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Research Report on IVD Industry

September 2025

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1 Economic Outlook

1.1 Global Economy

Global growth, which reached 3.5% in CY23, stabilized at 3.3% for CY24 and projected to decrease to 3.0% for CY25. Global trade is expected to be disrupted by new US tariffs and countermeasures from trading partners, leading to historically high tariff rates and negatively impacting economic growth projections. The global landscape is expected to change as countries rethink their priorities and policies in response to these new developments. Central banks priority will be to adjust policies, while smart fiscal planning and reforms are key to handling debt and reducing global inequalities.

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

	CY20	CY21	CY22	CY23	CY24	CY25P	CY26P	CY27P	CY28P	CY29P	CY30P
World	-2.7%	6.6%	3.6%	3.5%	3.3%	3.0%	3.1%	3.2%	3.2%	3.2%	3.1%
Advanced Economies	-4.0%	6.0%	2.9%	1.7%	1.8%	1.5%	1.6%	1.7%	1.7%	1.7%	1.7%
Emerging Market and Developing Economies	-1.7%	7.0%	4.1%	4.7%	4.3%	4.1%	4.0%	4.2%	4.1%	4.1%	4.0%

Source: IMF – World Economic Outlook, July 2025; Notes: P-Projection, E-Estimated

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 %)										
	CY20	CY21	CY22	CY23	CY24	CY25P	CY26P	CY27P	CY28P	CY29P	CY30P
India	-5.8	9.7	7.6	9.2	6.5	6.4	6.4	6.5	6.5	6.5	6.5
China	2.3	8.6	3.1	5.4	5.0	4.8	4.2	4.2	4.1	3.7	3.4
Indonesia	-2.1	3.7	5.3	5.0	5.0	4.8	4.8	4.9	5.0	5.1	5.1
Saudi Arabia	-3.6	5.1	7.5	-0.8	1.3	3.6	3.9	3.6	3.2	3.2	3.3
Brazil	-3.3	4.8	3.0	3.2	3.4	2.3	2.1	2.2	2.3	2.4	2.5
Euro Area	-6.0	6.3	3.5	0.4	0.9	1.0	1.2	1.3	1.3	1.2	1.1
United States	-2.2	6.1	2.5	2.9	2.8	1.9	2.0	2.0	2.1	2.1	2.1
Middle East	-2.2	4.4	5.5	2.2	2.4	3.4	3.5	4.0	3.7	3.7	3.7
Latin America	-6.9	7.4	4.2	2.4	2.4	2.2	2.4	2.7	2.7	2.7	2.6

Source: IMF- World Economic Outlook Database (July 2025)

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

1.2 Indian Economic Outlook

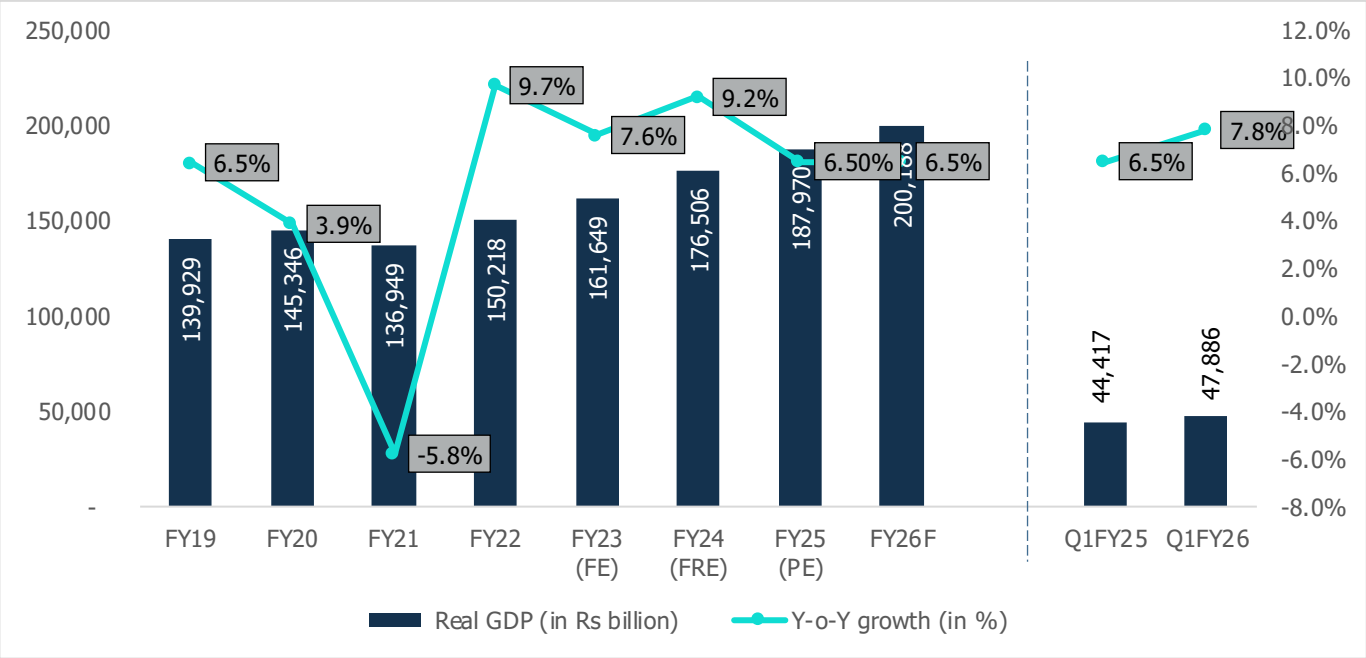
1.2.1 GDP Growth and Outlook

Resilience to External Shocks remains Critical for Near-Term Outlook

India's real GDP grew by 9.2% in FY24 (Rs. 176,506 billion) which is the highest in the previous 12 years (excluding FY22, on account of end of pandemic) and as per provisional estimates, it grew at 6.5% in FY25 (Rs. 187,970 billion), driven by double digit growth particularly in the Manufacturing sector, Construction sector and Financial, Real Estate & Professional Services. This growth is also led by private consumption increasing by 7.6% and government spending increasing by 3.8% Y-o-Y.

In Q1FY26, real GDP grew by 7.8% y-o-y as compared to 6.5% y-o-y in the previous year's quarter. Real GDP growth is projected at 6.5% in FY26 as well, driven by strong rural demand, improving employment, and robust business activity.

Chart 2: Trend in Real Indian GDP growth rate



Source: MOSPI, Reserve Bank of India.

Note: FE – Final Estimates, FRE- First Revised Estimates, PE – Provisional Estimates, F - Forecasted

GDP Growth Outlook (August 2025)

FY26 GDP Outlook: The RBI projects real GDP growth at 6.5% for 2025–26, driven by strong private consumption, steady investment, and resilient rural and urban demand. A favourable monsoon, robust services sector and improving corporate balance sheets support this outlook.

However, risks from prolonged geopolitical tensions, global trade disruptions, and weather-related uncertainties remain. Taking these into account, the RBI has reaffirmed its growth projections.

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

FY26P (complete year)	Q2FY26P	Q3FY26P	Q4FY26P	Q1FY27P
6.5%	6.7%	6.6%	6.3%	6.6%

Source: Reserve Bank of India; Note: P-Projected

1.2.2 Gross Value Added (GVA)

Gross Value Added (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. India's recovery 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 6.5% and GVA at 6.4%, as per MoSPI's provisional estimates released in May 2025.

The agriculture and allied sector grew by 4.6% in FY25 (up from 2.7% in FY24), contributing 14.4% to real GVA, supported by a good monsoon, better crop output, and strong allied activities. The industrial sector grew by 5.9% in FY25, down from 9.5% in FY24 due to weaker manufacturing, with FY24 growth driven by strong manufacturing sales, construction (9.4%), utilities, and supportive policies. The services sector grew by 6.4% in FY25, down from 8.6% in FY24, supported by public administration (8.9%), financial services (7.2%), and trade and transport (5.8%), contributing Rs 94.4 trillion to the economy. From Q1FY25 to Q1FY26, the overall GVA at basic price grew from 6.5% to 7.6%, indicating a stronger economic performance. Most sectors showed growth, with Services sector growing significantly from 6.8% to 9.3%, and Agriculture, Forestry & Fishing rebounding from 1.5% to 3.7%. However, Mining & Quarrying declined sharply from 6.6% to -3.1%, and Electricity, Gas & Water supply slowed considerably from 10.2% to 0.5%.

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

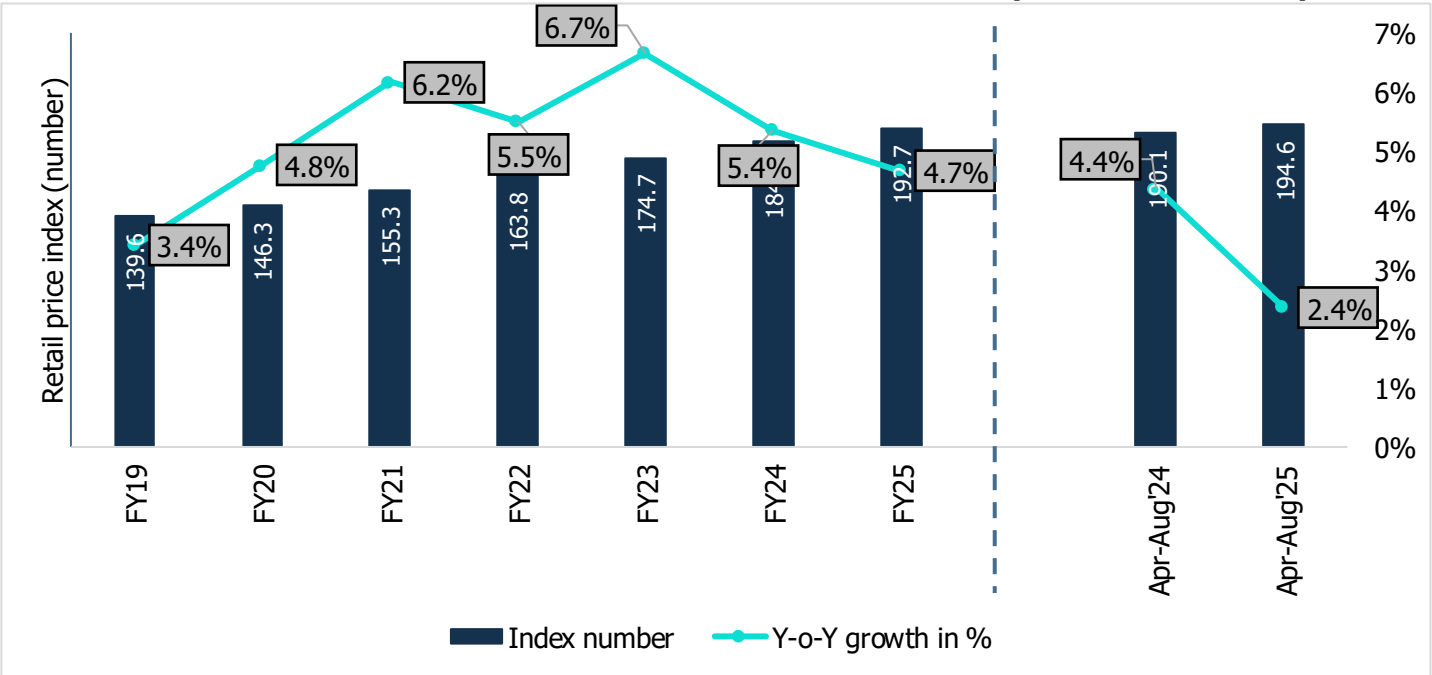
At constant Prices	FY19	FY20	FY21	FY22	FY23 (FE)	FY24 (FRE)	FY25 (PE)	Q1FY25	Q1FY26
Agriculture, Forestry & Fishing	**2.1**	**6.2**	**4.1**	**3.5**	**5.1**	**2.7**	**4.6**	**1.5**	**3.7**
Industry	**5.3**	**-1.4**	**-0.9**	**11.6**	**2.0**	**10.8**	**5.9**	**8.5**	**6.3**
Mining & Quarrying	-0.9	-3.0	-8.6	7.1	2.8	3.2	2.7	6.6	-3.1
Manufacturing	5.4	-3.0	2.9	11.1	-3.0	12.3	4.5	7.6	7.7
Electricity, Gas, Water Supply & Other Utility Services	7.9	2.3	-4.3	9.9	11.5	8.6	5.9	10.2	0.5
Construction	6.5	1.6	-5.7	14.8	10.0	10.4	9.4	10.1	7.6
Services	**7.2**	**6.4**	**-8.2**	**8.8**	**11.3**	**9.0**	**7.2**	**6.8**	**9.3**
Trade, Hotels, Transport, Communication & Broadcasting	7.2	6.0	-19.7	13.8	14.4	7.5	6.1	5.4	8.6
Financial, Real Estate & Professional Services	7.0	6.8	2.1	4.7	10.7	10.3	7.2	6.6	9.5
Public Administration, Defense and Other Services	7.5	6.6	-7.6	9.7	8.2	8.8	8.9	9.0	9.8
GVA at Basic Price	**5.8**	**3.9**	**-4.2**	**8.8**	**7.4**	**8.6**	**6.4**	**6.5**	**7.6**

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

1.2.3 Consumer Price Index

The Consumer Price Index (CPI) for the April–Aug 2025 recorded a combined inflation rate of 2.1%, marking the lowest quarterly retail inflation in six years. The moderation was driven by continued declines in Pulses, Transport and communication, Vegetables, Cereal, Education, Egg and Sugar and confectionery.

Chart 3: Retail Price Inflation in terms of index and Y-o-Y Growth in % (Base: 2011-12=100)



Source: MOSPI

The CPI is primarily factored in by RBI while preparing their bi-monthly monetary policy. At the bi-monthly meeting held in August 2025, RBI projected inflation at 3.1% for FY26 with inflation during Q2FY26 at 2.1% and Q3FY26 at 3.1%, Q4FY26 at 4.4% and Q1FY26 at 4.9%.

Considering the current inflation situation, RBI has maintained the repo rate to 5.5% in the August 2025 meeting of the Monetary Policy Committee.

1.2.4 Trends in Per capita Domestic Product (SDP)

State Domestic Product is the total value of goods and services produced during any financial year, within the geographical boundaries of a state. The top 10 best performing states on per capita SDP include Delhi, Gujarat, Karnataka, and Tamil Nadu.

As of FY24, major states having a per capita SDP below national average include Andhra Pradesh, Rajasthan, Madhya Pradesh, and Uttar Pradesh growing y-o-y by 7.20%, 6.94%, 4.83%, and 6.42% respectively. Bihar is the poorest performing state with a per capita SDP of Rs. 32,174. It has consistently been performing the poorest since FY18, growing merely at a CAGR of 3.14% from FY18 to FY24.

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

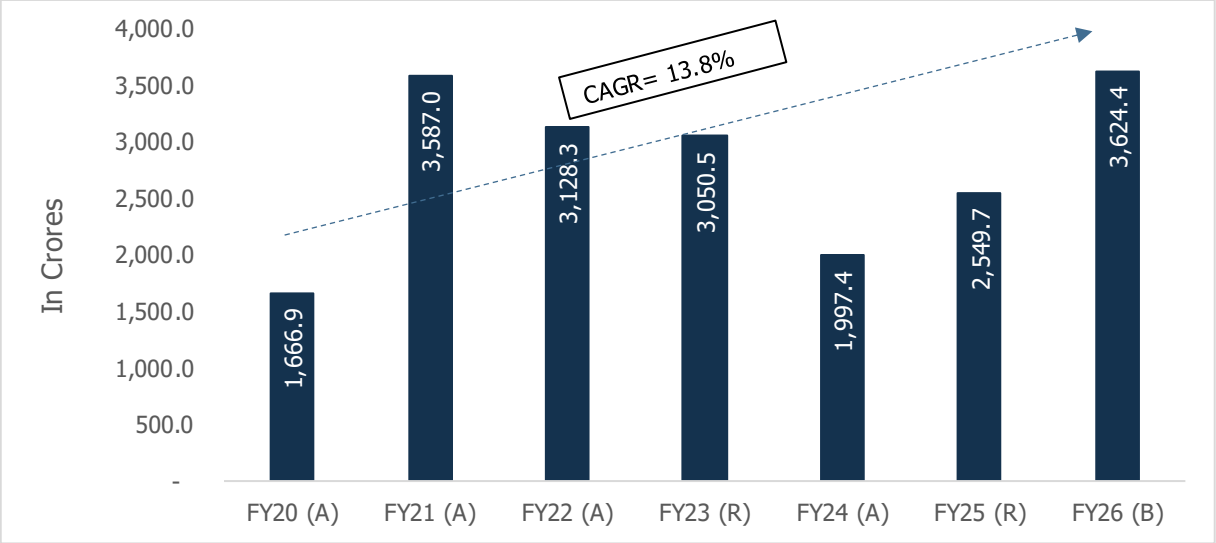
State\UT	FY18	FY19	FY20	FY21	FY22	FY23	FY24
Andhra Pradesh	1,03,177	1,08,853	1,10,587	1,10,971	1,21,762	1,26,690	1,35,806
Bihar	26,719	29,092	29,798	26,839	27,674	29,909	32,174
Gujarat	1,43,604	1,54,887	1,64,060	1,56,285	1,70,519	1,81,963	1,81,963
Karnataka	1,40,747	1,49,024	1,56,478	1,49,673	1,63,732	1,75,895	1,86,038
Madhya Pradesh	54,824	59,005	60,452	56,086	60,166	63,379	6,6441
Maharashtra	1,37,808	1,40,782	1,45,626	1,27,550	1,40,718	1,53,664	163,820
Rajasthan	73,529	73,975	76,840	73,447	79,507	84,935	90,831
Tamil Nadu	1,33,029	1,41,844	1,44,845	1,43,482	1,54,269	1,66,590	1,79,732
Uttar Pradesh	41,771	42,333	43,061	39,866	44,178	47,808	50,875
Delhi	2,52,960	2,57,597	2,60,559	2,28,162	2,44,024	2,58,941	2,73,687

Source: MOSPI

1.2.5 Budget capital expenditure towards the health sector

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 projected 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 reflects a phase of stabilization post-pandemic, with reduced emergency spending. However, the anticipated increase in FY25 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)



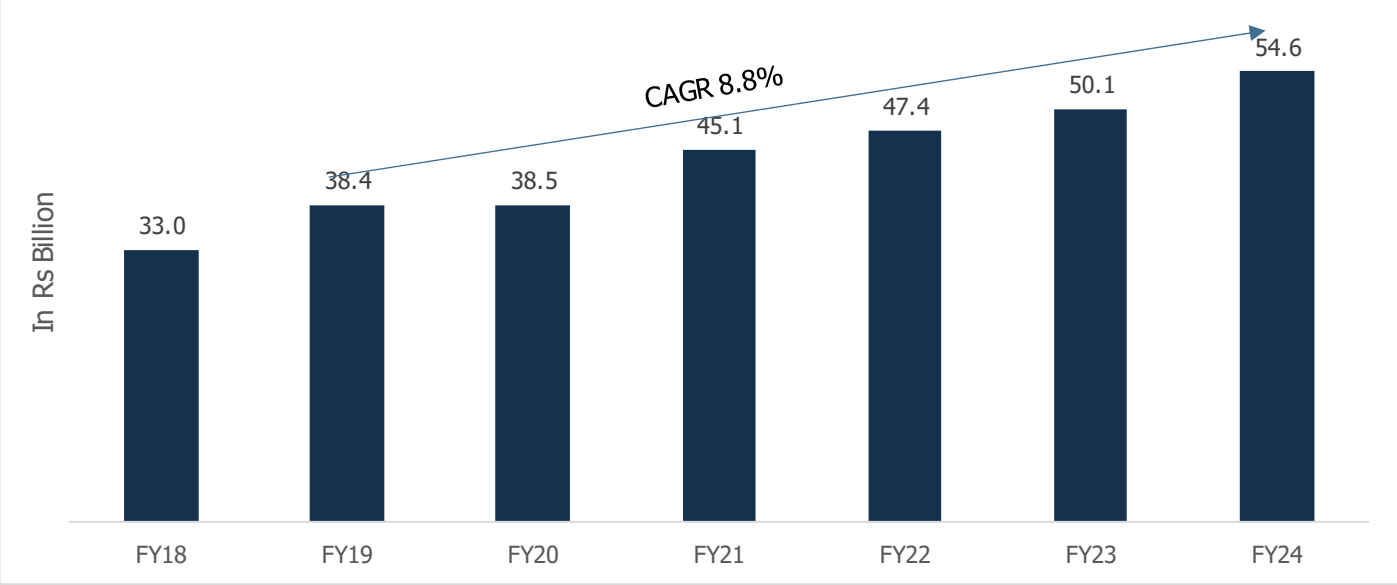
Source: Union Budget; Note: A- Actual, R-Revised, B- Budgeted

1.2.6 Trend in Household Savings

Household savings in India have grown at an 8.8% CAGR since FY18, reaching Rs. 54.61 billion in FY24, a 9% 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.

This trend is driven by heavy borrowing, especially in housing, auto, and personal loans, leading to a six-year high in household financial liabilities. Savings in mutual funds and life insurance also grew, with an 11.5% and 13.6% y-o-y increase, respectively, while 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

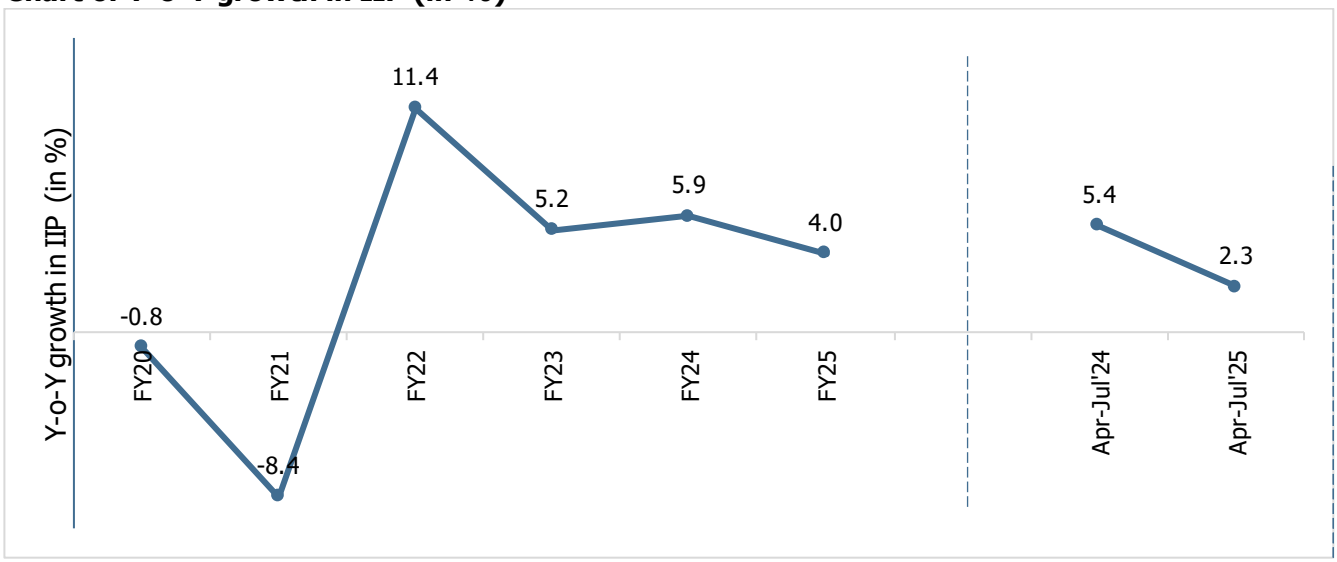
The Quick Estimates of the Index of Industrial Production (IIP) for July 2025 show a growth of 3.5%, compared to 4.9% in June 2025. The year-on-year moderation reflects weakness across major segments, primarily due to contractions in electricity, mining, and consumer non-durables.

In July 2025, industrial growth was supported by Manufacturing (5.4%), while Electricity declined by 1.2% and Mining contracted to -7.2%. Within manufacturing, notable growth was recorded in basic metals, machinery and equipment, and non-metallic mineral products. Specifically, these segments helped offset broader weakness.

Use-based indices reflected mixed trends, with strong growth in Infrastructure Goods (11.9%), but declines in Consumer Durables and Non-Durables indicating subdued consumption and Capital goods.

Manufacturing output grew by 5.4%, contributing significantly to overall industrial growth. This was primarily driven by strong performance in segments such as pharmaceuticals, motor vehicles, beverages, and electrical equipment.

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



Source: MOSPI

1.2.8 Overview of Key Demographic Parameters

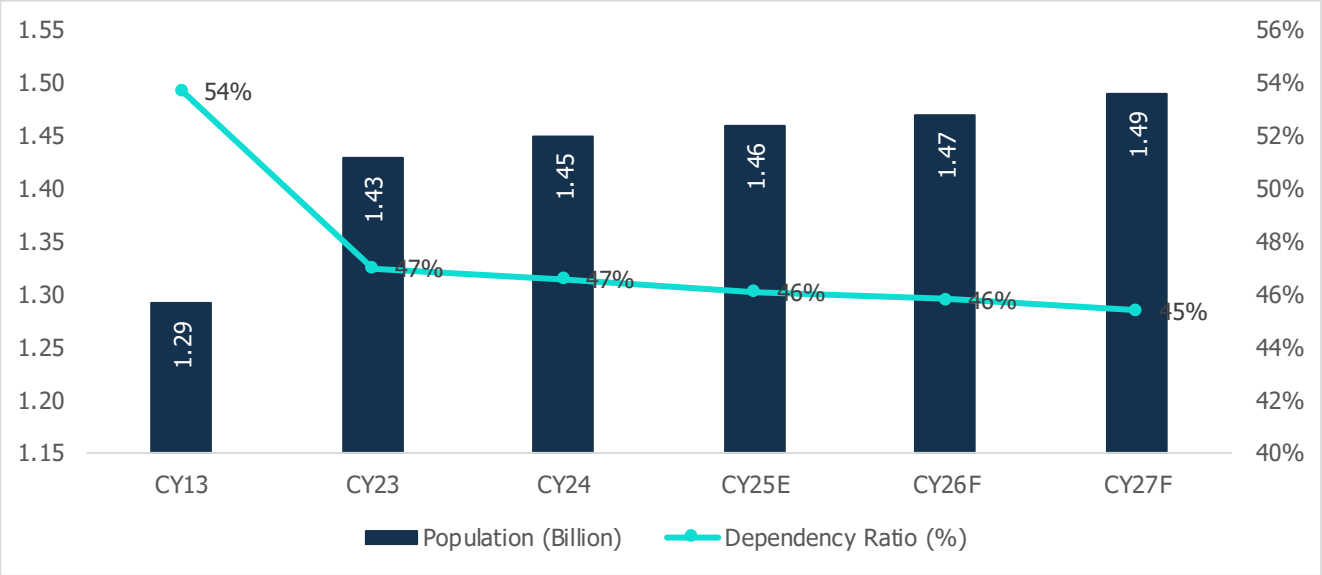
- **Population growth and Urbanization**

The trajectory of economic growth of India and private consumption is driven by socio-economic factors such as demographics and urbanization. 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.

Age Dependency Ratio is the ratio of dependents to the working age population, i.e., 15 to 64 years, wherein dependents are population younger than 15 and older than 64. This ratio has been on a declining trend. Declining dependency means 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.

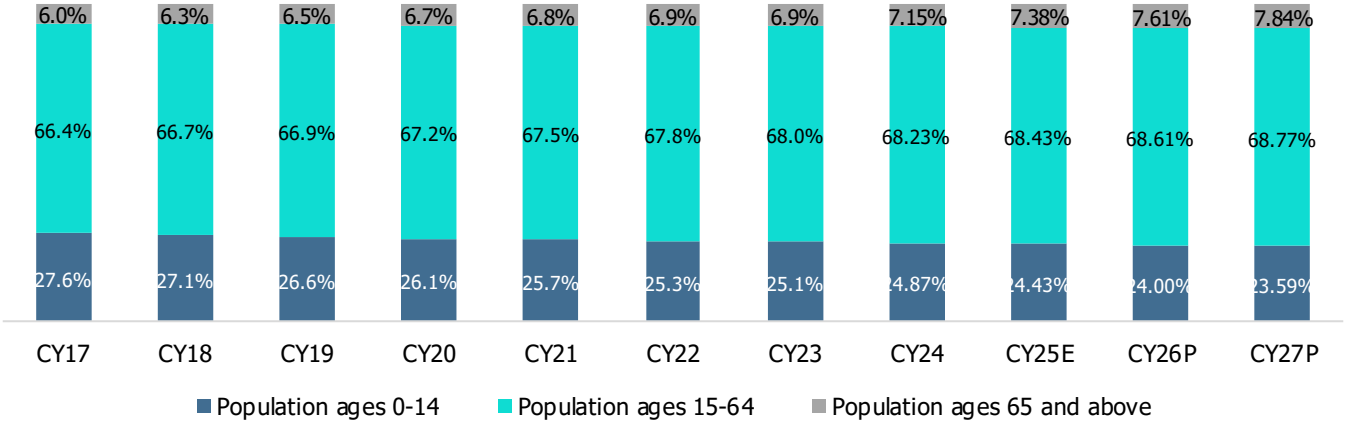
Chart 7: Trend in Population growth vis-à-vis dependency ratio in India (in Billion)



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 urbanized towns, will continue to drive income growth and consumer demand. This presents strong opportunities for sectors like consumer electronics, transportation, and railways. Rising employment, urbanization, 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)

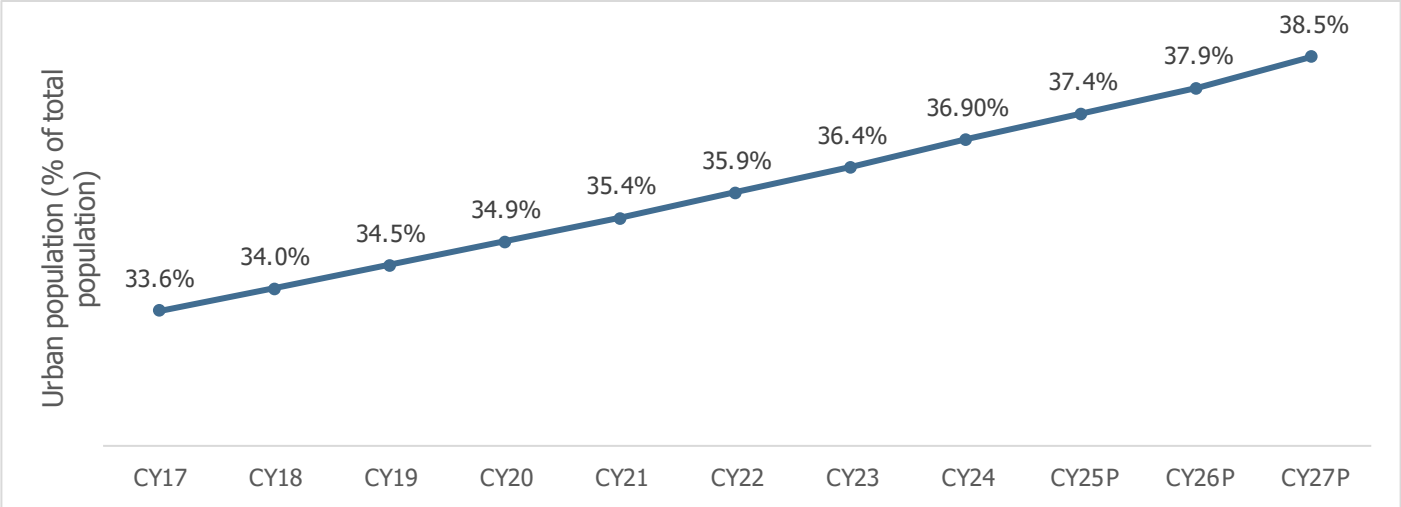


Source: World Bank Database; Note; E- Estimated, F- Forecasted

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 urbanization might necessitate substantial investments in infrastructure, housing, and transportation.

Chart 9: Urbanization Trend in India



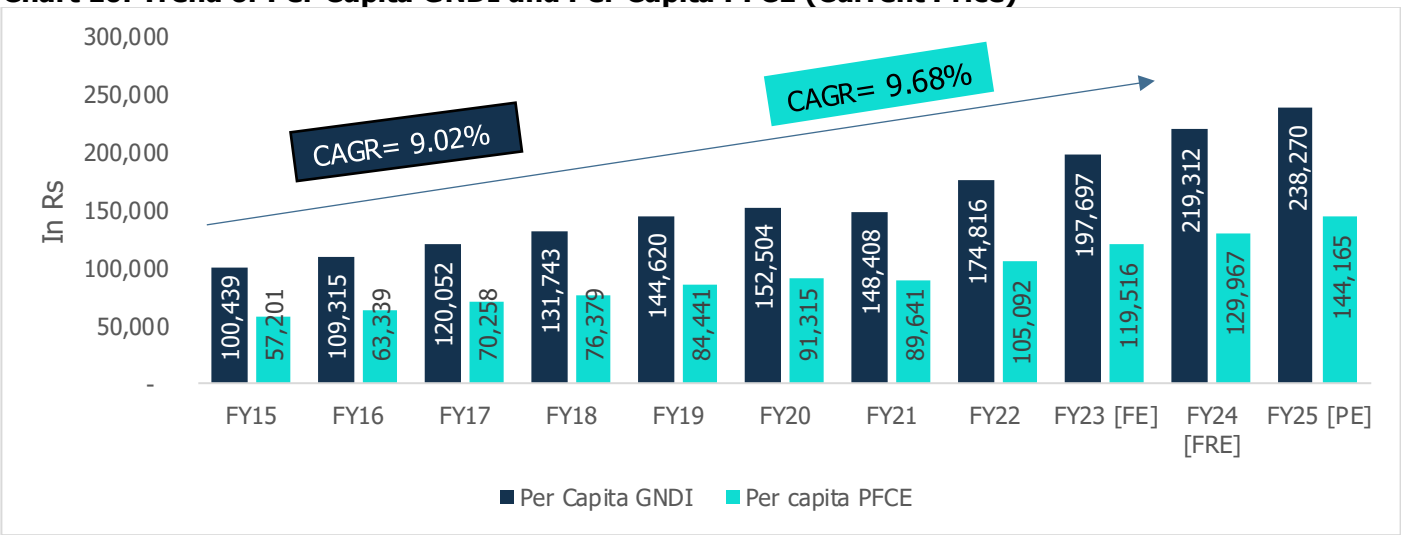
Source: World Bank Database; Note; E- Estimated, F- Forecasted

- **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 FY15 to FY25, per capita GNDI at current prices registered a CAGR of 9.02%. More disposable income drives more consumption, thereby driving economic growth.

With increase in disposable income, there has been a gradual change in consumer spending behavior as well. Per capita Private Final Consumption Expenditure (PFCE), which is measure of consumer spending, has also shown significant growth from FY15 to FY25 at a CAGR of 9.68%.

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



Source: MOSPI; Note: FRE – First Revised Estimates, FE – Final Estimates, PE- Provisional Estimates

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. However, India's economy remains relatively strong, with an IMF forecast of 6.4% GDP growth in CY25 (FY26 according to the fiscal year), compared to the global projection of 3.0%. Key drivers include strong domestic demand, government capital expenditure and moderate 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-pandemic, 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.

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 the 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. Normalizing the employment situation after opening up of the economy is supporting consumption expenditure. Public investment is set to grow with a Rs. 11.21 lakh crore capital expenditure allocation for FY26. 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.

The recent 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. The GST rationalization 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 the consumption.

The impact of U.S. tariffs on India's export trade is anticipated to be minimal. The engineering goods sector will have a potential U.S. tariff impact, whereas steel industry is affected by the 50% tariffs although the impact is expected to be minimal given the volume of goods exported is less.

On February 13th, 2025, Prime Minister Narendra Modi and President Donald Trump discussed enhancing the U.S.-India trade relationship, with a target to increase bilateral trade from USD 200 billion to USD 500 billion by 2030. As of September 2025, India and the U.S discussions seem "positive and forward looking", according to the Ministry of Commerce and Industry.

Thus, while U.S. tariffs may have a limited impact on India's exports, ongoing trade negotiations and India's competitive manufacturing advantage position it well for continued growth in global trade.

2 India's In-Vitro Diagnostics Market

2.1 Introduction

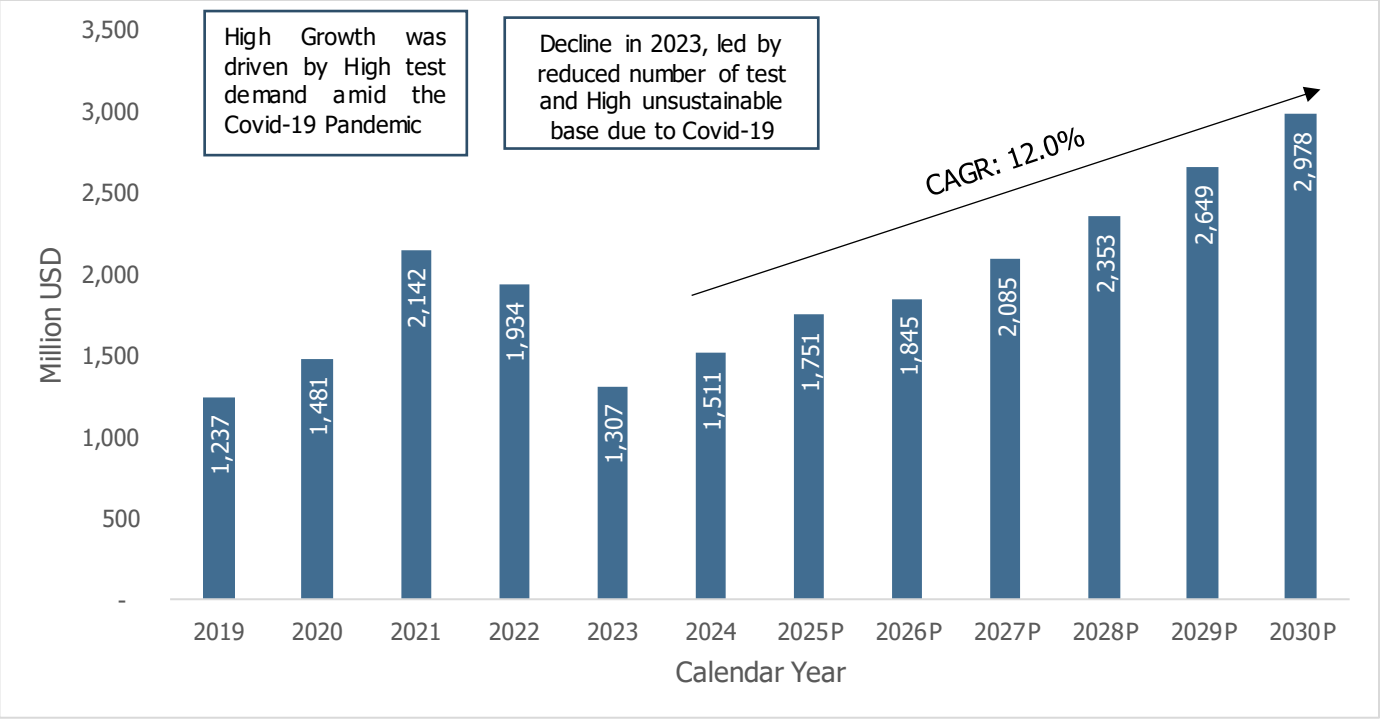
The In-Vitro Diagnostics (IVD) market serves as a critical component of healthcare infrastructure, facilitating early disease detection and accurate diagnosis. With the increasing demand for timely and precise medical testing, IVD has become crucial in clinical decision-making, directly influencing treatment 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

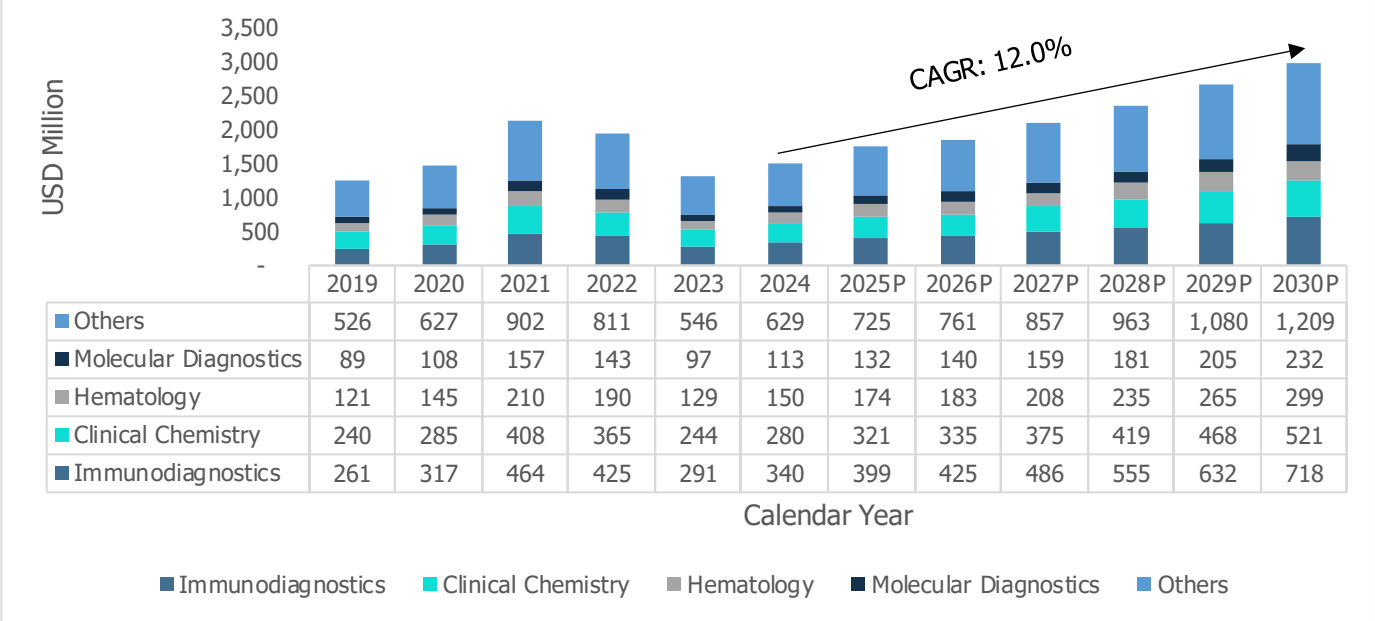
The India In-Vitro Diagnostics (IVD) market has experienced dynamic shifts, primarily driven by the COVID-19 pandemic. The market surged from 1,237 million USD in CY19 to 2,142 million USD in CY21 due to increased testing demand, followed by a sharp decline in CY22 and CY23 due to a high base from COVID-19 testing, which was not sustainable for continued growth, along with reduced pandemic-related testing. However, with growing healthcare awareness, and rising prevalence of chronic diseases, the market began recovering in CY24 and is projected to grow at a CAGR of up to 12.0%, reaching 2,978 million USD 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



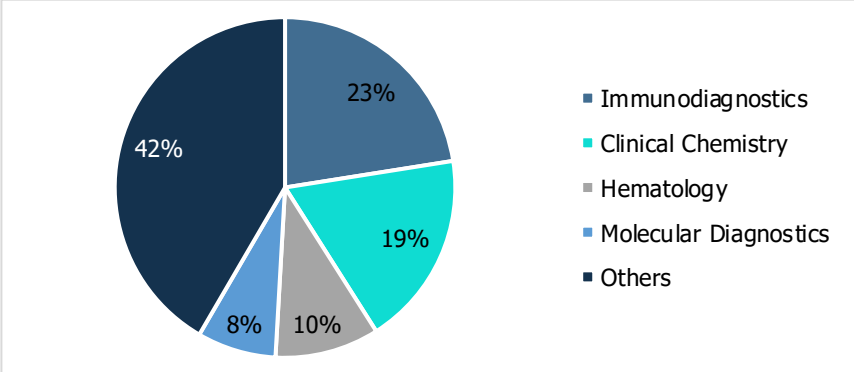
	2019	2020	2021	2022	2023	2024	2025P	2026P	2027P	2028P	2029P	2030P
Others	526	627	902	811	546	629	725	761	857	963	1,080	1,209
Molecular Diagnostics	89	108	157	143	97	113	132	140	159	181	205	232
Hematology	121	145	210	190	129	150	174	183	208	235	265	299
Clinical Chemistry	240	285	408	365	244	280	321	335	375	419	468	521
Immunodiagnostics	261	317	464	425	291	340	399	425	486	555	632	718

Source – Imarc Research, CareEdge Research

Others include

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. Way 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 – CY 2024



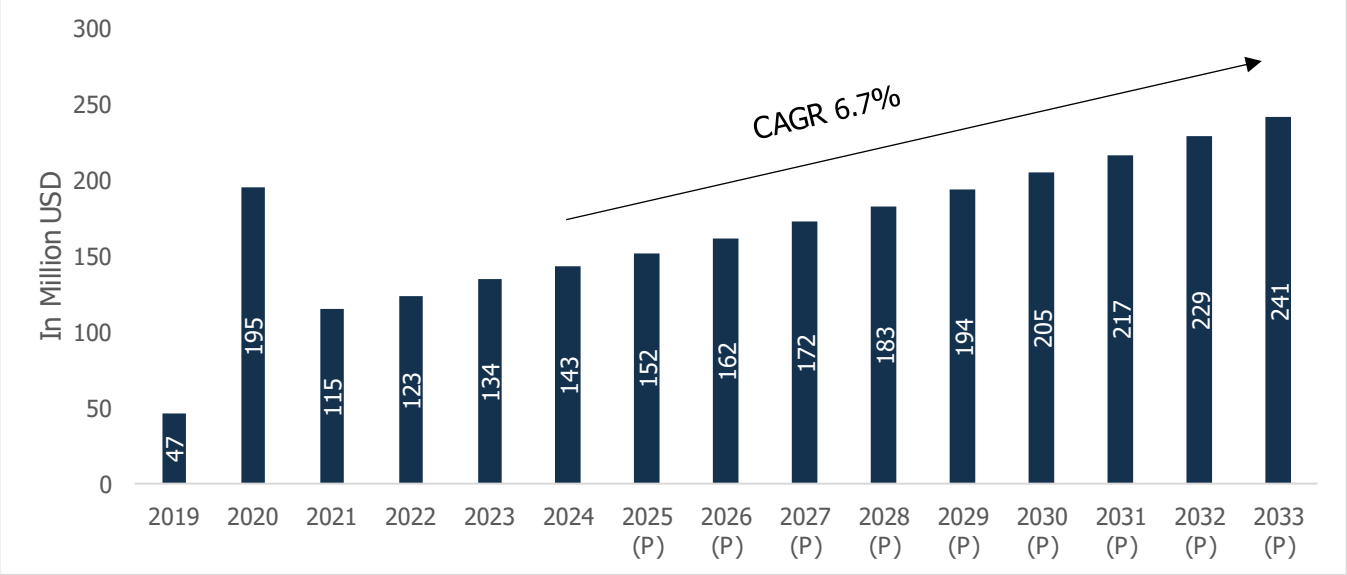
Source – Imarc Research, CareEdge Research

In CY24, the diagnostic testing market maintained a stable distribution across various test categories. The others segment continued to hold the largest share at 42%, 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 19% 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 2019 and 2024, starting at USD 47 million in 2019 and witnessing an unprecedented surge to USD 195 million in 2020, 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 2024. This post-pandemic stabilization indicates that while the emergency-driven demand declined, the foundation for routine and preventive usage of rapid tests remained strong.

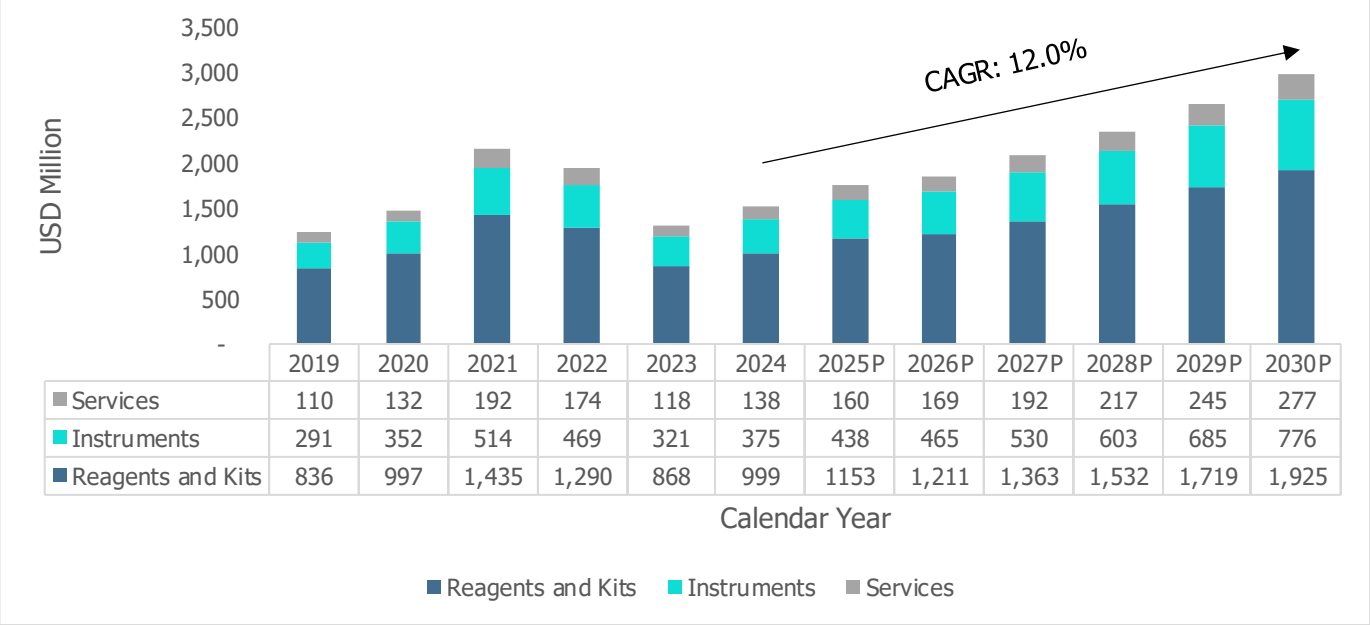
The market is projected to expand steadily, reaching USD 241 million by 2033. This future growth reflects a broader shift in India's healthcare approach, with increasing emphasis on early detection, at-home diagnostics, and point-of-care solutions. Factors such as improved healthcare infrastructure, 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

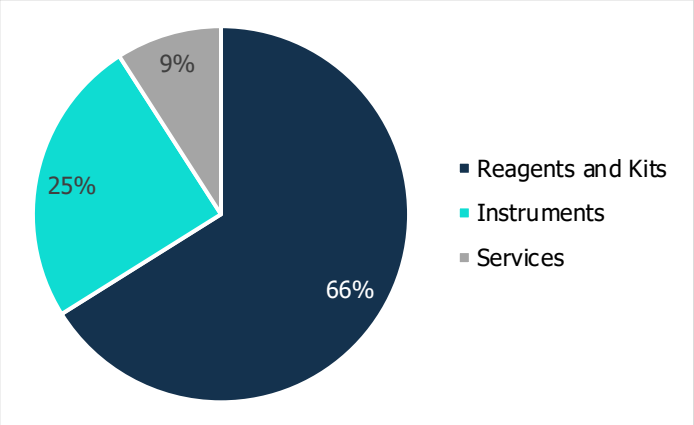


	2019	2020	2021	2022	2023	2024	2025P	2026P	2027P	2028P	2029P	2030P
Services	110	132	192	174	118	138	160	169	192	217	245	277
Instruments	291	352	514	469	321	375	438	465	530	603	685	776
Reagents and Kits	836	997	1,435	1,290	868	999	1153	1,211	1,363	1,532	1,719	1,925

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 836 million USD in CY19 to 999 million USD in CY24 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 291 million USD in CY19 to 375 million USD in CY24, 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 110 million USD in CY19 to 138 million USD in CY24 and anticipated to reach 277 million USD by CY30.

Chart 16: Market Share by Product Type - CY 2024

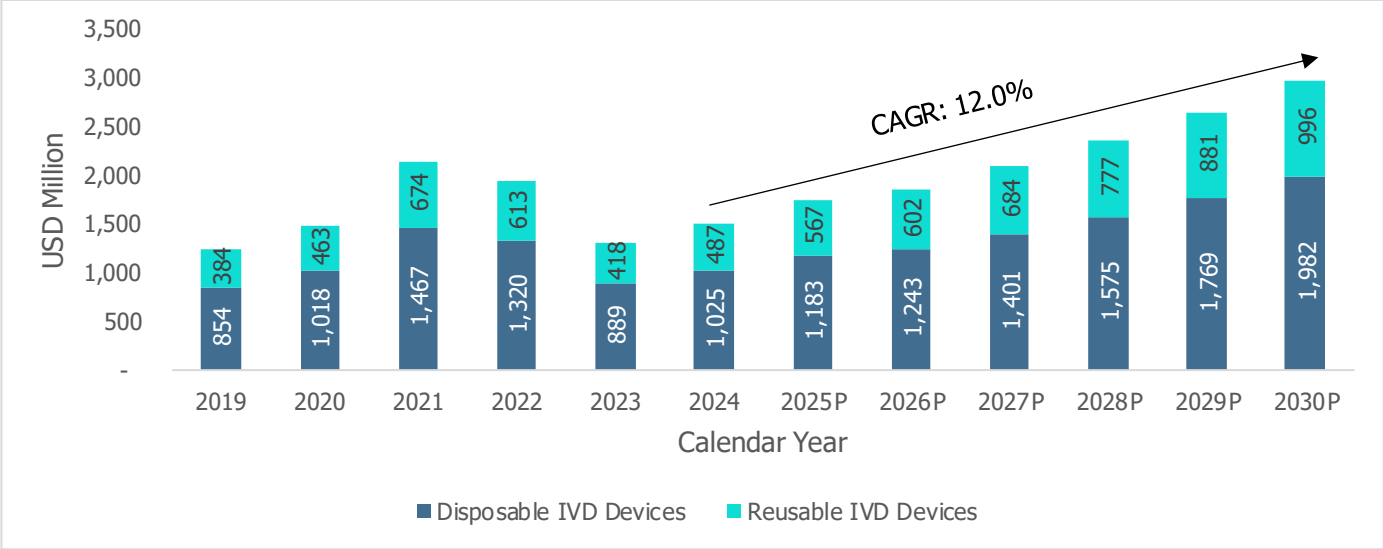


Source – Imarc Research, CareEdge Research

In CY24, 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

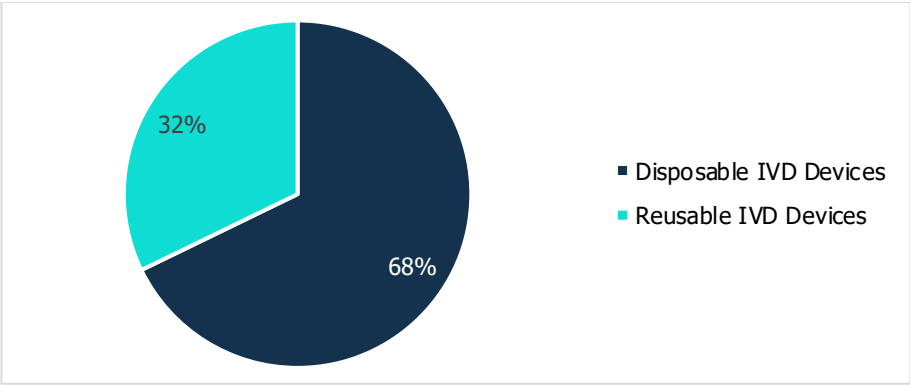
Chart 17 : India In-Vitro Diagnostics Market landscape – By Usability



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 CY24, the market size for Disposable IVD Devices stands at 1,025 million USD, while Reusable IVD Devices account for 487 million USD. The overall market reached 1,511 million USD in CY24, 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 - CY 2024



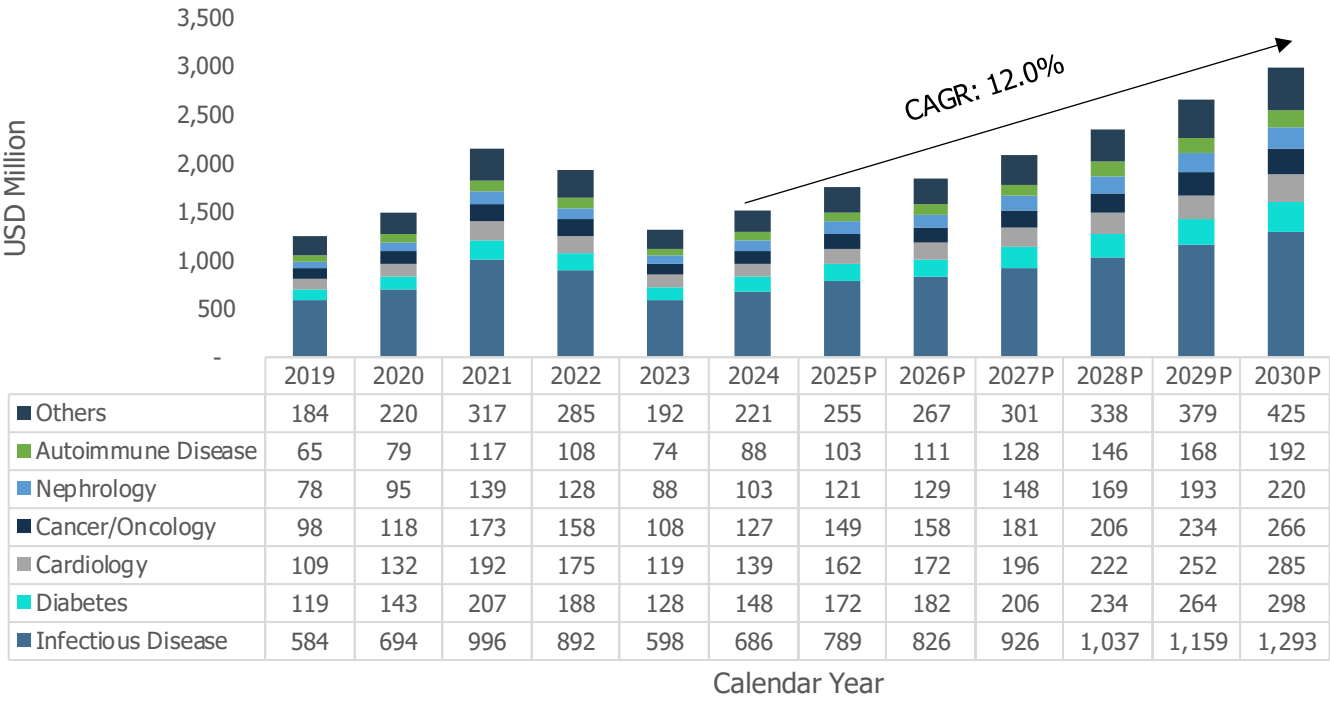
Source – Imarc Research, CareEdge Research

In CY24, 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 strong inclination toward disposable devices can be attributed to their advantages in reducing cross-contamination risks, ensuring regulatory compliance, and offering ease of use. As

healthcare facilities increasingly prioritize infection control and diagnostic accuracy, the demand for disposable IVD devices is expected to sustain its dominance in the market.

2.6 Market Segmentation by Application Usability

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



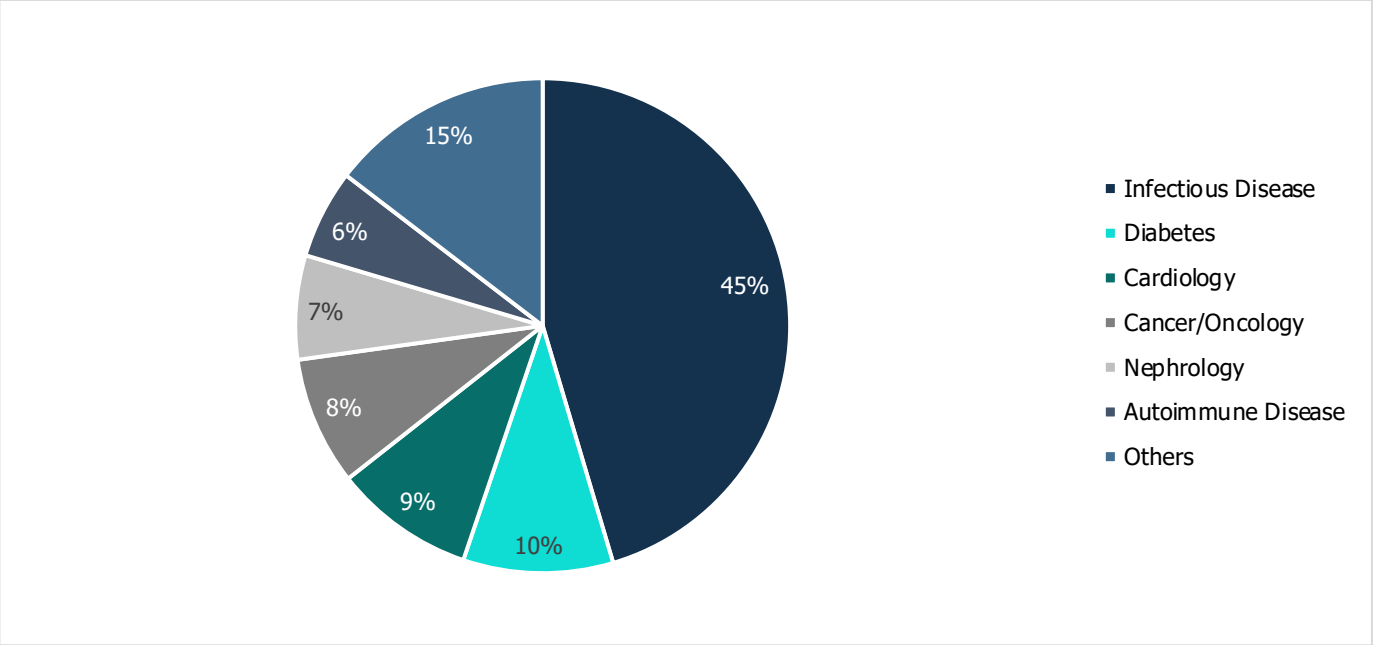
	2019	2020	2021	2022	2023	2024	2025P	2026P	2027P	2028P	2029P	2030P
Others	184	220	317	285	192	221	255	267	301	338	379	425
Autoimmune Disease	65	79	117	108	74	88	103	111	128	146	168	192
Nephrology	78	95	139	128	88	103	121	129	148	169	193	220
Cancer/Oncology	98	118	173	158	108	127	149	158	181	206	234	266
Cardiology	109	132	192	175	119	139	162	172	196	222	252	285
Diabetes	119	143	207	188	128	148	172	182	206	234	264	298
Infectious Disease	584	694	996	892	598	686	789	826	926	1,037	1,159	1,293

Calendar Year

Source – Imarc Research, CareEdge Research

The In Vitro Diagnostics (IVD) industry has experienced consistent growth from CY19 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 686 million USD in CY24 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 - CY 2024

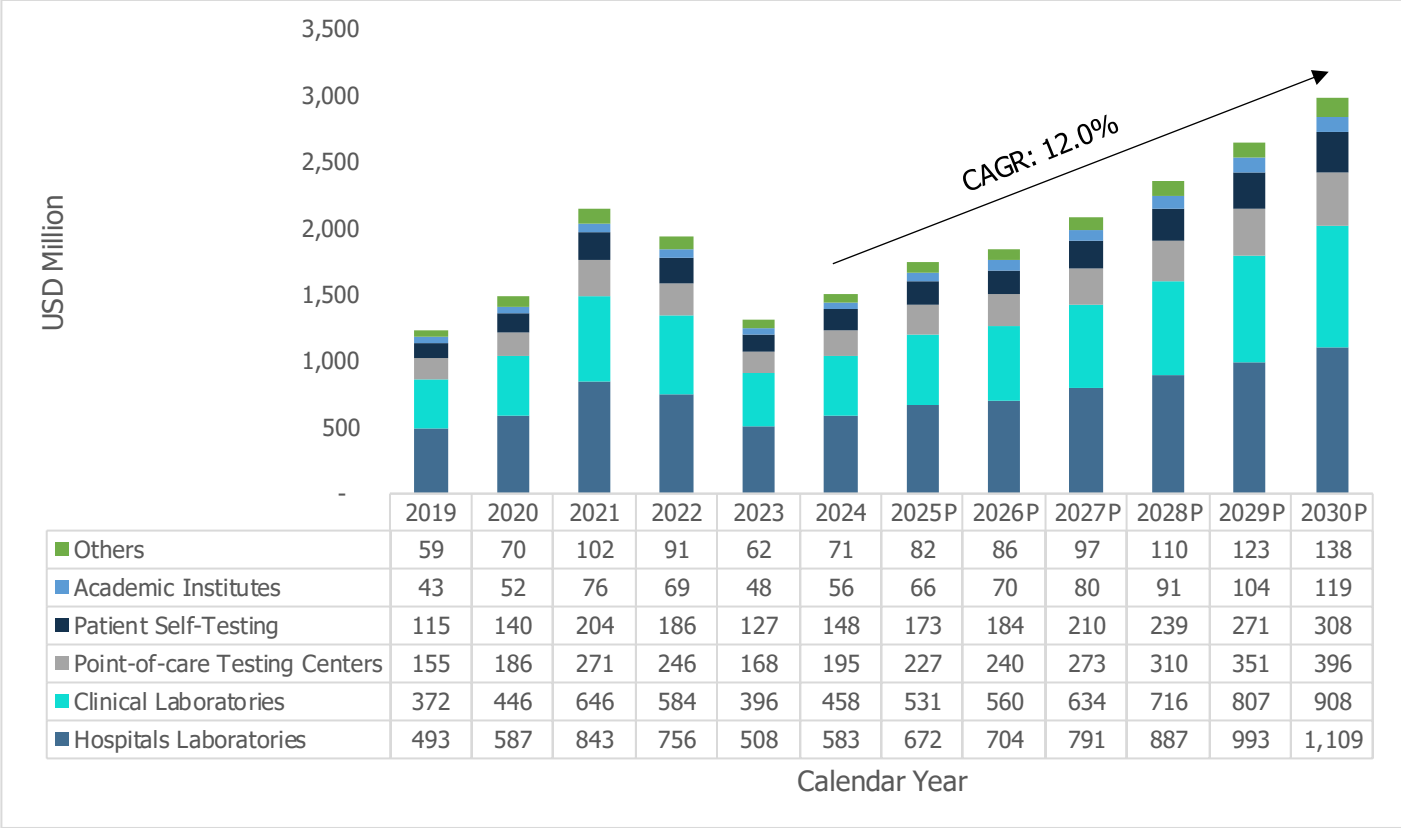


Source – Imarc Research, CareEdge Research

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 CY24, 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

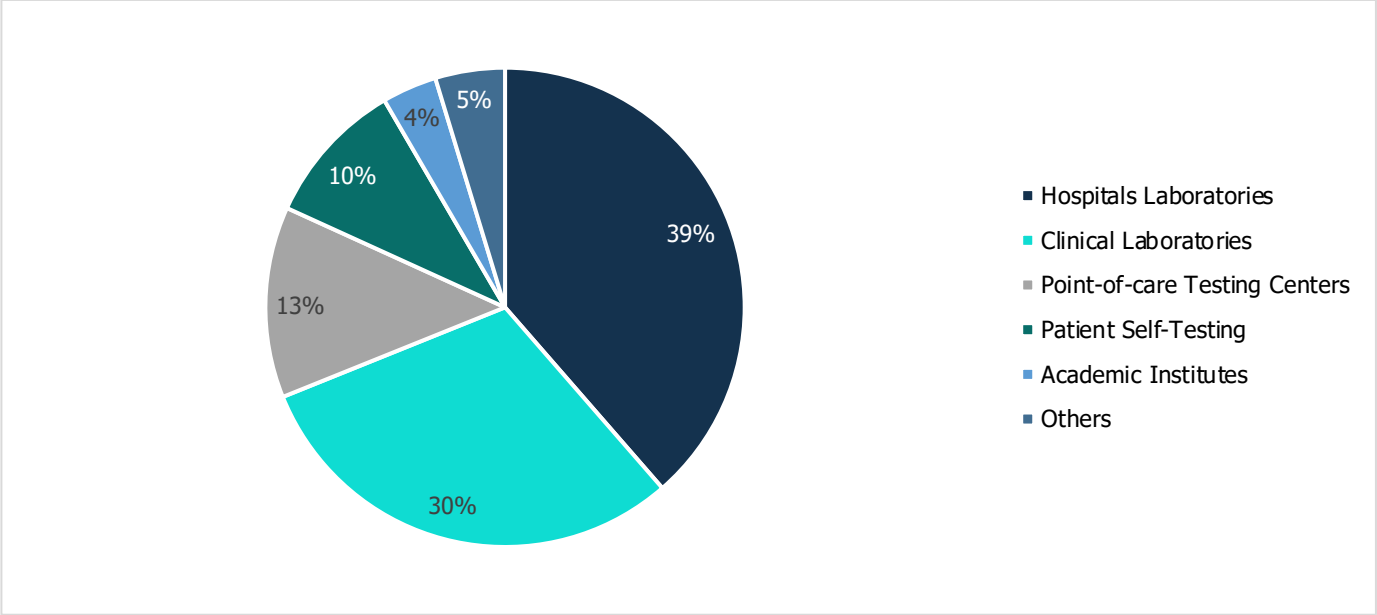


	2019	2020	2021	2022	2023	2024	2025P	2026P	2027P	2028P	2029P	2030P
Others	59	70	102	91	62	71	82	86	97	110	123	138
Academic Institutes	43	52	76	69	48	56	66	70	80	91	104	119
Patient Self-Testing	115	140	204	186	127	148	173	184	210	239	271	308
Point-of-care Testing Centers	155	186	271	246	168	195	227	240	273	310	351	396
Clinical Laboratories	372	446	646	584	396	458	531	560	634	716	807	908
Hospitals Laboratories	493	587	843	756	508	583	672	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 CY24, hospital laboratories accounted for 583 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 458 Million USD in CY24 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



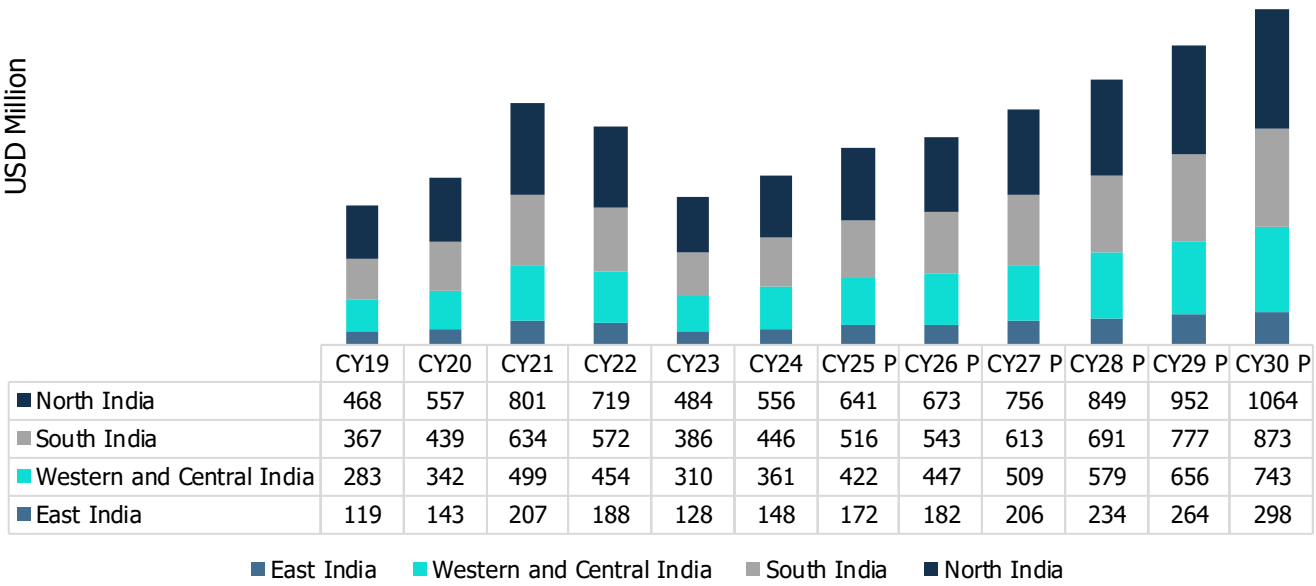
Source – Imarc Research, CareEdge Research

The India In-Vitro Diagnostics (IVD) market, segmented by end-user, is primarily dominated by hospital laboratories, which constitute 39% of the market in CY24, 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 2024 and its expected growth until 2030.

Chart 23: Market Breakup by Region: Sales Value



	CY19	CY20	CY21	CY22	CY23	CY24	CY25 P	CY26 P	CY27 P	CY28 P	CY29 P	CY30 P
North India	468	557	801	719	484	556	641	673	756	849	952	1064
South India	367	439	634	572	386	446	516	543	613	691	777	873
Western and Central India	283	342	499	454	310	361	422	447	509	579	656	743
East India	119	143	207	188	128	148	172	182	206	234	264	298

Source: Imarc Research, CareEdge Research

North India: In 2024, the IVD market in North India is estimated at USD 556 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 projected to reach USD 641 Million in 2025, driven by the increased demand for POCT, self-testing solutions, and expanding research collaborations in diagnostics.

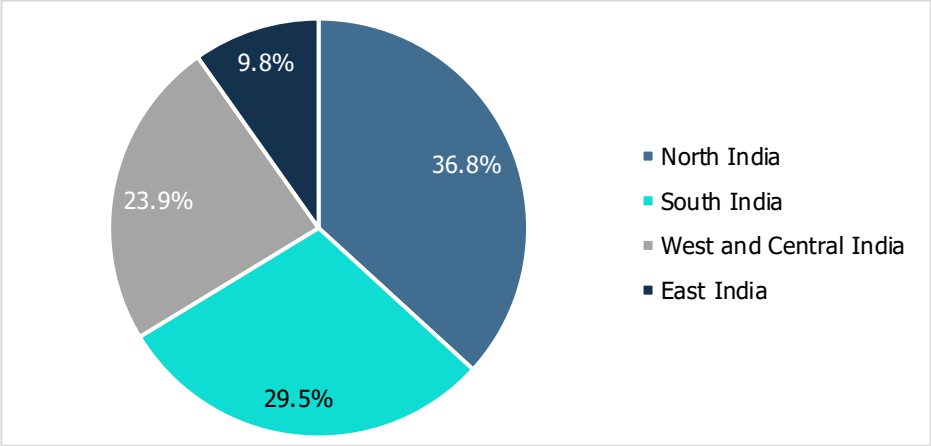
South India: The IVD market in South India is projected to reach USD 446 Million in 2024. South India is also experiencing a broad adoption of advanced diagnostic methodologies such as next-generation sequencing (NGS), liquid biopsy, and multiplex PCR testing. In addition, key government initiatives 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 2025, the South Indian IVD market is forecast to reach USD 516 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 2024, the IVD market in West and Central India is valued at USD 361 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 2025, the market in this region is projected to grow to USD 422 Million, propelled by continued advancements in technology, increasing investments, and a rising demand for precision diagnostics.

East and Northeast India: In 2024, the IVD market in East and Northeast India is valued at USD 148 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 2025, the market in this region is expected to grow to USD 172 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 – CY 2024



Source: Imarc Research, CareEdge Research

In 2024, the IVD market in India is led by North India, holding a 36.8% share, driven by the region's large metropolitan presence, high disease burden, and supportive government initiatives like Ayushman Bharat. South India follows with a 29.5% share, fueled by the prevalence of lifestyle diseases, strong healthcare programs, and being a manufacturing hub for medical devices. West and Central India contribute 23.9% 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 9.8%, 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 highly dependent on a complex global supply chain for raw materials, manufacturing components, and distribution. Interruptions by geopolitical instability, natural catastrophes, pandemics, or trade restrictions can cause delays in production, escalate costs, and result in product shortages. Such interruptions have a considerable influence on the availability of diagnostic devices, especially when there is an increase in demand, as experienced during the COVID-19 pandemic.

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.

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, during, 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 FY24, company has recorded sales of 2,696 million.

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

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
Revenue	Rs. Million	1,603	1,936
Revenue Growth	%	-	21%
Operating Profit	Rs. Millions	638	811
Operating Margins	%	40%	42%
PAT	Rs Million	481	626
PAT Margins	%	30%	32%
Debt Equity	Times	-	-
Return on Equity	%	14%	15%
Return on Assets	%	14%	15%
Return on Capital Employed	%	19%	20%

Source: Company Reports, note – FY25 data is not available.

- **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
Revenue	Rs. Million	14,456	-
Revenue Growth	%	-	-
Operating Profit	Rs. Million	383	
Operating Margins	%	3%	-
PAT	Rs Million	-872	-
PAT Margins	%	-6%	-
Debt Equity	Times	0.1	-
Return on Equity	%	-6%	-
Return on Assets	%	-4%	-
Return on Capital Employed	%	-0%	-

Source: Company Reports

Note: Since the EBIT is negative for FY23, Capital employed is reflecting negative, FY24 and FY25 are not available.

- **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
Revenue	Rs. Million	3,325	-
Revenue Growth	%	-	-
Operating Profit	Rs. Million	432	-
Operating Margins	%	13%	-
PAT	Rs Million	-34	-
PAT Margins	%	-1%	-
Debt to Equity	Times	0.1	-
Return on Equity	%	-0%	-
Return on Assets	%	-0%	-
Return on Capital Employed	%	2%	-

Source: Company Reports, note – FY24 and FY25 is not available.

➢ **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
Revenue	Rs. Million	3,905	4,426
Revenue Growth	%	-	13%
Operating Profit	Rs. Million	439	413
Operating Margins	%	11%	9%
PAT	Rs Million	235	174
PAT Margins	%	6%	4%
Debt to Equity	Times	0.2	0.2
Return on Equity	%	10%	7%
Return on Assets	%	6%	4%
Return on Capital Employed	%	13%	10%

Source: Company Reports, note – FY25 is not available.

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About:

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