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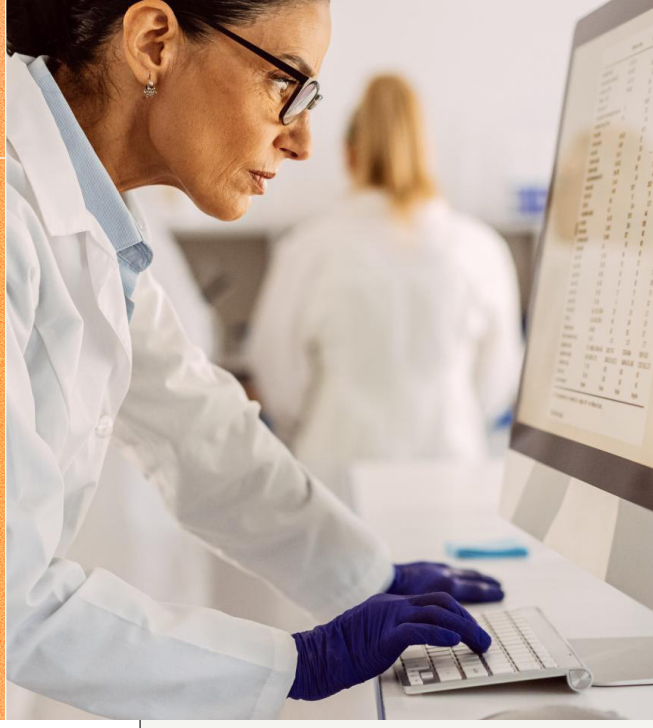
TruSight™ Oncology Comprehensive HRD (DRAGEN™)

CE-marked under IVDR, kitted solution for accurate HRD detection



TruSight Oncology Comprehensive HRD (DRAGEN) uses targeted NGS to enable assessment of Homologous Recombination Deficiency (HRD) using DNA extracted from formalin-fixed, paraffin-embedded tumor tissue from ovarian cancer patients.

This test is intended to be used as a companion diagnostic to identify cancer patients who may benefit from treatment with the targeted therapy listed below.

Companion Diagnostic Indication

Tumor Type	Biomarker(s) Detected	Therapy
Ovarian cancer, including epithelial ovarian, fallopian tube, and primary peritoneal cancer	Homologous Recombination Deficiency (HRD) (defined as deleterious or suspected deleterious mutations in *BRCA1* and *BRCA2* genes and/or positive Genomic Instability Score)	LYNPARZA® (olaparib)

TruSight Oncology Comprehensive HRD (DRAGEN) delivers decisive results

- Mutations in the *BRCA1* and *BRCA2* genes, including small DNA variants and large gene rearrangements, are key drivers of HRD.
- Aberrations that result in structural changes to chromosomes, or "genomic scars," including loss of heterozygosity (LOH), telomeric-allelic imbalance (TAI), and large-scale state transitions (LST) are indicators of the inability to repair DNA damage. These additional HRD biomarkers can be quantified and summed to generate a genomic instability score (GIS).
- TruSight Oncology Comprehensive HRD (DRAGEN), powered by Illumina NGS technology and the Myriad Genetics GIS algorithm, detects single nucleotide variants (SNVs), insertions and deletions, and large rearrangements (exon-level deletions) in *BRCA1* and *BRCA2*. It assesses GIS by combining measures of LOH, TAI, and LST.

Assess small variants, insertions, deletions, and exon-level deletions in *BRCA1* and *BRCA2* genes

Detect genomic instability with a proprietary algorithm powered by Myriad Genetics

Deliver an easy-to-read, clinically relevant report to help inform therapy decisions in ovarian cancer

System, workflow, and inputs

Feature	Description
Sequencing system	NextSeq 550Dx Instrument
Analysis	Performed on the DRAGEN server
Patient sample throughput	6–7 patient samples/flow cell
GIS	Numerical score
GIS algorithm	Powered by Myriad Genetics
DNA input requirement	40 ng DNA extracted from ovarian, fallopian tube, or primary peritoneal FFPE tissue
FFPE input requirement	Recommended tissue volume ≥ 1.0 mm^3 Minimum of 33% tumor content (by area) required to detect GIS
No. of biopsy slides	Minimum 5 recommended (10 µm sections, 20 mm^2 tissue area each)
Total assay time	4–5 days from nucleic acid to results report

Gene content, coverage, and variant detection

Feature	Description
Panel content	• *BRCA1* and *BRCA2* • GIS
Cross-ethnicity coverage	EAS, EUR, AFR, AMR, SAS
Variant types detected	• SNVs, insertions, deletions, and large rearrangements (exon-level deletions) in *BRCA1* and *BRCA2* • GIS, determined using a genome-wide SNP panel to assess genomic scars LOH, TAI, and LST

Performance characteristics

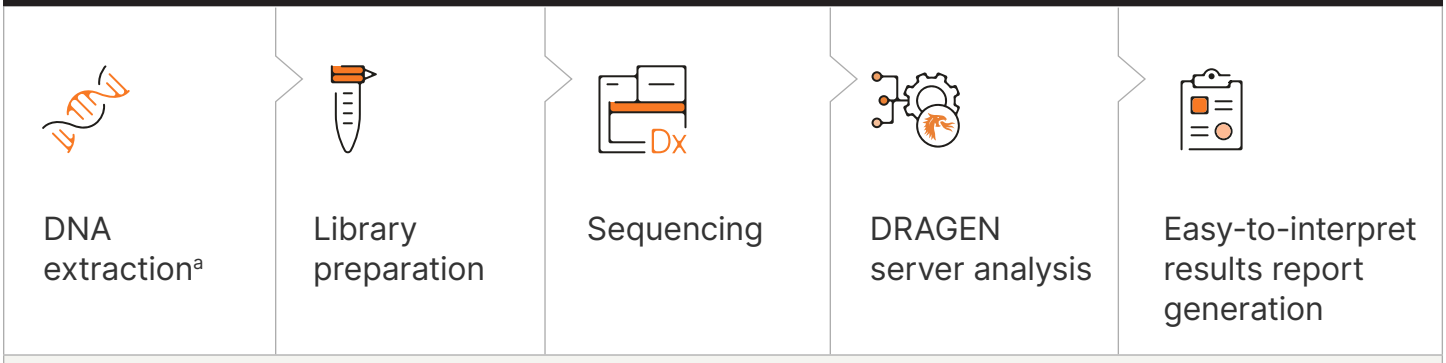
Feature	Description
Limit of blank (LoB)—false positives by variant type	• *BRCA1* and *BRCA2* small DNA variants: 0% • *BRCA1* and *BRCA2* LRs: 0% • GIS: 0%
Limit of detection (LoD)	• *BRCA1* and *BRCA2* (% VAF): - SNVs: 5 - Insertions and deletions ≥ 10 bp: 6 - Insertions and deletions < 10 bp: 7 - Variants in homopolymer regions (≥ 5 bp): 7 - LRs < 3 exons: 61 - LRs ≥ 3 exons: 46 • GIS: 33% tumor content
Clinical performance characteristics	• PPA: 97.6% (95% CI: 94.5%–99.2%) • NPA: 92.3% (95% CI: 86.9%–96.0%) • OPA: 95.3% (95% CI: 92.6%–97.3%)

AFR, African; AMR, Admixed American; CI, confidence interval; EAS, East Asian; EUR, European; FFPE, formalin-fixed, paraffin-embedded; GIS, genomic instability score; LOH, loss of heterozygosity; LR, large rearrangement; LST, large-scale state transition; NPA, negative percent agreement; OPA, overall percent agreement; PPA, positive percent agreement; SAS, South Asian; SNP, single nucleotide polymorphism; SNV, single nucleotide variant; TAI, telomeric allelic imbalance; VAF, variant allele frequency.

Integrated workflow

This comprehensive solution includes library preparation, sequencing on the NextSeq™ 550Dx Instrument, and automated software pipelines powered by DRAGEN secondary analysis. This regulated HRD test enables laboratories to produce timely, accurate information on HRD status without the need to send out samples, supporting faster turnaround times.

TruSight Oncology Comprehensive HRD (DRAGEN) workflow



Fully automated on-instrument process

Sequencing > Base calling and QC > Variant calling > Interpretation > Report generation

Batch up to seven patient samples and two control samples per run using TruSight Oncology Comprehensive HRD (DRAGEN). The library preparation and enrichment steps take two days. The fully automated workflow using the NextSeq 550Dx Instrument consists of sequencing samples and transferring raw data to the DRAGEN server for analysis and results report generation. The entire workflow is completed in four to five days.

a. Extraction kits must be purchased separately.

Bring HRD assessment into your lab

HRD assessment can inform therapy choices that have the potential to improve patient outcomes. HRD testing in your lab helps you:

- Be a precision medicine provider—implement a state-of-the-art test and generate a clinically actionable report in 4–5 days with reduced quantity not sufficient (QNS) rates and improved test success rates
- Be a trusted partner—consult with oncologists on therapy decisions and participate in molecular tumor boards

Implementing an in-house test can require significant time and effort. With the introduction of TruSight Oncology Comprehensive HRD (DRAGEN), Illumina has addressed some of the biggest challenges, streamlining the process.

- Reduces the time and expense of test implementation compared to a laboratory-developed test (LDT)
- Expedites moving HRD to a routine test, closer to patient point of care
- Supports labs in achieving compliance with *In Vitro* Diagnostic Regulation (IVDR) requirements

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