Companion Diagnostics - Market Share Analysis, Industry Trends & Statistics, Growth Forecasts (2025 - 2030)

Market Report | 2025-09-01 | 120 pages | Mordor Intelligence

AVAILABLE LICENSES:

- Single User License $4750.00
- Team License (1-7 Users) $5250.00
- Site License $6500.00
- Corporate License $8750.00

Report description:

Companion Diagnostics Market Analysis

The market size is valued at USD 8.70 billion in 2025 and is forecast to expand to USD 15.62 billion by 2030, reflecting a 12.42 % CAGR. Companion diagnostics integrate molecular testing with targeted therapeutics, aligning diagnostic information with optimal therapy choices. The widening application of precision medicine is simultaneously shifting investment priorities for drug makers and reshaping payer reimbursement models as policy makers recognize diagnostics as pivotal cost-containment tools.

Global Companion Diagnostics Market Trends and Insights

Companion Diagnostics Market Trends & Insights Rapid Adoption of Liquid-Biopsy CDx in Oncology Practices

Liquid biopsy companion diagnostics are redefining cancer management by providing a minimally invasive route for repeat testing that captures tumor heterogeneity in real time. Clinicians now track disease evolution through circulating tumor DNA, dynamically adjusting therapy rather than relying on static tissue snapshots. A second-order implication is that hospital laboratories must recalibrate throughput and cold-chain logistics to accommodate larger volumes of blood-based assays, affecting capital-allocation timelines across the entire oncology service line. FoundationOne Liquid CDx, granted multiple FDA approvals in 2024, illustrates the regulatory momentum that is quickening market uptake . Yet liquid biopsy sensitivity still varies by cancer stage and by tumor shedding biology, meaning providers are pressured to adopt hybrid tissue-plus-blood strategies that preserve diagnostic accuracy while controlling test redundancy.

Advancements in Personalized Medicine and Precision Oncology

Companion diagnostics have moved beyond optional add-ons; they are codified prerequisites for access to many targeted drugs. The FDA lists 168 biomarker-drug pairings linked to approved tests, signaling that reimbursement agencies will progressively withhold payment for therapy courses lacking molecular confirmation. This linkage is steering pharmaceutical companies to co-develop tests earlier in Phase I trials, compressing total program timelines but increasing preclinical complexity. An immediate knock-on effect is that contract research organizations (CROs) are expanding biomarker-validation benches to secure multi-year strategic outsourcing contracts, positioning themselves as de-facto molecular gatekeepers for biopharma pipelines.

High Development Costs

Developing a companion diagnostic can require USD 50-100 million and 3-5 years, framing diagnostics as long-cycle capital projects. Smaller firms increasingly tie their fortunes to big-pharma alliances, trading equity stakes for developmental funding. The second-order consequence is a consolidation of intellectual-property portfolios: as large companies absorb device rights, freedom-to-operate for newcomers narrows. This tightening IP landscape nudges venture investors to favor platform companies with expandable assay menus rather than single-marker concepts, subtly migrating venture dollars away from niche biomarkers toward scalable informatics-driven solutions.

Other drivers and restraints analyzed in the detailed report include:

Technological Innovations in Diagnostic Tools / Growing Prevalence of Chronic Diseases / Stringent Regulatory Policies /

For complete list of drivers and restraints, kindly check the Table Of Contents.

Segment Analysis

PCR still owns the largest 2024 slice at 22.2 % market share, yet NGS is expected to outpace all other technologies. NGS market size in companion diagnostics is forecast to outpace PCR-based alternatives, expanding at 14.3% CAGR between 2025-2030. Hospital procurement committees increasingly run total-cost-of-ownership analyses that reveal high sample throughput offsets higher NGS consumable costs over a three-year amortization window. Consequently, instrument vendors now bundle analytics software into reagent contracts, an arrangement that shifts revenue recognition from one-time hardware sales to recurring service streams-reshaping quarterly earnings visibility.

Melanoma companion diagnostics will capture a market share acceleration to 13.6% CAGR through 2030 as immunotherapy combinations proliferate. The downstream impact is that dermatology clinics must coordinate closely with molecular labs to ensure rapid reflex testing, effectively blending two historically separate clinical silos. This integration forces electronic medical record vendors to adapt order-entry modules to accommodate reflex molecular panels, an IT adjustment that, although minor on the surface, represents a notable administrative investment across health systems.

The Companion Diagnostics Market Report Segments the Industry Into Technology (Immunohistochemistry, Polymerase Chain Reaction, and More), Indication (Lung Cancer, Breast Cancer, and More), Product Type (Assays and Kits, and Instruments and Analyzers, and More), Sample Type (Tissue Biopsy, Liquid Biopsy, and More), End-User (Pharmaceutical and Biotechnology Companies, Contract Research Organizations (CROs), and More), and Geography

Geography Analysis

North America holds 40.4% market share in 2024. UnitedHealthcare's policy to cover FDA-approved companion diagnostics when matched with the corresponding drug signals payer endorsement that directly influences adoption velocity. An inferred outcome is that private insurers outside the UnitedHealthcare umbrella may emulate the policy to remain competitive, leading to a cascade that can stabilize test reimbursement rates industry-wide.

Asia-Pacific is projected to log a 12.7% CAGR from 2025-2030. Japan's government-supported cancer genome profiling (CGP) program forecasts a 54 billion-yen CGP market by 2035, prompting domestic labs to scale sequencing capacity. This governmental commitment sets a precedent that neighboring countries may replicate, harmonizing regulatory expectations and spurring cross-border clinical-trial enrollment that accelerates data accumulation in under-studied Asian populations.

Europe's In Vitro Diagnostic Regulation environment is prompting companies to reexamine launch strategies. The limited capacity of notified bodies amplifies time-to-market risk, causing diagnostic firms to consider centralized testing models as interim solutions. Such centralization may inadvertently strengthen select reference laboratories, creating a quasi-oligopoly that could sway pricing dynamics once test volumes peak.

List of Companies Covered in this Report:

Abbott Laboratories / Agilent Technologies / Roche / bioMerieux / QIAGEN / Siemens Healthineers / Thermo Fisher Scientific / Danaher Corp. (Beckman Coulter) / Illumina / Myriad Genetics / Guardant Health / Sysmex Corp. / Abnova Corp. / BioGenex / Tempus Labs Inc. / Foundation Medicine Inc. / Exact Sciences Corp. / PerkinElmer / Invivoscribe Inc. /

Additional Benefits:

The market estimate (ME) sheet in Excel format /
3 months of analyst support /

Table of Contents:

Companion Diagnostics - Market Share Analysis, Industry Trends & Statistics, Growth Forecasts (2025 - 2030)

Market Report | 2025-09-01 | 120 pages | Mordor Intelligence

To place an Order with Scotts International:

- - Print this form
- - Complete the relevant blank fields and sign
- - Send as a scanned email to support@scotts-international.com

ORDER FORM:

Select license	License	Price
	Single User License	$4750.00
	Team License (1-7 Users)	$5250.00
	Site License	$6500.00
	Corporate License	$8750.00
	VAT	
	Total	

*Please circle the relevant license option. For any questions please contact support@scotts-international.com or 0048 603 394 346.

** VAT will be added at 23% for Polish based companies, individuals and EU based companies who are unable to provide a valid EU Vat Numbers.

Email*		Phone*	
First Name*		Last Name*	
Job title*			
Company Name*		EU Vat / Tax ID / NIP number*	
Address*		City*	
Zip Code*		Country*	
		Date	2026-03-02
		Signature