GUARDANT
INFINITY™

Characterize Cancer

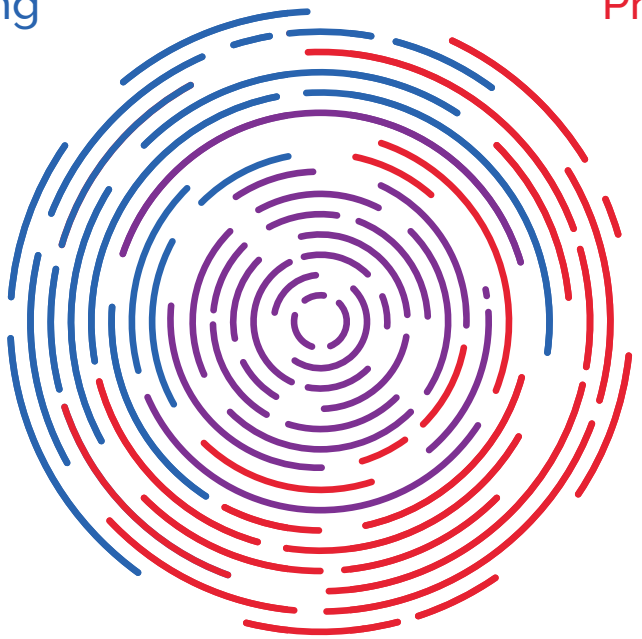
Comprehensive, Multi-Dimensional Insights from a Simple Blood Draw

GUARDANT™

Precision medicine requires **comprehensive multi-dimensional profiling**

Genomic Profiling

Epigenomic Profiling



Novel Insights

Guardant Infinity provides genomic and epigenomic insights from a single blood sample*

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

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*

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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

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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 360 CDx	GUARDANT OMNI	GUARDANT INFINITY™*
SNVs/Indels	74 genes	497 genes	753 genes
Amplifications	18 genes	107 genes	405 genes
Copy Number Loss	—	66 genes	78 genes
Fusions	6 genes	21 genes	30 genes
bTMB	—	✓	✓
MSI	✓	✓	✓

Comprehensive intronic coverage provides copy number amplifications and copy number loss detection of HRR and tumor supressor genes (e.g. *BRCA1*, *BRCA2*, *PTEN*, *MTAP*, *TP53*)

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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'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

Accuracy of Tumor Detection[1,2]

Guardant Infinity can detect methylation signals with an aggregate of 97% specificity and 91% sensitivity across multiple tumor types[1,2]

Model	Specificity	Sensitivity
Breast, Lung, CRC Sample Cohort	96.9%	91.3%

1. Greenwald WY et al. AACR. 2022.
2. Guardant. Data on file. 2022.

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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.**

ATRi=ataxia telangiectasia mutated and rad3-related inhibitor, DDR=DNA damage response, EBV=Epstein-Barr virus, HLA=human leukocyte antigen, HomDel=homozygous deletion, HRD=homologous recombination deficiency, HRR=homologous recombination repair, HPV=human papillomavirus, IFN=interferon, IO=immuno-oncology, KIR=killer-cell immunoglobulin-like receptor, LOH=loss of heterozygosity, PARPi=poly (ADP-ribose) polymerase inhibitor

GUARDANT™

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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Notes

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For more information about our biopharma solutions, **contact us at**:

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www.guardanthealth.com/guardantinfinity

BioPharmaSolutions

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