CORPORATE BACKGROUNDER

LIQUID BIOPSY IS AT THE CORE OF OUR MISSION TO CONQUER CANCER WITH DATA

Guardant Health is a leading precision oncology company dedicated to helping conquer cancer globally through the use of our proprietary blood tests, vast data sets and advanced analytics.

A company uniquely positioned to help patients across the entire cancer care continuum

At Guardant Health, we believe blood-based testing can transform cancer care by unlocking insights that will help patients at all stages of the disease. We’ve made great strides in early-stage and advanced cancer, and we now offer a screening test to detect cancer early, when patient survival rates can be impacted most. We are committed to helping patients across the cancer care continuum live longer, healthier lives.

Guardant Reveal™ liquid biopsy enables residual disease and recurrence monitoring for early-stage patients

Guardant Reveal™ is the first blood-only liquid biopsy test that detects residual and recurrent disease in two weeks from a simple blood draw. For oncologists, the test improves the management of early-stage patients by detecting circulating tumor DNA (ctDNA) in blood after surgery to identify patients with residual disease who may benefit most from adjuvant therapy, and by detecting recurrence months earlier than current standard-of-care methods like carcinoembryonic antigen (CEA) tests or imaging.8-13

• First indication for the test is early-stage colorectal cancer (CRC)
• Interrogates genomic alterations and methylation, to achieve high sensitivity (91%) in a surveillance setting14

Shield™ detects early signs of cancer in average-risk adults with high sensitivity

Guardant Health has developed highly sensitive technology to detect cancers early, when they are most treatable, using a simple blood draw. The Shield test uses a multimodal approach, integrating genomics, epigenomics and proteomics, to detect early signs of colorectal cancer in the bloodstream. It offers an accurate, easy-to-complete, blood-based approach to cancer screening that has the potential to improve screening rates.**

We are starting with colorectal cancer, but will soon expand into multi-cancer screening, including lung, pancreas and others, where we believe cancer screening can save lives.
PRODUCTS COVERING THE ENTIRE CANCER CARE CONTINUUM

For patients with advanced cancer: Insights to help inform treatment and improve outcomes

Guardant360® CDx liquid biopsy:
- First FDA-approved liquid biopsy for comprehensive genomic profiling.
- Guideline-complete genomic results to help inform treatment plans.
- Approved as a CDx to identify patients with advanced NSCLC who may benefit from specific treatments.
- Results in 7 days from a simple blood draw.

Guardant Reveal™ liquid biopsy:
- Informs adjuvant treatment decisions by detecting minimal residual disease and detects recurrence months earlier than current standard-of-care methods for early-stage cancer patients.8–13
- Clinical trials underway to validate the clinical utility of the Guardant Reveal liquid biopsy:
  - NRG-G1005 COBRA Study/Circulating Tumor DNA as a Predictive Biomarker in Adjuvant Chemotherapy in Stage II Colon Cancer (NCT04068103)
  - SU2C Study/Circulating Tumor DNA to identify Micrometastatic Disease for Treatment in Stage III Colon Cancer (NCT03803553)
  - PEGASUS Trial/Post-Surgical Liquid Biopsy-Guided Treatment of Stage III and High-Risk Stage II Colon Cancer Patients (NCT04259944)

For patients with early-stage cancer: Identify patients at high risk for recurrence

Shield™ blood test**
- Uses a multimodal approach to detect colorectal cancer signals in the bloodstream, including DNA that is shed by tumors, called circulating tumor DNA (ctDNA).
- Demonstrated sensitivity (true positive rate) of 91% in CRC and 20% in advanced adenoma detection with 92% specificity (true negative rate) in normal cases in validation studies.14
- 12,750+-patient ECLIPSE clinical trial underway to support pre-market approval (PMA) submission to the FDA for CRC screening:
  - ECLIPSE Evaluation of the ctDNA LUNAR Test in an Average Patient Screening Episode (NCT04136002)

For cancer screening: Find cancer early, when it’s most treatable
Each year, more than 600,000 people die from cancer, many of whom may have benefitted from targeted treatments. Guardant Health is proud to work with biopharmaceutical companies, more than 60+ to date, to help inform new precision oncology drug opportunities that can benefit more patients, through our extensive clinical-genomic datasets, advanced analytics and comprehensive suite of biopharma solutions.

Our GuardantOMNI® 500-gene test delivers performance comparable to our Guardant360 test but with greater breadth, incorporating most genes evaluated in cancer drug development pipelines plus biomarkers for immuno-oncology applications.

Our Guardant360® CDx offers partners comprehensive genomic profiling across all solid tumor cancers and an FDA-approved companion diagnostic for NSCLC. We are currently collaborating with companies including Amgen, Janssen and Radius Health, Inc. to add CDx claims to our validated platform. Guardant360 CDx is already FDA approved as a CDx to identify patients who may benefit from treatment with AstraZeneca’s Tagrisso® (osimertinib) and Janssen’s RYBREVANT™ (amivantamab-vmjw).

Helping biopharma partners accelerate precision oncology drug development

For biopharma companies: solutions to help accelerate precision oncology drug development

Biopharma Solutions

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Helping biopharma partners accelerate precision oncology drug development

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* Guardant Reveal, GuardantOMNI, Guardant360 and Shield tests were developed, and their performance characteristics determined, by the Guardant Health Clinical Laboratory in Redwood City, CA USA, which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high complexity clinical testing. Guardant360 refers to Guardant360 Laboratory Developed Test (LDT). These tests have not been cleared or approved by the U.S. FDA.

** Shield is currently available for use in the detection of early signs of colorectal cancer in average-risk adults. It is a Laboratory Developed Test (LDT) that is intended to be complementary to and not a replacement for current recommended CRC screening methods.

References


6. Gadgeel SM, Garassino MC, Esteban E, et al. KEYNOTE-189: Updated OS and progression after the next line of therapy (PFS2) with pembrolizumab (pembro) plus chemotherapy with pemetrexed and platinum vs placebo plus chemo for metastatic nonsquamous NSCLC. J Clin Oncol. 2019;37(suppl; abstr 9013).


