

GUARDANT INFINITY™

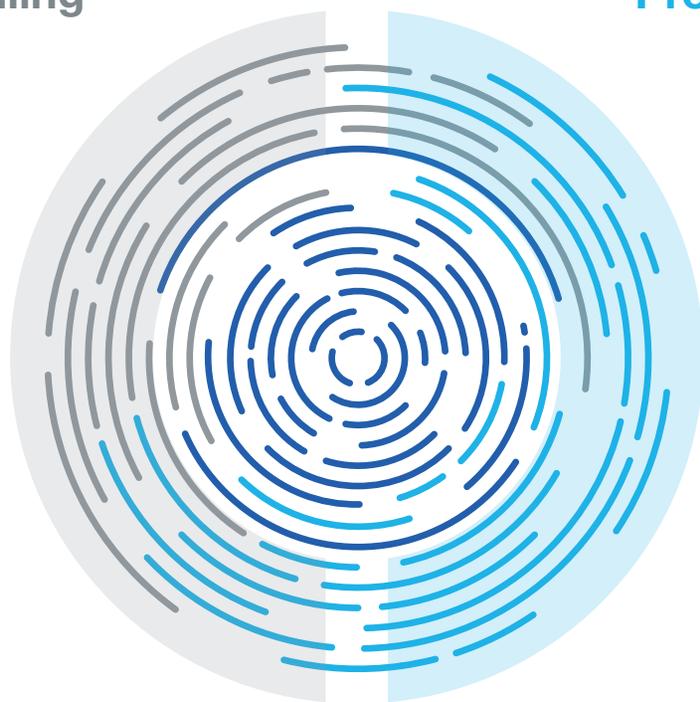
**Comprehensive,
Multi-Dimensional Insights
from a Simple Blood Draw**

 **GUARDANT™**

Precision medicine
requires comprehensive
multi-dimensional profiling

Genomic
Profiling

Epigenomic
Profiling



Novel Insights

GuardantINFINITY combines genomic and epigenomic profiles to create distinct molecular signatures

Capturing unseen complexities of each tumor sample by integrating tumor-specific methylation signatures with expanded genomic profiling to unveil insights into tumor recurrence, response, and progression

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 unique methylation pattern 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, HRD genes for IO, PARPi, ATRi, and DDR therapy selection

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

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

GuardantINFINITY provides genomic and epigenomic insights from a single blood sample





GuardantINFINITY's core module includes an expanded gene panel and methylome panel for multi-omic insights

An 800+ gene panel alongside an extensive SNP backbone enables comprehensive profiling to optimize patient selection

	GUARDANT 360 ^{cdx}	GUARDANT 6MN ⁺	GUARDANT INFINITY
SNVs/Indels	74 genes	497 genes	753 genes
Amplifications	18 genes	107 genes	415 genes
Copy Number Loss	—	66 genes	78 genes
Fusions	6 genes	21 genes	33 genes
bTMB	—	✓	✓
MSI	✓	✓	✓

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

GuardantINFINITY's methylation capabilities and robust genotyping provide a more comprehensive molecular 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

GuardantINFINITY can detect methylation signals with an aggregate of 97% specificity and 91% sensitivity across multiple tumor types

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

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*)



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 sample 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
- Genome-wide HRD score



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)

GuardantINFINITY 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 GuardantINFINITY.

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

More than 140 biopharma companies choose Guardant Health as their trusted oncology diagnostic partner

• Translational Research & Clinical Development

Liquid-led portfolio of proprietary tests:

- Liquid and tissue comprehensive profiling
- Molecular response
- MRD and longitudinal monitoring
- Accelerated clinical trial matching
- Publication support

• CDx Development

Informed regulatory guidance and deep CDx expertise:

- Design and development
- Analytical verification and validation
- Clinical validation
- Approval of Guardant360 CDx via PMA/sPMA

• US Commercialization

Established CDx platform and commercial experience:

- 12,000+ oncologist user base
- 175 field representatives
- Robust sales, medical affairs and marketing support
- RWE and market insights sharing
- Customer-centric: 80+ person client services team, future EMR integration

• Global Commercialization

Expanding global presence:

- IVDR submission (EU)
- PMDA approval (Japan)
- Lab partnership for in-country testing (China, 2023)
- Regional labs (2021-2023)
- In-country teams supporting commercial, medical affairs, and reimbursement

GUARDANTINFORM™

Real-World Evidence (RWE) database

250,000+ clinical-genomic linked samples provide insight into therapy use, tumor evolution, and treatment resistance

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

biopharmabd@guardanthealth.com

or visit

**[www.guardanthealth.com/
guardantinfinity](http://www.guardanthealth.com/guardantinfinity)**

