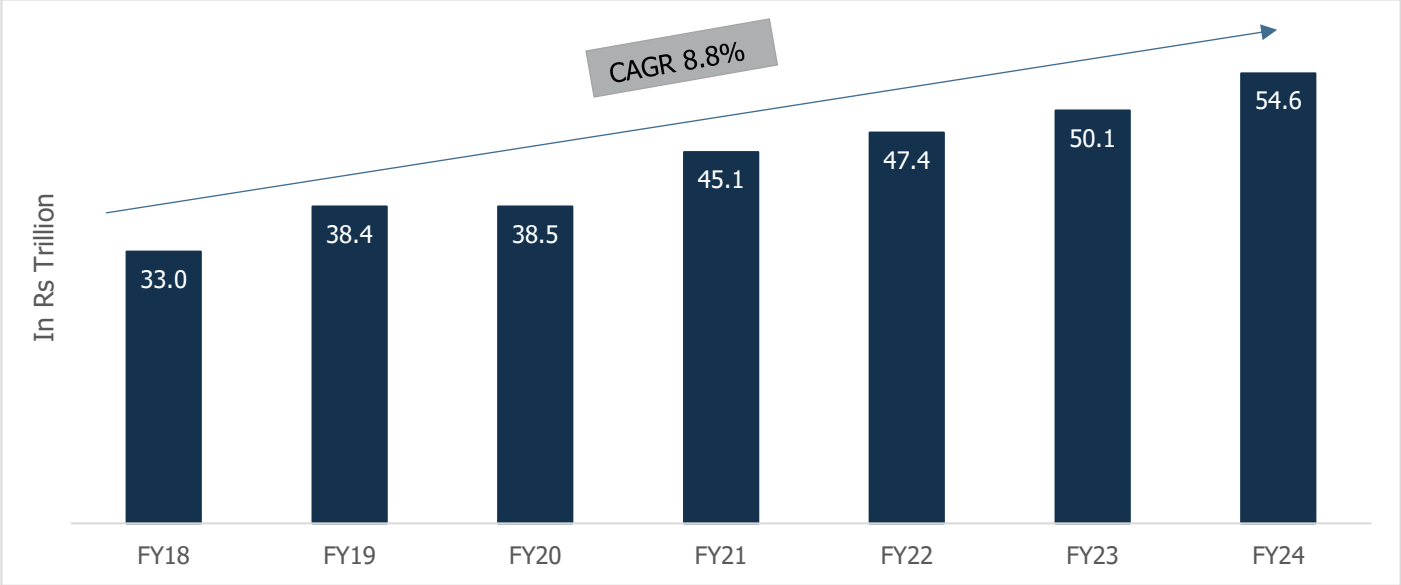
Source: Union Budget; Note: A- Actual, R-Revised, B- Budgeted

1.2.6 Household Savings' Shifting Focus from Physical Assets to Financial Assets

Household savings are of the household sector, measured as its excess of income over consumption and invested in financial assets and physical assets. Household savings in India have grown at an 8.8% CAGR since FY18, reaching Rs 54.6 trillion in FY24, a 9.0% Y-o-Y increase. A shift toward physical assets, particularly housing and gold/silver ornaments, reflects a preference for tangible investments amid high inflation and slow growth in monetary assets. Savings in the form of gold and silver ornaments (% of Household sector savings) was reported at 1.2% in FY24.

This increasing trend towards physical assets is occurring alongside a rise in household leverage, with borrowing, especially for housing, automobiles, and personal consumption, pushing household financial liabilities to a six-year high. As mutual funds and life insurance also grew, with an 11.5% and 13.6% Y-o-Y increase respectively, investment in equities and capital market instruments rose as they offer higher returns than bank deposits.

Chart 5: Household Savings (at Current Prices)



Source: MOSPI

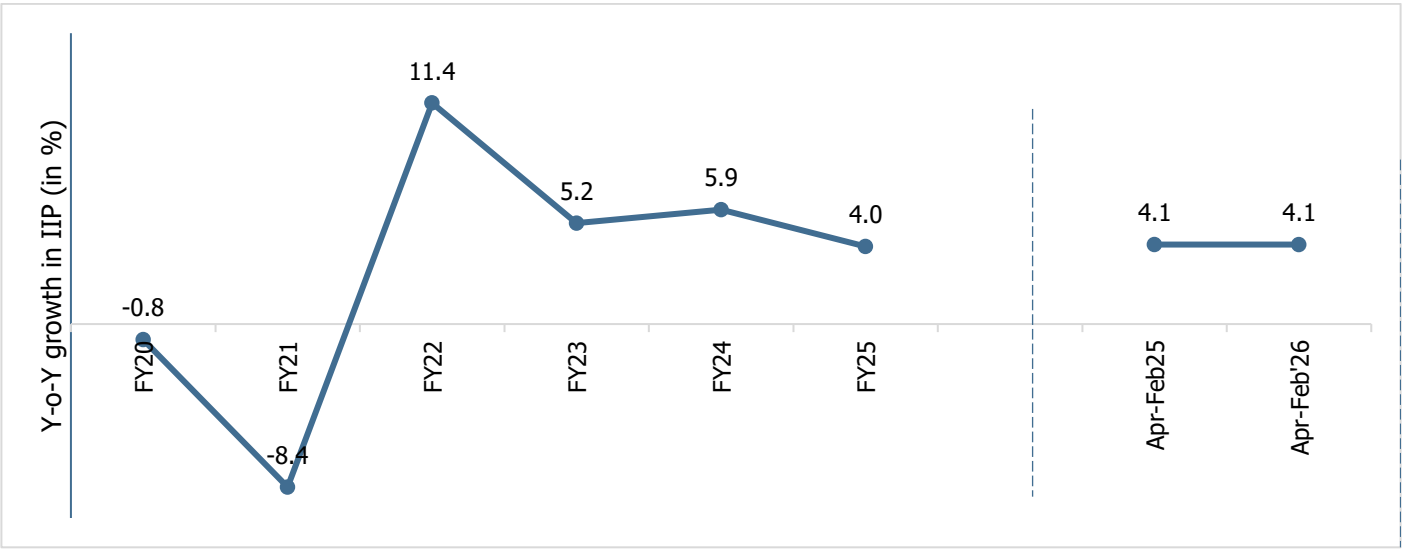
1.2.7 Industrial Growth

The quick estimates of the Index of Industrial Production (IIP) for February 2026 show a growth of 5.2%, an increase from 4.8% in January 2025. The Year-on-Year decline in IIP reflects weakness across major segments, primarily due to contractions in electricity, mining and consumer non-durables.

In February 2026, industrial growth was mainly supported by Mining, Manufacturing and Electricity sectors with indices standing at 157.2, 167.2 and 212.1 respectively.

Use-based indices indicate the top three positive contributors to the growth of IIP for the month of February 2026 are Infrastructure/ construction goods, Intermediate goods and Primary goods.

Chart 6: Y-o-Y growth in IIP (in %)



Source: MOSPI

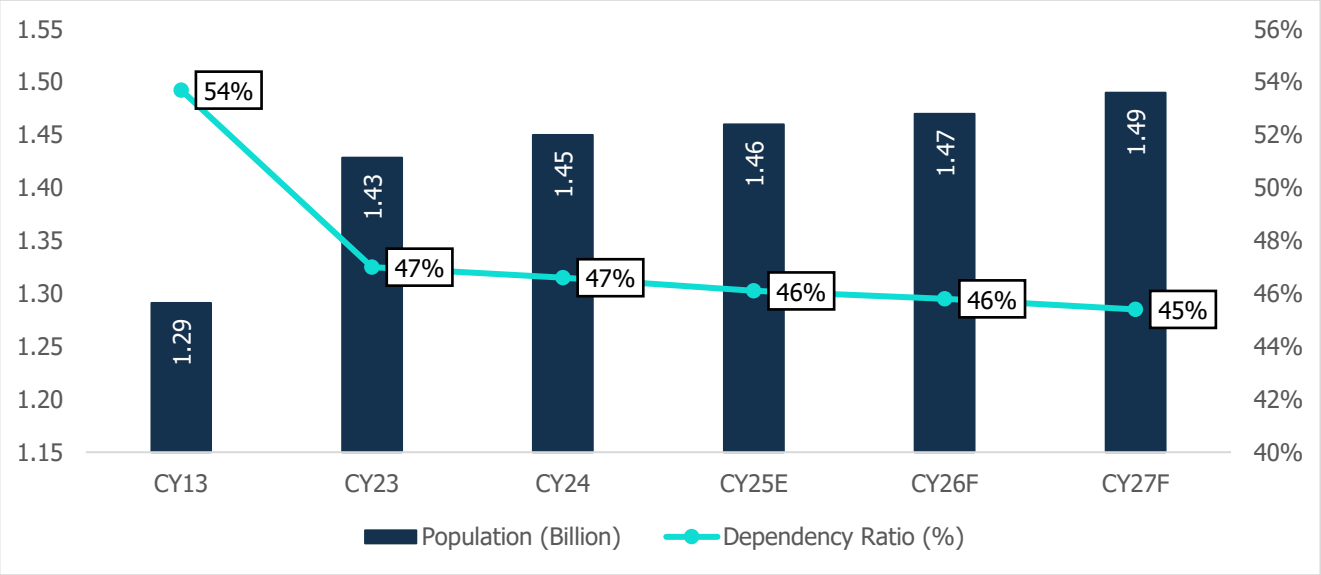
1.2.8 Overview of Key Demographic Parameters

- **Population growth and Urbanization**

The trajectory of economic growth and private consumption in India is driven by socio-economic factors such as demographics and urbanisation. According to the World Bank, India's population in CY22 surpassed 1.42 billion, slightly higher than China's population (1.41 billion) and became the most populous country in the world.

The Age Dependency Ratio, which is the ratio of dependents to the working age population has been on a declining trend. The ratio covers age 15 to 64 years, wherein dependents are population younger than 15 and older than 64. Declining dependency ratio indicates that the country has an improving share of working-age population generating income, which is a good sign for the economy. It was as high as 76% in 1983, which has reduced to 47% in CY23. However, this ratio is expected to rise again to 54% by CY36, driven by an increase in the elderly population as life expectancy improves.

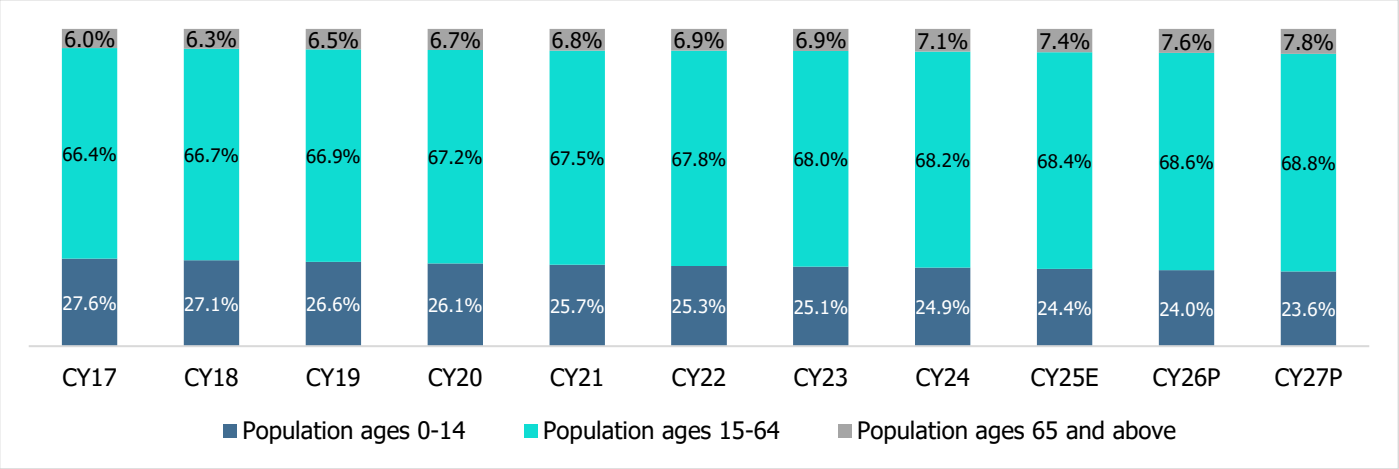
Chart 7: Trend in Population growth vis-à-vis dependency ratio in India (in Billion)



Source: World Bank Database, MOSPI; Note; E- Estimated, F- Forecasted

Despite a projected rise in the dependency ratio to 54% by CY36, India's young and growing workforce, especially in newly urbanised towns, will continue to drive income growth and consumer demand. This presents strong opportunities for sectors like consumer electronics, transportation and railways. Rising employment, urbanisation, and government investment in rural development and digital infrastructure will further boost demand, while increased tech adoption supports long-term consumption growth across both urban and rural markets.

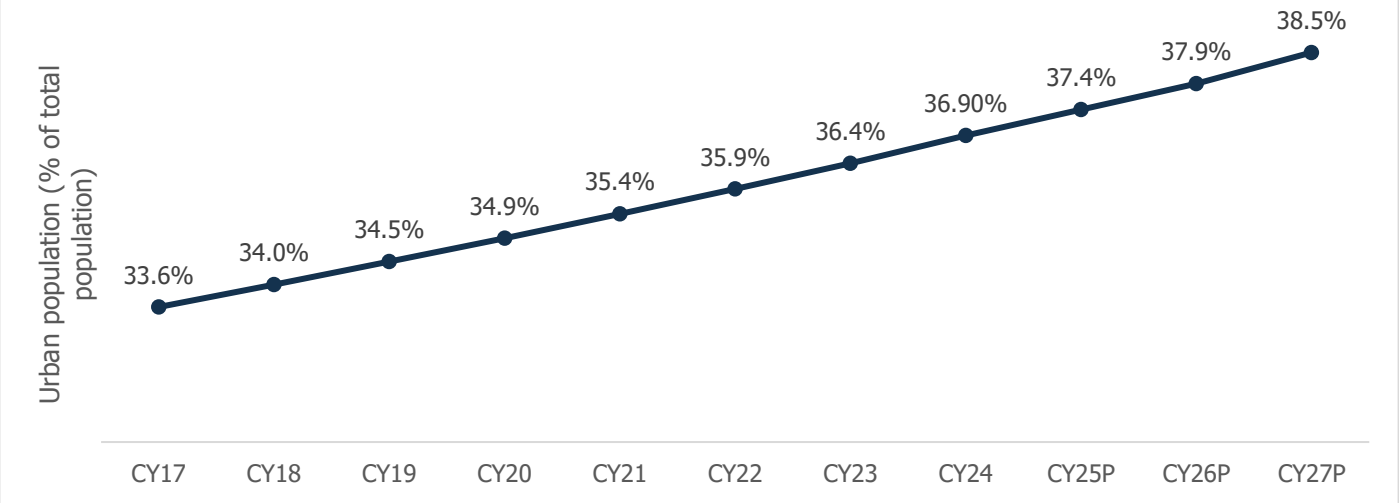
Chart 8: Age-Wise Break Up of Indian population (% of working-age population)



Source: World Bank Database; Note; E- Estimated, F- Forecasted

The urban population is significantly growing in India. The urban population in India is estimated to have increased from 413 million (32% of total population) in CY13 to 519.5 million (36.4% of total population) in the year CY23. India is undergoing a significant urban transformation, with the urban population projected to rise to 40% by CY36. This shift is driven by factors such as improved living standards, increased employment opportunities in urban areas and government initiatives aimed at urban development. This rapid urbanisation might necessitate substantial investments in infrastructure, housing and transportation.

Chart 9: Urbanization Trend in India



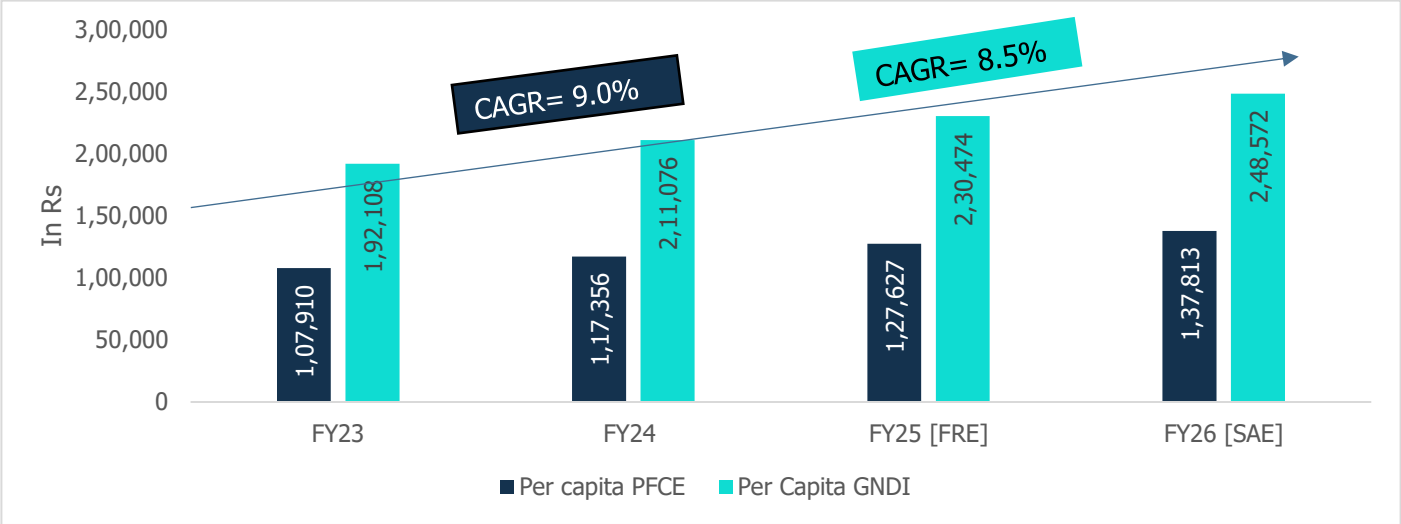
Source: World Bank Database; Note; E- Estimated, F- Forecasted

- **Increasing Disposable Income and Consumer Spending**

Gross National Disposable Income (GNDI) is a measure of the income available to the nation for final consumption and gross savings. Between the period FY23 to FY26, per capita GNDI at current prices registered a CAGR of 8.5%. More disposable income drives more consumption, thereby driving economic growth.

With increase in disposable income, there has been a gradual change in consumer spending behaviour of the country. Per capita Private Final Consumption Expenditure (PFCE) which is measure of consumer spending has also showcased significant growth from FY23 to FY26 at a CAGR of 9.0%.

Chart 10: Trend of Per Capita GNDI and Per Capita PFCE (Current Price)



Source: MOSPI; Note: FRE – First Revised Estimates, SAE- Second Advanced Estimates
The trend for FY23-FY26 is based on new series base year 2022-23

1.3 Concluding Remarks

Global economic growth faces headwinds from geopolitical tensions, volatile commodity prices, high interest rates, inflation, financial market volatility, climate change and rising public debt. The IMF forecasts GDP growth at 6.5% in CY26, far outpacing the estimated CY26 global average of 3.1%. Key drivers include strong domestic demand, government capital expenditure and moderating inflation.

The health sector in India has witnessed significant investments in recent years, driven largely by the need to strengthen infrastructure in response to the COVID-19 pandemic. While expenditures saw a decline post COVID-19pandemic, the projected increase in future capital expenditure reflects a renewed focus on addressing growing healthcare demands and long-term reforms. Continued investment in healthcare infrastructure will be crucial for ensuring equitable access to quality healthcare and sustaining overall economic growth.

Further, India's position as a manufacturing hub is strengthened by government initiatives, a skilled workforce and a growing startup ecosystem, with ongoing reforms and innovation enhancing its global role. Key growth indicators like PMI, E-way bills, bank credit, toll collections and GST collections have improved in FY24. India's economic growth in FY25-26 will be supported by strong growth in agriculture, industrial expansion and a surge in services exports. Key indicators point to sustained growth driven by improved infrastructure, private consumption and foreign investments. Normalising the employment situation after opening of the economy is supporting consumption expenditure. Public investment is set to grow with a Rs 12.20 lakh crore capital expenditure allocation for FY27. Private sector investment is also rising, supported by new project data and capital goods imports. Improved rural demand, favorable monsoon conditions and government policy will further boost the investment cycle.

Further, the 56th meeting of the Goods and Services Tax (GST) Council announced some major changes in the existing GST structure. The focus is majorly on simplifying it to a two-tiered GST tax structure of 5% and 18%, phasing out the currently existing 12% and 28% slabs. There is also a de-merit tax rate for luxury and 'sin' goods at a 40% tax slab. These changes are typically aimed at increasing the disposable income and in turn boosting consumption, as well as promoting the ease of doing business. GST rationalisation is expected to be a positive step towards economic growth,

stimulating private consumption and ease inflationary pressures. The recent revisions in income tax rates, coupled with the reduction in GST are expected to result in savings of over Rs 2.5 lakh crore, which is likely to further boost consumption.

As of April 2026, the India–US interim trade agreement is yet to be finalised, and negotiations remain ongoing due to legal and policy uncertainties in the United States. In February 2026, the United States agreed to reduce reciprocal tariffs on Indian exports to 18% from 25% as part of an interim trade understanding. This reduction was intended to improve India's export competitiveness and was expected to lead to a formal agreement by April 2026.

Beyond the US, India is actively broadening its export base to reduce dependency on any single market. Strengthening trade links with the European Union, ASEAN, and African economies is helping diversify risk and stabilise export earnings. Policy initiatives supporting logistics modernisation, lower tariff barriers and industrial corridor development continue to enhance India’s competitiveness as a global manufacturing hub.

The Iran conflict has led to an increase in input and freight costs for the chemical and pharma industry due to higher oil prices and disrupted supply chains. It is also delaying imports of key raw materials, leading to production slowdowns and higher medicine costs. Overall, this is leading to supply shortages, rising costs, and production slowdowns in India’s chemical and pharma sectors, with the impact likely to worsen if the conflict continues. Prolonged geopolitical tensions or conflict in the region could lead to sustained increases in crude oil and LPG prices, which may translate into higher input costs across industries and contribute to inflationary pressures in the Indian economy.

2 India's In-Vitro Diagnostics Market

2.1 Introduction

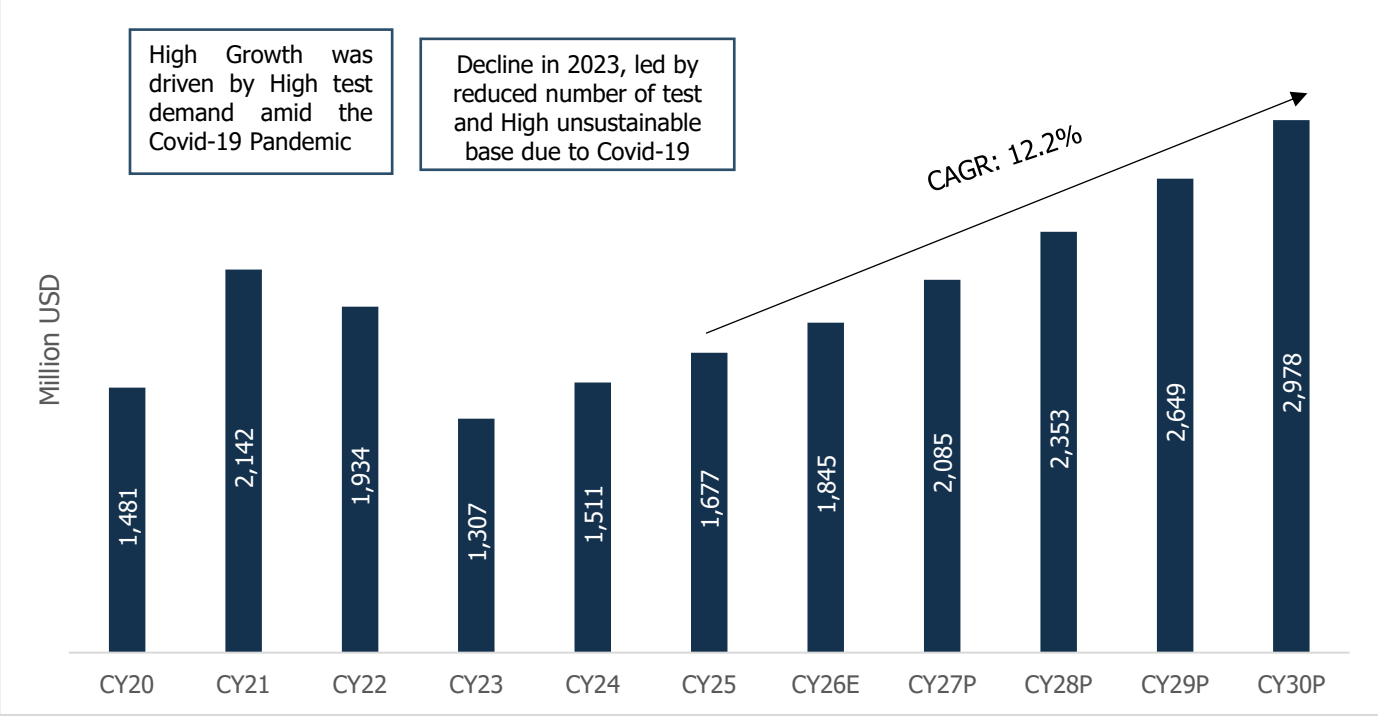
The In-Vitro Diagnostics (IVD) market serves as a critical component of healthcare infrastructure, facilitating early disease detection and accurate diagnosis. With the increasing demand for timely and precise medical testing, IVD has become crucial in clinical decision-making, directly influencing treatment outcomes. The market segments are based on usability and application, offering a comprehensive range of diagnostic solutions tailored to varying medical requirements. While the sector has been expanding at a steady pace, segments such as immunochemistry, clinical chemistry, hematology, and molecular diagnostics continue to gain traction, driven by technological advancements and a gradual transition toward automation and point-of-care testing.

The growing burden of chronic conditions, including diabetes, cardiovascular diseases, and cancer, alongside the ongoing prevalence of infectious diseases such as tuberculosis, dengue, and COVID-19, has been a key demand driver for IVD solutions. Additionally, the expansion of diagnostic laboratories, improved accessibility to healthcare services, and rising awareness of preventive diagnostics are shaping the market's growth trajectory.

As India's healthcare sector, the IVD industry is poised for steady growth, fueled by technological innovations, growing geriatric populations, cost-efficient solutions, and increased adoption. The industry is moving towards automation enhancing accuracy and efficiency in disease detection.

2.2 Market Landscape

Chart 11: India's In-Vitro Diagnostics Market



Source – Imarc Research, CareEdge Research

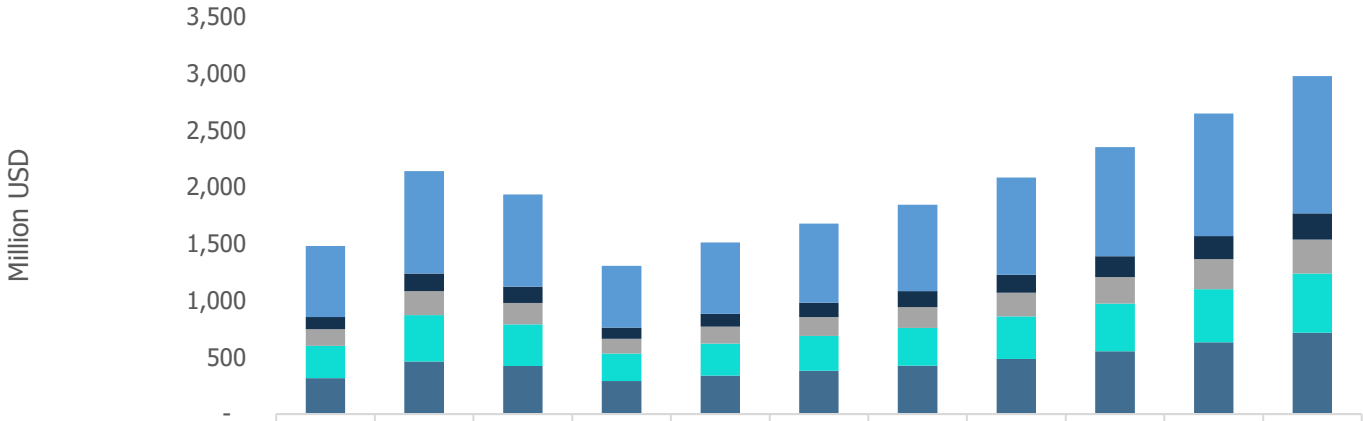
The India In-Vitro Diagnostics (IVD) market has experienced dynamic shifts, primarily driven by the COVID-19 pandemic. The market surged from 1,481 million USD in CY20 to 2,142 million USD in CY21 due to increased testing demand, followed by a sharp decline in CY22 and CY23 due to a high base from COVID-19 testing, which was not sustainable for continued growth, along with reduced pandemic-related testing. The market recorded a recovery, increasing from USD 1,511 million in CY24 to USD 1,677 million in CY25, supported by healthcare awareness and the prevalence of chronic diseases, and is projected to grow at a CAGR of up to 12.2%, reaching USD 2,978 million by CY30. This growth is likely to be driven by development of testing facilities and the rising burden of lifestyle diseases. With a steady demand for preventive healthcare, the market is expected to continue growth momentum, solidifying its critical role in India's healthcare sector.

2.3 Market Segmentation by Test Type

Table 5: Description of the Test Types in the In-Vitro Diagnostics

Sr No.	Test Type	Description
1	Immunodiagnostics	These tests use the body's immune response to detect or measure specific proteins, hormones, or antibodies in blood and other fluids. They are widely used for diagnosing infections, autoimmune diseases, and allergies. Examples include ELISA tests, rapid antigen tests, and immunoassays for hormone level measurement
2	Clinical Chemistry	This category includes tests that analyze chemical substances in bodily fluids, such as blood and urine, to assess organ function, metabolic health, and disease markers. Common examples are blood glucose tests for diabetes, liver and kidney function tests, and cholesterol panels for cardiovascular risk assessment.
3	Haematology	These tests examine blood components, including red and white blood cells, platelets, and haemoglobin levels, to diagnose conditions like anemia, infections, and blood clotting disorders. The Complete Blood Count (CBC) test is one of the most frequently conducted haematology tests.
4	Molecular Diagnostics	This field focuses on detecting genetic material (DNA or RNA) to diagnose infectious diseases, genetic disorders, and cancers. Polymerase Chain Reaction (PCR) tests for viruses like COVID-19, HIV, and genetic mutation analysis for hereditary conditions fall under this category.
5	Others	This group consists of various diagnostic tests that do not fit into the above categories, such as microbiology tests, urinalysis, toxicology screenings, and point-of-care diagnostics. These tests help detect infections, metabolic disorders, and substance use.

Chart 12: India In-Vitro Diagnostics Market Landscape – Breakup by Test Type

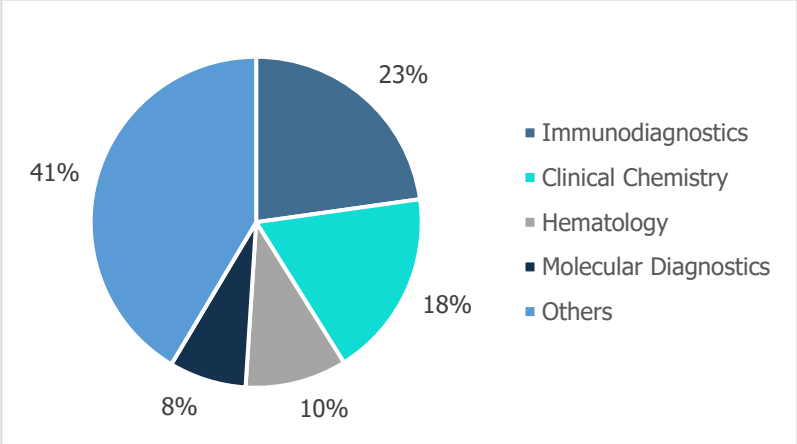


	CY20	CY21	CY22	CY23	CY24	CY25	CY26E	CY27P	CY28P	CY29P	CY30P
Others	627	902	811	546	629	695	761	857	963	1,080	1,209
Molecular Diagnostics	108	157	143	97	113	127	140	159	181	205	232
Hematology	145	210	190	129	150	166	183	208	235	265	299
Clinical Chemistry	285	408	365	244	280	307	335	375	419	468	521
Immunodiagnostics	317	464	425	291	340	382	425	486	555	632	718

Source – Imarc Research, CareEdge Research

The diagnostic testing industry comprises of a wide range of test types, each serving a unique purpose in disease detection, monitoring, and treatment planning. Immunodiagnostics, clinical chemistry, hematology, molecular diagnostics, and other specialized tests collectively form an integrated ecosystem, where multiple tests are often required for a comprehensive evaluation of a single disease. This interdependence drives synchronized growth across all segments. In CY23, the market recorded a total value of 1,307 million USD, with all test categories expanding at a similar pace. This momentum continued into CY24, reaching 1,511 million USD, fueled by technological advancements, increasing healthcare awareness, and the growing need for precise diagnostics. Further, in CY25, the market expanded to approximately USD 1,677 million, driven by continued adoption of advanced diagnostic technologies, increasing prevalence of chronic and infectious diseases, and expansion of diagnostic infrastructure across urban and semi-urban areas. Going forward, the market is projected to maintain its steady expansion, reaching 2,978 million USD in CY30, with each test type maintaining proportional growth. This underscores the crucial role of diagnostics in early disease detection, precision medicine, and the broader healthcare landscape.

Chart 13: Market Share by Test Type – CY25



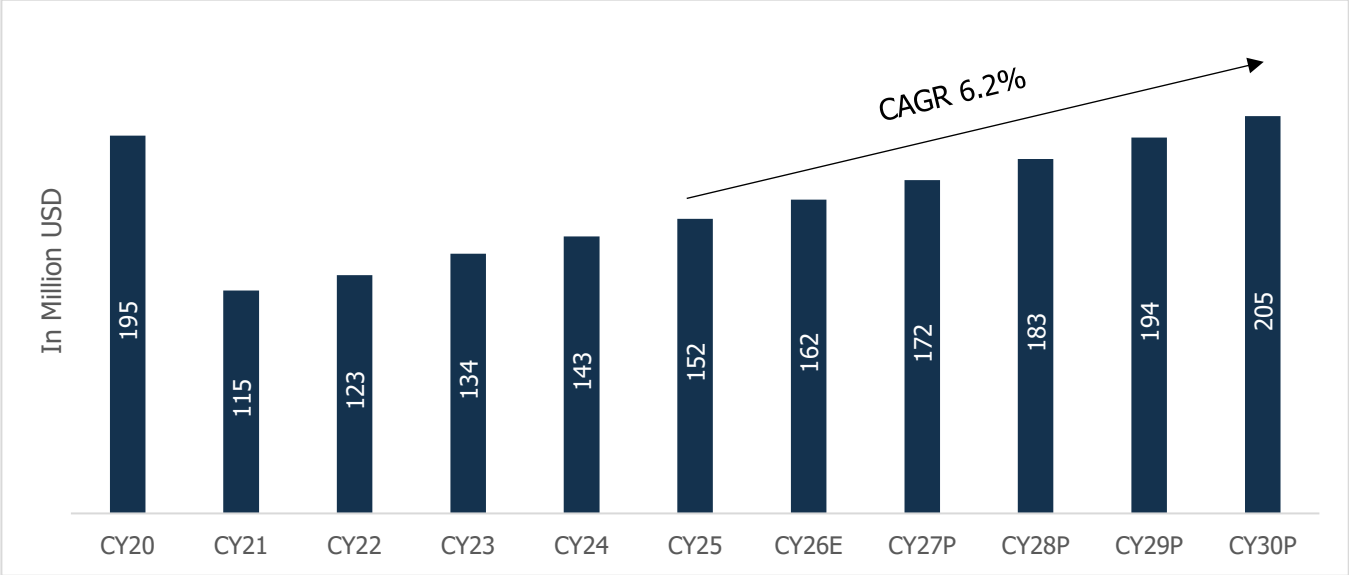
Source – Imarc Research, CareEdge Research

In CY25, the diagnostic testing market maintained a stable distribution across various test categories. The others segment continued to hold the largest share at 41%, reflecting the broad range of diagnostic solutions within this category. Immunodiagnostics accounted for 23% of the market, highlighting its critical role in disease detection and monitoring. Clinical Chemistry followed with a 18% share, emphasizing its importance in routine diagnostic procedures. Haematology and Molecular Diagnostics comprised 10% and 8% of the market, respectively, indicating their steady but essential contribution. The overall market distribution remains in line with historical trends, demonstrating the consistent demand for comprehensive diagnostic solutions, where multiple test types are often required for accurate disease assessment.

2.3.1 India Rapid Test Market

The rapid test market in India is being reshaped by a convergence of public health needs, consumer preferences, and technological advancements. Consumers, especially in urban and semi-urban areas, are increasingly adopting over-the-counter rapid tests for early diagnosis and convenience, while digital health platforms are enhancing accessibility through app-based tracking and teleconsultations. Local manufacturing is gaining momentum, with a focus on affordability and disease-specific customization. Though rural adoption is still limited, government and NGO-led screening initiatives are expanding in reach. With stricter regulatory oversight and growing emphasis on quality, rapid tests are evolving from emergency-use tools to essential components of routine healthcare.

Chart 14: India Rapid Test Market (By Value) in Mn USD



Source – Imarc Research, CareEdge Research

The Indian rapid test market has shown a dynamic trend between CY19 and CY25, starting at USD 195 million in CY20, primarily due to the COVID-19 pandemic. This spike reflects the urgent nationwide demand for rapid diagnostic solutions, especially for mass testing, screening, and containment efforts. However, following this peak, the market experienced a correction, with values moderating to USD 115 million in 2021 and gradually rising year-on-year to reach USD 143 million by CY24. This post-pandemic stabilization indicates that while the emergency-driven demand declined, the foundation for routine and preventive usage of rapid tests remained strong. In CY25, the market expanded to USD 152 million, supported by the adoption of point-of-care testing, awareness of early disease detection, and integration of rapid diagnostics in primary healthcare settings. The growth was also supported by initiatives to strengthen diagnostic infrastructure, expand access to healthcare services, and promote screening under public health programs.

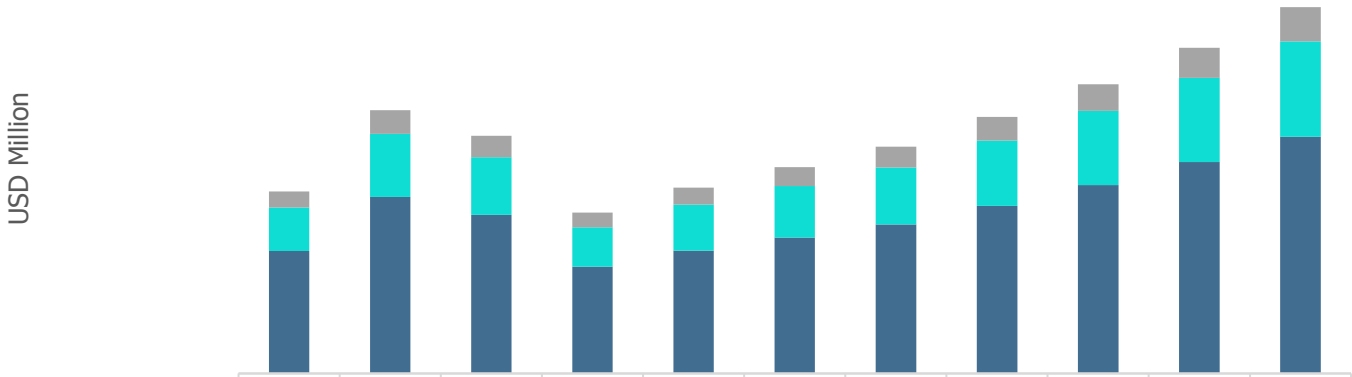
The market is projected to expand steadily, reaching USD 205 million by CY30. This future growth reflects a broader shift in India's healthcare approach, with increasing emphasis on early detection, at-home diagnostics, and point-of-care solutions. Factors such as improved healthcare infrastructure, growing awareness about lifestyle and infectious diseases, and government initiatives are expected to support this consistent rise. The forecast suggests the market will evolve from a reactive, crisis-driven sector to a more integrated part of everyday healthcare, particularly in urban and semi-urban settings, with potential to grow further as accessibility improves in rural areas.

2.4 Market Segmentation by Product

Table 6 : Description of Product Type

Sr No.	Product Type	Description
1	Reagents & Kits	This segment holds the largest market share as reagents and kits are essential consumables used in diagnostic tests across various applications, including immunoassays, molecular diagnostics, and clinical chemistry. The increasing prevalence of diseases and growing adoption of point-of-care testing are driving demand in this category.
2	Instruments	Diagnostic instruments, such as analyzers and automated testing machines, are critical for performing tests with high accuracy and efficiency. With advancements in technology and automation, this segment is witnessing steady growth, particularly in hospitals, laboratories, and diagnostic centers.
3	Services	The integration of digital health solutions, artificial intelligence, and data analytics in diagnostics has led to the growth of software solutions for result interpretation, lab automation, and remote diagnostics. Additionally, maintenance and support services for IVD instruments contribute to this segment's expansion.

Chart 15: India In-Vitro Diagnostics Market Landscape – by Product Type

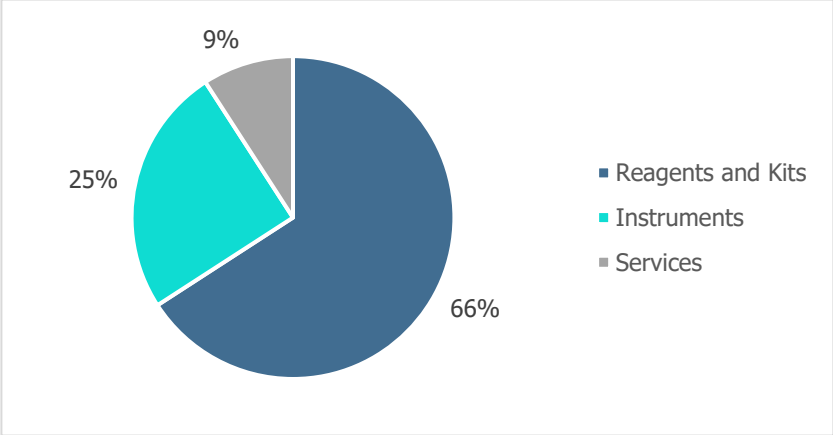


	CY20	CY21	CY22	CY23	CY24	CY25	CY26E	CY27P	CY28P	CY29P	CY30P
Services	132	192	174	118	138	153	169	192	217	245	277
Instruments	352	514	469	321	375	419	465	530	603	685	776
Reagents and Kits	997	1,435	1,290	868	999	1,105	1,211	1,363	1,532	1,719	1,925

Source – Imarc Research, CareEdge Research

Among the key segments, reagents and kits hold the largest share, contributing significantly to overall market growth. This segment grew from 997 million USD in CY20 to 1,105 million USD in CY25 and is projected to reach 1,925 million USD by CY30, driven by increasing diagnostic needs due to growing geriatric population and technological advancements. Instruments, which are vital for performing various diagnostic tests, have also seen steady growth, rising from 352 million USD in CY20 to 419 million USD in CY25, with an expected market size of 776 million USD by CY30. Although smaller in size, the services segment is essential for supporting the diagnostic ecosystem, growing from 132 million USD in CY20 to 153 million USD in CY25 and anticipated to reach 277 million USD by CY30.

Chart 16: Market Share by Product Type - CY25

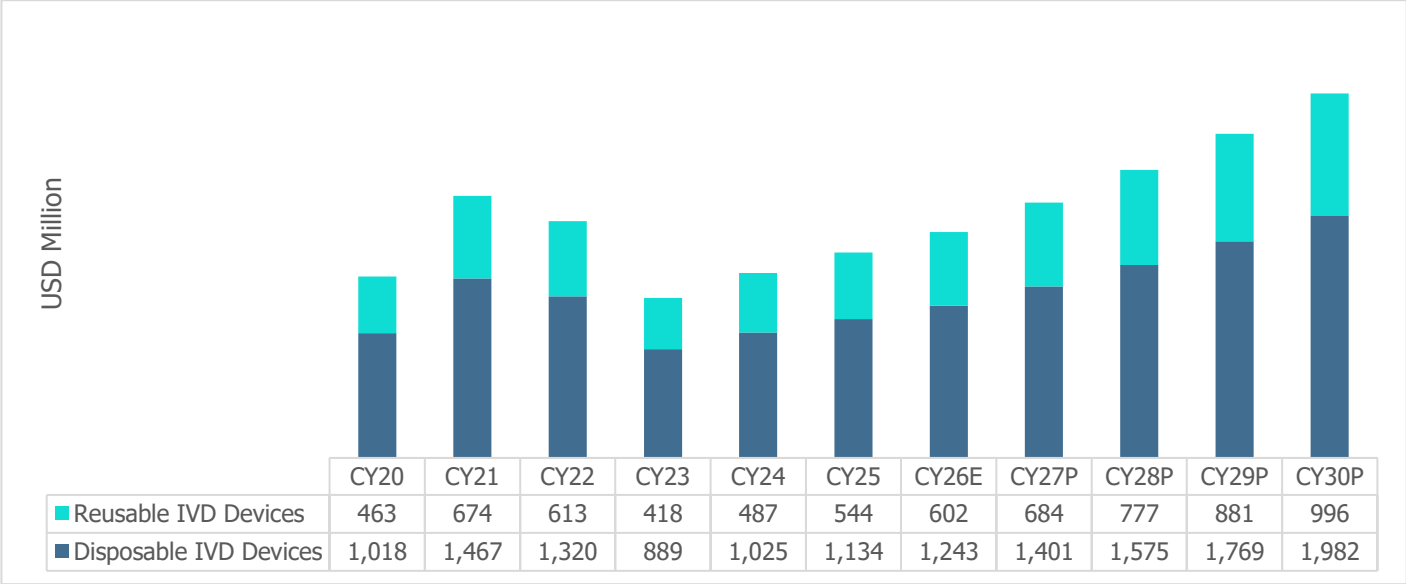


Source – Imarc Research, CareEdge Research

In CY25, the India In-Vitro Diagnostics (IVD) market is primarily dominated by the reagents and kits segment, which accounts for 66% of the total market share. This dominance is driven by the recurring demand for consumables required in diagnostic testing across various healthcare facilities. Instruments, which form the backbone of diagnostic testing by enabling accurate and efficient test execution, hold a 25% share of the market. Meanwhile, services, which encompass diagnostic support and maintenance, contribute 9% to the overall market. The balanced distribution among these segments highlights the interdependence of test execution, consumable usage, and associated services, ensuring a comprehensive and evolving diagnostic landscape.

2.5 Market Segmentation by Usability

Chart 17 : India In-Vitro Diagnostics Market landscape – By Usability

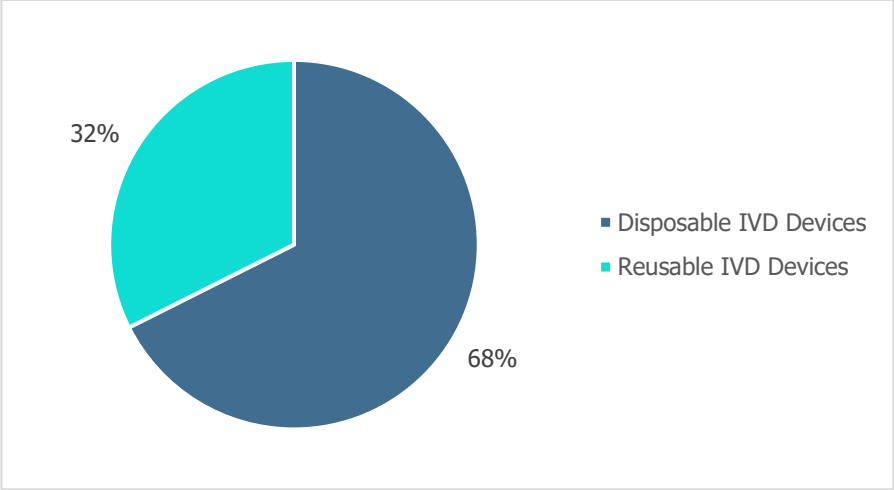


	CY20	CY21	CY22	CY23	CY24	CY25	CY26E	CY27P	CY28P	CY29P	CY30P
Reusable IVD Devices	463	674	613	418	487	544	602	684	777	881	996
Disposable IVD Devices	1,018	1,467	1,320	889	1,025	1,134	1,243	1,401	1,575	1,769	1,982

Source – Imarc Research, CareEdge Research

The India In-Vitro Diagnostics (IVD) market, segmented by usability, reflects a significant dominance of Disposable IVD Devices over Reusable IVD Devices. In CY25, the market size for Disposable IVD Devices stands at 1,134 million USD, while Reusable IVD Devices account for 544 million USD. The overall market reached 1,677 million USD in CY25, highlighting the continued preference for disposable devices due to their role in minimizing contamination risks and ensuring regulatory compliance. Way Forward, the market is expected to grow steadily and is projected to reach 2,978 million USD by CY30.

Chart 18: Market Share by Usability - CY25

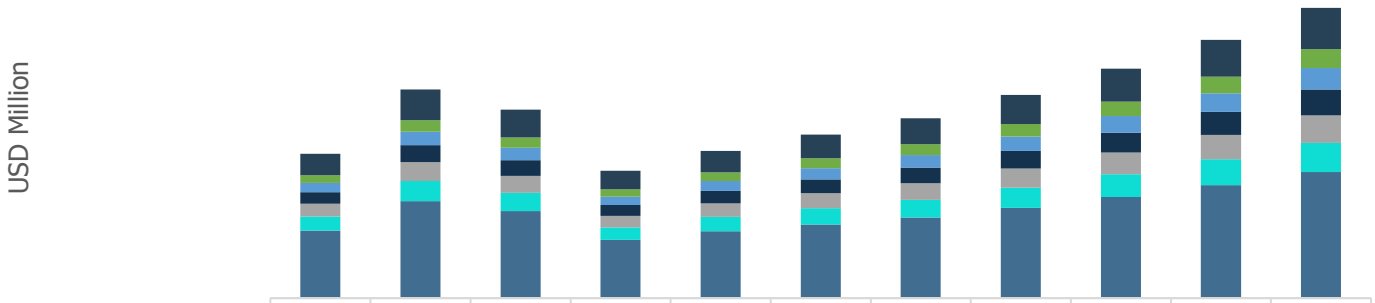


Source – Imarc Research, CareEdge Research

In CY25, the India In-Vitro Diagnostics (IVD) market, segmented by usability, is dominated by disposable IVD devices, which account for 68% of the total market share. Reusable IVD devices contribute 32% to the market, reflecting a significant but comparatively lower preference. The preference for disposable devices is driven by their ability to reduce cross-contamination risks, support infection control, and enable diagnostic outcomes, particularly in high-volume testing environments. The continued use of disposable devices is supported by emphasis on hygiene protocols, expansion of diagnostic services, and adoption of point-of-care testing across healthcare settings.

2.6 Market Segmentation by Application Usability

Chart 19: India In-Vitro Diagnostics Landscape - Application Usability

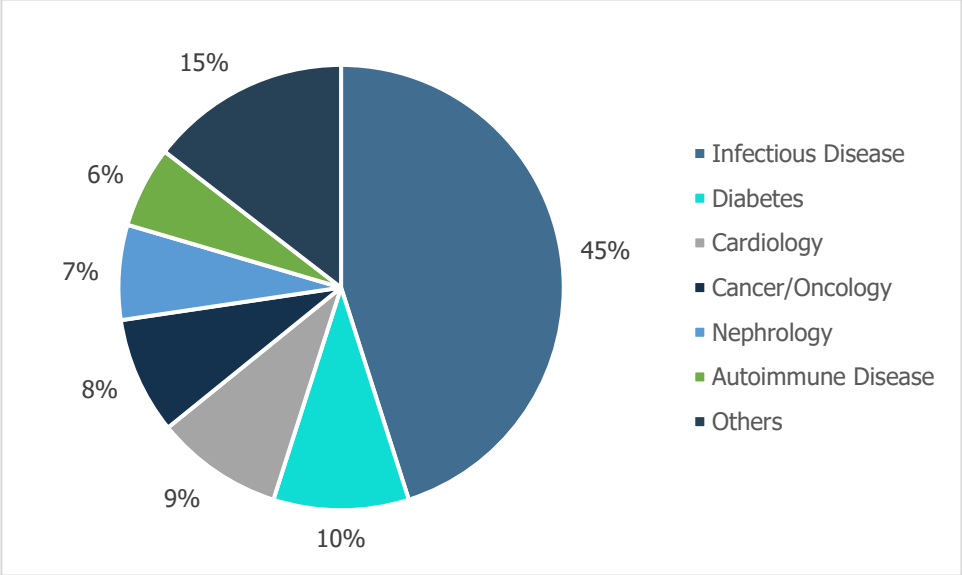


	CY20	CY21	CY22	CY23	CY24	CY25	CY26E	CY27P	CY28P	CY29P	CY30P
Others	220	317	285	192	221	244	267	301	338	379	425
Autoimmune Disease	79	117	108	74	88	99	111	128	146	168	192
Nephrology	95	139	128	88	103	116	129	148	169	193	220
Cancer/Oncology	118	173	158	108	127	142	158	181	206	234	266
Cardiology	132	192	175	119	139	155	172	196	222	252	285
Diabetes	143	207	188	128	148	165	182	206	234	264	298
Infectious Disease	694	996	892	598	686	756	826	926	1,037	1,159	1,293

Source – Imarc Research, CareEdge Research

The In Vitro Diagnostics (IVD) industry has experienced consistent growth from CY20 to CY24 across various applications, including infectious diseases, diabetes, cardiology, cancer/oncology, nephrology, autoimmune diseases, and others. Infectious diseases remain the dominant segment, showing consistent expansion, with the market size reaching 756 million USD in CY25 and projected to grow to 1,293 million USD by CY30. This growth highlights the essential role of diagnostics for infectious diseases in healthcare, fueled by the rising demand for early detection and effective management. Other applications also demonstrate steady upward trends, despite some occasional fluctuations. The ongoing need for precise and efficient diagnostics, along with technological advancements, increasing prevalence of chronic diseases and growing geriatric populations plays a significant role in this sustained growth.

Chart 20: Market Share by Application Usability - CY25

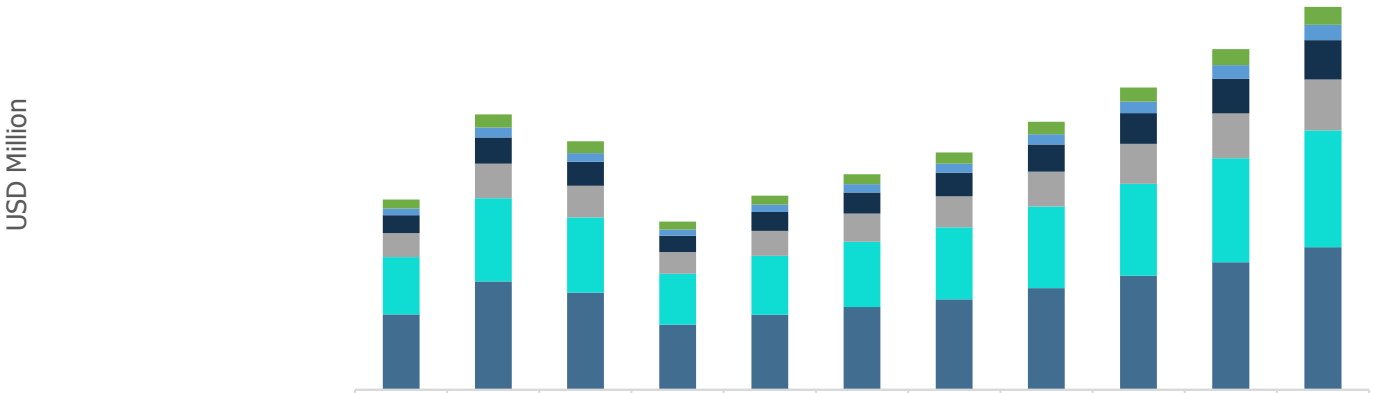


Source – Imarc Research, CareEdge Research

The India In-Vitro Diagnostics (IVD) market, when segmented by application, is mainly driven by the infectious disease segment, which accounts for 45% of the market in CY25, reflecting its critical role in disease detection and management. Diabetes and cardiology follow with 10% and 9% shares, respectively, highlighting the growing demand for diagnostic solutions in managing chronic diseases. Cancer/oncology, nephrology, and autoimmune diseases contribute 8%, 7%, and 6%, respectively, underscoring the need for advanced diagnostic tools in specialized medical fields. The remaining 15% falls under other applications, demonstrating the broad scope of the IVD market.

2.7 Market Landscape by End User Usability

Chart 21: India In-Vitro Diagnostics Landscape - By End User Usability

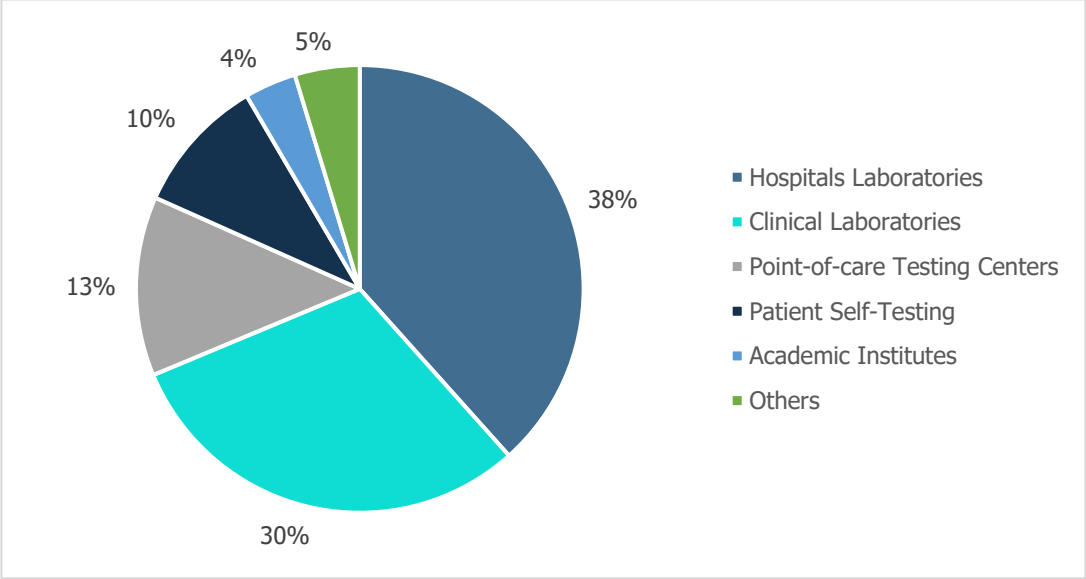


	CY20	CY21	CY22	CY23	CY24	CY25	CY26E	CY27P	CY28P	CY29P	CY30P
Others	70	102	91	62	71	79	86	97	110	123	138
Academic Institutes	52	76	69	48	56	63	70	80	91	104	119
Patient Self-Testing	140	204	186	127	148	166	184	210	239	271	308
Point-of-care Testing Centers	186	271	246	168	195	217	240	273	310	351	396
Clinical Laboratories	446	646	584	396	458	509	560	634	716	807	908
Hospitals Laboratories	587	843	756	508	583	644	704	791	887	993	1,109

Source – Imarc Research, CareEdge Research

The India In-Vitro Diagnostics (IVD) market, segmented by end-user usability, is significantly driven by hospital and clinical laboratories, which remain the primary diagnostic service providers. In CY25, hospital laboratories accounted for 644 million USD, projected to grow to 1,109 million USD by CY30, reflecting their critical role in comprehensive diagnostic testing. Similarly, clinical laboratories held a market share of 509 million USD in CY25 and are expected to reach 908 million USD by CY30, emphasizing their importance in routine and specialized testing. Other end-user segments, including point-of-care testing centers, patient self-testing, academic institutes, and others, continue to gain momentum.

Chart 22: Market Share by End User Usability



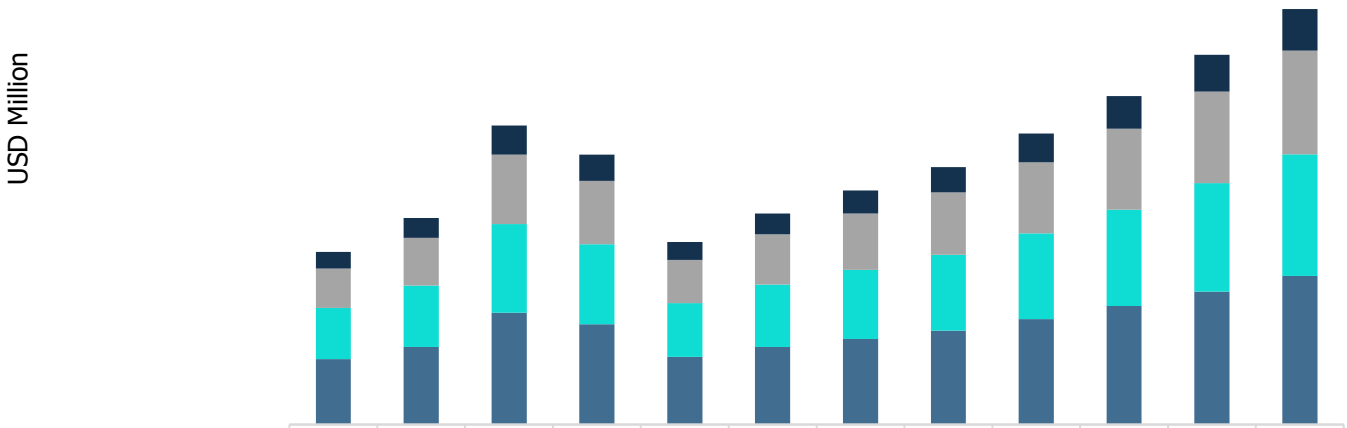
Source – Imarc Research, CareEdge Research

The India In-Vitro Diagnostics (IVD) market, segmented by end-user, is primarily dominated by hospital laboratories, which constitute 38% of the market in CY25, underscoring their critical role in diagnostic services for a wide range of medical conditions. Clinical laboratories follow closely, accounting for 30% of the market, driven by their extensive use in routine and specialized testing. Point-of-care testing centers represent 13% of the market, highlighting the growing demand for decentralized and rapid diagnostic solutions. Patient self-testing holds a 10% share, reflecting the increasing preference for home-based diagnostics. Academic institutes and other segments, comprising 4% and 5% respectively, contribute to research and specialized testing.

2.8 Market Segmentation by Region

The In-Vitro Diagnostics (IVD) market in India is experiencing significant growth, spurred by advancements in diagnostic technology, increased healthcare investments, and a rising demand for personalized and early disease detection solutions. With a focus on precision medicine and self-testing, the IVD market is expanding rapidly across different regions of the country. Each region is witnessing unique trends and growth opportunities, influenced by local healthcare needs, government initiatives, and evolving consumer behavior. Below is a regional breakdown of the IVD market in India in CY25 and its expected growth until CY30.

Chart 23: Market Breakup by Region: Sales Value



	CY19	CY20	CY21	CY22	CY23	CY24	CY25	CY26E	CY27P	CY28P	CY29P	CY30P
East India	119	143	207	188	128	148	165	182	206	234	264	298
West and Central India	283	342	499	454	310	361	404	447	509	579	656	743
South India	367	439	634	572	386	446	494	543	613	691	777	873
North India	468	557	801	719	484	556	614	673	756	849	952	1,064

Source: Imarc Research, CareEdge Research

North India: In CY25, the IVD market in North India stood at USD 614 million. This region, which includes prominent cities like Delhi, Chandigarh, Lucknow, and Jaipur, boasts a strong presence of multispecialty hospitals, diagnostic networks, and research institutions that encourage the uptake of advanced IVD technologies. The increasing demand for molecular diagnostics, immunoassays, and point-of-care testing (POCT) is driven by the high prevalence of chronic diseases such as diabetes, cardiovascular conditions, and cancer. Moreover, government-backed programs like Ayushman Bharat and the National Health Mission (NHM) are improving diagnostic infrastructure, particularly in tier 2 and tier 3 cities, thereby making affordable IVD solutions more accessible. Additionally, the growing popularity of self-testing for conditions like diabetes and infectious diseases is further boosting market growth. The North India IVD market is estimated to reach USD 673 million in CY26, driven by increasing penetration of diagnostic services across Tier II and III cities, rising adoption of point-of-care testing (POCT), and expansion of healthcare infrastructure.

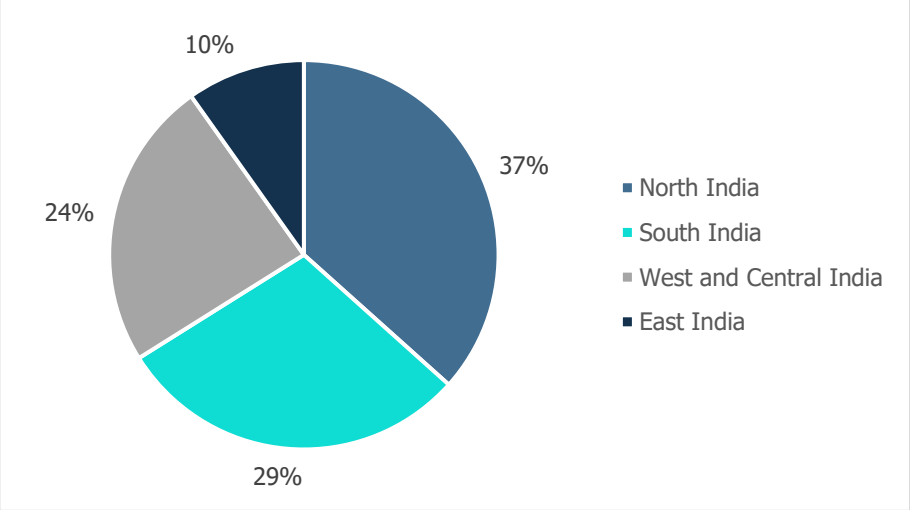
South India: The IVD market in South India reached USD 494 Million in CY25. South India is also experiencing a broad adoption of advanced diagnostic methodologies such as next-generation sequencing (NGS), liquid biopsy, and multiplex PCR testing. In addition, key government initiatives like the Tamil Nadu Health Systems Project, Telangana Diagnostics, and Kerala's eHealth Program are enhancing diagnostic facilities, particularly in underserved rural regions. South India is also a prominent center for the manufacturing of medical devices, with states like Karnataka and Tamil Nadu leading the production. By CY26, the South Indian IVD market is estimated to reach USD 543 Million, driven by the growth of digital diagnostics, the expansion of telemedicine, and the continuous support of government-led healthcare programs.

West and Central India: In CY25, the IVD market in West and Central India is valued at USD 404 Million. This region, comprising states like Maharashtra, Gujarat, Madhya Pradesh, and Chhattisgarh, is witnessing substantial growth due to the rapid development of diagnostic facilities in major urban centers such as Mumbai, Pune, Ahmedabad, and Indore. The adoption of cutting-edge technologies like molecular diagnostics, immunoassays, and point-of-care testing (POCT) is gaining momentum, fueled by the presence of prominent hospitals, diagnostic networks, and research institutions.

Moreover, cities like Pune and Ahmedabad are emerging as key innovation hubs, with industrial zones and biotech clusters driving significant research and development in diagnostics, especially in genetic testing and biomarker discovery. By CY26, the market in this region is estimated to grow to USD 447 Million, propelled by continued advancements in technology, increasing investments, and a rising demand for precision diagnostics.

East and Northeast India: In CY25, the IVD market in East and Northeast India is valued at USD 165 Million. This region, encompassing states like West Bengal, Odisha, Bihar, Jharkhand, Assam, and the northeastern states, has traditionally grappled with limited healthcare infrastructure and insufficient diagnostic facilities. However, ongoing healthcare reforms and advancements in laboratory networks are progressively advancing the market. There is also a noticeable surge in demand for molecular diagnostics, immunoassays, and automated diagnostic solutions for diseases like cancer, tuberculosis, and vector-borne diseases like malaria and dengue. By CY26, the market in this region is estimated to grow to USD 182 million, driven by the increasing adoption of digital diagnostics, molecular testing technologies, and the rise in local production of IVD kits under the Make in India initiative.

Chart 24: Market Share by Region – CY25



Source: Imarc Research, CareEdge Research

In CY25, the IVD market in India is led by North India, holding a 37% share, driven by the region's large metropolitan presence, high disease burden, and supportive government initiatives like Ayushman Bharat. South India follows with a 29% share, fueled by the prevalence of lifestyle diseases, strong healthcare programs, and being a manufacturing hub for medical devices. West and Central India contribute 24% to the market, benefiting from urban growth, advanced diagnostic adoption, and biotech clusters in cities like Pune and Ahmedabad. East India, with a smaller share of 10%, faces challenges in healthcare infrastructure but is witnessing growth due to ongoing reforms, rising infectious diseases, and emerging diagnostic hubs like Kolkata.

3 Key Growth Drivers of the Indian Vitro Industry

The in vitro diagnostics (IVD) market has been experiencing significant growth, driven by several factors. Below are key growth demands in the IVD market based on the following points:

1. Growing Geriatric Population: As the Indian geriatric population (typically aged 65 and above) continues to grow, there is an increased prevalence of age-related health issues such as diabetes, cancer, and neurological disorders. This shift drives a higher demand for IVD tests, which play a crucial role in monitoring, diagnosing, and managing these conditions. Older adults are more susceptible to chronic diseases, necessitating regular diagnostic testing for conditions like blood glucose levels, kidney function, and cholesterol management. This growing need for ongoing monitoring ensures a steady demand for IVD solutions that aid disease management. Furthermore, as the elderly population increases, personalized healthcare becomes more important. IVD tests enable physicians to tailor treatment plans to individual patients based on specific diagnostic results, ensuring more effective and customized care for aging individuals.

2. Technological Advancements: Technological advancements in the IVD market have significantly transformed the landscape of medical testing. Innovations in automation, miniaturization (the process of significantly reducing the size of medical diagnostic devices used to analyze bodily samples (like blood or urine) outside the body), and artificial intelligence have improved the accuracy, speed, and accessibility of diagnostic tools, encouraging more healthcare facilities to adopt these advanced technologies. Additionally, breakthroughs in molecular diagnostics (a laboratory method that identifies diseases or disease risk by analyzing molecules like DNA, RNA, and proteins present in a tissue or fluid sample), such as PCR (Polymerase Chain Reaction) and next-generation sequencing (NGS), have allowed for more precise and efficient detection of infections, genetic disorders, and cancers, further driving market growth. Furthermore, advancements in point-of-care (POC) technologies enable testing outside traditional laboratories, providing faster results and improving disease management, especially in remote or underserved regions where access to central healthcare facilities may be limited. These technological innovations are reshaping the way diagnostic testing is performed, fueling the expansion of the IVD market.

3. Increasing Demand for Point-of-Care (POC) Facilities: The increasing demand for point-of-care (POC) diagnostics is driven by the convenience, accessibility, and efficiency it offers. POC devices enable immediate testing and results, eliminating the need for patients, particularly those in rural or underserved areas, to travel to central laboratories, thus enhancing patient convenience. This accessibility also supports faster decision-making in critical clinical settings, such as emergency departments and intensive care units (ICUs), where quick diagnostic results are essential for effective treatment. Additionally, POC diagnostics are cost-effective, reducing the overall healthcare burden by minimizing hospital stay and streamlining care delivery. As a result, the demand for POC testing continues to grow, especially as healthcare systems increasingly prioritize quicker and more efficient diagnostic solutions.

4. Growing Prevalence of Target Diseases: The growing prevalence of target diseases, including both infectious and non-communicable diseases (NCDs), is significantly driving the demand for (IVD) tests. Infectious diseases, such as respiratory infections, sexually transmitted diseases, and hepatitis, require rapid detection to ensure timely containment and treatment, fueling the need for efficient IVD testing. Simultaneously, the rising burden of NCDs like diabetes, cardiovascular diseases, and cancer has heightened the demand for IVD solutions that enable early diagnosis, monitoring, and management, allowing for timely interventions. Moreover, the increasing prevalence of lifestyle diseases, such as obesity and hypertension, driven by urbanization, further emphasizes the need for regular IVD tests to monitor key health indicators like blood pressure and cholesterol levels, helping to mitigate the long-term impact of these conditions. As a result, IVD testing is becoming an essential tool in managing both infectious and chronic diseases.

5. Outbreak of COVID-19: The COVID-19 pandemic has drastically increased the demand for diagnostic tests, particularly PCR(polymerase chain reaction) and antigen tests (detect proteins (antigens) from a virus, like COVID-19, to identify a current infection), to detect SARS-CoV-2 infection, highlighting the critical role of IVD systems in real-time infectious disease detection. This surge in testing needs has driven the rapid development and widespread adoption of point-of-care and home testing solutions, enabling individuals to evaluate themselves without the need to visit healthcare facilities. As new variants of COVID-19 continue to emerge, the need for ongoing surveillance and monitoring of disease prevalence and mutations (a change in the DNA sequence of an organism) has further accelerated the growth of the IVD sector. Additionally, the pandemic has led to increased government and healthcare investments in diagnostic infrastructure, ensuring preparedness for future outbreaks and facilitating timely responses to pandemics. This collective demand has significantly expanded the IVD market, emphasizing the importance of diagnostic systems in global healthcare.

6. Shift from Sick Care to Wellness-Oriented Healthcare: There is a growing emphasis on preventive healthcare and wellness. Increasing health consciousness and lifestyle changes are encouraging routine health check-ups, early disease detection, and personalized diagnostics. This shift is significantly boosting the demand for IVD solutions, including molecular diagnostics, immunoassays, and point-of-care testing, as people seek proactive health monitoring rather than waiting for illnesses to develop.

7. Rising Penetration of Medical Insurance: The expanding coverage of health insurance in India is another critical factor driving the IVD industry. With increased awareness and regulatory policies promoting health insurance, more people now have financial access to diagnostics and medical treatments. Private insurers, government schemes like PMJAY (Pradhan Mantri Jan Arogya Yojana), and employer-sponsored health plans are improving affordability, leading to a surge in diagnostic testing. As more individuals gain access to insurance-backed diagnostic services, the demand for high-quality and early detection tests is on the rise, fueling the IVD market's expansion.

8. Growth of Public-Private Partnership (PPP) Models in Healthcare: The PPP model has become an essential pillar in India’s healthcare ecosystem, particularly in diagnostic services. The government is increasingly collaborating with private players to expand healthcare access, enhance infrastructure, and provide affordable diagnostic solutions to a broader population. Initiatives like outsourcing lab testing in government hospitals to private diagnostic chains, mobile health units, and AI-driven diagnostics are boosting IVD adoption. PPP models ensure advanced diagnostics reach underserved regions, creating immense growth opportunities for the IVD industry while improving healthcare accessibility and affordability.

4 Threats and Challenges in the Indian In-Vitro Diagnostics (IVD)

Challenges of the Indian Vitro Diagnostics

1. Challenges of Accessibility and Affordability in Advanced Diagnostic Testing: The advanced diagnostic tests and the devices used to perform the test can often be prohibitively expensive, placing a significant financial strain on both healthcare systems and patients. This challenge is particularly pronounced in low- and middle-income countries or rural regions, where access to healthcare resources may already be limited. The prohibitive costs associated with advanced diagnostic tools and tests make it difficult for a substantial portion of the population to afford essential diagnostic services, further exacerbating healthcare inequities. As a result, only certain segments of the population or specific healthcare institutions can access these sophisticated diagnostics, creating a gap in the availability of advanced testing. This issue affects market segmentation, where the prohibitive cost of these devices and tests restricts their use primarily to urban centers, private hospitals, or well-funded healthcare institutions. Rural areas, where poverty levels are higher and healthcare infrastructure is underdeveloped, often face the brunt of these disparities. This lack of accessibility to affordable diagnostics not only hinders the early detection and management of diseases but also affects the overall healthcare outcomes for large sections of the population. The inability to access advanced testing due to financial constraints leads to delayed diagnoses, worsened health conditions, and higher treatment costs. These challenges represent some of the most significant barriers in the IVD industry, making it a complex task to ensure that innovations in diagnostic technology are accessible to all, regardless of geographic location or economic status.

2. Supply Chain Disruptions: The IVD market is dependent on global supply chains for raw materials, manufacturing components, and distribution including key inputs such as diagnostic reagents, enzymes, antibodies, assay kits, culture media, plastic consumables, and specialized instrumentation parts. Disruptions arising from geopolitical developments, natural events, pandemics, or trade restrictions may lead to delays in production, increase costs, and result in product shortages, affecting the availability of diagnostic devices, particularly during periods of increased demand. Ongoing geopolitical tension may further affect shipping routes and global supply chains, leading to delays in the availability of diagnostic reagents and an increase in logistics costs, which may impact cost efficiency and operational timelines within the Indian in-vitro diagnostics (IVD) industry.

3. Stringent Regulations Regarding Product Approvals: The approval process for IVD devices is lengthy and complex due to stringent safety regulations, which can delay the introduction of innovative solutions. Global expansion-seeking companies struggle with navigating different regulatory standards in different nations. Clinical trials, safety evaluations, and quality checks are part of the process, which are all expensive. These other costs make it hard for small companies to compete with big players who have the resources to cope with regulatory requirements. Consequently, small businesses find it hard to penetrate the market, an indication that more efficient regulatory processes are needed to spur innovation and enhance access to the market.

Threats in the Indian Vitro Diagnostics

1. Technological Obsolescence: Rapid advancements in diagnostic technologies can render older IVD devices obsolete, posing a challenge for manufacturers that fail to keep pace with innovation. Devices that once offered innovative solutions may quickly be overshadowed by newer, more efficient technologies. This rapid technological evolution forces companies to invest continuously in research and development, adding financial pressure and making it difficult to stay competitive overall.

2. Market Competition and Price Pressure: As the IVD market expands, competition increases among both established companies and new entrants, putting pressure on prices. This often leads to price wars, where lower-cost alternatives from emerging markets make it harder for premium-priced products to maintain their market share. The

result is a reduction in profit margins and an increased need for cost-efficient manufacturing and innovative marketing strategies to stay competitive.

5 Regulatory Policies in the Indian Vitro Industry

In India, the regulation of in-vitro diagnostic (IVD) devices is governed by the Central Drugs Standard Control Organization (CDSCO), under the Ministry of Health and Family Welfare. Here are the key regulatory aspects:

1. Regulatory Authority & Framework: IVD devices are regulated by the CDSCO under the Medical Device Rules (MDR) 2017, which classify devices into four categories based on risk (Class A, B, C, and D {Class A being Low Risk to Class D being High Risk). These rules set standards for approval, manufacturing, and distribution of IVDs in India, aligning them with international best practices.
2. Approval and Licensing: Before marketing an IVD device in India, manufacturers must obtain a license from the CDSCO. This includes submitting documents such as clinical trial data, technical specifications, and product details. Higher-risk devices (Class C and D) require more detailed clinical evaluations.
3. Post-Market Surveillance and Compliance: Manufacturers must implement post-market surveillance to track the performance of IVD devices after approval. They are required to report adverse events and maintain compliance with safety standards. This ensures continued monitoring of product safety and efficacy.
4. Labelling and Clinical Trials: IVD devices must have proper labelling with Instructions for Use (IFU), product specifications, and safety warnings. Higher-risk devices may require clinical trials or performance evaluations to demonstrate safety and accuracy, and all devices must comply with Good Manufacturing Practices (GMP).

These regulations aim to ensure that IVD devices available in India meet safety, quality, and efficacy standards for the benefit of patients and healthcare providers.

6 Government Initiatives for the In Vitro Diagnostics (IVD) Industry in India

The Indian government has taken several initiatives to strengthen the IVD industry, recognizing its critical role in disease detection, monitoring, and healthcare management. The COVID-19 pandemic highlighted the importance of robust diagnostic capabilities, prompting regulatory reforms, financial incentives, and policy support to enhance domestic manufacturing and innovation. These efforts aim to reduce dependency on imports, promote indigenous production, and make high-quality diagnostic solutions accessible and affordable. Below are some key initiatives that have shaped the growth of the IVD sector in India.

1.Production-Linked Incentive (PLI) Scheme: To encourage domestic manufacturing of medical devices, including diagnostic tools, the government introduced the PLI scheme for medical devices. This initiative provides financial incentives to manufacturers producing high-end diagnostic kits, reagents, and analyzers in India. By promoting local production, the scheme reduces reliance on imports and enhances India's competitiveness in the global IVD market.

2.Make in India & Atmanirbhar Bharat (Self-Reliant India): The Make in India and Atmanirbhar Bharat Abhiyan initiatives have been instrumental in boosting local production of IVD products. The government has encouraged research and development in the diagnostic sector by offering financial aid, reduced import duties on raw materials, and support for startups and MSMEs. These efforts aim to make India a global hub for affordable and high-quality diagnostic solutions.

3. ICMR Support for Diagnostic Innovation: The Indian Council of Medical Research (ICMR) has played a key role in advancing the IVD sector by supporting the development and validation of indigenous testing kits. It collaborated with private players to accelerate the approval of COVID-19 diagnostics, including RT-PCR, ELISA, and rapid antigen tests. ICMR's research and funding support have strengthened India's diagnostic infrastructure, making high-quality testing more accessible.

4.Public Procurement & Subsidies: To ensure affordability and widespread availability of diagnostic tests, the government has undertaken large-scale public procurement of IVD kits. This was especially crucial during the pandemic, when bulk purchasing of test kits helped control the spread of the virus. Additionally, subsidies and financial support have been provided to research institutions and manufacturers, ensuring a stable supply chain for diagnostic products.

5. National Health Mission & Ayushman Bharat: Under the Ayushman Bharat Health & Wellness Centers (HWCs) and National Health Mission (NHM), the government has expanded access to diagnostic services, particularly in rural areas. By upgrading public health labs and integrating advanced diagnostic tools, these initiatives aim to provide affordable and high-quality testing to underserved populations. Strengthening diagnostic capabilities at the primary healthcare level is a significant step toward early disease detection and better healthcare outcomes.

These initiatives have collectively transformed the IVD industry in India, fostering innovation, self-reliance, and improved healthcare accessibility. The government's continued focus on regulatory reforms, local manufacturing, and public health infrastructure will further accelerate the growth of the sector.

7 Outlook for Indian Vitro Diagnostic Industry:

The IVD industry in India is experiencing a significant transformation, driven by multiple factors that are reshaping the landscape of healthcare diagnostics. Diagnostic testing has always been a crucial aspect of healthcare, enabling medical professionals to identify conditions accurately and determine appropriate treatments. The COVID-19 pandemic, although it led to an initial surge in demand for IVD products, continues to influence the market, with growth stabilizing following a decline in cases. However, the underlying momentum for growth remains strong due to evolving healthcare needs and improvements in accessibility.

As India's population grows and life expectancy increases, the demand for diagnostic solutions continues to rise. Better accessibility to healthcare services, the increasing burden of chronic diseases such as diabetes, cardiovascular diseases, and cancer, and a growing focus on preventative healthcare are transforming the market. The changing attitudes towards early disease detection and proactive health management have also contributed to this trend, shifting the emphasis from treatment to prevention.

Government policies such as Make in India, Atmanirbhar Bharat, and Ayushman Bharat have provided significant support to the Indian IVD industry. These initiatives have encouraged the development of affordable, high-quality indigenous products, making India less reliant on imports and more self-sufficient in meeting domestic demand. As a result, the Indian IVD market is poised to make its mark globally, with the potential for increased exports and international partnerships.

The next-generation IVD market is booming, fueled by the rise in infectious diseases, increased awareness, and the growing demand for personalized healthcare. Consumers and healthcare providers are increasingly focused on early detection, creating a surge in demand for diagnostic solutions that can identify health issues at the earliest stages. This demand is amplified by advances in technology from automation and digitization to the development of customized diagnostic tools.

Several key drivers are contributing to the rapid growth of the IVD market in India. Technological advancements, such as automation, multiplex panel testing, and Point-of-Care (POC) diagnostics, are revolutionizing early disease detection and prevention. These innovations are enabling faster, more accurate testing, reducing the time between diagnosis and treatment. Furthermore, the increased reliance on IVD by biotech sectors, along with a surge in investments and R&D in diagnostics, is fostering innovation and improving diagnostic capabilities.

Geopolitical tensions in West Asia may lead to risks for the Indian in-vitro diagnostics (IVD) industry through disruptions in global supply chains, changes in freight and input costs, and delays in the procurement of reagents and equipment. The industry is supported by healthcare awareness, diagnostic penetration, and demand for preventive and routine testing. While these factors may affect margins and operational efficiency in the short term, the domestic demand base and localisation of manufacturing may support stability over the medium term.

The future of the Indian IVD industry is promising. With continued advancements in diagnostic technologies, greater adoption of automation and digital health solutions, and a focus on accessibility, the industry is well-positioned for sustained growth. As India continues to evolve into a global player in diagnostics, its ability to provide affordable and high-quality solutions will be a critical factor in shaping the future of healthcare both domestically and internationally. The demand for rapid, accurate, and personalized diagnostic solutions will drive the industry forward, with a strong focus on preventative care, early detection, and disease management.

8 Competitive Landscape

➢ **Q-Line Biotech Pvt Limited**

Q-Line Biotech has been operating in the Indian IVD industry since 2013, offering a range of products such as haematology POC testing, molecular diagnostics, special diagnostics, ELISA, and rapid tests. The company focuses on the indigenous manufacturing of biochemistry reagents and consumables, rapid cards, in-vitro diagnostics (IVD), and pathology equipment. The company has a wide distribution network across India, aiming to provide products at standard prices while driving innovation in diagnostics and healthcare.

Q-Line's sales revenue showed a significant shift pre-COVID-19, during COVID-19, and post-COVID-19, reflecting its crucial contributions during the pandemic. Pre-COVID, the company recorded sales of INR 943.59 million in FY19. The company developed ICMR-approved COVID-19 testing products, oxygen concentrators, launched mobile testing units, and expanded diagnostic capabilities to support national healthcare needs. As of 9MFY26, company has recorded sales of 2,324 million.

	Unit	FY23	FY24	FY25	9MFY26
Revenue	Rs. Million	1,827	2,036	3,138	2,324
Revenue Growth	%		11%	54%	-
Operating Profit	Rs. Millions	337	380	574	651
Operating Margins	%	18%	19%	18%	28%
PAT	Rs Million	321	344	281	387
PAT Margins	%	17%	17%	9%	16%
Debt Equity	Times	0.6	0.6	0.9	1.1
Return on Equity	%	25%	21%	15%	17%
Return on Assets	%	13%	10%	6%	7%
Return on Capital Employed	%	23%	19%	21%	19%

Source: Company Reports

➢ **J Mitra & Co**

J Mitra & Co. manufactures a wide range of in vitro diagnostic kits and reagents, specializing in diagnostic tests for infectious diseases, diabetes, cardiovascular conditions, and pregnancy. The company operates a production facility capable of manufacturing 5 lakh test kits daily, which equates to 1 crore test kits per month. With a focus on quality and innovation, J Mitra continuously introduces new products to meet evolving healthcare needs, establishing its presence in both the Indian and international diagnostics markets.

	Unit	FY23	FY24	FY25
Revenue	Rs. Million	1,603	1,936	2,018
Revenue Growth	%	-	21%	4%
Operating Profit	Rs. Millions	638	811	742
Operating Margins	%	40%	42%	37%
PAT	Rs Million	481	626	575
PAT Margins	%	30%	32%	27%
Debt Equity	Times	-	-	-
Return on Equity	%	14%	15%	12%
Return on Assets	%	14%	15%	12%

	Unit	FY23	FY24	FY25
Return on Capital Employed	%	19%	20%	16%

Source: Company Reports.

- **Transasia Bio-Medicals Limited**

Transasia Bio-Medicals Limited offers a wide range of diagnostic products including haematology reagents, clinical chemistry, and immunoassays. The company manufactures diagnostic instruments and provides integrated solutions for healthcare. Transasia provides services such as haematology diagnostics, providing reagents and instruments for blood testing. It also offers immunoassay and clinical chemistry solutions for hospitals, labs, and diagnostic centers. Transasia operates haematology reagent filling lines, with a daily capacity of 30,000 liters and a production capability of 6,000 instruments per month. The company focuses on R&D and innovation to develop innovative diagnostic solutions for various diseases.

	Unit	FY23	FY24	FY25
Revenue	Rs. Million	14,456	15,243	14,016
Revenue Growth	%	-	5%	-8%
Operating Profit	Rs. Million	383	1,553	2,421
Operating Margins	%	3%	10%	17%
PAT	Rs Million	-872	-155	2,022
PAT Margins	%	-6%	-1%	14%
Debt Equity	Times	0.1	-	-
Return on Equity	%	-6%	-1%	13%
Return on Assets	%	-4%	-1%	10%
Return on Capital Employed	%	0%	11%	14%

Source: Company Reports

Note: Since the EBIT is negative for FY23, Capital employed is reflecting negative.

- **Molbio Diagnostics Pvt Ltd,**

Molbio Diagnostics Pvt Ltd, specializes in molecular diagnostics, focusing on diseases like tuberculosis, COVID-19, and HIV. The company manufactures Truenat test kits, which enable point-of-care molecular testing, providing rapid and accurate results. With a production capacity of 3.5 lakh units per day by a new manufacturing unit in Goa, Molbio serves a global market with high demand for diagnostic solutions. The company is dedicated to making molecular testing more accessible, particularly in resource-limited areas, and has improved their diagnostics system for infectious diseases, especially tuberculosis.

	Unit	FY23	FY24	FY25
Revenue	Rs. Million	3,325	8,366	10,204
Revenue Growth	%	-	152%	22%
Operating Profit	Rs. Million	432	1,810	2,491
Operating Margins	%	13%	22%	24%
PAT	Rs Million	-34	835	1,386
PAT Margins	%	-1%	10%	14%
Debt to Equity	Times	0.1	0.2	0.1
Return on Equity	%	0%	10%	14%
Return on Assets	%	0%	7%	9%
Return on Capital Employed	%	2%	16%	21%

Source: Company Reports.

- **Agappe Diagnostics**

Agappe Diagnostics produces reagents for diagnostic testing and immunoassay kits for various diseases, including infections and chronic conditions. Agappe's Diagnostics production capacity includes 120,000 kits per shift per month and 1,250 pieces of equipment per shift per month. The company places an emphasis on R&D and manufacturing excellence. Agappe Diagnostics provides affordable diagnostic solutions in both domestic and international markets.

	Unit	FY23	FY24	FY25
Revenue	Rs. Million	3,905	4,426	5,168
Revenue Growth	%	-	13%	17%
Operating Profit	Rs. Million	439	413	693
Operating Margins	%	11%	9%	13%
PAT	Rs Million	235	174	313
PAT Margins	%	6%	4%	6%
Debt to Equity	Times	0.2	0.2	0.3
Return on Equity	%	10%	7%	11%
Return on Assets	%	6%	4%	7%
Return on Capital Employed	%	13%	10%	15%

Source: Company Reports.

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