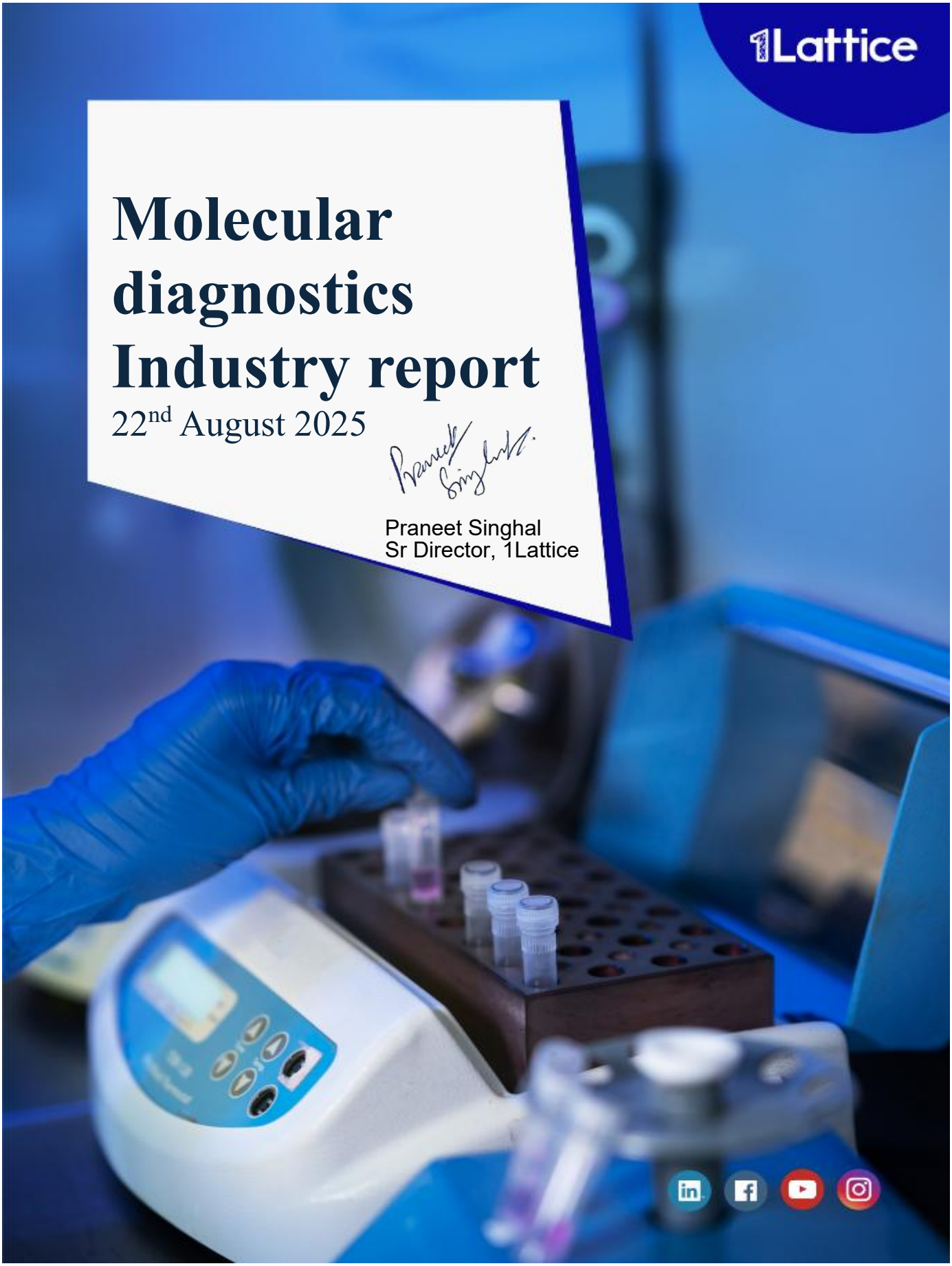
1Lattice
Molecular diagnostics Industry report
22nd August 2025
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1. Macro-Economic Overview

1.1. Global Macroeconomic Overview

1.1.1 The global real GDP is growing at 3.1% from CY24-29, while India's economy is expected to grow at a rate of 6.5% over the same period

Global growth in CY24 remained at 3.3% despite several headwinds, including higher interest rates, tighter financial conditions, and multiple geopolitical conflicts. These include the war between Russia and Ukraine, the evolving conflict in the Middle East, and turbulent US-China relations, marked by a growing trend of US sanctions globally, ranging from solar cells to computer chips. Real GDP growth is projected to average 3.1% from CY24-29. In comparison, India is expected to maintain the highest growth rate, with its current real GDP growth rate at 6.5% in CY24 and is expected to grow at 6.5% till CY29.

1.1.2 Global per capita income is at ~US$ 13,933.3 in CY24 and is expected to reach ~US$ 16,605.3 in CY29

Global per capita GDP stands at US$ 13,933.3 in CY24 and is expected to increase at a CAGR of 3.6% reaching US$ 16,605.3 in CY29. Global per capita has increased by 3.8% CAGR over CY19 to CY24, driven by both public and private investments in infrastructure, education, healthcare, and technology. These factors will continue to shape the trajectory of global per capita GDP growth.

1.2. Indian Macroeconomic Overview

1.2.1. India’s Nominal GDP was at US$ 3.9T in CY24 and is estimated to reach US$ 6.2T in CY29, growing at a CAGR of 9.5% from CY24 to CY29

India is the fourth largest economy in the world and is expected to be the third largest by CY29. Over the next 10-15 years, India is expected to be one of the fastest-growing economies, driven by rising demand, robust growth in various sectors, and increased private consumption. Indian private consumption is expected to be driven by an increasing proportion of the male and female working-age population and a rise in household income. Between CY19 and CY24, India’s GDP (at current prices) rose from US$ 2.8T to US$ 3.9T, supported by key reforms such as GST, corporate tax revision, and revised FDI limits.

1.2.2. India’s per capita income US$ 2,711.4 in CY24 is expected to reach US$ 4,089.5 by CY29

India's per capita income is projected to rise from US$ 2,711.4 in CY24 to US$ 4,089.5 by CY29, growing at a CAGR of 8.6%. With increased demand, substantial per capita income growth, and a demographic advantage, India is positioned as a market with vast growth opportunities. Over CY24-29, India’s GDP per capita growth is expected to be, driven by strong manufacturing, rising healthcare spending, and robust government spending, making it the fastest-growing major economy, followed by China (5.7%), the UK (4.5%), the USA (3.5%), and Germany (3.0%).

1.2.3. India’s population is projected to reach 1.5B by CY29, which accounts for 17.6% of the world’s population

The world's population has grown significantly over the past century, reaching 8.2B in CY24 from 7.8B in CY19, and is expected to reach 8.5B by CY29. Improved survival rates, longer lifespans, urbanisation, and migration drive the rise in population. The world population is expected to grow by 0.8% from CY24 to CY29. India and China are currently the two most populous countries, with over 1B people each. India's population grew from 1.4B in CY19 to 1.5B in CY24, at a CAGR of 0.9%; the Indian population is expected to grow at 0.8% CAGR over CY24-29. India has surpassed China to become the most populous country in the world in CY23.

1.2.4. Global median age is expected to increase to 31.8 years by CY29 from 30.6 years in CY24, while India’s median age is expected to be 30.4 years in CY29

The global median age increased from 20.3 years in 1970 to 30.6 years in CY24, with developed countries like the US and UK having higher median ages. India's median age is 28.4 years in CY24, the lowest among its BRICS peers, indicating a favourable demographic dividend. This trend is expected to continue until CY29, India's demographic advantage includes a projected highest working-age population share of 68.8% by CY29 and a median age of 30.4 years. This offers significant economic benefits, with India expected to contribute 24.3% of the incremental global workforce in the next decade.

As of CY24, the 15-64 years age group constitutes 68.2% of the population, which is projected to increase to 68.8% by CY29. The 0-14 years age group population is on a declining trend with 26.1% share in CY20, 24.5% in CY24 & 22.7% in CY29. Advancements in healthcare, education, and access to family planning have contributed to a decline in fertility rates, thereby resulting in a sustained reduction in the population aged below 15 years.

1.3. Healthcare sector overview

1.3.1. India’s healthcare expenditure constituted 1.9% of the GDP in CY24, which is less than both developing and developed countries, indicating significant headroom for growth

In CY24, India allocated 1.9% of its GDP to healthcare. In CY23, developing countries like Indonesia and Philippines allocated 2.9% and 2.2%, respectively. In contrast, developed economies like the United Kingdom, Germany, and the United States spend 8.9%, 10.1% and 13.9% respectively of their GDP on healthcare, leading to superior health outcomes and high life expectancy globally. Compared to both its developed and developing peers, India lags behind.

1.3.2. Budgetary allocation towards healthcare has seen a significant increase from US$ 9.2B in FY20 to US$ 10.6B in FY25

In FY25, the budget has seen an increase in allocation towards healthcare, compared to previous years, with room for improvement as allocations still slightly lag the targets set in national health policies, and investment in primary healthcare can further enhance overall health outcomes. India is allocating a majority of its healthcare budget towards various aspects, including the National Health Mission, regulatory and autonomous bodies, the Pradhan Mantri Jan Arogya Yojana (PM-JAY), and the Pradhan Mantri Swasthya Suraksha Yojana (PMSSY). The budget also includes allocations for the establishment of new AIIMS and the upgrading of Government Medical Colleges across states. Additionally, there is a focus on primary healthcare infrastructure through the Pradhan Mantri Ayushman Bharat Health Infrastructure Mission (PM-ABHIM).

1.3.3. India's per capita spending on healthcare has increased from US$ 60.7 in CY19 to US$ 79.5 in CY22 at a CAGR of 5.6%, higher than that of Germany and USA

In CY22, India's per capita health expenditure reached US$ 79.5, marking a consistent rise from the US$ 60.7 recorded in CY19. China experienced a similar trend, with per capita health expenditure increasing from US$ 539.0 in CY19 to US$ 672.5 in CY22. In comparison, consumers in Germany, United Kingdom, and the United States spent US$ 6,182.3, US$ 5,035.6 and US$ 12,434.4 respectively, on pharmaceutical products in CY22. Factors such as market penetration of generics, availability of insurance coverage, and government policies have influenced pharmaceutical expenditure levels.

1.3.4. India's government health expenditure as a percentage of current health expenditure stood at ~39.1% in CY22, which is far lower than developed countries like UK (83.1%) and Germany (80.3%)

In CY22, India's government health expenditure as a percentage of total health expenditure stood at ~39.1%. During the same period, government healthcare expenditure stood at 83.1% for UK, 80.3% for Germany, 51.8% for Indonesia, 55.2% for USA, 54.9% for China and 40.3% for Sri Lanka. India relies heavily on private health expenditures relative to developing and developed countries.

2. Global & Indian disease burden

Infectious diseases are caused by pathogenic microorganisms, such as bacteria, viruses, parasites, or fungi and can spread, directly or indirectly, from one person to another. These diseases can be grouped into three categories: diseases which cause high levels of mortality; diseases which place heavy burdens of disability on populations, owing to the rapid and unexpected nature of their spread, potentially leading to severe global repercussions.

In CY21, 2.9B DALYs were lost globally due to premature death and disability, up from 2.6B in CY10. During this period, infectious diseases such as tuberculosis, malaria, hepatitis, and HPV have continued to significantly impact global DALYs, especially in low- and middle-income countries. Communicable diseases, caused by infectious agents and transmitted from person to person or through vectors, remain a persistent global health burden. The COVID-19 pandemic significantly disrupted global health systems in CY20 and CY21 and contributed substantially to the burden of infectious diseases. It contributed notably to the overall burden of infectious diseases during this period. This underscores the importance of systematic and timely disease burden analysis to understand their collective and long-term impact.

2.1 Overview of global infectious disease burden

Infectious diseases remain one of the most critical global health challenges, accounting for approximately 33.0% (52.0M) of global deaths in CY22. Of the estimated 17.2M deaths globally caused by infectious diseases like TB, hepatitis, and HPV, an average of over 47,123 deaths occurred daily, with the key impacted regions being Asia (39.0%), Africa (37.8%), America (13.4%) and Europe (9.7%).

2.1.1 Global risks and response strategies for infectious diseases

Infectious diseases vary across regions and populations and are influenced by factors such as human mobility, which facilitates exposure to pathogens and their global spread. Efforts to address these threats focus on assessing emerging risks, evaluating response capacities, and identifying necessary investments in research and preparedness.

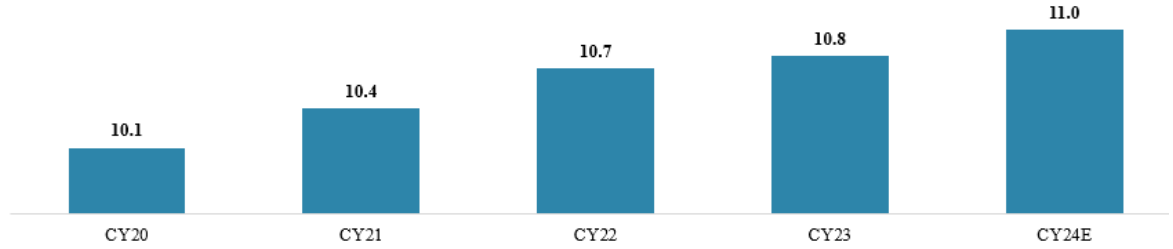
2.2 Global overview of TB (tuberculosis)

Tuberculosis (TB), a highly contagious disease that primarily affects the lungs, is a significant contributor to this burden. It spreads through the air when individuals with active TB cough, sneeze, or spit. Despite being both preventable and curable, TB continues to pose a major global health threat. In CY24, an estimated 11.0M people contracted TB, up from 10.1M in CY20. TB is the world's leading cause of death from a single infectious agent (replacing COVID-19) and claims twice as many lives as HIV/AIDS, with ~3500 deaths daily on a global scale.

There is a widespread need to increase TB diagnosis and treatment due to substantial under-diagnosis, with about 2.7M people either not diagnosed or not officially reported to national authorities in CY23. Once COVID-19 testing declined, the public health programs for TB resumed their normal course. Global efforts toward TB eradication have shown promising progress, particularly with significant recovery in TB diagnosis and treatment post-COVID-19, helping reverse some of the pandemic's detrimental effects. While TB remains widespread, there is a critical need to increase diagnosis and treatment efforts, as only 8.2M cases out of the 10.8M cases were detected in CY23. Programs focusing on improving access to diagnostic tools, increasing public awareness, enhancing healthcare infrastructure, and providing more comprehensive treatment plans are critical in combating TB globally.

2.2.1 In CY23, TB cases rose to about 10.8M and are estimated to reach 11.0M in CY24, up from 10.7M in CY22 and 10.1M in CY20

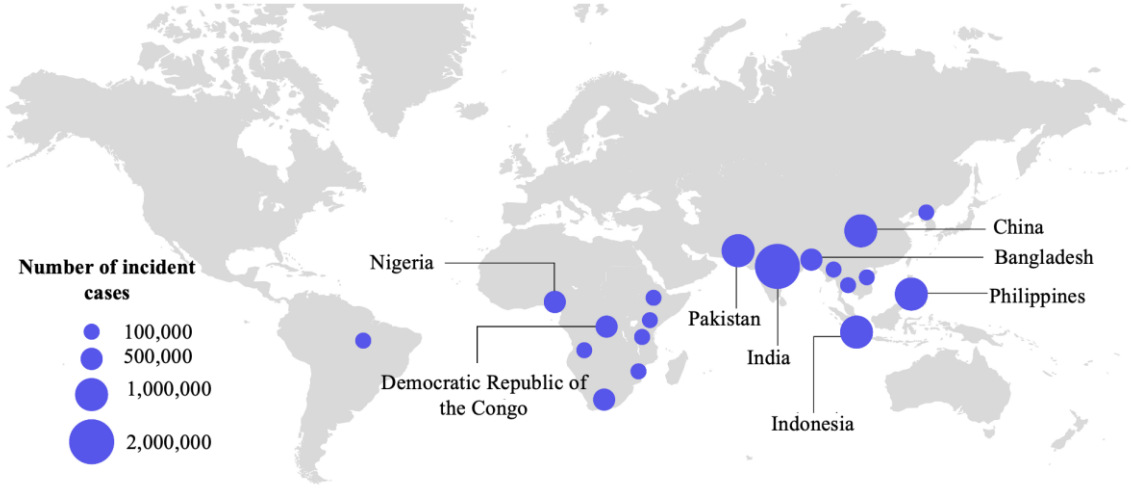
Number of TB cases globally
(#M, CY20-24E)



Note(s): The CY24 figures have been estimated based on the available historical data
Source(s): World Health Organization, 1Lattice analysis

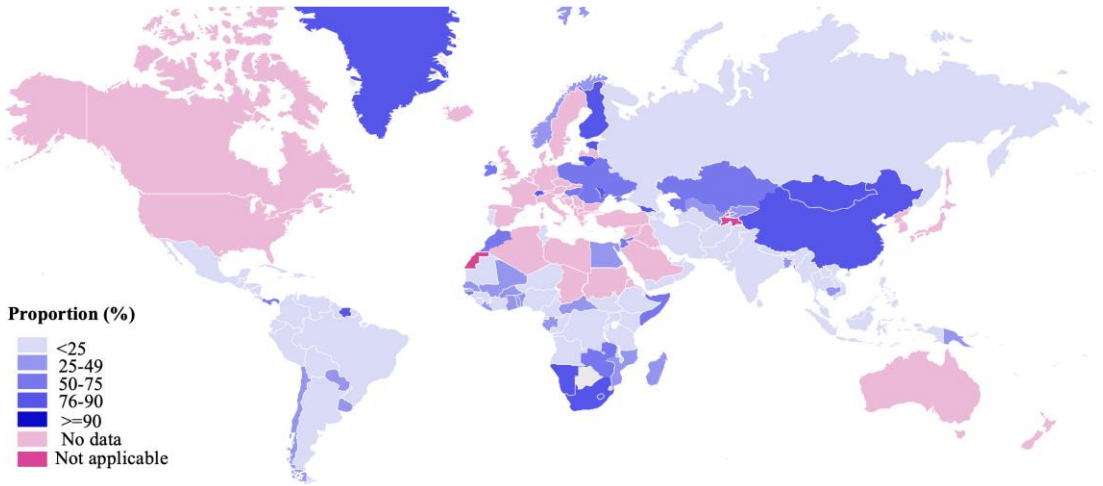
In CY23, 10.8M people worldwide contracted TB, an increase from 10.1M in CY20. Of these, 8.2M were newly diagnosed, leaving a significant gap, with 2.7M people (about 25.0%) who contracted TB remaining undiagnosed. In CY24, TB cases are estimated to have reached 11.0M(E). An untreated individual can spread TB to up to 10-15 other people through close contact over the course of a year, and without proper treatment, up to two-thirds of those with active TB may die. This underscores the urgent need for timely diagnosis and effective treatment to control TB transmission and reduce mortality.

8 Countries Contributed to 67% of Global TB cases in 2023



Note(s): Circles shown for countries with at least 100,000 estimated cases

Proportion of Diagnostic Sites for TB with Access to WHO-Recommended Rapid Diagnostic Tests (WRDs), by Country, 2022



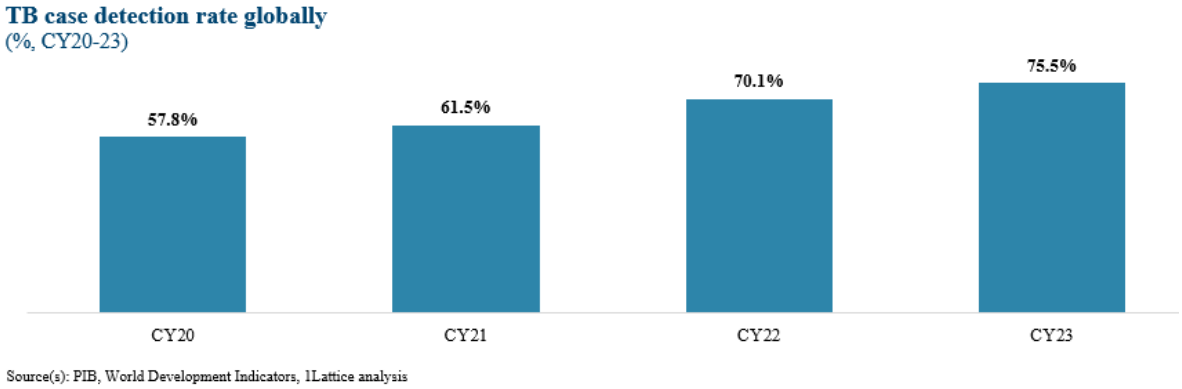
The top 30 high TB burden countries contribute to 87.0% of all global TB cases, with 8 of these nations accounting for two-thirds of the estimated 10.8M new active cases present globally in CY23: India (26.0% of global cases), Indonesia (10.0%), China (6.8%), Philippines (6.8%), Pakistan (6.3%), Nigeria (4.6%), Bangladesh (3.5%), and the Democratic Republic of the Congo (3.1%). In these regions, morbidity rates can reach up to 95.0%, and mortality rates can be as high as 98.0%. This underscores the ongoing challenge of TB and highlights the need for improved detection and reporting efforts. Smear test for TB testing has witnessed a significant shift to molecular platforms for TB testing. The global transition from smear TB tests to molecular diagnostics presents a significant opportunity, with an estimated 150 to 200M smear tests conducted annually worldwide that could potentially shift to molecular diagnostics.. The share of molecular sites has seen a rising shift in different demographics. In Nigeria, the share of molecular testing sites rose from 9% in CY20 to 14% in CY22. India had 7% share in CY18 and is now 18%. Democratic Republic of Congo, Kenya, Indonesia and Philippines have also witnessed a rise in the share of molecular sites from 6%, 6%, 14%, 18%, respectively, in 2020 to 10%, 10%, 20% and 30%, respectively, in CY22.

2.2.2 ~1.3M people died of TB globally in CY23, with CY24 estimated at 1.3M(E), seeing a decreasing trend from CY22, CY21, and CY20 that reported approximately 1.3M, 1.4M, and 1.4M deaths in each year respectively

Globally, TB caused an estimated 1.3M deaths in CY23 and is projected to remain at 1.3M(E) in CY24, continuing a gradual decline from 1.4M in CY20 and aligning with CY19 levels. Low- and middle-income countries bear a disproportionate burden of TB, experiencing high rates of morbidity and mortality. Most people who developed TB in CY23 were in Southeast Asia (45.0%), Africa (24.0%), and the Western Pacific (17.0%). The overall decrease in TB-related deaths from CY15 to CY23 was 23.0%. Despite this reduction, TB continues to cause 2 deaths per minute globally. The emergence of drug-resistant TB strains, particularly resistant to rifampicin and other TB drugs, also presents a significant challenge.

2.2.3 An improved detection rate for TB was observed, increasing to 75.5% in CY23 from 57.8% in CY20

The detection rate of TB cases has significantly increased from 57.8% in CY20 to75.5% in CY23, indicating improvements in detection and testing mechanisms through point of care settings. This increase is partly due to advancements in diagnostic facilities, such as the expansion of high-quality TB testing laboratories and the establishment of specialised TB centres that enhance early and accurate case identification.



Source(s): PIB, World Development Indicators, 1Lattice analysis

Notes: *TB case detection rate (all forms) is the number of new and relapse TB cases notified to WHO each year, divided by WHO's estimate of the number of incident TB cases for the same year, expressed as a percentage*

2.3 Global overview of hepatitis

Hepatitis, caused by various infectious viruses and non-infectious agents, leads to liver inflammation and a range of potentially fatal health problems. Hepatitis Type B and C cause chronic disease in hundreds of millions, being the leading causes of liver cirrhosis, liver cancer, and deaths from viral hepatitis. A WHO study estimated that 4.5M premature deaths could be prevented in low and middle-income countries by CY30 through better access to vaccines, diagnostic tests, medicines, and educational campaigns. WHO's global hepatitis strategy aims to reduce new hepatitis infections by 90.0% and deaths by 65.0% between CY16 and CY30.

In CY22, the global burden of Hepatitis C Virus (HCV) infections stood at approximately 50.0M cases, with only 36.4% diagnosed. This highlights a significant gap in diagnosis, with 63.6% of HCV cases remaining undiagnosed. Similarly, Hepatitis B Virus (HBV) infections totalled around 254.0M cases globally in the same year, but only 13.4% of these were diagnosed, leaving a vast majority of 85.6% underdiagnosed. HBV and HCV account for the majority of hepatitis cases worldwide. This substantial underdiagnosis in both HCV and HBV infections underscores the critical need for improved diagnostic solutions to address these gaps and ensure timely and accurate detection.

2.3.1 In CY22, global hepatitis cases declined to 304.0M from 354.0M in CY19, with estimates suggesting a further drop to 274.7M(E) by CY24

The estimated number of viral hepatitis infections decreased from 354.0M in CY19 to 274.7M(E) in CY24. Of these cases in CY22, 254.0M were hepatitis B, and 50.0M were hepatitis C. The estimated number of people newly infected with viral hepatitis decreased from 2.5M in CY19 to 2.2M in CY22. Of the 2.2M new infections in CY22, 1.2M were hepatitis B cases and 1.0M were hepatitis C cases. This trend indicates that prevention efforts, such as vaccinations and safe injections, as well as more accessible cures for hepatitis C, have helped lower the number of new cases. This decline reflects positive progress, global diagnosis coverage with 13.0% of hepatitis B and 36.0% of hepatitis C cases diagnosed as of CY22. To continue improving, it is important to keep focusing on prevention and making hepatitis C treatments more available.

2.3.2 In CY22, 1.3M deaths were attributed to hepatitis B and C

In CY22, an estimated 1.3M people died from chronic viral hepatitis B and C, equivalent to 3,671 deaths per day. Additionally, ~6,000 new infections occur daily. Many individuals remain undiagnosed, and even when diagnosed, the number of people receiving treatment remains critically low. Viral hepatitis is a significant public health challenge of this decade.

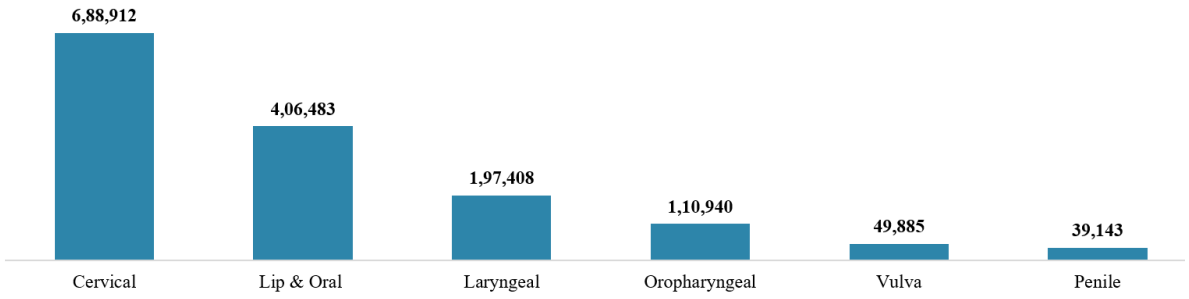
2.4 Global overview of HPV (Human Papillomavirus)

2.4.1 In CY24, cervical and lip & oral cancers alone accounted for over 1.1M new HPV-related cancer cases globally, underscoring HPV's widespread health impact

HPV is a highly prevalent viral infection and the primary cause of cervical cancer, which is the second most common cancer in women after breast cancer. HPV causes over 90.0% of cervical cancer cases and is also linked to other cancers, including lip & oral, anal, vaginal, vulvar, penile, and oropharyngeal cancers. The virus is widespread, affecting both men and women, but its impact on women, particularly in relation to cervical cancer, is profound. People with weakened immune systems, such as those living with HIV/AIDS, are more susceptible to persistent HPV infections and the associated health complications. Most HPV infections are transient and asymptomatic, with over 90.0% clearing within 2 years. Persistent high-risk HPV is the main risk factor for HPV-related diseases, including

cervical cancer. There are no routine tests to detect HPV infections themselves; HPV is typically identified only when it progresses to cancer, as screening tests are currently available only for cervical cancer. In CY24, the global incidence of HPV-related cancers varied significantly across different types. Cervical cancer accounted for the highest number of new cases at 6,88,912, followed by lip & oral cancer with 4,06,483 cases. The high prevalence of cervical and lip & oral cancers underscores the critical public health impact of HPV, highlighting the urgent need for effective preventive, screening, and treatment strategies to mitigate this growing burden. Vaccination efforts are crucial in reducing these numbers, as the vaccine can prevent over 90.0% of cancers caused by HPV.

New cases of HPV-related cancers globally
(#, CY24)

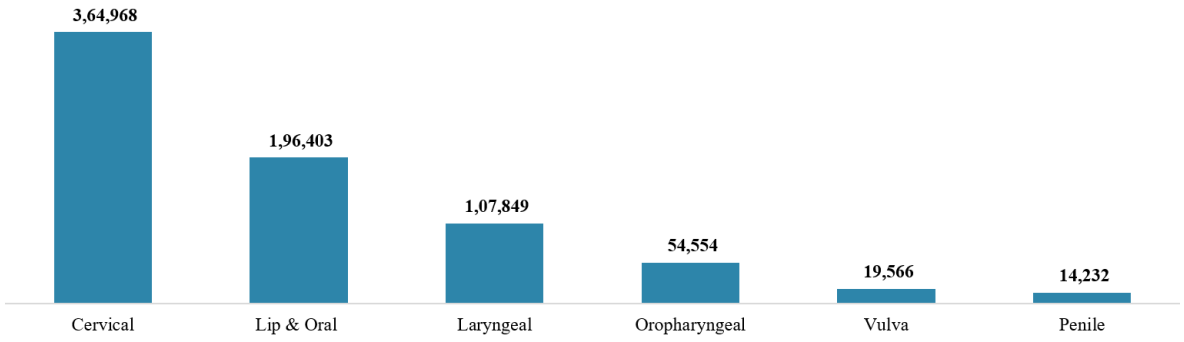


Source(s): GLOBOCAN, 1Lattice analysis

2.4.2 In CY24, HPV-related cancer contributed to 7.5% of global cancer deaths

HPV-related cancer remains a significant cause of mortality worldwide, contributing to approximately 7.5% of global cancer deaths in CY24. In total, it resulted in 7,57,572 deaths globally, averaging about 2,076 deaths per day. The substantial mortality rates associated with these cancers highlight the severe impact of HPV, emphasising the urgent need for enhanced preventive measures, including widespread vaccination and early detection strategies, to reduce the global burden of HPV-related diseases. From CY20 to CY24, cervical cancer deaths remained a major health concern, emphasising the need for widespread vaccination.

Deaths due to HPV-related cancers globally
(#, CY24)



Source(s): GLOBOCAN, 1Lattice analysis

2.5 Global overview of other infectious diseases

Other Infectious diseases include influenza, tropical diseases (vector-borne diseases) such as malaria and dengue, gastrointestinal infections, sepsis, etc. Vector-borne diseases account for approximately 17.0% of infectious diseases globally, resulting in an annual death toll of 0.7M in CY24. Malaria, a parasitic infection transmitted by Anopheline mosquitoes, leads to an estimated 263.0M cases worldwide and causes over 0.6M deaths annually, which translates to approximately 1,643 deaths per day. Most of these deaths occur in children under five years of age. Dengue is the most prevalent Aedes mosquito-borne viral infection. Globally, more than 3.9B people across 132 countries are at risk of dengue. The disease causes approximately 96.0M symptomatic cases and ~40,000 deaths each year, equivalent to about 110 deaths per day.

Influenza, commonly known as the flu, is a seasonal virus that circulates primarily during the winter season. Each year, it infects up to 1.0B people globally, making it one of the most widespread infectious respiratory viruses after the common cold. While many cases are mild, an estimated 3.0 to 5.0M cases result in severe illness. Influenza is estimated to cause approximately 2,90,000 to approximately 6,50,000 respiratory deaths annually worldwide.

2.6 Overview of infectious diseases in India

Infectious diseases are among the top 10 causes of total deaths in the country, dominated by diarrheal diseases, neonatal disorders, lower respiratory infections, and tuberculosis. For India as a whole, the disease burden or DALY rate for diarrhoeal diseases, iron-deficiency anaemia, and tuberculosis is 2.5 to 3.5 times higher than the average globally. The high burden of communicable diseases in India is driven by poor sanitation, poor hygiene and clean drinking water. Among the number of infectious diseases prevalent in the country, Tuberculosis, Typhoid, Dengue, Malaria, and Pneumonia pose significant challenges to the healthcare system in India. Around 2.6M cases of tuberculosis were notified in India in CY24, the highest ever reported, highlighting improvements in case detection and reporting. Typhoid affects around 4.5M people annually, causing approximately 9,000 deaths in India. Rising temperatures create optimal conditions for Aedes mosquitoes to survive and proliferate and spread the dengue virus. In CY22, India recorded the greatest number of malaria cases (5.2M) in Southeast Asia. Pneumonia, an infection of the lungs, is another prevalent infectious disease in India. Infants and people above 65 years of age are more at risk of developing the disease. To address this high burden of infectious diseases, the Indian Central and State governments, along with international aid agencies, run several healthcare programs. For examples, the Indian government has public healthcare programs such as the National Tuberculosis Elimination Program (NTEP), the National Vector Borne Disease Control Program (NVBDCP), the National Viral Hepatitis Control Program (NVHCP), and the National AIDS Control Organisation (NACO). These initiatives aim to enhance disease surveillance, provide quality diagnostic services, and ensure timely treatment. Diagnostic tests and supplies under these programs are procured centrally and distributed based on consumption data and disease surveillance outcomes.

2.7 Overview of TB in India

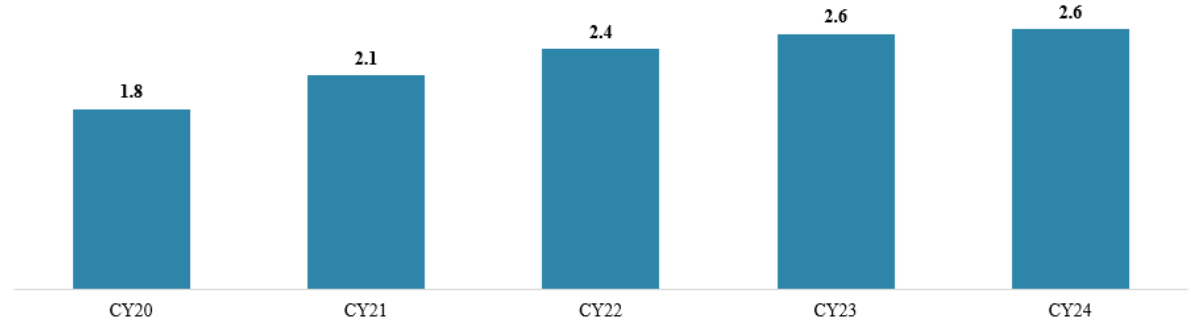
India faces significant challenges with TB, accounting for approximately 26.0% of new TB cases worldwide. TB caused 0.2-0.4M deaths in CY23. The TB detection rate in India rose from 59.0% in CY20 to 85.0% in CY23, marking a significant milestone in TB surveillance with 2.6M cases, a 19.5% increase from CY21. CY23 witnessed a substantial increase in the TB case notification rate, currently recorded as approximately 179.0 cases per 100,000 population. The increase reflects a good recovery in access to health services in India and indicates the diagnosis of a sizeable backlog of people who developed TB in previous years but whose diagnosis was delayed due to COVID-related disruptions. India has shown remarkable progress in enhancing case detection and overcoming the impact of COVID-19 on TB programs. Advanced diagnostic techniques like Truenat and CBNAAT have significantly boosted TB case detection rates, highlighting the integration of molecular diagnostics into public health strategies. In CY23, treatment coverage increased to 80.0% of estimated TB cases, up by 19.0% from the previous year. India's efforts have resulted in a 17.7% reduction in TB incidence from CY15 to CY23, outpacing the global decline rate of 8.3%. TB mortality has also declined by 18.0% in India and globally during the same period. The World Health Organization has revised TB mortality rates downward from 0.4M deaths in CY21 to 0.3M deaths in CY23, reflecting a reduction of over 12.5%.

2.7.1 TB cases in India increased from 1.8M in CY20 to 2.6M in CY24

In CY24, India reported 2.6M TB cases, surpassing the CY22 total of 2.4M cases. The public sector achieved 93.5% of its target by notifying approximately 1.7M TB cases, while the private sector reached 90.1% of its set objectives by reporting around 0.8M. The CY23 TB notifications marked a significant increase, with a 19.5% rise from CY21 and the highest ever private sector notifications at 0.8M (90.1% of the target).

TB cases in India

(#M , CY20-24)



Source(s) India TB report-2024, PIB, 1Lattice analysis

2.7.2 TB mortality rate in India has reduced from 28 to 22 per 1,00,000 people from CY19 to CY23

Between CY19-23, the mortality rate of TB has reduced from 28 to 22 deaths per 100,000 people annually. This consistency suggests a persistent public health challenge despite efforts to combat the disease. In India, approximately

2 deaths occur every 3 minutes, underscoring the urgent need for developing targeted interventions to further reduce TB-related mortality rates in the coming years.

2.7.3 TB detection rate in India rose from 59.0% in CY20 to 85.0% in CY23

The TB case detection rate in India has shown substantial improvement from 59.0% in CY20 to 85.0% in CY23. This indicates significant progress in identifying and treating TB cases promptly, which is crucial for reducing transmission and improving public health outcomes.

2.7.4 The number of drug-resistant TB cases in India has reduced by 21.4% from ~1,40,000 in CY15 to ~1,10,000 in CY22

As per the Global TB Report 2023, published by the WHO, the estimated number of drug-resistant TB cases in India has reduced by 21.4% from ~1,40,000 in CY15 to ~1,10,000 in CY22. The Government has scaled up the availability of molecular diagnostic facilities, and thereby, there has been an increase in the proportion of TB patients being screened for the presence of drug resistance.

2.8 Overview of hepatitis in India

In India, hepatitis remains a significant public health concern. Current estimates indicate that 29.8M people are chronically infected with hepatitis B, while 5.5M are chronically infected with hepatitis C. Hepatitis E virus is the leading cause of epidemic hepatitis in the country, although hepatitis A virus is more prevalent among children. Additionally, hepatitis E is a major contributor to most cases of acute liver failure diagnosed in India. These statistics highlight the critical need for ongoing surveillance, prevention, and treatment efforts to manage and mitigate the impact of hepatitis in the population.

2.8.1 The number of new hepatitis cases in India decreased from 2.5M in CY19 to 2.2M in CY22

From CY20 to CY22, India has faced a substantial hepatitis burden, accounting for 11.6% of global cases in CY22, according to the global hepatitis report by the WHO. In CY22 alone, India recorded over 35.3M hepatitis infections, with 29.8M cases of hepatitis B and 5.5M cases of hepatitis C. This places India second only to China, which had 83.8M cases, contributing 27.5% of the global total.

2.8.2 Death rates from hepatitis B and C are steadily increasing, contributing to a higher overall mortality rate

In CY22, mortality rates due to hepatitis B and hepatitis C showed a steady upward trend. Deaths from hepatitis B reached 98,305, while fatalities attributed to hepatitis C stood at 26,206. In India, ~78.9% of these fatalities were attributed to hepatitis B, while 21.0% were due to hepatitis C, reflecting the burden of hepatitis-related mortality and highlighting the need for enhanced public health interventions to combat these diseases through prevention, early detection, and treatment.

2.9 Overview of HPV in India

HPV, a common sexually transmitted virus, is a major public health concern in India due to its strong link to cervical cancer. In India, 10.0% to 15.0% of women with HPV infections develop persistent infections, significantly increasing their risk of cervical cancer. Almost all cervical cancer cases (99.0%) are associated with HPV. The high incidence and mortality rates are exacerbated by non-healthcare access, lack of awareness, and inadequate screening programs.

2.9.1 High incidence of HPV is notable in cervical, lip & oral cancer cases, affecting ~11 people per 100,000

In CY22, the incidence rates of HPV-related cancers per 100,000 population reveal varying levels of prevalence across different types. Lip & oral cancer incidence is at 5.6 per 100,000 population, followed closely by cervical cancer at 11.2. The lack of specified data for laryngeal cancer underscores the need for enhanced reporting and surveillance efforts. The pathway from HPV incidence to detected cases annually in India illustrates significant gaps in prevention and detection. Despite the widespread prevalence of HPV among sexually active women, many infections remain asymptomatic and undetected due to limited access to screening facilities and low awareness. This delay in detection allows HPV, particularly high-risk types, to persist and potentially progress to cervical cancer over time. Enhancing screening coverage, promoting regular HPV vaccination, and improving public education are essential strategies to effectively intercept and manage HPV infections before they escalate into life-threatening conditions like cervical cancer.

2.9.2 Cervical cancer caused around ~80,000 deaths and has reached 84,940 in CY24, underscoring the urgent need for better prevention and treatment

HPV-related cervical cancer accounts for ~84,940 deaths annually in India, reflecting the severe health consequences of untreated HPV infections. In CY24, HPV-related cancers caused substantial mortality across different types.

2.9.3 Cervical cancer incidence in India 1,27,526 in CY22 and has reached to 1,34,981 cases in CY24

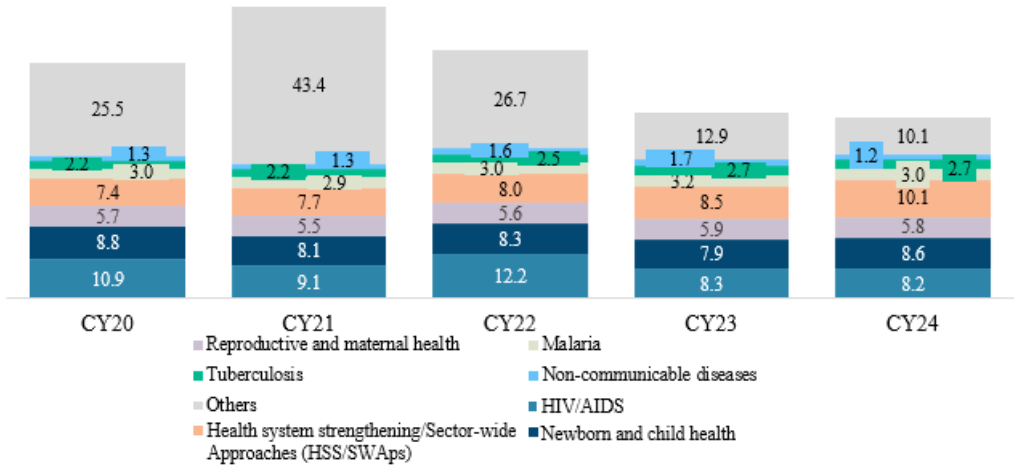
Cervical cancer accounted for 1,27,526 cases in India in CY22, with the incidence increased to 1,34,981 by CY24. HPV-related cancers exhibit significant prevalence across various types, reflecting the widespread impact of HPV infections on different parts of the body. This highlights the critical need for enhanced HPV vaccination campaigns and effective screening programmes. Despite initiatives like the National Cancer Registry, accurate assessment of HPV's true burden remains challenging due to limited coverage in urban and rural.

2.10 Funding initiatives to fight infectious diseases

2.10.1 Global funding initiatives

Developmental assistance for health from multilateral organisations is crucial in addressing global health challenges. Funding has prioritised newborn and child health, maternal health, non-communicable diseases, and infectious diseases like malaria and tuberculosis. Infectious disease funding remained a key focus.

Developmental assistance for health by multilateral organisations (disease-wise)
(US$ B, CY20-24)



Note(s): Others includes other infectious diseases and unallowable amount
Sources: IHME Financing Global Health Data, 1Lattice analysis

The fight against tuberculosis (TB), HPV-related cervical cancer, and hepatitis continues to receive significant global financial support. The Global Fund's cumulative investments (till June CY24) reached US$ 9.9B in TB programs and US$ 1.9B in TB/HIV collaborative programs. This has contributed to a 38.0% reduction in TB deaths and a 1.0% drop in new cases between CY02 and CY22. Additionally, the Global Fund allocated US$ 812.0M to TB in CY22, a 1.6-fold increase from CY15, with US$ 145.0M of the CY22 TB R&D funding directed to diagnostics. The Bill & Melinda Gates Foundation has pledged US$ 912.0M for TB, HIV, and malaria by CY30, increasing its TB funding by 1.5x from US$ 154.0M in CY15 to US$ 226.0M in CY23. In CY23, the total TB R&D funding amounted to US$ 1.2B, with US$ 167.0M (13.9% of the total) allocated to drugs and diagnostics. The annual target funding for TB research US$ 5B by CY27.

Global efforts to combat HPV-related cervical cancer received US$ 600.0M in new commitments at the Global Cervical Cancer Elimination Forum, aiming to expand HPV vaccination and improve screening and treatment programs. Despite these efforts, funding remains insufficient to meet global elimination targets, posing ongoing challenges for TB, cervical cancer, and hepatitis.

2.10.2 Funding efforts in India

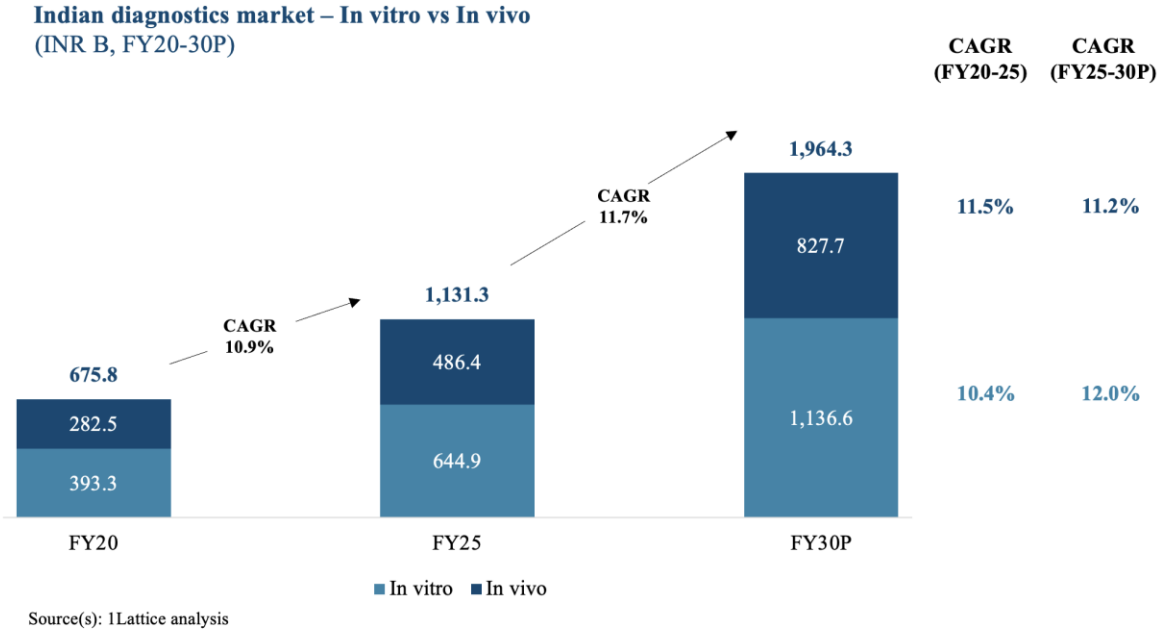
India has received considerable funding for the fight against TB, HPV-related cervical cancer, and hepatitis. The Global Fund allocated US$ 500.0M for HIV, and TB programs in India during the CY23-CY25 period. In collaboration with the World Bank, India signed a US$ 400.0M loan agreement for the "Program Towards Elimination of Tuberculosis," aiming to implement TB control interventions across nine states. This collaboration has helped ensure universal access to diagnostics and high-quality TB care, including services for multidrug-resistant TB. Since 1998, these initiatives have treated over 20.0M people and prevented 3.5M deaths. Despite a decline in overall TB funding from US$ 33.5M in FY19 to US$ 28.8M in FY23, diagnostics have consistently received a substantial share, increasing from 6.0% (US$ 2.0M) in FY19 to 10.0% (US$ 2.9M) in FY23.

India's HPV vaccination campaign has benefited from US$ 600.0M in global funding to reduce the prevalence of HPV-related cancers. This effort targets girls aged 9 to 14 as part of a broader initiative to fight cervical cancer. Additionally, the Mukh-Mantri Punjab Hepatitis C Relief Fund has treated over 69.6M patients between 2016 to

August 2019, with the state setting a goal to eliminate hepatitis C by 2030. This initiative has the potential to save US$ 188.0M in the long term. These funding efforts highlight India's ongoing commitment to tackling TB, HPV-related cervical cancer, and hepatitis, although additional support is needed to meet global elimination targets.

3. Overview of the Diagnostics market

3.1 The diagnostics market in India is valued at INR 1,131.3B (US$ 13.3B) in FY25, with in vitro diagnostics contributing to ~57.0% of the market share.



Source(s): 1Lattice analysis

The diagnostics industry is increasingly recognised as the cornerstone of India's expanding healthcare sector, propelled by the essential need for accurate diagnosis as the first step in effective healthcare delivery. This market encompasses a wide range of tests and procedures, classified broadly as in vitro diagnosis (pathological tests), which involve tests performed on samples taken from the human body, and in vivo tests (radiology), which involve tests and procedures within the living body to visualise or measure internal body functions and structures. The Indian diagnostics market has shown significant growth between FY20-25 and is projected to continue this robust trend through FY29. The diagnostics market was valued at INR 675.8B (US$ 9.6B) in FY20 and grew to INR 1,131.3B (US$ 13.4B) in FY25, at a CAGR of 10.9% for the said period. The in vitro diagnostics market (IVD) accounts for 57.0% of the diagnostics market, valued at INR 644.9B (US$ 7.6B) in FY25. Looking ahead, the diagnostics market is projected to grow at a CAGR of 11.7% from FY25-30 and is estimated to reach a market value of INR 1,964.3B (US$ 23.2B) in FY30. This growth trajectory will be propelled by the growing incidence of chronic illnesses, increasing demand for preventive screenings, rising geriatric population, and government healthcare access programs.

The Indian in vitro diagnostics (IVD) market can be studied under the following segments:

Based on techniques:

1) **Immunodiagnostics** – This segment utilises immunoassays to detect specific molecules such as antibodies or antigens in biological samples. It includes techniques such as ELISA (Enzyme-linked immunosorbent assay) and CLIA (Chemiluminescent immunoassay)
2) **Haematology** – Focuses on analysing blood components such as red blood cells, white blood cells, and platelets to diagnose conditions such as anaemia, infections, and leukaemia. Haematology analysers are commonly used in this segment
3) **Molecular diagnostics** – Involves analysing nucleic acids (DNA, RNA) to detect genetic disorders, infections, and cancers. Techniques include PCR (Polymerase chain reaction) for amplifying DNA segments and sequencing technologies for analysing genetic sequences

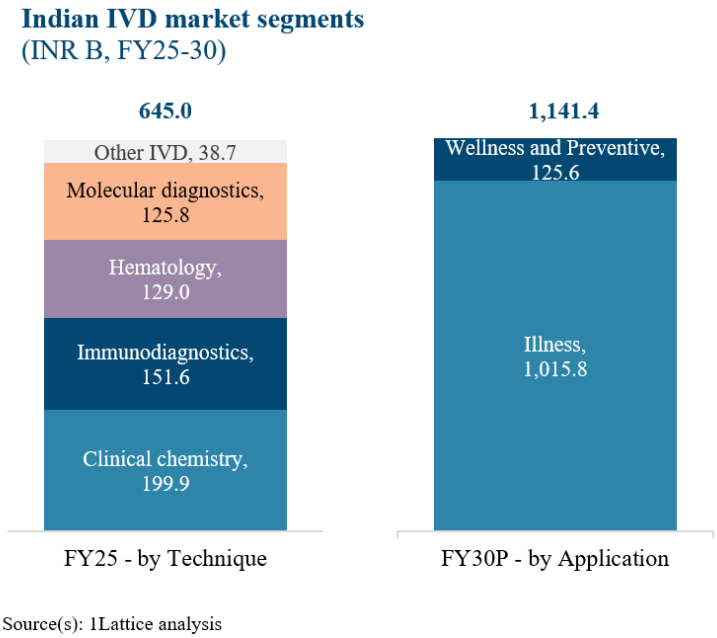
4) **Clinical chemistry** – Encompasses the analysis of blood serum, plasma, or urine to measure substances such as electrolytes, enzymes, and hormones. Techniques such as spectrophotometry and chromatography are used to quantify these substances
5) **Other IVD** – Includes other diagnostic techniques and tools not covered explicitly by the above segments. It may include coagulation testing, urinalysis, and specialised tests for specific biomarkers or conditions

Based on products:

1) **Reagents** – These are substances or chemicals used in diagnostic tests to react with a sample to detect or measure a target substance. Reagents are essential components in immunodiagnostics, molecular diagnostics, and clinical chemistry tests
2) **Instruments/Devices** – These are devices or equipment used to perform diagnostic tests and analyse samples. Instruments can include haematology analysers, PCR machines, spectrophotometers, and other systems
3) **Software** – Diagnostic software plays a critical role in data analysis, interpretation of results, and integration of diagnostic systems. It includes software for instrument control, data management, patient information systems, and interpretation algorithms for molecular diagnostics and other complex tests

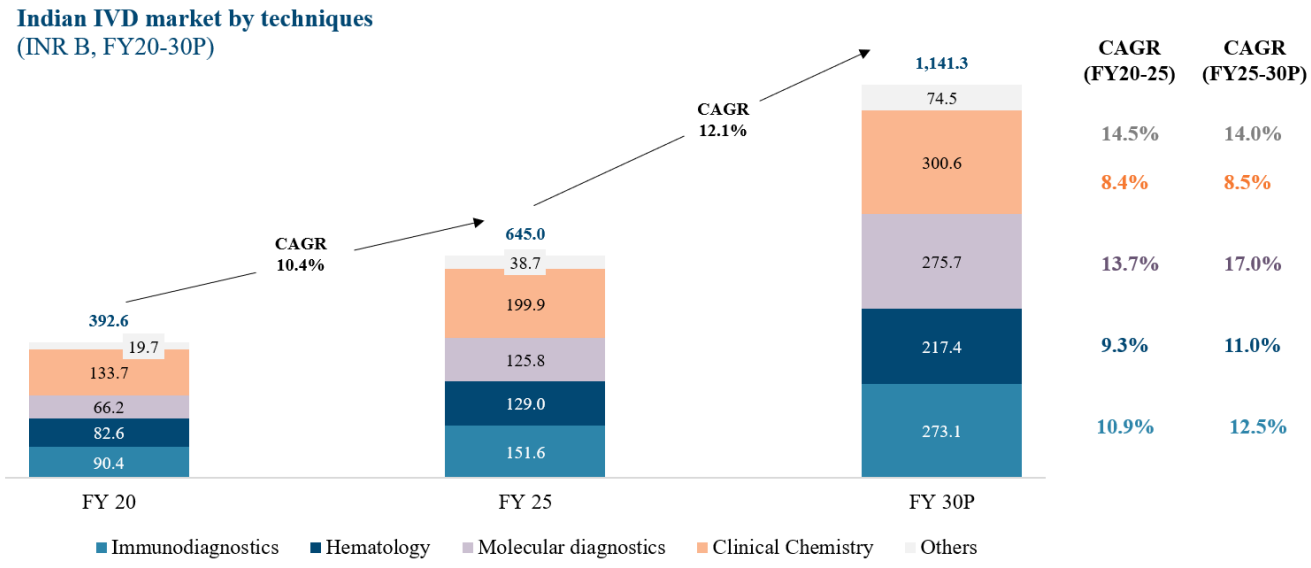
Based on the application:

1) **Illness** – Includes diagnostic tests used for detecting and diagnosing diseases, infections, and medical conditions. It can include tests for infectious diseases (like HIV and hepatitis), cancer diagnosis (using molecular and immunoassay techniques), autoimmune disease (such as rheumatoid arthritis), and cardiovascular disease (like cardiac biomarker tests)
2) **Wellness and preventive tests** – Focus on diagnostic tests aimed at preventive healthcare, wellness monitoring, and early detection of potential health risks before symptoms appear. It includes screening tests for diabetes (glucose tests), cholesterol levels, genetic predispositions, and general health assessment (like vitamin levels and metabolic panels)



Source(s): 1Lattice analysis

Clinical chemistry is the leading technique contributing 31.0% share of all IVD techniques practiced and as of FY25 has a market size of INR 199.9B (US$ 2.4B) followed by immunodiagnostics valued at INR 151.6B (US$1.8B). India is still a reactive market compared to the developed countries which are proactive. Most IVD tests are illness-based and only ~11% of tests are wellness and preventive tests. Molecular diagnostics tests play a crucial role in detecting specific infectious and non-communicable diseases, conditions, and genetic variances, enabling healthcare providers to enhance patient outcomes and reduce healthcare costs by facilitating early and accurate disease diagnosis and improved disease monitoring.



Source(s): 1Lattice analysis

The molecular diagnostics segment in India's IVD market is poised for rapid growth, with a projected CAGR of 17.0% from FY25 to FY30. This growth is fuelled by advancements in POCT diagnostic technologies, an increasing focus on personalised medicine, and heightened awareness of the importance of early and accurate disease detection. The COVID-19 pandemic significantly increased public awareness of molecular diagnostics, with PCR tests gaining widespread popularity for their effectiveness in detecting viral infections.

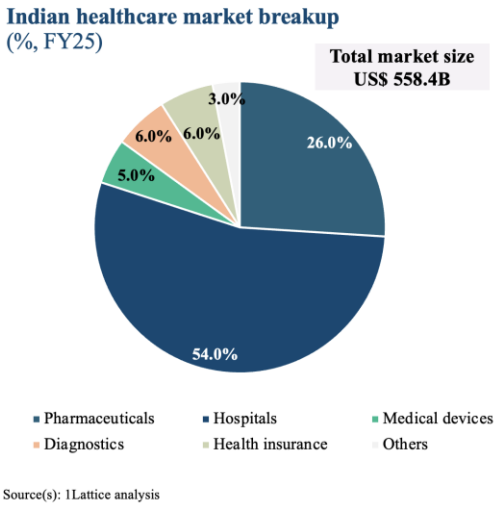
3.2 The per spend on diagnostics in India (US$ 9), is markedly lower than that of other developed and emerging economies of the world

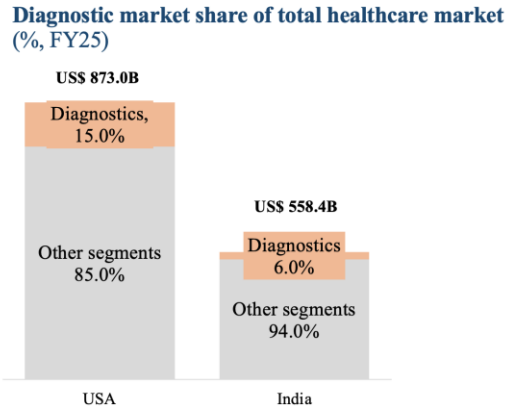
The diagnostic market's growth potential can be better understood by examining its per capita spending on diagnostics and comparing it with other countries. As of CY24, the USA has the highest per capita spend on diagnostics at US$ 290 followed by the UK (US$ 265) and Germany (US$ 252). Such high per capita spending is indicative of the country's advanced healthcare infrastructure, robust healthcare system, and usage of cutting-edge technology. Globally, for CY24, an estimated US$ 175.0B was spent on pathology annually, and over 14.3B slides were prepared for diagnostics evaluation.

Brazil (US$ 60) and Saudi Arabia (US$ 53) show moderate spending levels per capita reflecting ongoing improvements in the healthcare infrastructure. India's per capita spend of US$ 9 falls on the lower spectrum, indicating significant challenges in healthcare accessibility and infrastructure. Countries with a higher per capita spend benefit from early detection and timely medical interventions. Countries with low public healthcare spending place a high economic burden on the individuals. The high out-of-pocket expense for diagnostics in India can deter patients from seeking necessary medical care and increase long-term healthcare costs.

3.3 Low per capita health expenditure and significantly lower number of diagnostic tests conducted per capita reflect under penetration of diagnostic services in India

India, being one of the fastest-growing economies, has immense opportunities for growth in the healthcare sector, particularly in improving the reach of diagnostic services. Currently, the market is under penetrated, and the difference in penetration is stark when compared to global counterparts, including other developed and emerging economies.





Source(s): 1Lattice analysis

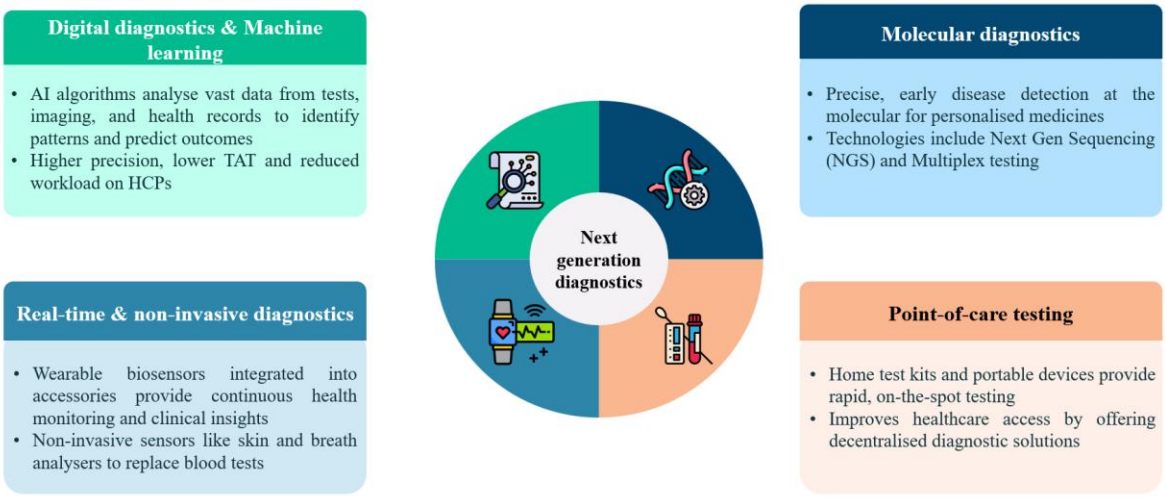
In India, the healthcare market is largely dominated by healthcare delivery providers, i.e., hospitals, which constitute 54.0% of the market, followed by pharmaceuticals (26.0%), and health insurance (6.0%). The diagnostics segment contributes only 6.0% to the healthcare landscape in India, reflecting lower overall expenditure on diagnostics in the country. While the diagnostic sector constitutes a significantly larger share (15.0%) of the US healthcare market, valued at US$ 873.0B in CY24. A more robust healthcare infrastructure ensures wider accessibility and availability of diagnostic services, reflected by the larger market share.

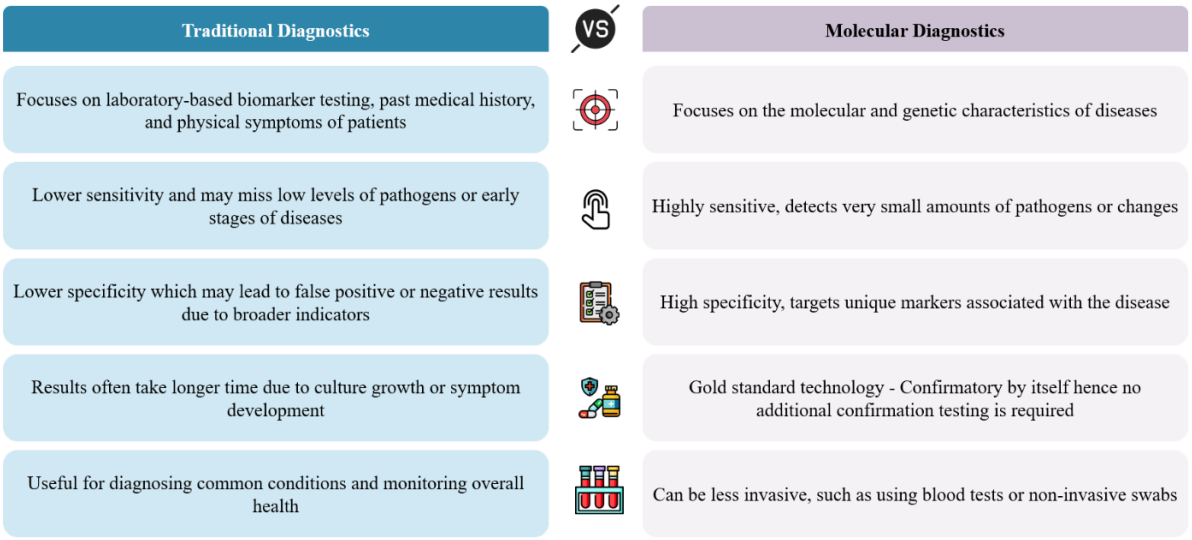
Limited access to affordable diagnostics solutions, inadequate infrastructure, including electricity and laboratory resources, and a lack of facilities pose significant obstacles to providing healthcare for patients with infectious and non-communicable diseases, particularly in underserved populations across the globe.

The number of diagnostic tests conducted per capita further reflects the disparities. The USA conducts the highest number of diagnostic tests at 21 tests per capita. Australia (19), France (19), and Germany (17) are among the leaders in conducting diagnostic tests among their populations. Developing economies like Brazil also perform 9 tests per capita. Conversely, India performs only 2 diagnostic tests per capita. The low contribution of diagnostics in the healthcare market and the limited volume of diagnostic tests suggest a significant under-penetration of diagnostic services.

3.3.1. Next-generation diagnostic services are addressing long-standing issues in the healthcare system, including accessibility, affordability, and accuracy

The diagnostic sector in India is witnessing significant transformation with the advent of next-generation technologies. A few crucial trends that are shaping the future of diagnostics are as follows:





3.3.2. Scale-up of Integrated Public Health Laboratory (IPHL) by government, increasing the diagnosis of disease

Recent developments in the policy, volume of investments, and innovation are gradually affecting change in India's diagnostics sector.

- Infrastructure scale-up of Designated Microscopy Centres (DMCs) by ~90% (~13,500 in CY14 to ~25,500 in CY24), along with the establishment of ~8,300 molecular diagnostic laboratories (CBNAAT & Truenat) in the public sector and ~1,400 installations in the private sector till date
- Molecular diagnostic testing facilities in India have the potential to scale up to ~50,000 (with ~17,000 private installations and ~33,000 public), driven by public–private investments and rising demand for precision diagnostics.
- The number of drug-resistant TB treatment centres has increased from 127 in CY14 to 792 in CY22.
- Increasing health insurance penetration, through government initiatives like AB-PMJAY, alleviates financial burdens for patients seeking diagnostic tests, boosting utilisation rates.
- The Government of India and the Centre for Disease Control and Prevention (CDC) support the scale-up of the Integrated Public Health Laboratory (IPHL) across all 730 districts in India by streamlining laboratory practices and increasing laboratory diagnostic capacity.

3.4 The diagnostics industry is shifting from centralised labs to more accessible peripheral and decentralised testing models, reducing turnaround times and enhancing patient care

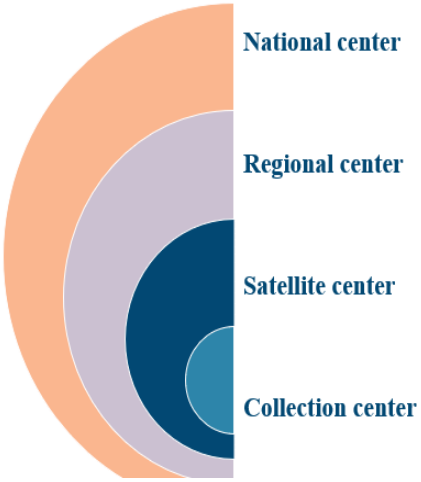
The diagnostics industry is significantly shifting from traditional centralised lab testing to more distributed and accessible models. Centralised labs have historically provided a wide range of specialised tests, but this model of diagnostic testing present several shortcomings, Patients are required to schedule in-person appointments, travel to separate testing facilities, and rely on sample transportation from remote locations, which often leads to longer turnaround times (TAT) and delays in healthcare delivery (i.e. detection and treatment). These logistical and technical challenges result in increased costs and delayed results. The lack of timely access to reliable diagnostics has been a major issue, particularly in low- and middle-income countries. Additionally, centralised systems often struggle to manage disruptions, such as pandemics, and may not effectively serve remote populations and those with limited access to traditional healthcare.

Additionally, there is a growing trend toward decentralised testing, including point-of-care (POC) and home-based testing. Initially limited to glucose monitoring and pregnancy tests, the scope of decentralised testing has significantly broadened, especially following the COVID-19 pandemic. These methods have proven crucial for rapid diagnostics, offering immediate results and supporting timely medical decisions. POC testing offers several advantages over tests performed at centralised laboratories, including improved quality of care, rapid turnaround time, and cost-effectiveness. These advantages highlight the potential of POC molecular diagnostics to significantly enhance patient care, public health efforts, and overall healthcare delivery. POC testing also enables mass testing within a short timeframe, which can help contain the spread of diseases within communities. It can also be conducted in constrained environments with limited space and electricity, making it valuable for various healthcare settings.

Centralised PCR machines present several notable challenges that impact their efficiency and accessibility. The turnaround time for results ranges from 2 to 7 days, delaying critical diagnostic and treatment processes. These machines require a minimum batch of 100 samples to operate efficiently, which can cause further delays if sample

numbers are insufficient. Centralised PCR testing necessitates controlled laboratory environments, posing risks to sample integrity due to potential contamination or mishandling. The requirement for specialised setups also results in significant capital expenditure, demanding substantial investment in equipment and facilities. These factors collectively hinder the overall effectiveness of centralised PCR testing solutions.

3.5 Traditional diagnostic services rely on the hub-and-spoke model, but the rise of molecular diagnostics and home-based POC testing is transforming healthcare delivery



Diagnostic services in India employ various operating models to cater to the diverse healthcare needs of the population. These models include a hub and spoke model (comprising national centres, regional centres, satellite centres, and collection centres), hospital labs, standalone labs, and home-based testing provisions. They are designed to increase the accessibility, efficiency, and comprehensibility of diagnostic tests in the country.

Central Laboratories	Decentralised POC testing
Samples need to be transported to central labs, leading to longer turnaround times for results and delayed diagnosis	POC tests can provide results within minutes, enabling immediate clinical decision-making and treatment initiation
Limited to specific locations with centralised facilities, can't adequately serve remote populations	POC testing can be performed closer to patient in various settings, including clinics, pharmacies, and even at home, making it more accessible, especially in remote or underserved areas
Requires patients to visit the lab or healthcare facility, high waiting time and leading to higher turn around / lead time for test results	Reduced need for patient travel and lesser waiting time
Higher costs associated with transport, processing, and facility maintenance	Potentially lower costs due to reduced logistics and transportation
Higher risk of cross-contamination in centralised settings	Reduced risk of cross-contamination and infections at the point of care
Scaling requires significant investment in infrastructure	Ease to conduct tests even in resource limited environments
Complex and large instruments can lead to technical challenges also leading to increased costs and delayed results	Minimal training required to operate POC testing equipment offering easy accessibility

3.6 IVDs and medical devices in India are regulated by the CDSCO and fall under the purview of the Medical Devices Rules 2017

The regulatory landscape for IVDs and medical devices in India underwent a comprehensive revamp with the introduction of the 'Medical Device Rules,' 2017. These regulations, which came into effect in January 2018, represent a significant shift in how IVDs and medical devices are governed and control the licensing, registration, and sales of medical devices. The regulations address labelling, registration requirements, production standards, licensing authority, classification, and quality management system compliance. Clinical investigations, audits, adherence to safety standards, and Medical Device Officer enforcement are all covered under the legislation.

CDSCO, an agency under the Ministry of Health and Family Welfare, is the primary regulatory body responsible for overseeing the import, manufacture, sale, and distribution of IVD kits and reagents. The CDSCO operates in accordance with the provisions set out in the Drugs & Cosmetics Act, 1940 & Rules of 1945.

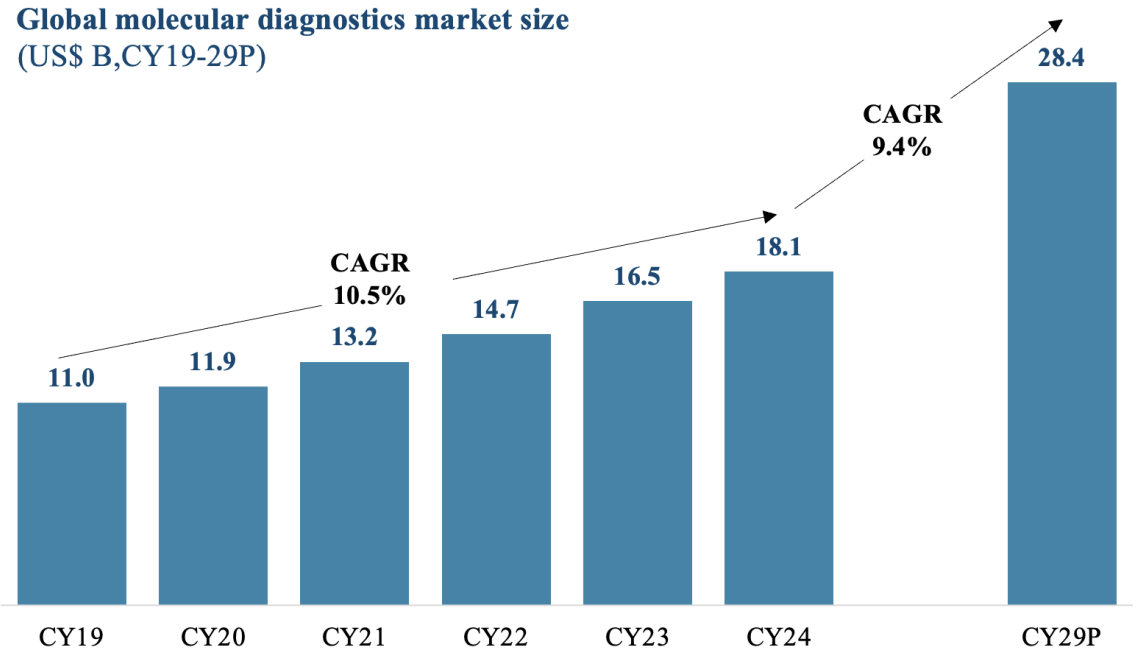
Impact on molecular diagnostics:

1) **Regulatory support for innovation –** The Indian regulatory framework has fostered an environment that encourages innovation in molecular diagnostics. The introduction of policies has enabled the commercialisation of advanced technologies and led to increased availability of cutting-edge diagnostic tools such as Next-Gen Sequencing (NGS) and CRISPR–based diagnostics
2) **Improved quality standards –** The implementation of stringent quality control measures and standards for challenge products ensures that only high-quality and reliable diagnostic tools are available in the market. This has increased the credibility of Indian diagnostic products both domestically and internationally, contributing to market growth
3) **Expanded testing capacities –** Regulatory initiatives during the COVID-19 pandemic significantly expanded the capacity of molecular testing in India. The establishment of numerous RT-PCR labs across the country increased testing capabilities, which remain in place post-pandemic, ensuring high capacity for molecular diagnostics
4) **Promotion of POCT –** Increased accuracy of POCT tests has increased access and acceptance of POCT in India. This promotes decentralisation of diagnostic services, making diagnostic services more accessible and improving overall healthcare outcomes
5) **Global collaborations and increased investments –** The favourable regulatory environment has attracted investments from global IVD companies, further driving the growth of the molecular diagnostics market in India

4 Molecular diagnosis market

4.1 The global molecular diagnostics market was valued at US$ 18.1B in CY24 and is expected to reach US$ 28.4B in CY29, growing with a CAGR of 9.4 % from CY24-29, driven by the increasing prevalence of infectious and non-communicable diseases and genetic disorders globally.

Molecular diagnostics, also known as molecular pathology, involves examining DNA or RNA, the unique genetic codes within our cells, to identify sequences that signal the potential onset of specific diseases. They enable rapid and accurate identification of pathogens like bacteria and viruses through techniques such as PCR. They are used for managing diseases by analysing genetic mutations to guide personalised treatment, monitoring disease progression, predicting treatment responses, and facilitating precision medicine approaches.



Source(s): 1Lattice analysis

4.1.1. Indian Innovator: Pioneering accessible molecular diagnostics and revolutionising global healthcare

Molecular diagnostics started with centralised PCR labs in the 1980s designed for large cities and hubs, with high infrastructure cost and high TAT of 2-7 days, turned to Integrated PCR in mid-2000s, which had comparatively lower infrastructure cost and low TAT of 1-2 hours. Since the mid-2010s, PoC PCR has been used. PoC PCR have low infra cost and TAT of less than one hour. Molbio has launched Truenat, a PCR platform which has been endorsed by WHO. Molbio is the only global PoC-PCR platform that can operate in a resource-limited setting, reaching the Primary care

level. These newer systems are often portable, battery-operated, and capable of functioning in resource-limited settings with room temperature-stable reagents, making them highly suitable for primary care use.

Molbio has pioneered this shift with its Truenat PCR platform, which is a POCT PCR solution proven to operate in low-resource environments and endorsed by the WHO. For diseases like TB, hepatitis & HPV, HIV and STDs & STIs, two key players, Cepheid and Molbio, are found to have the major market share. Molbio launched its Truenat system in 2017, the Truenat micro-PCR platform-based diagnostic kit was launched in October 2018, marking a significant step in TB diagnostics. It was endorsed by the WHO in January 2020 as an initial diagnostic test for pulmonary TB and rifampicin resistance and has since been integrated into India's National Tuberculosis Elimination Programme. Cepheid's Xpert TB testing system has been in the market since 2010, providing molecular diagnostics for TB.

4.2 Molecular diagnostics offer several key advantages, including higher sensitivity and specificity, as well as faster results

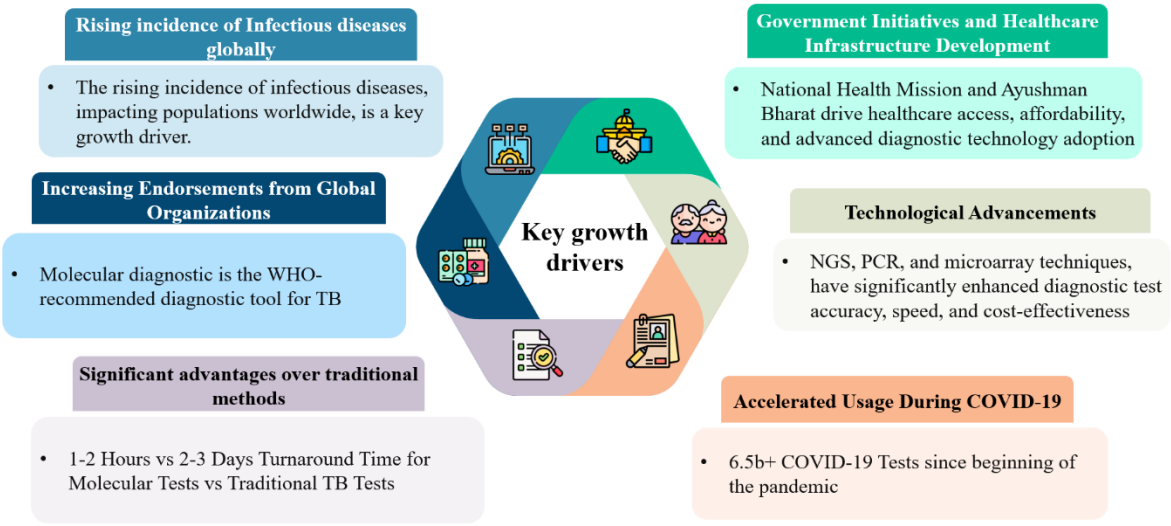
Molecular diagnostics offers precise and rapid detection of genetic and infectious diseases by analysing nucleic acids. This technology enables early diagnosis, personalised treatment, and better management of diseases, making it a powerful tool in modern healthcare. Its accuracy and speed significantly improve patient outcomes and reduce healthcare costs. The advantages of molecular diagnostics include:

Advantages of molecular diagnostics		
	**Higher sensitivity and specificity**	• **Detection of low-level pathogens:** Molecular diagnostics can detect very low levels of pathogens or genetic mutations, which may be missed by traditional methods that rely on larger quantities or growth of the organism. • **Precise identification:** They can identify specific strains or mutations of pathogens, which can be crucial for accurate diagnosis and treatment.
	**Faster results**	• **Rapid turnaround:** Many molecular tests can provide results much faster than traditional methods. For example, PCR (Polymerase Chain Reaction) can detect the presence of a pathogen in a matter of hours, whereas culture methods might take days
	**No need for cultivation**	• **Direct detection:** Molecular diagnostics can often detect pathogens directly from clinical samples without the need to culture them first, which is especially useful for pathogens that are difficult or slow to grow in the lab.
	**Early detection**	• **Detection before symptoms:** They can identify infections or genetic conditions before symptoms appear, which can be crucial for early intervention and treatment.
	**Precision medicine**	• **Tailored treatments:** Molecular diagnostics enable the identification of specific genetic markers or mutations that can guide personalised treatment plans, especially in oncology, for targeting specific cancer mutations.
	**Reduced risk of contamination**	• **Controlled environment:** Molecular techniques often involve closed systems and automated processes that minimise the risk of contamination, unlike traditional methods that may involve more manual handling.

Traditional diagnostics primarily depend on physical symptoms, patient history, and laboratory-based biomarker tests. They often suffer from poor accuracy and frequently require further confirmatory testing. Traditional methods may not always pinpoint the exact cause of a disease. In contrast, molecular diagnostics focus on the molecular and genetic characteristics of diseases, offering a high level of accuracy. This gold standard technology is confirmatory by itself and allows for targeted treatment and personalised medicine, significantly enhancing the precision and effectiveness of diagnostic processes.

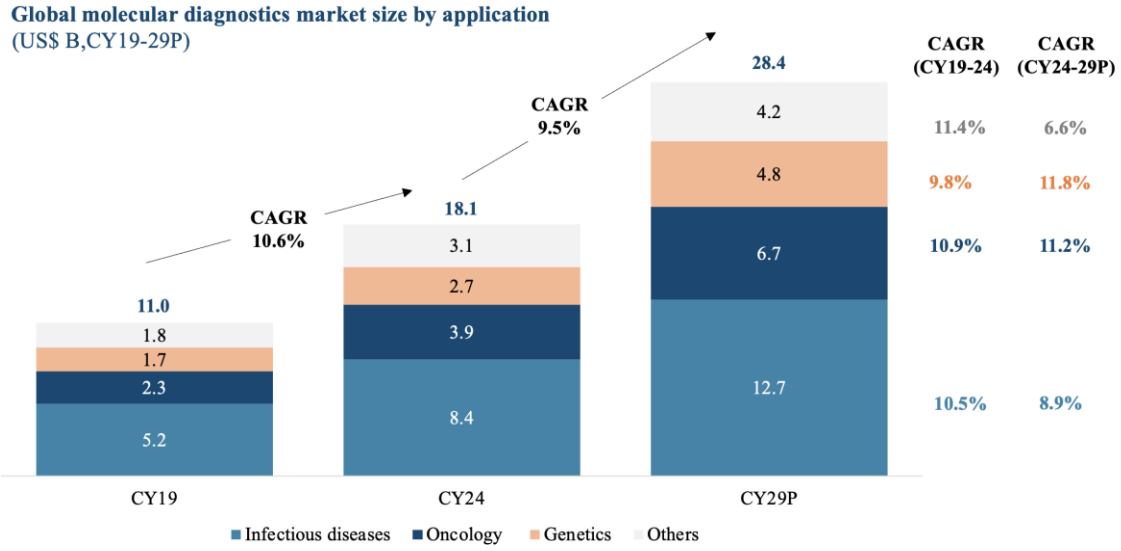
4.3 Growth drivers of the global molecular diagnostics market

The molecular diagnostic industry has high entry barriers and is characterized by extensive R&D and rapid technological changes. These dynamics, while challenging for new entrants, also fuel continuous innovation and market evolution. As a result, the molecular diagnostic market is propelled by key drivers like advancements in genetic testing and sequencing technologies, broader applications in personalised medicine and rising global demand for precise and swift diagnostic solutions. Below are several significant drivers fostering growth in the industry:



4.4 In CY24, Infectious diseases contribute to 46.4% of the total global molecular diagnostics market, followed by oncology with 21.5%

The global molecular diagnostics market is divided into three main segments. The infectious disease segment dominates, making up to 46.4% of the market in CY24. This is followed by the oncology segment, which accounts for 21.5%, and genetic testing, which holds a 15.0% share. The remaining 17.1% of the market is comprised of various other applications, including pharmacogenomics, microbiology, human leukocyte antigen (HLA) typing, and blood screening. Infectious diseases hold the majority of the share in the global molecular diagnostics market with a market value of US$ 8.4B in CY24, which is projected to grow to US$ 12.9B in CY29 with a CAGR of 9.0%. The fastest growing segments would be the genetics diagnostic and oncology segment, growing at a CAGR of 12.0% and 11.3% from CY24-29.

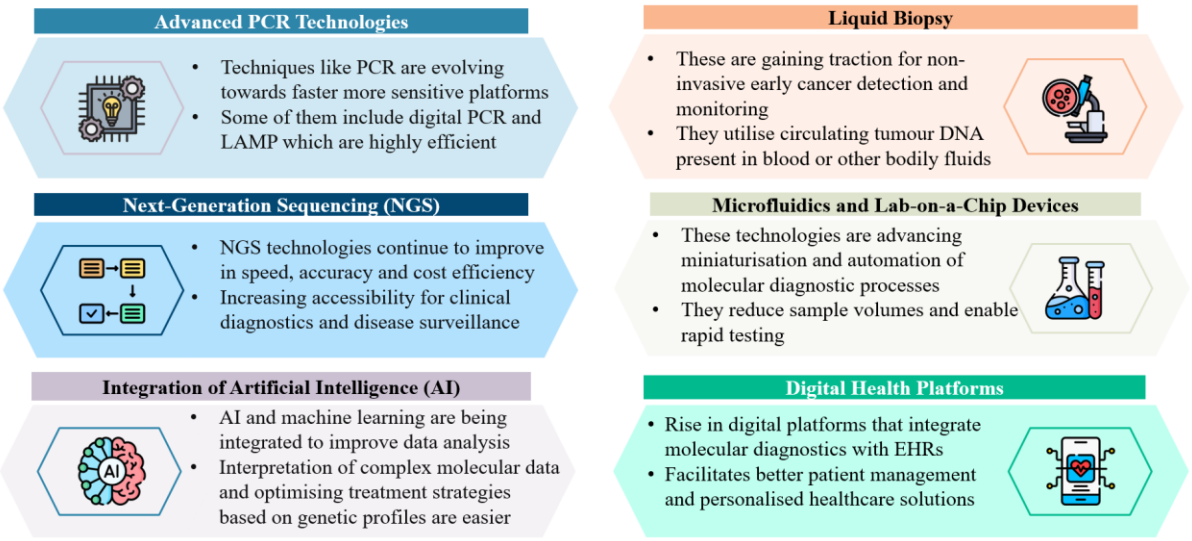


Source(s): 1Lattice analysis

4.5 Advanced PCR technologies, alongside next-generation sequencing and liquid biopsy, are some of the emerging trends and innovations in the molecular diagnostics market

Recent trends and innovations in the global molecular diagnostic technology market have revolutionised healthcare diagnostics. Advances in PCR, digital PCR, and LAMP are enhancing speed, sensitivity, and portability. These developments underscore a shift towards more precise, efficient, and accessible molecular diagnostics worldwide. Listed below are some of the latest trends and innovations in the market:

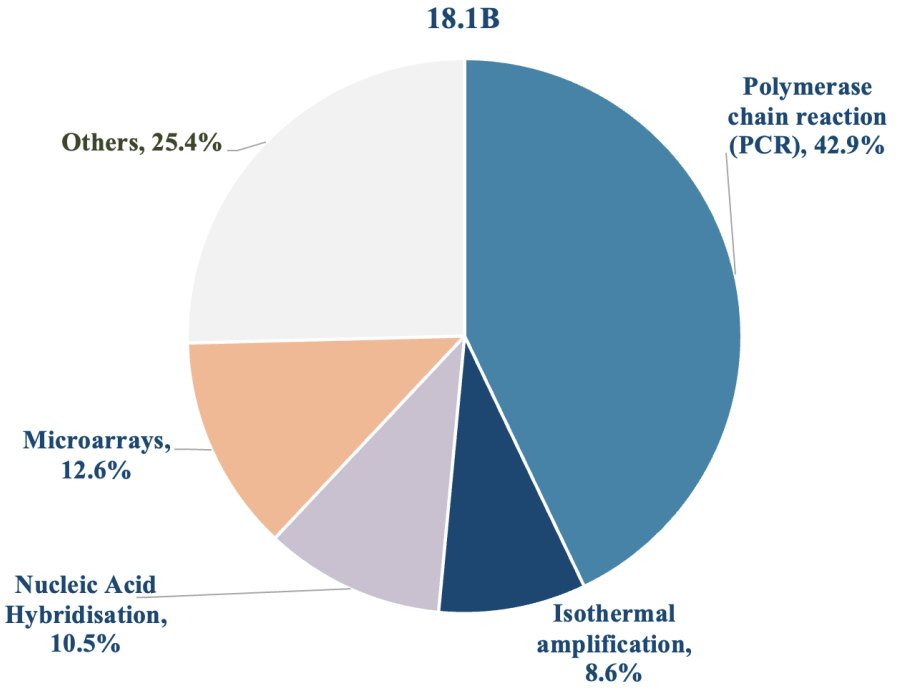
Recent technological trends and innovation in the global molecular diagnostic market



4.6 Polymerase Chain Reaction (PCR) holds a majority share in the global molecular diagnostics market at 42.9%, followed by Microarrays with a 12.6% share. Isothermal amplification and nucleic acid hybridisation hold 8.6% & 10.5% share respectively

The global molecular diagnostics market, valued at US$ 18.1B in CY24, is segmented into four primary categories: PCR, isothermal amplification, nucleic acid hybridisation, and microarrays. PCR holds the largest share at 42.9%, followed by microarrays at 12.6%, nucleic acid hybridisation at 10.5%, and isothermal amplification at 8.6%. The remaining 25.4% of the market is occupied by other technologies, including next-generation sequencing and immunochemistry. This distribution reflects the extensive adoption and versatility of PCR, as well as the growing importance of other molecular diagnostic methods in various clinical and research applications.

Global molecular diagnostics market size by technology
(%, CY24)



Source(s): 1Lattice analysis

4.6.1 **Polymerase Chain Reaction (PCR):** PCR is a technique used to amplify small segments of DNA or RNA. It involves repeated cycles of heating and cooling, allowing specific sequences to be copied millions of times over. The key steps in PCR are:

- **Denaturation:** Heating the DNA to separate its two strands.
- **Annealing:** Cooling the DNA so that primers can attach to the target sequences.
- **Extension:** Using a DNA polymerase enzyme to extend the primers, synthesising new DNA strands

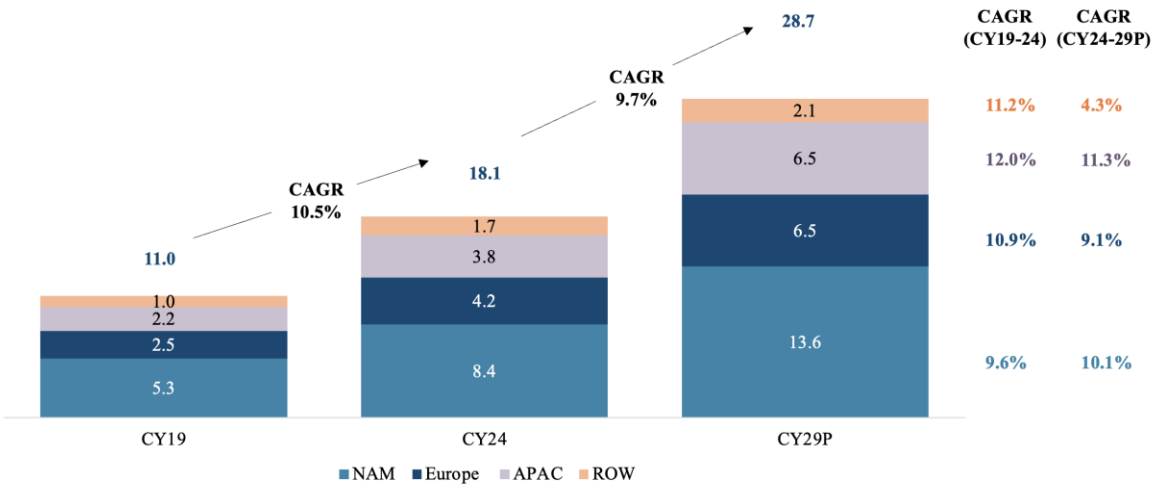
PCR has gained popularity, especially for TB testing, shifting from traditional sputum microscopy because it offers higher sensitivity and specificity than sputum testing, enabling quicker and more accurate detection of TB bacteria, including drug-resistant strains, thereby improving diagnostic reliability and patient outcomes. The shift to PCR testing offers a large market opportunity with major contributions from Asia and Africa because these regions have high TB prevalence and significant healthcare challenges. PCR's superior accuracy and rapid results enhance TB control efforts, making it a critical tool in these under-resourced areas. PCR is extremely advantageous for POC testing as it provides rapid, accurate, and sensitive detection of pathogens directly at the site of patient care, facilitating immediate clinical decision making. COVID-19 tests, conducted globally, have played a crucial role in identifying and controlling the spread of the virus. These tests, including molecular, antigen, and antibody tests, have enabled widespread screening, early diagnosis, and tracking. During the pandemic, facilities like the University of Washington Medical Centre in the USA experienced a massive surge in PCR testing, with volumes increasing from 50,000 tests annually to 4M tests over just 22 months, due to COVID-19. This reflects a significant escalation in the scale and frequency of PCR testing compared to pre-pandemic levels. In the UK, PCR tests accounted for 26% of all COVID-19 tests conducted by the end of the pandemic. Whereas, in India, PCR tests accounted for 49.4% of all COVID-19.

- **Isothermal amplification:** It refers to DNA amplification techniques that occur at a constant temperature, unlike PCR, which requires thermal cycling.
- **Nucleic acid hybridisation:** It involves the pairing of complementary nucleic acid strands to form double-stranded molecules.
- **Microarrays:** They are tools used to analyse the expression of many genes simultaneously or to genotype multiple regions of a genome. They consist of a grid of microscopic spots, each containing a specific DNA probe.

4.7 North America accounts for 46.4% of the total molecular diagnostics market value, followed by Europe and APAC

In CY24, North America led the global molecular diagnostics market, commanding a significant share of 46.4%, followed by Europe at 23.2%, and Asia Pacific at 20.9%. This distribution underscores North America's prominent position in the industry, due to advanced healthcare infrastructure, robust R&D investments, and widespread adoption of molecular diagnostic technologies.

Global molecular diagnostics market size by region
(US$ B, CY19-29P)



Source(s): 1Lattice analysis

China, India, Indonesia, and Philippines markets are experiencing rapid growth in healthcare infrastructure and spending to improve healthcare access and quality. In Africa, countries like South Africa, Nigeria, and Kenya are witnessing growth in molecular diagnostics to address infectious diseases and improve healthcare outcomes. In South

America and the MENA regions, the market is driven by increasing healthcare infrastructure investments, a rising prevalence of infectious diseases, and growing awareness of early disease detection. Additionally, government initiatives to improve healthcare access and the adoption of advanced diagnostic technologies significantly contribute to market expansion in these regions.

The molecular / POC testing market is also gaining traction in other emerging or developing economies (like India, Brazil, Cambodia, Turkey, etc.) as it improves access to advanced diagnostic tools, bypassing the typical constraints of centralised labs. These technologies deliver rapid and accurate results, crucial for timely diagnosis and treatment in regions with scarce healthcare resources. By lowering costs and reducing turnaround times, POC testing enhances healthcare efficiency, addressing the significant burden of infectious diseases and chronic conditions. Additionally, the decentralised approach of POC testing empowers local healthcare providers, leading to better patient outcomes and overall public health advancements.

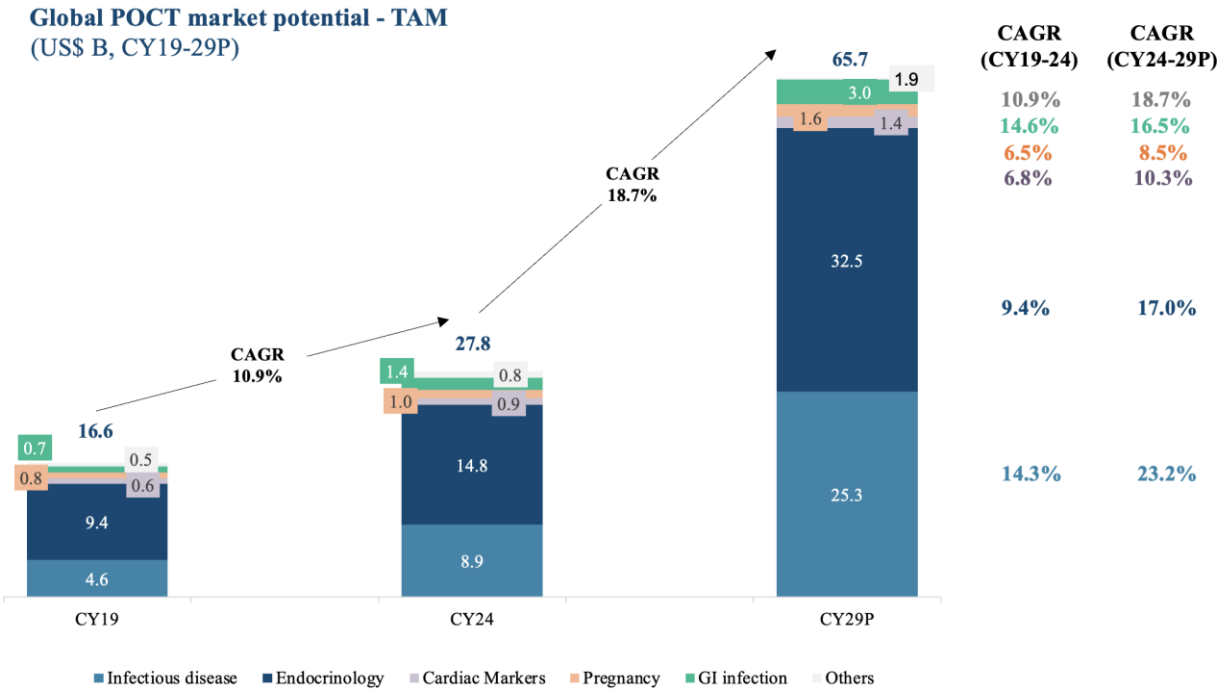
5. Overview of the global molecular POCT market

5.1 Point of care diagnostics currently has a market potential (TAM) of US$ 27.8B, with Endocrinology and infectious diseases being major contributors

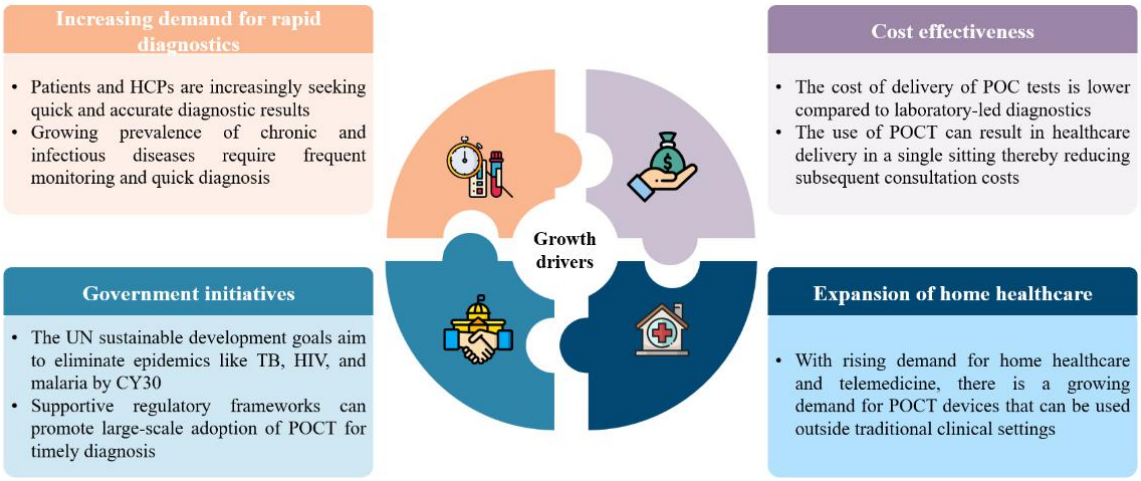
Point-of-care testing (POCT) refers to diagnostic tests conducted at or near the site of patient care, rather than in a centralised laboratory, enabling healthcare providers with onsite diagnosis and making immediate clinical decisions. POCT also enables the HCPs to monitor patient health remotely, improving healthcare access.

5.1.1 The global POCT market is valued at US$ 27.8B in CY24 and expected to grow at a CAGR of 18.7% over CY24-29P, with the APAC region being the largest market

With a growing emphasis on rapid and accessible diagnostics, the total addressable market for global POCT (based on the number of tests conducted) currently stands at US$ 27.8B (INR 2,350.8B) (infectious and non-infectious diseases) and is projected to grow at 18.7% CAGR between CY24-29 to be a US$ 65.7B (INR 5,555.6B) market by CY29P. This growth is expected to be fuelled by technological advancements, increased awareness and adoption of point-of-care testing, and the rising prevalence of both chronic and infectious diseases globally.



The rising prevalence of infectious diseases like TB, HPV and other STIs, and the rising demand for rapid and accurate diagnosis have fuelled the growth of the POCT market. Advancements in technology and the development of more user-friendly and sophisticated POCT devices have made them more accessible even in remote and resource-limited settings.

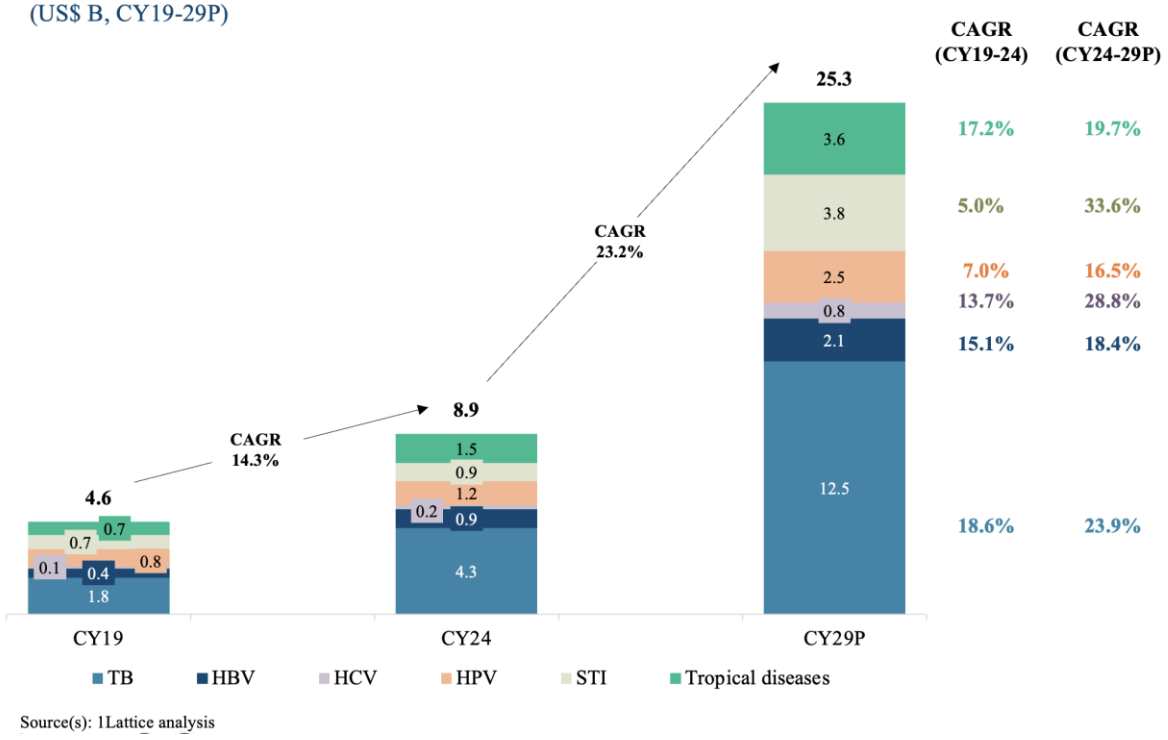


In CY24, the global POCT market was predominantly led by APAC, North America, and Europe, which accounted for 28.1%, 25.5%, and 16.1% of the market share, respectively. The advanced healthcare infrastructure and substantial healthcare expenditures in these developed regions have facilitated their early adoption of POCT technology. MENA and Latin America collectively represent 21.0% of the market in CY24. These regions present significant growth opportunities due to their large populations and high prevalence of infectious diseases such as tuberculosis, malaria, and dengue. APAC is expected to grow at a CAGR of 18.9%, while MENA and Latin America are projected to grow at a CAGR of 18.8% and 17.2% respectively, between CY24 and CY29. POCT is poised to enhance the availability, accessibility, and affordability of healthcare and diagnostic services in APAC, Latin, and MENA regions, which are currently challenged by economic disparities and inadequate healthcare infrastructure.

5.2 TB and other related respiratory diseases drive the molecular POCT markets globally

The Total Addressable Market for the global point-of-care testing market for infectious diseases expanded from US$ 4.6B in CY19 to US$ 8.9B in CY24, with a CAGR of 14.3%, and is further expected to accelerate to US$ 25.3B by CY29P, driven by a higher CAGR of 23.2% from CY24-29. STI and HCV exhibit the highest projected growth of 33.6% and 28.8% respectively, for CY24-29P. Advancements in rapid diagnostic technologies fuel the increasing demand for POCT solutions across diverse disease categories.

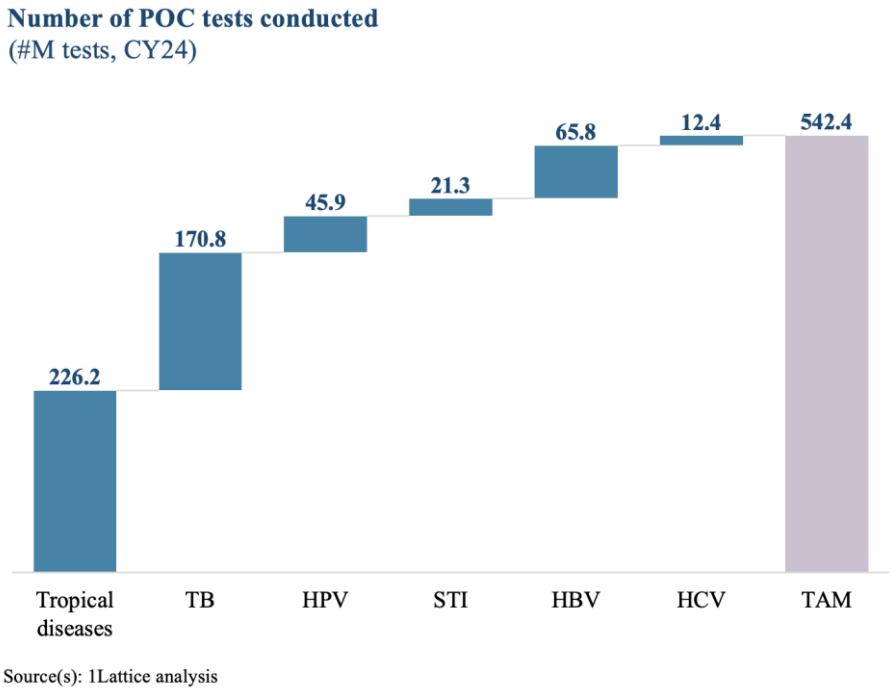
Global POCT market for infectious diseases – TAM
(US$ B, CY19-29P)



Source(s): 1Lattice analysis

Infectious disease testing constitutes a significant segment of the global POCT market, accounting for ~31.4% of the total market. Within this segment, TB testing stands out as the largest contributor, followed by HPV, HCV, HBV, and

sexually transmitted infections, which also contribute to the infectious disease testing market. Sputum collection for TB tests has been problematic due to the risk of aerosolisation, difficulty in obtaining high-quality samples, and the complexity of DNA extraction methods.



Source(s): 1Lattice analysis

POCT is commonly used in a variety of settings, including hospitals, clinics, pharmacies, and even at home, covering a wide range of conditions. This segment of tests gained significant attention, especially during the COVID-19 pandemic. Rapid antigen and antibody tests are performed to provide quick results for conditions like influenza, HIV, and COVID-19. Nucleic Acid Amplification Test (NAAT) detects genetic material from pathogens for confirmation of diseases such as TB, malaria, gonorrhoea, and chlamydia.

The Point-of-Care testing (POCT) market can be classified under the following segments:

Based on disease type:

1) **Tuberculosis –** TB is a highly contagious respiratory disease with over 10.8M new cases reported globally in the year CY24 (expected). It causes about 1.3M deaths globally, with HIV patients at a higher risk of TB-related death. TB is the largest contributor to the infectious diseases market. In 2024, ~170.8M tests were performed, valued at US$ 2,329.1M. The UN's SDG targets TB elimination by CY30, with WHO aiming for 100% molecular testing. Rising demand from high-TB nations and national TB programs will drive the POCT market growth.
2) **Cervical cancer –** Cervical cancer is the fourth most common cancer in women worldwide, caused by the human papillomavirus (HPV). In 2022, HPV led to ~6,60,000 cervical cancers in women and ~72,000 cancers in men. HPV test and Pap smear are the most common screening tests for the detection of HPV.
3) **Sexually transmitted infections –** STIs such as HIV, Syphilis, Gonorrhoea, and Chlamydia affect over 200M patients every year. The global incident cases were reported as 374M in CY20. While POC tests such as viral load tests are gaining popularity for the diagnosis of HIV, the lack of cost-effective rapid diagnostic tests (RDTs) for Syphilis, Gonorrhoea, and Chlamydia has led to lower POCT adoption for these diseases. An estimated 21.2M POC tests were conducted for STIs globally in CY24 at an estimated value of US$ 663.5M.
4) **Hepatitis** – Hepatitis is severely underdiagnosed worldwide, with 80-90% of the population unaware of their infection. Currently, point-of-care testing of Hepatitis B and Hepatitis C contributes US$ 1,130.3M to the infectious disease market, with an estimated 65.8M point-of-care tests conducted annually for Hepatitis B and 12.3M for Hepatitis C. Currently, serological and molecular tests are available for the diagnosis of Hepatitis B and C. Rapid diagnostic tests generally have lower analytical sensitivity. Although some viral hepatitis markers are already available in POCT formats, there is a need to develop and validate tests for additional markers or novel technologies for clinical use. WHO's global hepatitis strategy, endorsed by all WHO member states, aims to reduce infections by 90% and deaths by 65% by CY30.
5) **Other infectious diseases –** Include influenza and tropical diseases such as malaria and dengue, GI infections, sepsis, etc.

Based on the test setting:

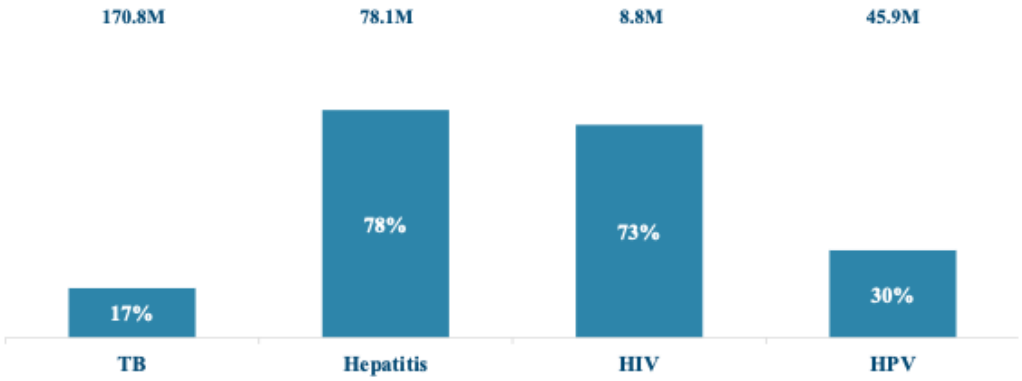
1) **Clinical setting** – POCT in primary care clinics, emergency departments, and outpatient clinics typically use basic lab infrastructure. These testing devices often function with or without external power and require minimal training. Operated by skilled professionals like nurses, technicians, or lab workers.
2) **Alternate settings** – POCT for home use or community outreach requires no specialised infrastructure and includes basic rapid diagnostic tests (RDTs) like pregnancy and tests for infectious diseases such as Dengue and Malaria. POCT for TB is now being extensively promoted at the primary healthcare level through community outreach programs organised by the government and NGOs.

	Clinic POC test units	Alternative settings
Location	Primary care clinics, hospitals	Community outreach, home testing
Lab infrastructure	Minimal lab equipment needed with power supply	No infrastructure required
Test types	PCR, basic microscopy, Rapid diagnostic tests (RDT)	Rapid diagnostic tests (RDT)
Sample handling	Upper respiratory specimens, some blood samples	Fingerstick blood, nasal swabs, saliva, urine
Operator skill	Nurse, trained laboratory technicians	Nurse, pharmacist, community care worker, self

5.2.1 POCT is a game-changer in LMICs, providing rapid, on-site diagnostics for infectious diseases, improving access to timely treatment in resource-limited settings

Point-of-Care Testing (POCT) plays a crucial role in Low and Middle-Income Countries (LMICs), offering several significant benefits. In these regions, healthcare infrastructure is often limited, and access to centralised laboratories can be challenging due to geographical barriers, underfunded healthcare systems, and limited resources. POCT allows for rapid diagnosis at the point of care, improving access to timely and accurate healthcare in rural and remote areas. A large portion of molecular POCT is conducted in LMICs, primarily for the diagnosis of infectious diseases such as tuberculosis, HIV, and malaria. These regions face a high burden of infectious diseases, and molecular POCT offers rapid, sensitive, and accurate detection. Tests such as Truenat and GeneXpert for TB, rapid HIV viral load assays, and rapid tests for malaria and tropical diseases are vital for managing public health in LMICs. The portability, speed, accuracy, and ease of use of POCT make it an essential tool for resource-limited settings, where immediate diagnosis is often critical to prevent disease spread and provide timely treatment.

Share of POCT for major infectious diseases in LMIC
(% tests, CY24)



Source(s): 1Lattice analysis

5.3 Overview of the POCT equipment market

The success and expansion of point-of-care testing are fundamentally tied to the advancements in the underlying technology. Innovations such as the "lab on a chip" have significantly reduced test turnaround times and have extended diagnostic capabilities to regions where traditional methods were previously inaccessible. Point-of-care devices have played a crucial role in enhancing access to essential diagnostic services and making a substantial impact on global healthcare delivery. Moreover, the minimal training required for personnel to operate POC testing

equipment sets it apart from traditional laboratory-based systems, making it more accessible and feasible for a wider range of healthcare providers to utilise.

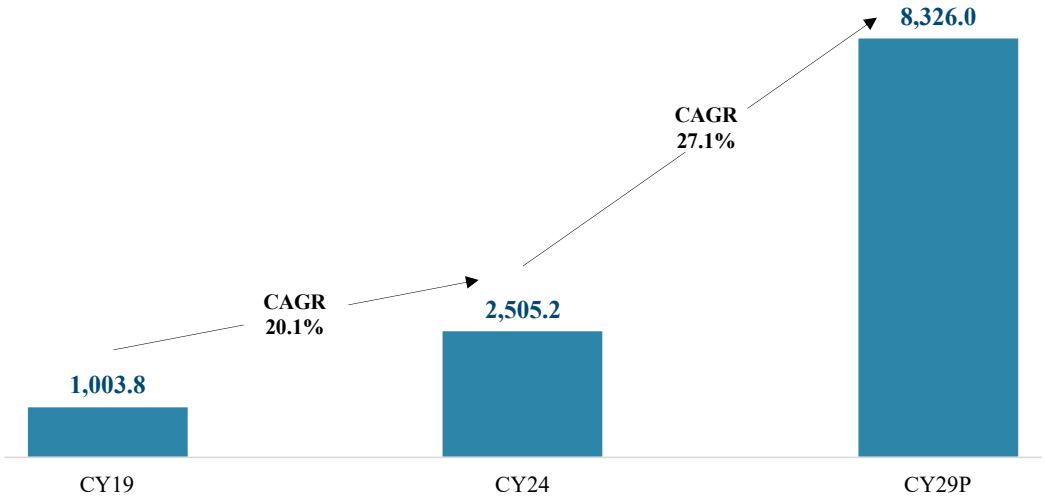
Point-of-care devices can be classified into two types:

1) **Disposable POCT devices** – Include RDT kits such as Dengue, Malaria, and COVID-19 tests that are disposed off after a single use
2) **Tabletop analysers** – Sophisticated, portable machines that are usually battery-powered or electrically operated to perform specialised molecular or immunodiagnostic tests to detect infectious diseases such as TB, HPV, STIs, and GI disorders. These machines usually include a cartridge onto which a patient sample is loaded and analysed using innovative technologies and platforms to receive accurate results.

5.3.1 The global molecular POCT equipment market valued at US$ 2,505.2M (~INR 211.8B) is projected to grow at a CAGR of 27.1% between CY24-29

The global Molecular POCT equipment market, valued at US$ 1,003.8M in CY19, grew at a CAGR of 20.1% between CY19-24, fuelled by the increased demand for rapid diagnosis and screening tests. The market is expected to continue expanding significantly as POCT devices become more integrated into regular diagnostic methods worldwide, thus poised to grow at a CAGR of 27.1% from CY24-29P.

Molecular POCT equipment market - Global
(US$ M, CY19-29P)

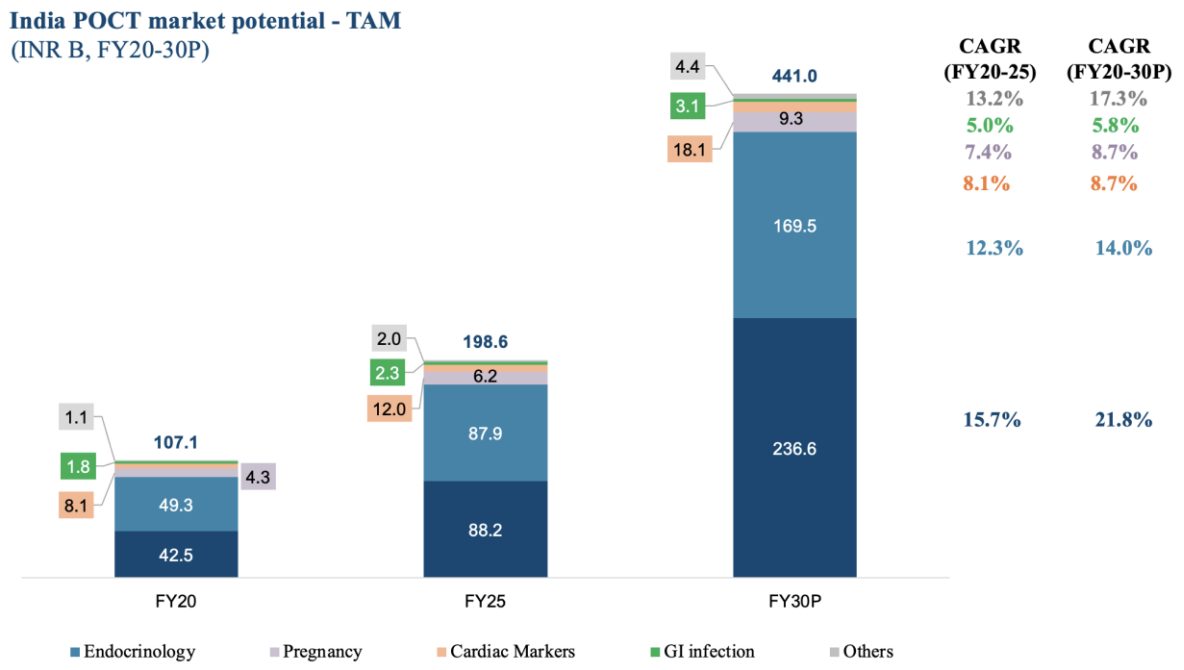


Source(s): 1Lattice analysis

6. Overview of Indian molecular diagnostics & POCT market

6.1. India holds a huge market for POCT with the current market potential (TAM) at INR ~198.5B (US$ ~2.3B) in FY25, projected to grow at 17.3 % CAGR to be at INR ~440.9B (US$ 5.2B) market by FY30

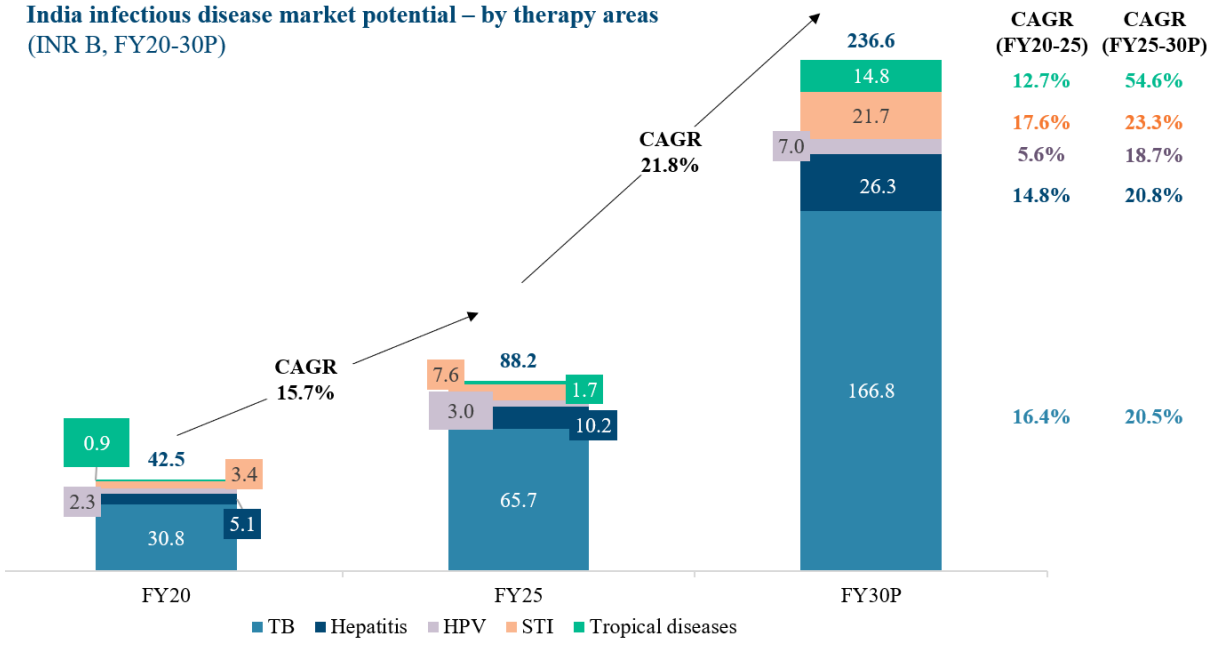
India has become the diabetes capital of the world and a hotbed for major infectious diseases such as TB. It is evident that India holds significant market potential in both Endocrinology and Infectious disease (based on the number of tests performed). The infectious POCT market is estimated to have a market potential of INR 88.2B (US$ 1.0B), closely followed by endocrinology diseases with a market potential of INR 87.9B (US$ 1.0B) in FY25. These markets are projected to reach INR 236.6B (US$ 2.8B) and INR 169.5B (US$ 2.0) respectively, by FY30, due to the high prevalence of lifestyle diseases and the growing incidence of infectious diseases in the region. Enhanced healthcare infrastructure, increased investments in diagnostic technologies, and growing awareness about early disease detection are expected to drive the infectious disease market further, resulting in a higher CAGR of 21.8 % between FY 25-30P.



Source(s): 1Lattice analysis

6.2. India holds a vast market for infectious diseases, with the current market potential (TAM) at INR ~ 88.2B (US$ 1.0B) in FY25, projected to grow at a robust 21.8% CAGR to reach INR ~236.6B (US$ 2.8B) by FY30.

India's infectious disease burden remains high, driven by a large population, high prevalence of diseases like TB, and growing cases of viral infections such as hepatitis and HPV. The market for infectious disease diagnostics is significantly influenced by factors such as healthcare infrastructure advancements, increased investment in diagnostic technologies, and heightened awareness around early disease detection.

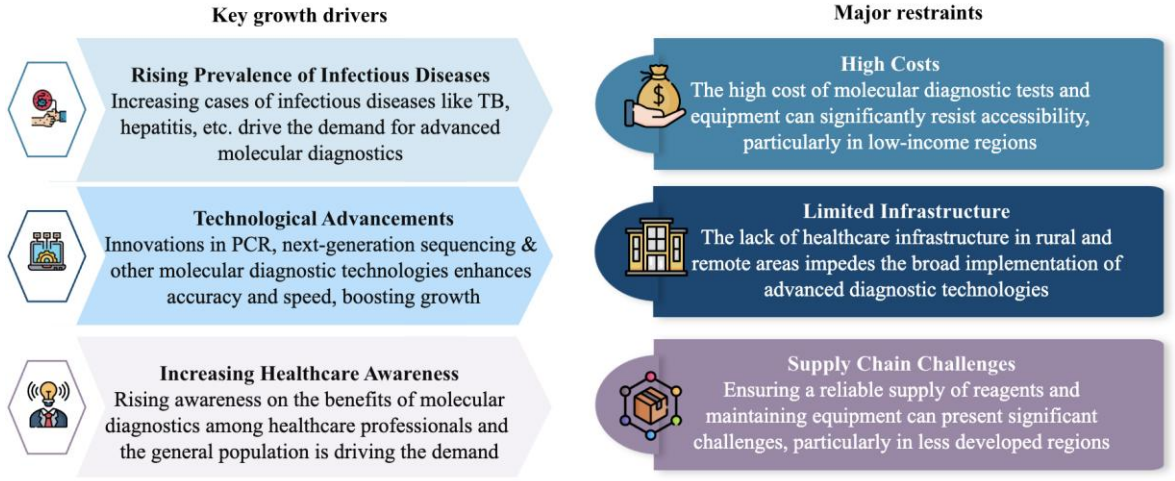


Source(s): 1Lattice analysis

Between FY20-25, the infectious disease market witnessed a notable 15.7 % CAGR, fuelled by increasing demand for testing and diagnostics. Looking ahead, the market is anticipated to expand even faster, underpinned by an increase in disease awareness, government initiatives, and a strong push toward improving early diagnostic capabilities across the country. The TB diagnostics market in India is expected to grow at a CAGR of 20.5% between FY25 and FY30P

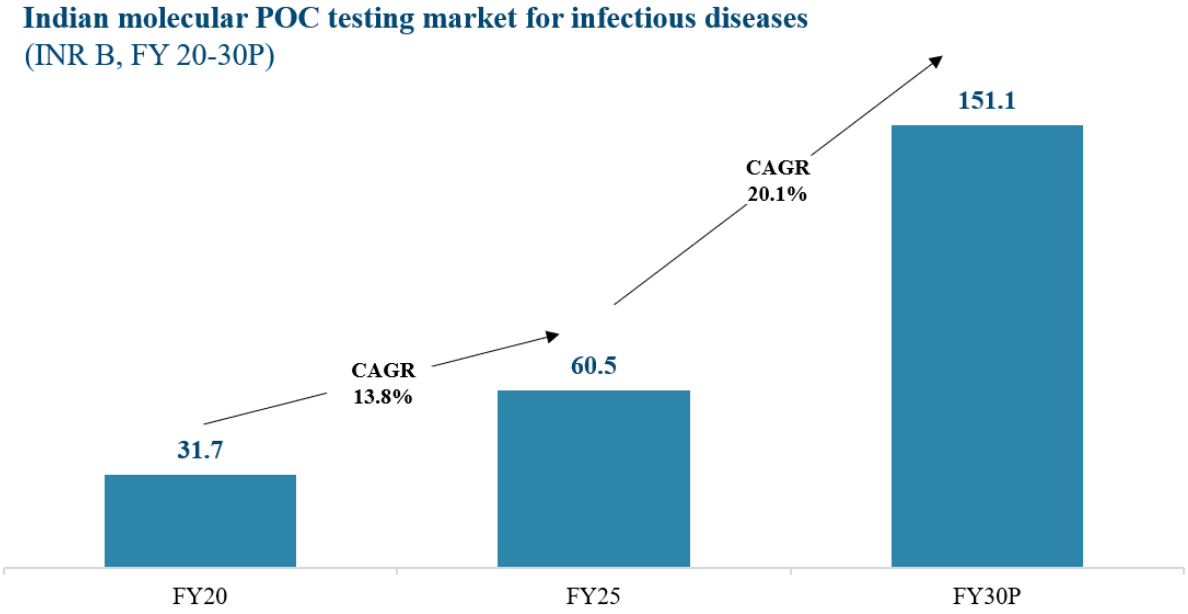
from INR 65.7B (~US$ 0.8B) to reach INR166.8B (~US$ 2.0B), reflecting its critical public health significance. TB is followed by Hepatitis (viral infections) diagnostics with a share of INR 10.3B (US$ 0.1B) in FY25.

6.3. The growth of the Indian infectious diseases market is driven by increasing awareness, expanding healthcare infrastructure, and increased adoption.



6.4. The Indian molecular point-of-care testing market for infectious diseases is valued at INR 60.5B (US$ 0.7B) in FY25 and is expected to reach ~INR 151.1B (US$ 1.8B) by FY30P, at a CAGR of 20.1%

Valued at INR 31.7B (US$ 0.4B) in FY20, the Indian POCT market grew to INR 60.5B (US$ 0.7B) in FY25, achieving a CAGR of 13.8 %. This market growth is expected to accelerate further with a CAGR of 20.1 % from FY25 to FY30P, projecting the market to reach INR 151.1B (US$ 1.8B) by FY30P.

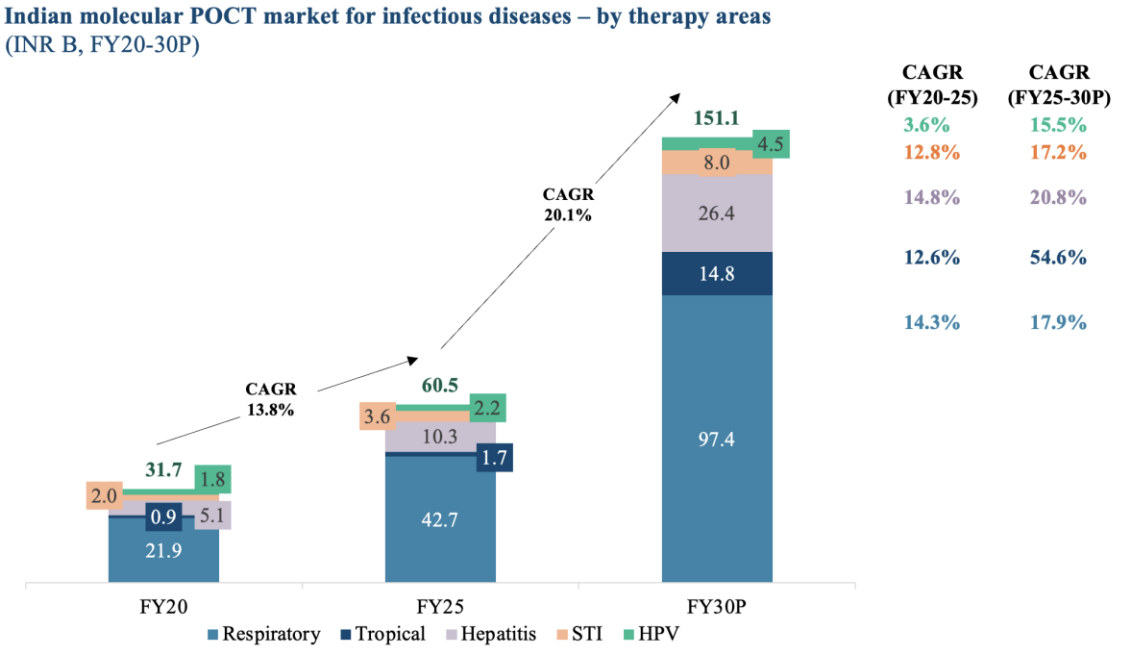


Source(s): 1Lattice analysis

6.4.1. Increased accessibility, cost efficiency, and a rising market for TB are the major trends driving the adoption of Point-of-Care Testing (POCT) across healthcare settings

Point-of-care testing (POCT) transforms healthcare with fast diagnostic results directly at patient care sites like clinics, pharmacies, or homes. It boosts efficiency, accelerates treatment decisions, enhances patient outcomes, and reduces reliance on centralised laboratories. These developments have significantly impacted the healthcare industry by improving accessibility, cost-efficiency, and diagnostic capabilities, especially in resource-limited settings and for critical conditions like tuberculosis, HIV, cancers, etc.

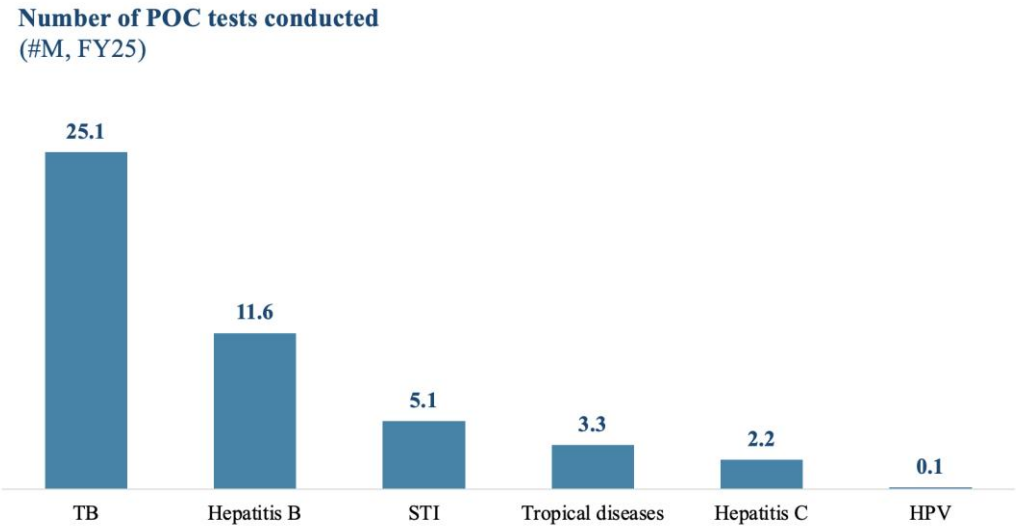
The POCT testing market for infectious diseases in India is an INR 60.5B (US$ 0.7B) market, with ~70.6% of the market share attributed to point-of-care tests for TB and other respiratory diseases.



Source(s): 1Lattice analysis

The Indian POCT market is segmented by various disease types, reflecting its diverse applications. Key segments include respiratory disease diagnostics, comprising TB tests, rapid tests for diseases like dengue and malaria, hepatitis, STI and HPV tests. Each therapy area drives growth by addressing specific healthcare needs and enhancing the accessibility and efficiency of diagnostic solutions across different patient populations.

In India, 25.1M point-of-care tests were conducted for TB in FY25. The list is followed by Hepatitis B (11.6M tests) and tests for STIs such as HIV and Syphilis (5.1M tests). Some of the other tests include tests for tropical diseases (Malaria, Dengue) and Hepatitis C. Although the prevalence of HPV related diseases such as cervical cancer is high in India, its regular screening or monitoring is not very frequent. Less than 2% of the female population susceptible to cervical cancer get screened in India, and 0.1M molecular POC tests are conducted for HPV. HPV screening may be added to the national programs, expected to rapidly push the market for HPV testing in India.

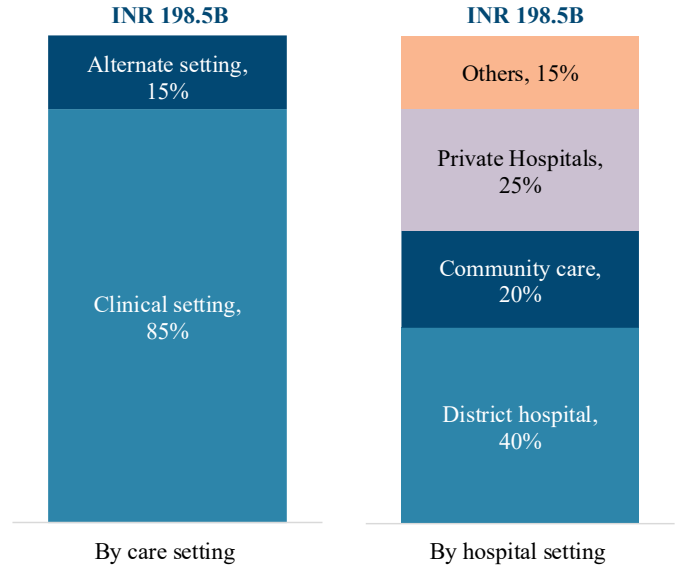


Source(s): India TB report 25, 1Lattice analysis

~85% of these POC tests are based out of clinical settings with HCPs, nurses, or lab technicians performing them.

In different hospital settings, POCT is more prevalent in district hospitals with ~40% share of the market due to their deeper penetration, minimal infrastructure, skilled manpower requirements, faster turnaround time and capacity to manage a broader range of diagnostic tests.
District hospitals have better infrastructure, resources, and trained personnel to operate advanced POCT devices.

Indian molecular POCT market (TAM) by care & hospital setting
(%, FY25)



Source(s):1Lattice analysis

Additionally, these hospitals cater to a higher patient volume and offer specialised services that require immediate and precise diagnostics. This makes POCT a critical tool in their daily operations. Both government district hospitals and community care centres adopt various models for the implementation of POCT, such as:

1. **Community care centres:**
   - **Mobile POCT units:** Mobile POCT units are specialised vehicles equipped with POCT devices that travel to remote or underserved areas, providing essential healthcare services. These units are ideal for screening programs and vaccination drives, ensuring that healthcare reaches populations who have limited access to fixed medical facilities.
   - **Community health workers:** Community Health Workers (CHWs) are trained individuals who carry POCT devices to patients' homes, providing essential healthcare services directly within the community. They are particularly effective in managing chronic diseases, offering antenatal care, and conducting follow-up visits
2. **District hospitals:**
   - **Decentralised labs:** Decentralised POCT stations involve the distribution and utilisation of POCT devices across various hospital departments, including emergency rooms, ICUs, and outpatient departments. These stations enable rapid diagnostics for critical care situations, pre-surgical assessments, and routine outpatient diagnostics.
   - **Centralised labs:** Centralised POCT laboratories are specialised sections within a hospital's main laboratory dedicated to performing POCT. These labs handle high-throughput tests, accommodating a large volume of patients, including those in emergency and inpatient care.

6.4.2. The Indian Molecular POCT equipment market valued at INR 27.8B (US$ 0.3B) is projected to grow at a CAGR of 25.2% between FY25-30 P

The Indian market for molecular POCT equipment is projected to grow drastically, backed primarily by strong government intervention to expand the reach of point-of-care testing to rural areas and PHCs. The market is INR 27.8B (US$ 0.3B) in FY25 and displayed a robust growth of 20.94% in the period spanning FY20-25. Fuelled by the increasing penetration of POCT in India, the market is projected to grow at a CAGR of 25.2% between FY25-30P to reach INR 85.7B (US$ 1.0B) by FY30P.

6.4.3. Cost, skill gaps and limited infrastructure are the key challenges in the adoption of molecular POCT at primary health centres (PHCs)

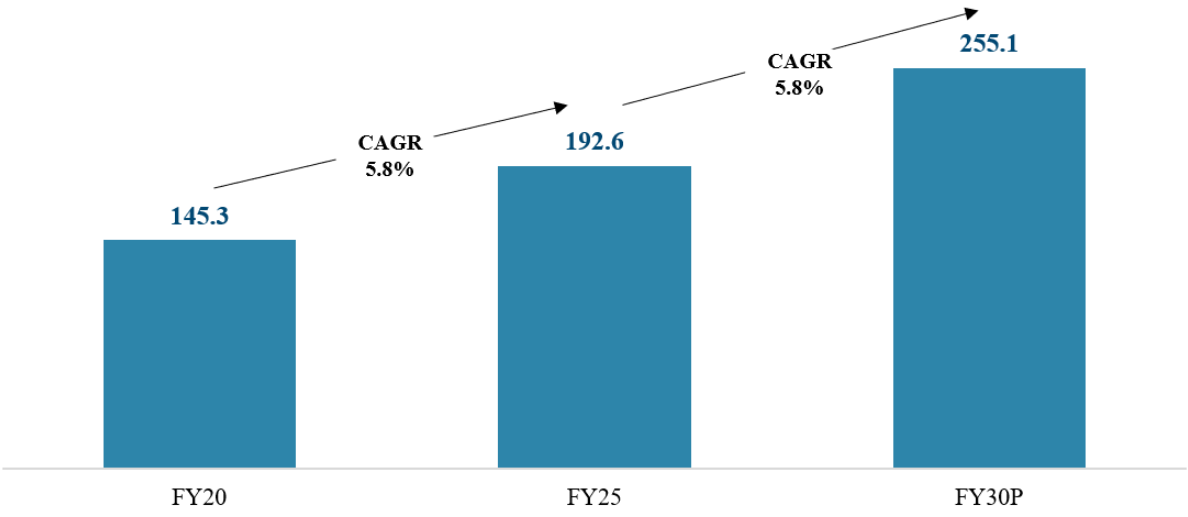
The adoption of molecular point-of-care testing (POCT) by primary healthcare centres is increasing due to its potential for providing rapid, on-site diagnostic results. This advancement enhances patient management and reduces wait

times. However, challenges such as high costs, the need for specialised training, infrastructure limitations, and maintaining quality control hinder widespread implementation. Addressing these obstacles is crucial for optimising the benefits of POCT in primary healthcare settings.

6.5. With over 33,000 PHCs in India, the molecular POCT market has great potential to penetrate public healthcare and increase accessibility to diagnostic services

The government has been actively promoting PHCs as the cornerstone of the public healthcare system in India. This is evident from the increasing expenditure on improving PHC infrastructure, staffing, and medical equipment. It is estimated that the government of India spends INR 192.6B (US$ 2.3B) annually to deliver healthcare facilities across the ~33,000 PHCs operational in India.

Government expenditure on healthcare delivery through PHCs
(INR B, FY20-30P)



Source(s): 1Lattice analysis

PHCs are often the first point of contact for patients suffering from ailments such as TB, Malaria, and Dengue. As part of the government's efforts to enhance the reach of diagnostic services, more PHCs are being equipped with POCT equipment and kits, which offer rapid, cost-effective, and on-the-spot testing. This decentralisation of diagnostics through POCT aligns with the broader goal of improving healthcare access and early disease detection. The adoption of WHO-recommended rapid molecular tests as the initial diagnostic method for tuberculosis is improving. In CY22, ~47% of the patients tested for TB were diagnosed through rapid molecular tests, up from 38% in CY21. However, this is still significantly below the United Nations' global target of 100% by CY27. Currently, there are ~8,300 molecular testing laboratories (CBNAAT & Truenat centres) across India, including ~8,000 PHCs. Private sector adoption remains limited with only ~1,400 healthcare facilities that have molecular diagnostic capabilities today, against an estimated potential install base of ~17,000.

The India TB Report 2024 emphasises the Truenat platform's vital role in enhancing TB control by facilitating decentralised, rapid testing at rural primary healthcare centres, supporting India's National Strategic Plan for TB Elimination. Truenat reduces the need for patient travel, minimises diagnosis delays, and enables swift treatment, cutting down transmission rates. Its broad rollout across thousands of centres showcases high accuracy, particularly in detecting multi-drug-resistant TB, making it integral to managing drug-resistant cases. Additionally, Truenat' s scalability and ability to diagnose multiple infectious diseases increase its versatility, benefiting a wide range of infectious disease control efforts.

6.6. Accuracy and affordability & ease of use are some of the key purchase criteria for organised and unorganised labs respectively

In the Indian molecular diagnostics and point-of-care testing (POCT) market, purchasing criteria differ significantly between organised and unorganised laboratories. Organised laboratories prioritise accuracy, technological advancements, regulatory compliance, and integration capabilities, while also valuing cost-efficiency and comprehensive support. Conversely, unorganised laboratories emphasise affordability, ease of usage, essential functionality, and local support, with a strong focus on quick turnaround times and flexibility.

The emergence of new businesses and industrial consolidation is the latest trend in large, centralised labs. Enhanced surveillance of infectious diseases increases the need for decentralised diagnostics. Currently, the diagnostic

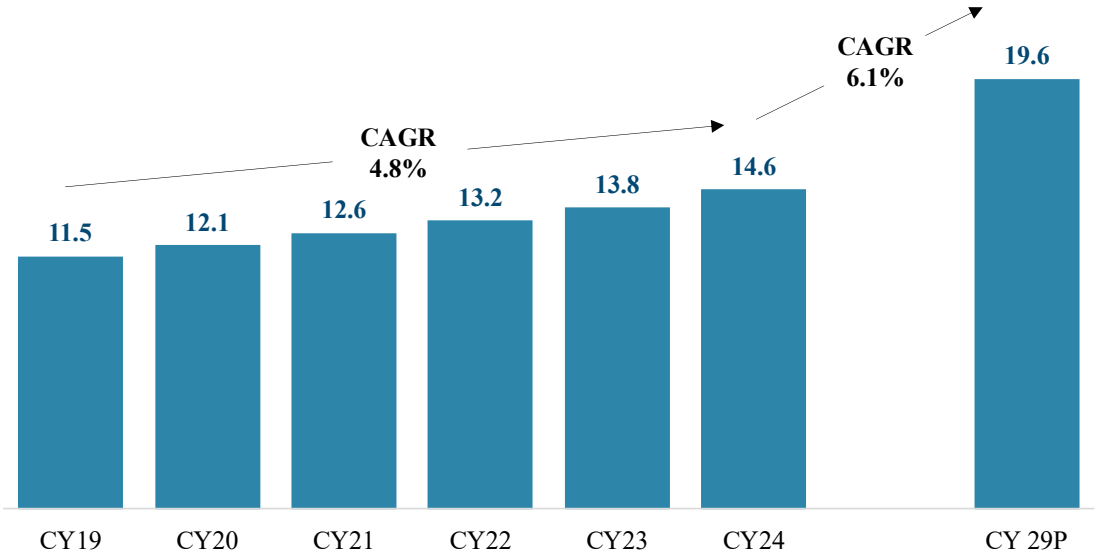
landscape is predominantly centralised, with major tests and analyses conducted in centralised laboratories. However, there is an increasing demand for decentralised diagnostic solutions, driven by the need for faster and more accessible testing options. Decentralised diagnostics provide the benefit of immediate results and can be implemented across a variety of settings, thereby enhancing healthcare delivery, particularly in remote or underserved regions. This shift aligns with the broader trend towards more personalised and efficient patient care.

7. Global and Indian X-ray imaging diagnostics market overview

7.1. The global X-ray imaging market has expanded from US$ 11.5B in CY19 to US$ 14.6B in CY24 and projected to reach US$ 19.6B by CY29 at a CAGR of 6.1%

The radiology market can be broadly divided into two broad categories based on the modality: soft and advanced radiology. Soft radiology includes X-ray and ultrasound modalities, widely used for basic imaging needs. Within the soft radiology segment, the X-ray modality commands the highest market share, due to its wide range of applications, routine medical examinations, and cost-effectiveness. Ultrasound, while also a significant component, primarily serves in areas like obstetrics, gynaecology, and cardiology due to its ability to provide real-time imaging without radiation exposure. On the other hand, advanced radiology encompasses more sophisticated imaging technologies such as CT scans, MRI, nuclear imaging, and interventional radiology procedures. These modalities are typically employed for more detailed and comprehensive diagnostic purposes, allowing for in-depth examination of complex medical conditions. Advanced radiology often requires higher investment in equipment and infrastructure, but it provides critical insights that are pivotal for the diagnosis and treatment of various diseases such as cancer, cardiovascular disease, musculoskeletal conditions, and infectious diseases. The global X-ray imaging market has shown steady growth from CY19 to CY24, advancing from US$ 11.5B in CY19 to US$ 14.6B in CY24, reflecting a CAGR of 4.8%. Looking ahead, the growth of the market is anticipated to expand at a faster rate compared to previous years, driven by the growing prevalence of infectious diseases, technological advancements, and rising demand for early diagnostics procedures. The market is projected to reach US$ 19.6B by CY29P, at a CAGR of 6.1%.

Global X-ray imaging market
(US$ B, CY19-29P)



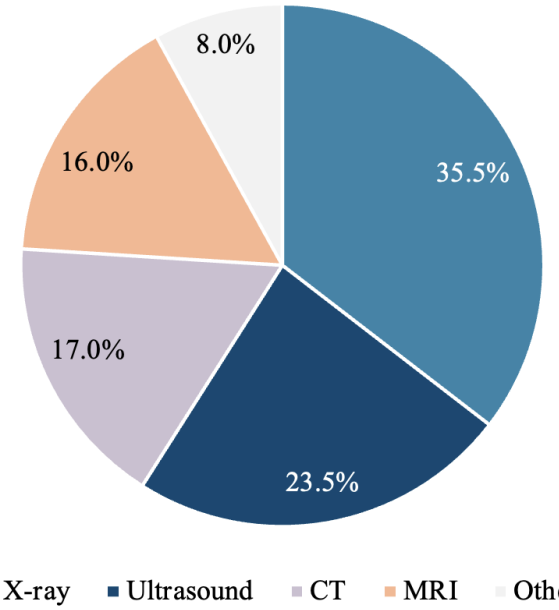
Source(s): 1Lattice analysis

In the global radiology sector, X-ray imaging holds the largest market share at 35%, followed by ultrasound with 24%. CT scans account for 17%, while MRI represents 16% of the market share.

7.1.1. Post-COVID, India saw a sharp rise in the installed base of X-ray machines, propelled by growing diagnostic needs. It grew by 18.3% in FY24 and is projected to grow by 16.6% in FY25P, with increased demand for portable units

The installed base of X-rays in India saw a rapid rise, clocking year-on-year growth rates of 18.3% between FY23-24 and 16.6% between FY24-25P after the COVID-19 pandemic. This was backed by growing demand for imaging diagnostics in the country, which saw the rise and expansion of several standalone and corporate chain diagnostic centres. While the share of fixed and mobile X-ray machines in the market was almost similar (~33%), a noteworthy segment was portable X-rays in the country, with ~1,400 machines as part of the country's installed base in FY25.

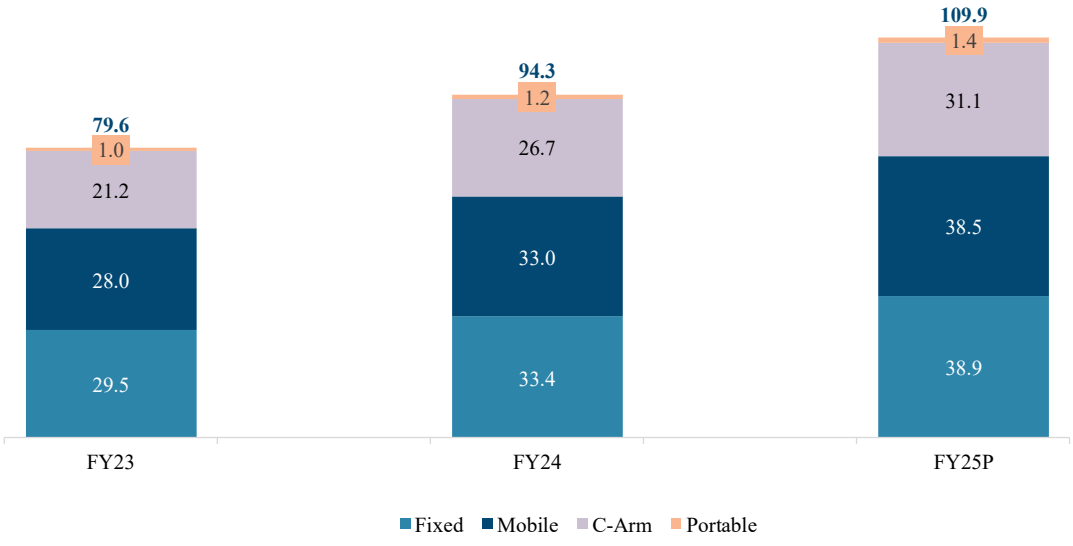
Market share distribution of radiology modalities globally
(%, CY24)



Source(s): 1Lattice analysis

The Indian X-ray market is currently valued at INR 27.6M (US$ 0.3B), following a robust growth rate of 6.1% between FY20 and FY25. The market in India is still expected to grow, catering to the rising demand for chest X-rays as a part of the national TB elimination program. The Indian X-ray market is projected to reach INR 28.8B (US$ 0.3B) by FY30P, growing at a rate of 5% between FY25-30P.

Installed base of X-ray machines in India
(Thousand units, FY23-25P)



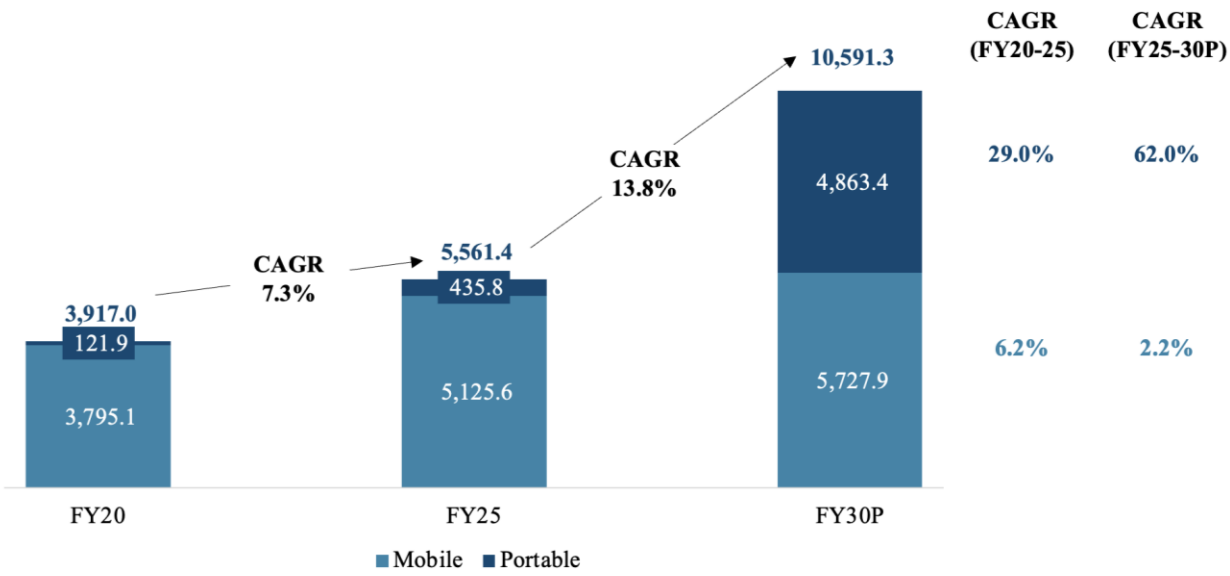
Source(s): AERB database, 1Lattice analysis

7.1.2. Point-of-care imaging represents a paradigm shift in the diagnostic industry, with mobile and handheld X-ray devices improving healthcare access and clinical outcomes

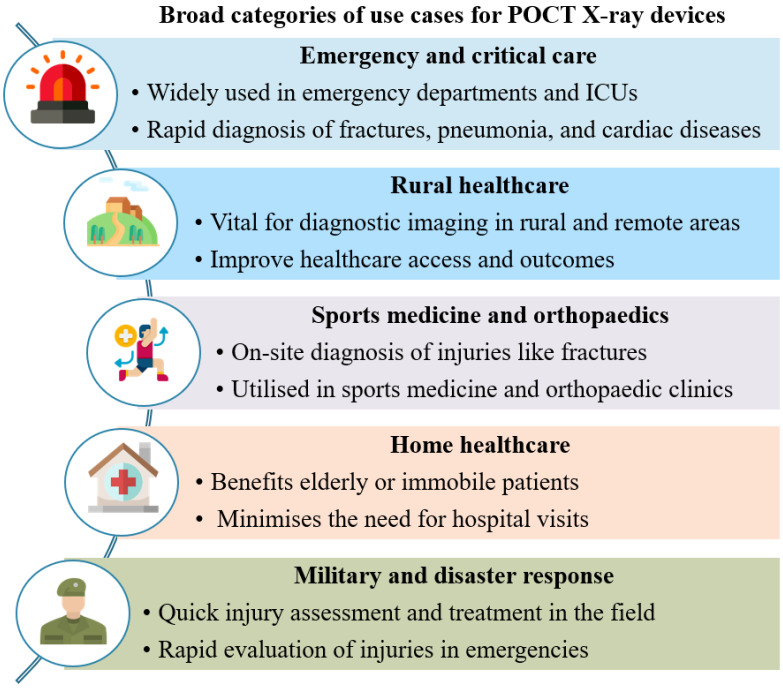
Point-of-care imaging is a transformative approach that brings diagnostic radiology directly to the patients. Mobile X-ray machines are wheeled units that can be moved to different locations, with scans such as chest X-rays, spine X-rays, bone X-rays, etc., performed at the bedside of patients. Portable and ultra-portable X-rays are smaller,

lightweight devices that are battery-operated and can be carried to remote locations or rural homes. Advancement in technology have allowed the miniaturisation of technology to increase its portability and reach.

Point of care X-ray devices market - India
(# units sold annually, FY20-30P)



Source(s): 1Lattice analysis



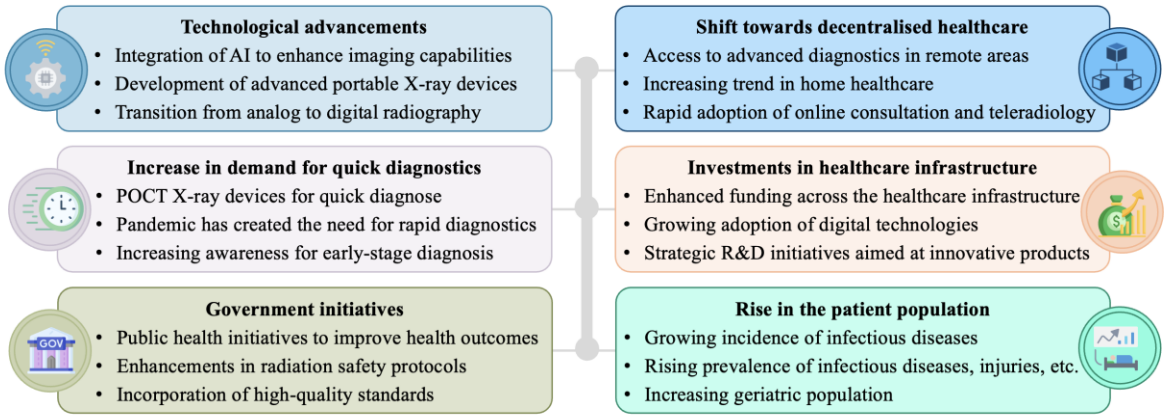
Over ~5,500 point-of-care imaging X-ray devices are estimated to have been added to the Indian point-of-care imaging market in FY25, with mobile X-ray machines dominating the segment. A significant shift is underway with the entry of new players into the ultra-portable, handheld X-ray segment. These devices are rapidly gaining traction, driven by the government's aggressive push for TB elimination. In the initial phase, the government is expected to be the largest purchaser, equipping a large number of PHCs and CHCs with these ultra-portable X-ray machines to complement the existing POCT TB test kits. This development marks a transformative moment in the market, aligning with broader public health initiatives. The Indian government is promoting domestic manufacturers and encouraging industry-academia partnerships to ingeniously produce handheld X-ray machines as a substitute for expensive imported X-ray machines. The portable X-ray market is expected to show a staggering growth of 62.0% CAGR

between FY25-30P, with annual sales expected to reach ~4,900 units in FY30. Over the course of the next five years, i.e., FY25-30, ~7,500 handheld/ultra-portable devices are estimated to be added to the market.

POCT X-ray devices play a critical role in the fight against this persistent threat of TB. These devices allow for quick screening and diagnosis in remote locations where access to conventional X-ray machines is limited. Large populations in high-risk locations can be screened by mobile van units, which helps with early detection and treatment.

7.2. Advancements in technology, growing government investments and a shift towards rapid decentralised healthcare are expected to fuel the growth of the X-ray market in India

Key growth drivers of X-ray imaging diagnostics market

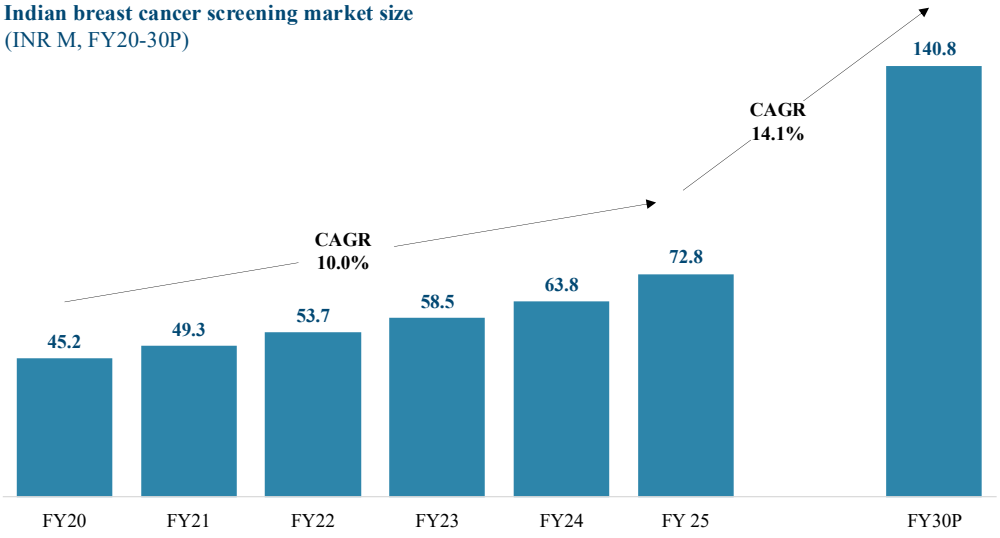


7.3. The global breast cancer screening market was valued at US$ 5.3B in CY24 and is expected to reach US$ 7.9B in CY29P at a CAGR of 8.3%

Breast cancer is the leading cancer in women, occurring frequently and contributing to the high number of cancer incidences and mortality rates. It is equally prevalent in developed and developing countries; however, developed countries record higher incidences because of lifestyle choices, reproductive patterns, and early detection through screening. The overall market for breast cancer screening has been steadily growing around the world, increasing from US$ 3.4B in CY19 to US$ 5.3B in CY24 at a CAGR of 9.6%, it is expected to reach US$ 7.9B by CY29P at a CAGR of 8.3%. Factors contributing to this growth are improved awareness about breast cancer, better visualisation techniques like digital mammography and tomosynthesis, as well as the increase in the incidence of the disease.

7.4. The Indian breast cancer screening market was valued at INR 72.8M (US$ 0.8M) in FY25 and is projected to grow at a CAGR of 14.1% in the next 5 years

Indian breast cancer screening market size
(INR M, FY20-30P)



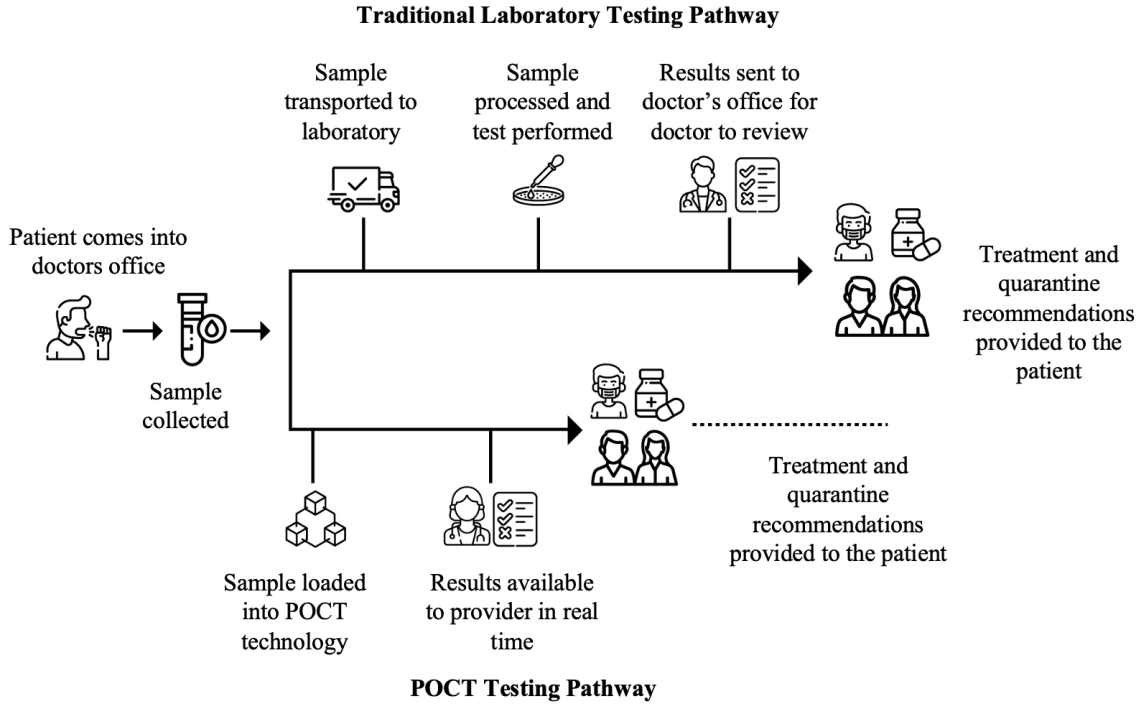
Source(s): 1Lattice analysis

With an estimated annual incidence of 0.2M breast cancer cases in India, the Indian breast cancer screening market is expanding due to increased awareness and advancements in healthcare infrastructure, demanding effective screening methods, including mammograms, ultrasound, and MRI. With growing disposable incomes and healthcare investments, the market is poised for continued growth and improvement in screening services. The Indian breast cancer screening market is valued at INR 72.8M (US$ 0.8M) in FY25 and is expected to grow to INR 140.8M (US$ 1.7M) in FY30P at a rapid CAGR of 14.1% from FY25-30. The market has a growing emphasis on early detection and personalised care, fuelled by the introduction of innovative screening methods such as thermography and IR screening, digital mammography, and educational programs. Companies like Niramai have introduced non-invasive, radiation-free screening options suitable for younger women with dense breast tissue, increasing accessibility across India, particularly in rural areas.

8. Competitive landscape in molecular diagnostics and POCT

Molbio Diagnostics, founded in 2000 along with its R&D arm Bigtec Labs, is recognised for its pioneering innovations. Sriram Natarajan, CEO and Director of Molbio Diagnostics, also co-founded Tulip Diagnostics Private Limited in 1990 and grew it to become one of the largest in-vitro diagnostics reagent companies in India and a significant global player. Building on this legacy of innovation, Molbio developed and commercialised 'Truenat,' a portable battery-operated point-of-care (POC) molecular diagnostics platform using real-time PCR technology for rapid and accurate disease diagnosis. Molbio's 'Truenat' platform for diagnosing TB is the only one by an Indian company and one of the only two rapid molecular tests in the world, which has been endorsed by the World Health Organization ("WHO"), the Indian Council of Medical Research ("ICMR") and the Foundation for Innovative New Diagnostics ("FIND") for an initial diagnosis of TB and rifampicin resistance detection using molecular diagnostic technology. WHO has endorsed Truenat as a complete replacement for smear microscopy, highlighting its superior reliability. This remarkable achievement highlights Molbio's dedication to innovation, with 13 years of R&D to obtain ICMR certification, demonstrating both the company's commitment to excellence and the high barriers to entry in the market.

Figure 1: Comparison of POCT and Traditional Laboratory Pathways



The molecular diagnostic industry is competitive, characterised by extensive R&D and rapid technological changes. Molbio has shifted the paradigm from centralised testing to decentralised molecular diagnostics. Its multi-disease platform, equipped with automated, user-friendly features such as portability, simple workflow, and rapid sample-to-result turnaround time, is designed to perform a wide array of tests swiftly and efficiently with high sensitivity and specificity compared to conventional diagnostic methods. These features address the challenges faced by underserved populations worldwide, including limited access to diagnostic facilities, cost-effective diagnostic solutions, timely detection and treatment of diseases and electricity-dependent laboratory infrastructure.

Continuous assay development and regulatory approvals underscore Molbio's commitment to accessible and advanced diagnostics. Truenat revolutionises molecular diagnostics by bringing PCR technology to the POC. Its battery operation enables functionality in remote settings, with wireless data transfer enhancing global disease management. Truenat decentralises diagnostics by providing reliable, rapid, and cost-effective testing outside traditional labs. Truenat offers greater reliability compared to conventional methods like microscopy and antigen-antibody tests, which take 2 to 7 days. It provides faster results, significantly reducing turnaround times and improving patient outcomes, compared to other PCR platforms. The ability to swiftly assess and diagnose infectious and non-communicable diseases at the POC testing enables immediate evidence-based treatment and mass testing, aiding disease containment.

Truenat can be used in constrained environments with minimal training, making it accessible for diverse healthcare settings. Disease-specific Truenat microchips perform real-time PCR, with sample preparation handled by the Trueprep AUTO device, ensuring early and accurate diagnosis. Truenat offers high sensitivity and specificity compared to conventional diagnostic methods. As a real-time PCR platform, it provides precise and accurate results that have been validated. Its sensitivity and specificity are comparable to those of PCR tests used in advanced laboratories, making it a trusted choice for rapid and reliable diagnostics across diverse healthcare settings.

Truenat is one of the earliest POC PCR platforms that aids in the confirmatory diagnosis of influenza infections and swine flu. Further, the 'Truenat' Nipah virus test chip became the first in India to receive emergency use authorisation from the Drug Controller General of India for diagnosing the Nipah virus. With over 40 validated assays, including TB, hepatitis, dengue, and malaria, Molbio continues to expand its diagnostic suite. During the COVID-19 pandemic, Truenat was crucial in India's efforts to fight the COVID virus and was among the first to be approved by ICMR for testing of COVID.

Molbio's portable, battery-operated platform delivers rapid results, addressing marginalised communities' diagnostic challenges compared to conventional methods requiring 2-7 days. Truenat has reduced the turnaround time for tests and the delivery of results in comparison with traditional testing methods from several days to ~60 minutes. It is cost-effective in both capital expenditure and per-test cost. Truenat platform is cost-effective for healthcare providers on a long-term basis in terms of the initial capital expenditure required for its installation as well as the recurring cost per test. The Treatment Action Group recognised Molbio's collaboration with global partners in reducing Truenat's TB test price from US$ 9 to US$ 7.90, marking the first major price reduction in TB molecular tests in over a decade.

Molbio's portfolio features over 43 infectious disease tests, with 30 micro-PCR tests and 45 additional tests in development for infectious and non-communicable diseases. The global molecular diagnostics market is projected to grow from US$ 18.1B in CY24 to US$ 28.4B by CY29, growing at a CAGR of 9.4 %, positioning Molbio to capitalise on increasing demand. Truenat has the highest market share in installations under India's NTEP (Outside of Designated Microscopy Centres) from 2020-2022, holding a 92% share of incremental installations since 2019.

Molbio's infrastructure-independent design enhances healthcare accessibility and diagnostic capabilities, particularly in remote locations. Truenat mitigates challenges of centralised PCR testing, including high costs, long turnaround times, and complex infrastructure requirements. Unlike conventional PCR systems, which require batch processing and specialised labs, Truenat enables rapid, cost-effective, and decentralised molecular diagnostics, transforming global disease management. Molbio's Truenat is the only platform globally with a battery-operated POC PCR platform for multi-disease testing (for infectious diseases such as TB, Malaria, Nipah virus, HIV, HPV, Swine flu, dengue, malaria etc.). Many players in the molecular diagnostics space may possess greater financial, manufacturing,

Parameters	Current PCR machines (Centralised)	Truenat (Decentralised)
TAT	120 mins	60 mins
Cost	INR 12-15lakhs	INR 6.5-13lakhs
Power source	Primary power source	Battery operated
Temperature	4°C to 99°C	Can work in high temperature
Samples	Batch processing upto 96 tests (require fixed number of samples to start the test)	1/2/4 samples processed simultaneously
Portability	Not portable	Portable, designed for field use
Training	Training is required	User-friendly, minimal training
Maintenance	Proper and routine maintenance	Low maintenance, minimal calibration

R&D, marketing and other resources, they may also have more experience in obtaining regulatory approvals, greater geographic reach, broader product ranges or a stronger sales force. For Molbio, the key competitive factors impacting their success include the accuracy, utility, turnaround time and economics of Molbio's products, and commercial execution

Key threats and challenges faced by the company

Some of the key challenges faced are-

1. **Skilled workforce retention**: The industry relies on highly specialised talent to drive its innovation and regulatory processes. If key personnel leave the company, companies might face delays in product development and regulatory submissions, impacting their competitive position.
2. **Future potential competition:** While there is no significant competitive risk in the industry today, established brands with strong market presence and customer loyalty could pose a potential future threat by introducing advanced POCT solutions.
3. **Higher dependence on public health initiatives:** Current adoption is driven mainly by public health initiatives. If these initiatives are reduced, delayed, or redirected to other healthcare initiatives, they could experience a significant decrease in demand.
4. **Supply chain risks:** Reliance on a global network for sourcing key components of its diagnostic devices. Any disruption, such as the unavailability of specific electronic components or reagents, could lead to production delays.
5. **Requirement of high working capital**: Higher reliance on public health might lead to longer and potential delay in payment cycles, leading to higher working capital.
6. **Slower adoption or penetration:** Despite the advantages of the platform, government bureaucracy and higher time for adoption among private healthcare operators due to factors like high switching costs, lack of awareness, or resistance to switching from existing diagnostic methods. might lead to slower adoption of POCT devices

GLOSSARY OF ABBREVIATIONS USED

S.No.	Abbreviation used	Full form
1	AI	Artificial Intelligence
2	AIDS	Acquired Immunodeficiency Syndrome
3	APAC	Asia Pacific
4	B	Billion
5	BNP	Brain natriuretic peptide
6	BRICS	Brazil, Russia, India, China, South Africa
7	CAGR	Compound Annual Growth Rate
8	CDC	Centres for Disease Control and Prevention
9	CDSCO	Central Drugs Standard Control Organisation
10	CLIA	Clinical Laboratory Improvement Amendments
11	COVID-19	Coronavirus Disease 2019
12	CRISPR	Clustered regularly interspaced short palindromic repeats
13	CT	Computed tomography
14	CY	Calendar Year
15	DALYs	Disability-Adjusted Life Year
16	DMCs	Designated Microscopy Centres
17	DNA	Deoxyribonucleic Acid
18	ECRP-II	Emergency Response & Health System Preparedness Package: Phase-II
19	ELISA	Enzyme-linked Immunosorbent Assay
20	EU	European Union
21	FDI	Foreign Direct Investment
22	FIND	Foundation for Innovative New Diagnostics
23	FY	Financial Year
24	GDP	Gross Domestic Product
25	GI	Gastrointestinal
26	GST	Goods and Services Tax
27	HCPs	Health Care Professionals
28	HCV	Hepatitis C virus
29	HDU	High Dependency Unit
30	HIV	Human Immunodeficiency Viruses
31	HLA	Human leukocyte antigen
32	HPV	Human Papillomavirus
33	ICMR	Indian Council of Medical Research
34	ICU	Intensive Care Unit
35	IMF	International Monetary Fund
36	INAAT	Isothermal Nucleic Acid Amplification Technology
37	INR	Indian Rupee
38	IPHL	Integrated Public Health Laboratory
39	ISH	In Situ Hybridisation
40	IVD	In vitro diagnostics
41	JEET	Joint Effort to Eliminate TB
42	K	Thousand
43	L	Lakh
44	LAMP	Loop-mediated Isothermal Amplification
45	LMICs	Low- and Middle-income countries
46	M	Million
47	MENA	Middle East / North Africa
48	MRI	Magnetic resonance imaging
49	NGOs	Non-governmental Organisation
50	NGS	Next generation sequencing
51	NSP	National Strategic Plan
52	NTEP	National Tuberculosis Elimination Programme
53	PCR	Polymerase Chain Reaction

54	PHCs	Primary Healthcare Centres
55	PM-ABHIM	PM-Ayushman Bharat Health Infrastructure Mission
56	PMJAY	Pradhan Mantri Jan Arogya Yojana
57	PMSSY	Pradhan Mantri Swasthya Suraksha Yojana
58	POC	Point-of-Care
59	POCT	Point-of-Care Testing
60	R&D	Research & Development
61	RDTs	Rapid Diagnostic Tests
62	RNA	Ribonucleic Acid
63	RPA	Recombinase Polymerase Amplification
64	RT-PCR	Real-Time Reverse Transcription – Polymerase Chain
65	SNPs	Single Nucleotide Polymorphisms
66	STDs	Sexually transmitted diseases
67	STIs	Sexually transmitted infections
68	T	Trillion
69	TAM	Total Addressable Market
70	TAT	Turn Around Time
71	TB	Tuberculosis
72	UK	United Kingdom
73	US	United States
74	USAID	United States Agency for International Development
75	WHO	World Health Organisation
76	Y-o-Y	Year-on-Year