illumina®

# TruSight™ Oncology Comprehensive HRD (DRAGEN™)

## Results report example

## Easy-to-interpret results report

TruSight Oncology Comprehensive HRD (DRAGEN) makes homologous recombination deficiency (HRD) testing accessible to laboratories and health care professionals. It detects small DNA variants and large gene rearrangements in *BRCA1* and *BRCA2* (*BRCA1/2*) while also determining a genomic instability score (GIS), all in less time than conventional, iterative testing methods.

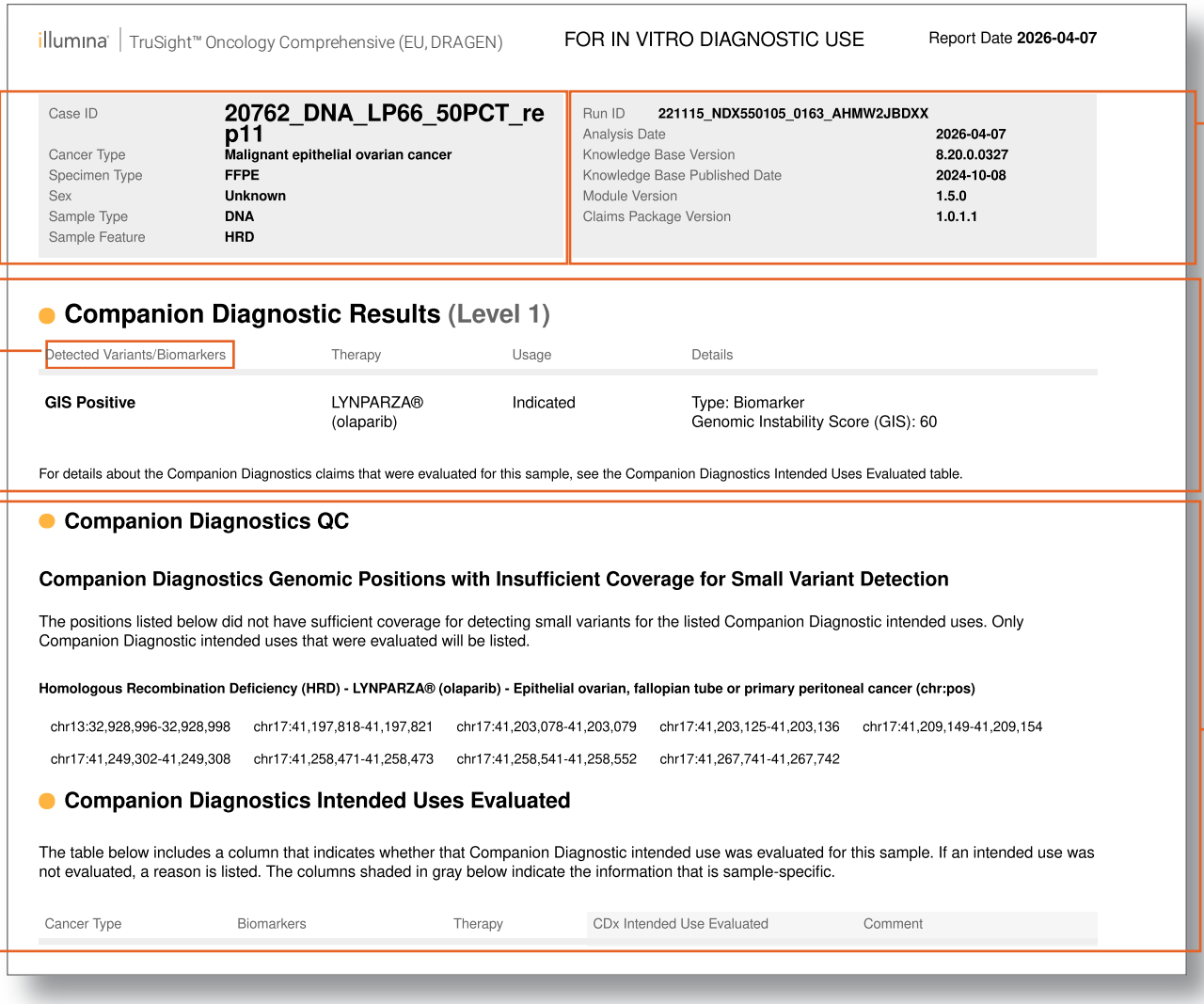
Integral to the solution is the TruSight Oncology Comprehensive HRD (EU, DRAGEN) results report. This report is automatically generated on the DRAGEN server during the TruSight Oncology Comprehensive HRD (DRAGEN) analysis workflow. The streamlined results report:

- Presents clear and easy-to-read information, indicating patient sample information and test findings
- Reports *BRCA1/2* small variants and large gene rearrangements of clinical significance, as identified by Myriad Genetics
- Determines GIS using the Myriad Genetics algorithm, which assesses loss of heterozygosity (LOH), telomeric allelic imbalance (TAI), and large-scale state transitions (LST) across the entire genome
- Provides companion diagnostic (CDx) indication for LYNPARZA® (olaparib), taking into account *BRCA1/2* status and GIS

## The TruSight Oncology Comprehensive HRD (EU, DRAGEN) example results report

Patient sample information: case ID, cancer type, specimen type, sex, sample type, and sample feature.

Assay information: run ID and software details.



illumina | TruSight™ Oncology Comprehensive (EU, DRAGEN) FOR IN VITRO DIAGNOSTIC USE Report Date **2026-04-07**

| | |
|---|---|
| Case ID | **20762_DNA_LP66_50PCT_rep11** |
| Cancer Type | **Malignant epithelial ovarian cancer** |
| Specimen Type | **FFPE** |
| Sex | **Unknown** |
| Sample Type | **DNA** |
| Sample Feature | **HRD** |

| | |
|---|---|
| Run ID | **221115_NDX550105_0163_AHMW2JBDXX** |
| Analysis Date | **2026-04-07** |
| Knowledge Base Version | **8.20.0.0327** |
| Knowledge Base Published Date | **2024-10-08** |
| Module Version | **1.5.0** |
| Claims Package Version | **1.0.1.1** |

**Companion Diagnostic Results (Level 1)**

| Detected Variants/Biomarkers | Therapy | Usage | Details |
|---|---|---|---|
| **GIS Positive** | LYNPARZA® (olaparib) | Indicated | Type: Biomarker<br>Genomic Instability Score (GIS): 60 |

For details about the Companion Diagnostics claims that were evaluated for this sample, see the Companion Diagnostics Intended Uses Evaluated table.

**Companion Diagnostics QC**

**Companion Diagnostics Genomic Positions with Insufficient Coverage for Small Variant Detection**

The positions listed below did not have sufficient coverage for detecting small variants for the listed Companion Diagnostic intended uses. Only Companion Diagnostic intended uses that were evaluated will be listed.

**Homologous Recombination Deficiency (HRD) - LYNPARZA® (olaparib) - Epithelial ovarian, fallopian tube or primary peritoneal cancer (chr:pos)**

chr13:32,928,996-32,928,998 chr17:41,197,818-41,197,821 chr17:41,203,078-41,203,079 chr17:41,203,125-41,203,136 chr17:41,209,149-41,209,154
chr17:41,249,302-41,249,308 chr17:41,258,471-41,258,473 chr17:41,258,541-41,258,552 chr17:41,267,741-41,267,742

**Companion Diagnostics Intended Uses Evaluated**

The table below includes a column that indicates whether that Companion Diagnostic intended use was evaluated for this sample. If an intended use was not evaluated, a reason is listed. The columns shaded in gray below indicate the information that is sample-specific.

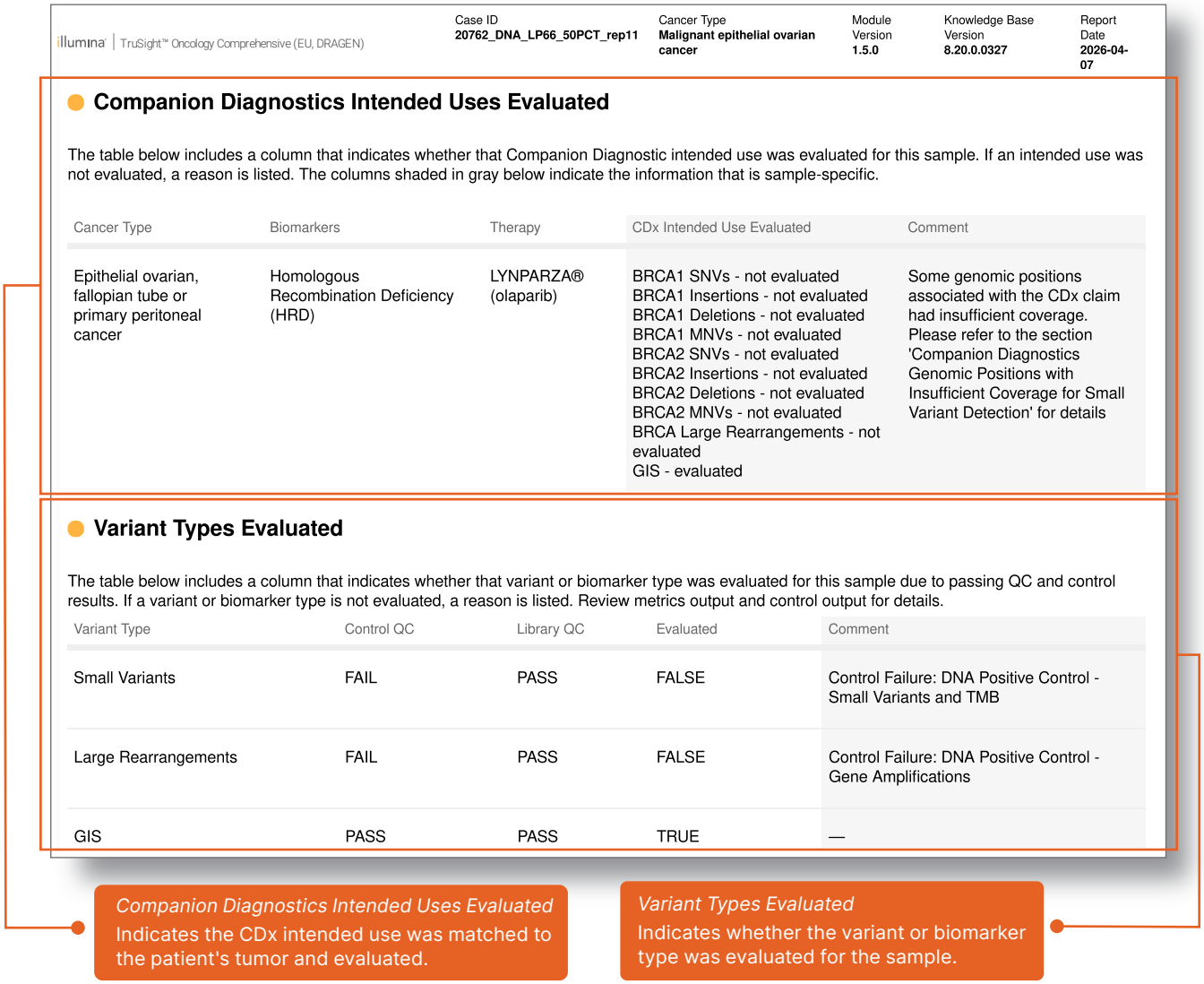
| Cancer Type | Biomarkers | Therapy | CDx Intended Use Evaluated | Comment |
|---|---|---|---|---|

*Companion Diagnostic Results*
These findings identify small DNA variants and large gene rearrangements in *BRCA1/2* and GIS, with the associated therapy indication. Example report shows results for a sample that is positive for the CDx indication.

*Companion Diagnostics Quality Control (QC)*
Genomic positions that did not have sufficient coverage for small variant detection.

*Detected Variants/Biomarkers*
The genomic findings meet at least one of the following criteria[1]:
- Deleterious or suspected deleterious mutation in *BRCA1* or *BRCA2*

## The TruSight Oncology Comprehensive HRD (EU, DRAGEN) results report



illumina | TruSight™ Oncology Comprehensive (EU, DRAGEN)

| Case ID | Cancer Type | Module Version | Knowledge Base Version | Report Date |
|---|---|---|---|---|
| **20762_DNA_LP66_50PCT_rep11** | **Malignant epithelial ovarian cancer** | **1.5.0** | **8.20.0.0327** | **2026-04-07** |

### Companion Diagnostics Intended Uses Evaluated

The table below includes a column that indicates whether that Companion Diagnostic intended use was evaluated for this sample. If an intended use was not evaluated, a reason is listed. The columns shaded in gray below indicate the information that is sample-specific.

| Cancer Type | Biomarkers | Therapy | CDx Intended Use Evaluated | Comment |
|---|---|---|---|---|
| Epithelial ovarian, fallopian tube or primary peritoneal cancer | Homologous Recombination Deficiency (HRD) | LYNPARZA® (olaparib) | BRCA1 SNVs - not evaluated<br>BRCA1 Insertions - not evaluated<br>BRCA1 Deletions - not evaluated<br>BRCA1 MNVs - not evaluated<br>BRCA2 SNVs - not evaluated<br>BRCA2 Insertions - not evaluated<br>BRCA2 Deletions - not evaluated<br>BRCA2 MNVs - not evaluated<br>BRCA Large Rearrangements - not evaluated<br>GIS - evaluated | Some genomic positions associated with the CDx claim had insufficient coverage. Please refer to the section 'Companion Diagnostics Genomic Positions with Insufficient Coverage for Small Variant Detection' for details |

### Variant Types Evaluated

The table below includes a column that indicates whether that variant or biomarker type was evaluated for this sample due to passing QC and control results. If a variant or biomarker type is not evaluated, a reason is listed. Review metrics output and control output for details.

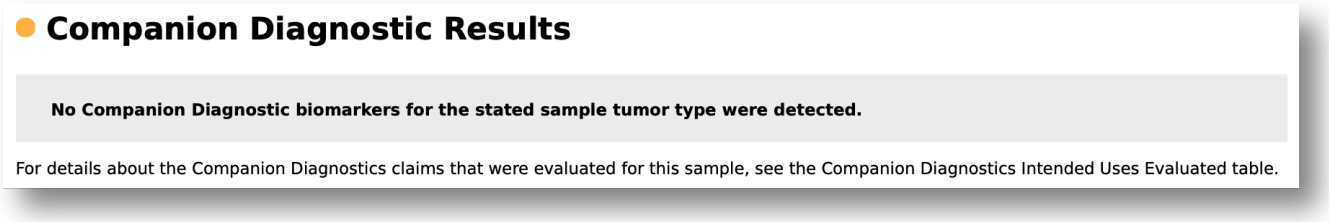
| Variant Type | Control QC | Library QC | Evaluated | Comment |
|---|---|---|---|---|
| Small Variants | FAIL | PASS | FALSE | Control Failure: DNA Positive Control - Small Variants and TMB |
| Large Rearrangements | FAIL | PASS | FALSE | Control Failure: DNA Positive Control - Gene Amplifications |
| GIS | PASS | PASS | TRUE | — |

*Companion Diagnostics Intended Uses Evaluated*
Indicates the CDx intended use was matched to the patient's tumor and evaluated.

*Variant Types Evaluated*
Indicates whether the variant or biomarker type was evaluated for the sample.

## The TruSight Oncology Comprehensive HRD (EU, DRAGEN) results report when a CDx is not detected

If a clinical diagnostic result is not detected, the TruSight Oncology Comprehensive HRD (EU, DRAGEN) results report will contain the same reporting fields as described on pages 3 and 4 of this document. Instead of listing a possible CDx, the section entitled "Companion Diagnostic Results" will indicate that "No Companion Diagnostic biomarkers for the stated sample tumor type were detected." Please see the Companion Diagnostics Intended Use Evaluated table for more information.




**Learn more** →

TruSight Oncology Comprehensive HRD (DRAGEN)

## Reference

1. Ray-Coquard I, Pautier P, Pignata S, et al. Olaparib plus bevacizumab as first-line maintenance in ovarian cancer. *N Engl J Med.* 2019;381(25):2416-2428. doi:10.1056/NEJMoa1911361

## Intended use statement

TruSight™ Oncology Comprehensive HRD (DRAGEN™) is a qualitative *in vitro* diagnostic test that uses targeted next-generation sequencing to enable assessment of Homologous Recombination Deficiency (HRD) using DNA extracted from formalin-fixed, paraffin-embedded (FFPE) tumor tissue samples from ovarian cancer patients using the Illumina® NextSeq™ 550Dx Instrument. The test can be used to detect single nucleotide variants, insertions, deletions, and large rearrangements in *BRCA1* and *BRCA2* genes, and report a Genomic Instability Score (GIS).

The test is intended to be used as a companion diagnostic to identify cancer patients who may benefit from treatment with the targeted therapy listed in Table 1, in accordance with the approved therapeutic product labeling.

Table 1: Companion diagnostic indication

| Tumor type | Biomarker | 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) |

illumina®

1.800.809.4566 toll-free (US) | +1.858.202.4566 tel
techsupport@illumina.com | www.illumina.com


M-EMEA-01638 v2.0