A deep learning-powered diagnostic application leveraging low-pass whole genome sequencing (WGS) to identify patterns of genomic instability in ovarian cancer samples. Supports accurate detection homologous recombination deficiency (HRD) status with the analytical capabilities and advanced features of the SOPHIA DDM™ Platform.

Main Features

The SOPHIA DDM™ DxD HRD Solution is an in vitro diagnostic medical device that can be used as an aid to determine the HRD status of tumors in patients with ovarian cancer by the semi-quantitative detection of the Genomic Instability biomarker. The device is intended to be used by healthcare professionals and is based on a next-generation sequencing (NGS) workflow taking genomic DNA extracted from FFPE treated tumor material as input.

Gene panel (CDS only) | Gene amplifications | SNPs | Indels
---|---|---|---
AKT1*, ATM, BRCA1, BRCA2, BRIP1, CCNE1, CDK12, CHEK1, CHEK2, ESRT1*, FANCA, FANCD2, FANC1, FGFR1*, FGFR2*, FGFR3, MRE11, NBN, PALB2, PK3CA*, PPARGA, PTEN, RAD51B, RAD51C, RAD51D, RAD54L, TP53

Starting material
- 50 ng DNA

Sample type
- FFPE ovarian cancer tissue

Samples per run / Sequencer
- 8 for Illumina® NextSeq® 500/550 Mid Output Kit
- 24 for Illumina® NextSeq® 500/550 High Output Kit

Analytical Performance

Analysis time from FASTQ: < 8 hours

Concordance with comparator NGS assay: 92.9%
Negative Percent Agreement: 95.8%
Overall Percent Agreement: 94.4%
Repeatability: 100%
Reproducibility: 100%
Limit of detection: 28.5% tumor content

One Simple Intuitive Platform: Beyond Analytics

Accelerated assessment and reporting of genomic integrity

The SOPHIA DDM™ Platform provides the user with a web-based portal and workspace to upload and analyze genomic sample data for our CE-IVD marked products. It enables a fully automated and validated workflow reaching clinical-grade performance.

Global support at every step

We offer local support anywhere in the world. Our dedicated bioinformaticians help save time and resources, ensuring fast resolution of workflow disruptions. In addition, our Set Up Program provides assistance with application set up for fast and worry-free transition to routine testing.

Secure and unlimited data storage

The SOPHIA DDM™ Platform provides unlimited and unrestricted storage, while keeping data safe by applying the highest industrial standards of encryption in compliance with local data security policies.

Product codes:
- B501203LCLSMM08-32

*Hotspot coverage only.

Gene Panel

Gene Panel1 (CDS only) Variants Called1 (CDS only) Recommendations Wet Lab

<table>
<thead>
<tr>
<th>Gene</th>
<th>CDS</th>
<th>Only</th>
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</thead>
<tbody>
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Day 1:
- Library Preparation

Day 2:
- Capture and Sequencing

Total library preparation time: 1.5 days

**Limit of detection established by measuring the lowest tumor content for which sensitivity is larger or equal to 95%.

***Based on results obtained by seven independent laboratories provided with aliquots of the same reference samples.

****Established by measuring the lower tumor content for which sensitivity is larger or equal to 95%.

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