Characterize Cancer

Comprehensive, Multi-Dimensional Insights from a Simple Blood Draw
Precision medicine requires comprehensive multi-dimensional profiling

Guardant Infinity combines genomic and epigenomic profiles to create distinct molecular patterns

Uncover a deeper understanding of tumor recurrence, response and progression, with a single assay tailored to fit your needs:

- Expanded genotyping panel for improved coverage of clinically relevant and emerging biomarkers
- Extensive methylome panel to identify the differentially methylated regions each tumor delivers, providing an unexplored dimension of novel biomarker targets and deeper understanding of therapeutic response and resistance
- Optional modules providing insights into biomarkers in IO, HLA, IFN, and HRD genes for IO, PARPi, ATRi, and DDR therapy selection

Unlock content modules as needed for additional insights using the same blood sample*

*Available for Research Use only; Investigational Use and LDT available Q3 2023

ATRi=ataxia telangiectasia mutated and rad3-related inhibitor, DDR=DNA damage response, HLA=human leukocyte antigen, HRD=homologous recombination deficiency, IFN=interferon, IO=immuno-oncology, PARPi=poly (ADP-ribose) polymerase inhibitor

Guardant Infinity provides genomic and epigenomic insights from a single blood sample*
The Guardant Infinity blood-based treatment selection core module includes an **expanded gene panel and methylome panel** for multi-omic insights.

A 753 gene panel alongside an extensive SNP backbone enables comprehensive profiling to optimize patient selection.

Guardant Infinity’s **methylation capabilities and robust genotyping** provide a more comprehensive tumor profile.

- **Sample-Level Methylation Detection**
  Genome-wide tumor methylation signals enhance sensitivity and lower variation for detecting ctDNA when compared to detecting genomic signal alone.

- **Sample-Level Methylation Tumor Fraction Score**
  Quantify changes in sample-level tumor fraction across multiple timepoints to understand molecular response and disease progression.

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<thead>
<tr>
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<th>GUARDANT 360&lt;sup&gt;®&lt;/sup&gt;</th>
<th>GUARDANT 60&lt;sup&gt;®&lt;/sup&gt;</th>
<th>INFINITY&lt;sup&gt;®&lt;/sup&gt;</th>
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<tbody>
<tr>
<td><strong>SNVs/Indels</strong></td>
<td>74 genes</td>
<td>497 genes</td>
<td>753 genes</td>
</tr>
<tr>
<td><strong>Amplifications</strong></td>
<td>18 genes</td>
<td>107 genes</td>
<td>405 genes</td>
</tr>
<tr>
<td><strong>Copy Number Loss</strong></td>
<td>—</td>
<td>66 genes</td>
<td>78 genes</td>
</tr>
<tr>
<td><strong>Fusions</strong></td>
<td>6 genes</td>
<td>21 genes</td>
<td>30 genes</td>
</tr>
<tr>
<td><strong>bTMB</strong></td>
<td>—</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>MSI</strong></td>
<td>✓</td>
<td>✓</td>
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**Comprehensive intronic coverage provides copy number amplifications and copy number loss detection of HRR and tumor suppressor genes (e.g. BRCA1, BRCA2, PTEN, MTAP, TP53)**

- **bTMB**: blood tumor mutational burden
- **ctDNA**: circulating tumor DNA
- **CRC**: colorectal cancer
- **HRR**: homologous recombination repair
- **Indel**: insertion/deletion
- **MSI**: microsatellite instability
- **SNP**: single-nucleotide polymorphism
- **SNV**: single-nucleotide variant

Guardant Infinity can detect methylation signals with an aggregate of 97% specificity and 91% sensitivity across multiple tumor types<sup>1,2</sup>.

**Accuracy of Tumor Detection**<sup>1,2</sup>

<table>
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<tr>
<th>Model</th>
<th>Specificity</th>
<th>Sensitivity</th>
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<tr>
<td>Breast, Lung, CRC Sample Cohort</td>
<td>96.9%</td>
<td>91.3%</td>
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Unlock modules at any time, with no burden or delay of additional sample collection

**IO Module**

Identify patients most likely to benefit from IO therapy with all-in-one somatic and germline detection
- HLA and KIR genotyping (germline)
- HLA and IFN copy number loss (somatic: HomDel or LOH)
- Promoter methylation status of IO, HLA and IFN genes to better understand gene silencing

**HRD Module**

Identify patients most likely to respond to PARPi/ATRi/DDR therapies with additional methylation content
- Better understand gene silencing with promoter methylation status from 24 HRR genes and 170+ tumor suppressor genes

**Viral Module**

Confirm viral presence to characterize virally-associated tumors (cervical, head, neck, gastric and esophageal)
- EBV virus detection
- HPV virus detection (14 strains, including HPV16 and HPV18)

Guardant Infinity has the foundation to enable countless applications over time—from much more sensitive therapeutic monitoring and identification of complex prognostic signatures, to innate resistance to certain therapies—all from the original sample. Future-proof your research with Guardant Infinity.

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Partner with Guardant Health to expedite your drug development, regulatory submission, and commercialization

More than 150 biopharma companies choose Guardant Health as their trusted oncology diagnostic partner

Translational Research & Clinical Development

- Portfolio of proprietary tests and services:
  - Liquid and tissue CGP
  - MRD & monitoring assessment
  - Accelerated clinical trial matching
  - Publication support

CDx Development

- Informed regulatory guidance and deep CDx expertise:
  - Design and development
  - Analytical validation
  - Clinical validation
  - Submission to regulatory authorities for approval of Guardant360 CDx
  - Path to include China clinical data in global CDx submissions

US Commercialization

- Established CDx platform and commercial experience:
  - 12,000+ oncologist user base
  - 200+ field sales team
  - Robust medical affairs and marketing support
  - RWE and market insights sharing
  - Customer-centric: 80+ person client services team, EMR integration

Global Commercialization

- Expanding global presence:
  - Lab partnerships for in-country testing (Vall D’Hebron, Spain; Royal Marsden, UK; Adicon, China), with more to come
  - MHLW approval (Japan)
  - In-country teams supporting commercial, medical affairs, and reimbursement

GUARDANT INFORM™

Real-World Evidence (RWE) database

- 263,000+ clinical-genomic linked samples provide insight into therapy use, tumor evolution, and treatment resistance

CGP=comprehensive genomic profiling, EMR=electronic medical record, IVDR=In Vitro Diagnostic Medical Devices Regulation, MRD=minimal residual disease, PMA=Premarket Approval Application, PMDA=Pharmaceuticals and Medical Devices Agency, RWE=Real-World Evidence, sPMA=Supplementary Premarket Approval Application

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