

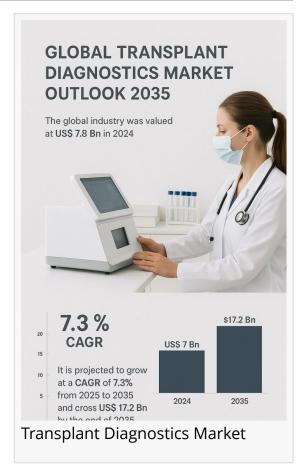
Transplant Diagnostics Market to Reach USD 17.2 Billion by 2035, Expanding at 7.3% CAGR from 2025 | TMR

Transplant Diagnostics Market to reach US\$ 17.2 Bn by 2035, growing at 7.3% CAGR, driven by rising organ transplants and next-gen molecular testing.

WILMINGTON, DE, UNITED STATES, August 25, 2025 /EINPresswire.com/ -- The global transplant diagnostics market is undergoing a period of significant growth and transformation, driven by increasing organ transplant procedures, rapid advancements in molecular and genetic diagnostics, and a growing awareness of the importance of organ donation. Valued at US\$ 7.8 billion in 2024, the industry is projected to expand at a CAGR of 7.3% between 2025 and 2035, surpassing US\$ 17.2 billion by 2035. This robust growth reflects not only the rising demand for transplants but also the medical community's increasing reliance on advanced diagnostic tools to ensure precision and success in transplantation.

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Market Size and Growth

The rising incidence of chronic diseases such as kidney failure, cardiovascular disease, diabetes, and liver disorders has significantly increased the demand for organ transplantation across the globe. With this surge comes a parallel demand for more accurate and efficient diagnostic tools that can ensure donor-recipient compatibility and minimize rejection risks. The market's anticipated growth to over US\$ 17 billion by 2035 is strongly tied to these demographic and clinical trends.

Technological innovation is playing a key role in driving growth. Advancements in next-

generation sequencing (NGS), molecular assays, and non-invasive cfDNA testing are improving the precision and predictive power of diagnostics. Moreover, the integration of artificial intelligence and machine learning into diagnostic workflows is enabling faster and more accurate data analysis, ultimately contributing to improved patient outcomes. The expansion of healthcare infrastructure in emerging economies and favorable reimbursement policies in developed markets are expected to further accelerate the market trajectory.

Market Segmentation

The transplant diagnostics market can be segmented by product type, technology, application, and end-user.

By product and service, kits and reagents dominate the market due to their indispensable role in donor-recipient compatibility testing. Their growing demand stems from the increasing number of transplant procedures globally, alongside the need for rapid and reliable testing solutions in clinical settings.

By technology, molecular assays hold the largest share, primarily due to their ability to deliver highly sensitive and specific results. Techniques such as PCR and NGS are widely adopted for HLA typing, infectious disease testing, and post-transplant monitoring. The growing application of molecular profiling in personalized medicine is likely to keep this segment at the forefront.

By application, the market serves both solid organ and stem cell transplantation. With rising kidney, liver, and heart transplants worldwide, the solid organ segment remains dominant.

By end-user, hospitals and transplant centers constitute the largest share due to their direct involvement in transplantation procedures, while research laboratories and academic institutes also play a significant role in advancing diagnostic methodologies.

Regional Analysis

North America leads the global market, accounting for the highest share in 2024, largely owing to its robust healthcare infrastructure, high research and development spending, and strong presence of key industry players. The United States remains the single largest market, driven by advanced medical technologies, a large patient pool requiring transplants, and supportive government initiatives. Additionally, stringent regulatory standards in the U.S. drive continuous innovation and quality improvements in diagnostic tools.

Europe is another major region, where countries such as Germany, France, and the U.K. are investing heavily in healthcare innovation and organ transplant programs. Supportive legislation on organ donation and collaborative networks between hospitals are further strengthening market growth.

Asia-Pacific is projected to record the fastest growth through 2035, supported by expanding

healthcare infrastructure, rising awareness of organ donation, and increasing incidence of chronic diseases. Countries like India, China, and South Korea are witnessing a steady rise in transplant programs, with governments investing in capacity-building and public health initiatives.

Latin America and the Middle East & Africa are also emerging as significant contributors, largely driven by gradual improvements in healthcare systems, rising awareness, and increasing collaborations with global diagnostic firms.

Market Drivers and Challenges

Rising Incidence of Organ Transplants

The most critical driver of this market is the consistent rise in the number of organ transplant procedures worldwide. In the U.S. alone, the Organ Procurement and Transplantation Network (OPTN) reported 48,149 transplants in 2024, marking a steady increase over previous years. Similar upward trends are being recorded globally, necessitating efficient diagnostic solutions for compatibility testing, donor screening, and post-transplant monitoring. Increasing Awareness and Acceptance of Organ Donation

Awareness campaigns by healthcare institutions, governments, and non-profits are breaking myths and encouraging more people to sign up as organ donors. The growing pool of donors is driving demand for advanced diagnostics to ensure successful transplantation outcomes. Digital platforms and social media have further amplified these awareness campaigns, reaching broader audiences and encouraging societal acceptance of organ donation.

Challenges

Despite strong growth drivers, the industry faces challenges such as high testing costs, regulatory hurdles, and the complexity of reimbursement structures in certain regions. Additionally, limited access to advanced diagnostic tools in low- and middle-income countries remains a barrier, though partnerships and investments are beginning to address this gap.

Market Trends

Several transformative trends are shaping the future of transplant diagnostics. Next-generation sequencing is becoming the gold standard for high-resolution HLA typing, while cfDNA testing is emerging as a non-invasive method for detecting early signs of organ rejection. The adoption of AI and machine learning in diagnostics is improving workflow efficiency and predictive accuracy.

Another important trend is the growing emphasis on personalized medicine, where genomic and biomarker-based diagnostics are tailoring treatment strategies to individual patients.

Additionally, mergers and acquisitions among leading players are consolidating expertise and

expanding access to new technologies, particularly in emerging economies.

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Competitive Landscape

The transplant diagnostics market is moderately consolidated, with several global players driving innovation through continuous R&D investments and strategic collaborations. Key companies include:

- Abbott
- Bio-Rad Laboratories, Inc.
- QIAGEN N.V.
- F. Hoffmann-La Roche Ltd.
- Thermo Fisher Scientific, Inc.
- Illumina, Inc.
- · Siemens Healthineers
- Agilent Technologies, Inc.

These players are competing on the basis of product innovation, technological integration, global expansion, and collaborations with healthcare institutions. Expanding into developing markets remains a key growth strategy, as rising transplant volumes in these regions present lucrative opportunities.

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