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Precision Oncology Diagnostics Market Forecasts to 2034 – Global Analysis By Product Type (Companion Diagnostics, Comprehensive Genomic Profiling (CGP), Liquid Biopsy Assays, Single Biomarker Tests, Molecular Diagnostic Tests, Next-Generation Sequencing (NGS)-Based Tests, and Other Product Types), Technology, Biomarker Type, Sample Type, Cancer Type, End User and By Geography

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Abstracts

According to Stratistics MRC, the Global Precision Oncology Diagnostics Market is accounted for $8.3 billion in 2026 and is expected to reach $28.6 billion by 2034, growing at a CAGR of 16.7% during the forecast period. Precision Oncology Diagnostics encompasses advanced molecular and genomic testing technologies designed to characterize individual tumor biology at the genetic, proteomic, and epigenetic levels, enabling oncologists to select therapies with the highest probability of clinical efficacy for each patient. This discipline integrates next-generation sequencing, liquid biopsy, companion diagnostics, and AI-powered bioinformatics to deliver comprehensive tumor profiling and biomarker identification.

Market Dynamics:

Driver:

Surge in oncology drug approvals tied to companion diagnostic requirements

Regulatory agencies including the FDA and EMA have increasingly mandated

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companion diagnostic co-development and co-approval as a condition for targeted therapy market authorization, creating a structural link between drug launches and diagnostic adoption. As the pipeline of biomarker-driven oncology therapies expands across indications including non-small cell lung cancer, breast cancer, and hematologic malignancies, the demand for validated companion diagnostic assays grows proportionally. This regulatory architecture ensures sustained diagnostic market expansion as each approved targeted therapy generates a corresponding requirement for validated patient selection testing before treatment initiation.

Restraint:

High test costs and limited access in resource-constrained healthcare systems

Comprehensive genomic profiling and NGS-based precision diagnostics carry significant per-test costs that frequently exceed reimbursement thresholds, particularly in lower-middle income countries and payer systems applying conservative coverage criteria. The specialized infrastructure, trained laboratory personnel, and bioinformatics expertise required for molecular oncology testing place additional barriers on adoption outside major academic medical centers. Turnaround times for complex genomic analyses can delay time-sensitive treatment decisions. These access inequities mean that precision oncology benefits remain disproportionately concentrated among patients in well-resourced health systems, limiting the market's full growth potential.

Opportunity:

Liquid biopsy commercialization and multi-cancer early detection programs

Liquid biopsy technologies enabling minimally invasive detection of circulating tumor DNA, RNA, and proteins represent a transformative commercial opportunity, allowing real-time tumor monitoring, therapy response assessment, and treatment resistance detection without repeated tissue sampling. The emergence of multi-cancer early detection panels capable of identifying signal across dozens of cancer types from a single blood draw is creating an entirely new screening market segment. As clinical validation data matures and reimbursement pathways for liquid biopsy indications expand, these platforms are positioned to generate substantial revenue growth while fundamentally reshaping how cancers are detected and managed.

Threat:

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Bioinformatics interpretation complexity and variant classification uncertainty

The clinical utility of NGS-based oncology diagnostics is contingent upon accurate bioinformatics analysis and variant classification a domain characterized by significant interlaboratory variability and evolving scientific consensus. Variants of uncertain significance generate clinical ambiguity that complicates treatment decision-making and can undermine clinician confidence in molecular testing results. The rapid proliferation of genetic variants discovered through expanding genomic databases requires continuous updates to interpretation algorithms and clinical guidelines. Failure to maintain analytical accuracy and transparent reporting standards exposes diagnostic providers to regulatory scrutiny and limits the uptake of comprehensive genomic profiling in routine oncology practice.

Covid-19 Impact:

The COVID-19 pandemic temporarily disrupted precision oncology diagnostics through laboratory closures, oncology care deferrals, and reallocation of molecular testing capacity toward infectious disease applications. However, the crisis accelerated laboratory digitalization and remote pathology capabilities while highlighting the efficiency advantages of liquid biopsy for patients hesitant to visit medical facilities. Post-pandemic recovery has been robust, with oncology programs prioritizing backlog clearance and increasing investment in scalable molecular diagnostic platforms. The pandemic ultimately reinforced the strategic value of integrated precision diagnostics within oncology care pathways.

The Companion Diagnostics segment is expected to be the largest during the forecast period

The companion diagnostics segment is expected to account for the largest market share during the forecast period, driven by regulatory mandates linking targeted therapy approvals to validated patient selection assays across major oncology indications. Companion diagnostics for established blockbuster therapies in breast, lung, and colorectal cancer continue to generate substantial recurring test volumes within oncology clinical workflows. The expanding targeted therapy pipeline ensures continuous new companion diagnostic development opportunities, sustaining this segment's market leadership through increasing biomarker-stratified drug approvals over the forecast period.

The Liquid Biopsy Assays segment is expected to have the highest CAGR during the

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forecast period

Over the forecast period, the Liquid Biopsy Assays segment is predicted to witness the highest growth rate, reflecting accelerating clinical adoption driven by expanding reimbursement approvals, compelling clinical utility data, and significant ongoing investment in platform sensitivity improvements. The ability to monitor treatment response, detect minimal residual disease, and identify emerging resistance mutations through serial blood sampling represents a paradigm shift in cancer management. Regulatory approvals for new liquid biopsy indications across therapy monitoring, early detection, and recurrence surveillance are expanding the addressable market considerably.

Region with largest share:

During the forecast period, the North America region is expected to hold the largest market share, driven by high per-capita cancer incidence, strong insurance coverage for molecular diagnostic testing, and a dense ecosystem of genomics companies, academic cancer centers, and biopharmaceutical developers pursuing companion diagnostic partnerships. The United States leads globally in approved companion diagnostic assays and comprehensive genomic profiling adoption, supported by Medicare coverage policies that have progressively expanded molecular testing reimbursement for advanced cancer patients.

Region with highest CAGR:

Over the forecast period, the Asia Pacific region is anticipated to exhibit the highest CAGR, propelled by rapidly expanding cancer incidence, growing patient awareness, and government investments in genomic medicine infrastructure across China, India, Japan, and South Korea. National cancer genome projects and precision medicine initiatives are building molecular diagnostic capabilities while increasing clinician familiarity with biomarker-driven treatment selection. Decreasing NGS sequencing costs and the establishment of local genomics service providers are democratizing access to comprehensive tumor profiling across the region's diverse healthcare markets.

Key players in the market

Some of the key players in Precision Oncology Diagnostics Market include F. Hoffmann-La Roche Ltd, Illumina, Inc., Thermo Fisher Scientific Inc., QIAGEN N.V., Guardant Health, Inc., Agilent Technologies, Inc., Myriad Genetics, Inc., Exact Sciences

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Corporation, Bio-Rad Laboratories, Inc., Tempus AI, Inc., Caris Life Sciences, Natera, Inc., SOPHIA GENETICS SA, bioM?rieux SA, and Abbott Laboratories.

Key Developments:

In March 2026, Guardant Health received FDA approval for an expanded indication of its liquid biopsy platform for therapy selection in advanced colorectal cancer, enabling comprehensive genomic profiling from a standard blood draw and significantly broadening reimbursement access for patients ineligible for repeat tissue biopsy.

In February 2026, Illumina announced a collaboration with a leading biopharmaceutical company to co-develop a next-generation NGS-based companion diagnostic panel for a novel pan-tumor targeted therapy, advancing an integrated precision oncology approach linking biomarker testing directly to matched treatment selection at diagnosis.

Product Types Covered:

- Companion Diagnostics
- Comprehensive Genomic Profiling (CGP)
- Liquid Biopsy Assays
- Single Biomarker Tests
- Molecular Diagnostic Tests
- Next-Generation Sequencing (NGS)-Based Tests
- Other Product Types

Technologies Covered:

- Next-Generation Sequencing (NGS)
- Polymerase Chain Reaction (PCR)
- Immunohistochemistry (IHC)

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In Situ Hybridization (ISH)

Microarray Technology

Mass Spectrometry

Artificial Intelligence & Bioinformatics

Biomarker Types Covered:

Genetic Biomarkers

Protein Biomarkers

Epigenetic Biomarkers

Metabolomic Biomarkers

Multi-Omics Biomarkers

Sample Types Covered:

Tissue Biopsy

Liquid Biopsy

Blood Samples

Urine Samples

Saliva Samples

Other Sample Types

Cancer Types Covered:

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- Breast Cancer
- Lung Cancer
- Colorectal Cancer
- Prostate Cancer
- Cervical Cancer
- Hematologic Cancers
- Ovarian Cancer
- Pancreatic Cancer

End Users Covered:

- Hospitals
- Diagnostic Laboratories
- Cancer Research Institutes
- Academic & Research Centers
- Pharmaceutical & Biotechnology Companies
- Specialty Clinics
- Other End Users

Regions Covered:

- North America
- United States

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Canada

Mexico

Europe

United Kingdom

Germany

France

Italy

Spain

Netherlands

Belgium

Sweden

Switzerland

Poland

Rest of Europe

Asia Pacific

China

Japan

India

South Korea

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Indonesia

Thailand

Malaysia

Singapore

Vietnam

Rest of Asia Pacific

South America

Brazil

Argentina

Colombia

Chile

Peru

Rest of South America

Rest of the World (RoW)

Middle East

Saudi Arabia

United Arab Emirates

Qatar

Israel

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- Rest of Middle East
- Africa
  - South Africa
  - Egypt
  - Morocco
  - Rest of Africa

What our report offers:

- Market share assessments for the regional and country-level segments
- Strategic recommendations for the new entrants
- Covers Market data for the years 2023, 2024, 2025, 2026, 2027, 2028, 2030, 2032 and 2034
- Market Trends (Drivers, Constraints, Opportunities, Threats, Challenges, Investment Opportunities, and recommendations)
- Strategic recommendations in key business segments based on the market estimations
- Competitive landscaping mapping the key common trends
- Company profiling with detailed strategies, financials, and recent developments
- Supply chain trends mapping the latest technological advancements

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Comprehensive profiling of additional market players (up to 3)

SWOT Analysis of key players (up to 3)

Regional Segmentation

Market estimations, Forecasts and CAGR of any prominent country as per the client's interest (Note: Depends on feasibility check)

Competitive Benchmarking

Benchmarking of key players based on product portfolio, geographical presence, and strategic alliances

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Note: Tables for North America, Europe, APAC, South America, and Rest of the World (RoW) are also represented in the same manner as above.

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