

Company

Guardant Health

Drug or Device Name

Guardant360 CDx

Category

Medical Technology

Compound/Technical Name

Guardant360® CDx

Trade Name

Guardant360® CDx

Date of Approval

08/07/2020

Therapeutic Categories

Oncology, companion diagnostic, comprehensive genomic profiling

Indications

Guardant360® is a blood test for comprehensive genomic profiling (CGP) of advanced cancer patients across all solid tumors. With a simple blood draw, this test enables healthcare providers to match patients with the right targeted therapy, which can significantly extend survival.¹⁻⁷ In August 2020, Guardant360 CDx became the first comprehensive liquid biopsy test to receive approval by the U.S. Food and Drug Administration.⁸ That same day, the test received FDA approval as a companion diagnostic to identify patients with non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) alterations who may benefit from treatment with TAGRISSO® (Osimertinib).⁹ In May 2021, Guardant360 CDx became the first and only FDA approved companion diagnostic for use in patients with advanced NSCLC with EGFR Exon 20 insert mutation who may benefit from RYBREVENT (amivantamab-vmjw)¹⁰ and for use in advanced NSCLC patients who harbor the KRAS G12C mutation who may benefit from LUMAKRAS™ (sotorasib).¹¹ This year, it is estimated that there will be about 1.9 million new cancer cases diagnosed and 609,360 cancer deaths in the United States. This equates to about 1,670 deaths a day.¹² The Guardant360 blood test is being used to successfully enable more patients with advanced cancer to get appropriate therapy more quickly.¹³ Guardant Health's tests are used by oncologists around the world to guide treatment decisions across solid tumor cancers, and by pharmaceutical companies and academic researchers in clinical trials to accelerate precision medicine drug development.

Background

Guardant360 offers advanced cancer patients and clinicians a simple, faster blood test to help inform personalized treatment options. Guardant360, provides guideline-recommended genomic results in 7

days in a fully annotated report, to facilitate rapid clinical decision making.^{1,2} Predictive biomarkers historically measured through tissue-based molecular testing, analyze the changes present in a patient's tumor. Knowing these alterations enables doctors to match patients with the right precision medicine, which in turn can significantly extend patient survival compared to chemotherapy alone.³⁻⁹ However, due to the systemic challenges of tissue biopsies, which are invasive, have a high failure rate and often have long turnaround times, many patients today are not receiving complete biomarker results before starting treatment. Consequently, chemotherapy or immunotherapy are frequently prescribed, despite many clinical studies indicating that biomarker-positive patients who receive the appropriate targeted therapy have greater progression-free survival rates and higher overall response rates.¹⁰⁻¹⁶ The Guardant360 blood test for comprehensive genomic profiling overcomes many of the challenges of tissue biomarker testing, thereby helping to speed time to results, increase the percentage of patients who are successfully and comprehensively genotyped and help widen adoption of comprehensive testing. Additionally, research indicates that patients have a better experience with liquid biopsy over surgical, tissue biopsy.¹⁷ Our assays use many innovative technologies, including biochemistry and artificial intelligence to simultaneously detect mutations in a broad panel of clinically relevant solid tumor genes. Real-time notifications are sent when results are ready, so that providers can quickly see the report with matched therapy or clinical trial insights. Leading with blood testing circumvents the unpredictable and lengthy process of tissue testing, providing a minimally invasive, swift, accurate, and repeatable alternative. As precision medicine continues to advance the practice of oncology, the Guardant360 blood test is quickly becoming the new standard of care for patients with advanced cancer.

Development

Guardant Health was founded in 2012 with the mission to help transform cancer care through the development of blood tests that can guard patients against cancer. First, the company addressed the stages of cancer where patients are most in need – those suffering from advanced cancer. In 2020, Guardant360 CDx was the first U.S. FDA approved blood test for comprehensive genomic profiling across all solid cancers. FDA approval was based on clinical and analytical validation data from over 5,000 samples. In a retrospective analysis of data from pivotal phase III clinical trials, FLAURA and AURA3, non-small cell lung cancer patients identified for treatment with TAGRISSO (osimertinib) using Guardant360 demonstrated progression-free survival rates consistent with those identified using traditional tissue-based biomarker testing. Guardant360® is a qualitative next generation sequencing-based in vitro diagnostic device that uses targeted high throughput hybridization-based capture technology for detection of single nucleotide variants (SNVs), insertions and deletions (indels) in 55 genes, copy number amplifications (CNAs) in two (2) genes, and fusions in four (4) genes. Guardant360 utilizes circulating cell-free DNA (cfDNA) from plasma of peripheral whole blood collected in Streck Cell-Free DNA Blood Collection Tubes. The test leverages the company's digital sequencing platform, providing high-fidelity tumor sequencing data at the single-molecule level. It combines cutting-edge technologies like biochemistry, next-generation sequencing, and machine learning. The platform detects all four classes of genomic alterations and microsatellite instability at sensitivity levels that detect ultra-low variant frequency mutation in low volume samples.

Innovation

For patients diagnosed with late-stage cancer, the longer treatment is delayed, the poorer the prognosis,¹⁻⁴ yet capturing a comprehensive picture of the disease early is essential for determining the most appropriate first-line treatment. Targeted cancer therapies are prolonging patient survival times and improving quality of life¹ and outcomes which are facilitated by tumor mutation profiling.²

Because cancer genomes are complex, comprehensive genomic profiling (CGP) offers the greatest insight into optimal treatment.⁵ In a 2020 study published in *Cancers (Basel)*⁶, “CGP identified at least one potentially clinically actionable genomic alteration in 95% of all patients tested.” It is critical that patients are both tested and then treated based on CGP results. The easiest, most expedient way to ensure patients receive tumor genotyping is with blood testing like Guardant360 CDx. The ability to identify tumor mutations in a minimally-invasive, swift, accurate, cost-effective, and repeatable way has a significantly favorable impact on both patients and providers. Adopting liquid biopsy as a standard of care is highly appealing to oncologists for all the rational reasons—ease of use, lower cost, and rapid results—but perhaps most convincing for healthcare providers is the superiority in detection.⁷ Finding more patients with oncogenic drivers ultimately leads to improved patient care and more favorable outcomes.⁸⁻¹³ Since being introduced as a laboratory developed test in 2014, the Guardant360 liquid biopsy LDT has become widely accepted for blood-based CGP with more than 250 peer-reviewed publications. It has been used by more than 11,000 oncologists, and more than 250,000 tests have been performed to date.¹⁴

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Attachments

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- 1655771323Prix_Galien_USA_References.pdf
- 1655771514Prix_Galien_USA_References.pdf
- 1655771157Prix_Galien_USA_References.pdf
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