The molecular diagnostic application that streamlines the analysis of the complex mutational landscape associated with major hereditary cancer disorders by combining a capture-based target enrichment kit with the analytical capabilities and advanced features of the SOPHiA DDM™ Platform.

**Main Features**

The SOPHiA DDM™ Dx Hereditary Cancer Solution is an in vitro diagnostic test intended for the identification of germline variations occurring in 27 most common genes involved in predispositions to breast and ovarian cancers as well as intestinal cancers in germline DNA samples isolated from peripheral blood. It is intended to be used as an aid to healthcare professionals and to provide molecular rationale to make a clinical decision related to germline mutations associated with breast and ovarian cancer, intestinal polyposis syndromes, and Lynch syndrome.

**Analytical Performance**

The web-based SOPHiA DDM™ Platform analyzes complex NGS data with highly accurate detection of SNVs and Indels. SOPHiA DDM™ core offers a Clinical Decision Support (CDS) component that allows visualization and interpretation of variants in a single workflow. The Platform reaches clinical-grade performance.**

**Gene Panel Variants Called**

<table>
<thead>
<tr>
<th>Gene Panel</th>
<th>Variants Called</th>
<th>Recommendations</th>
<th>Wet Lab</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABRA51, APC, ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, EPCAM, MLH1, MRE11, MSH2, MSH6, MUTHY, NBN, PALB2, PIK3CA, PM2, PM2SCL1, PTEN, RAD50, RAD51C, RAD51D, STK11, TP53, VRCC2</td>
<td>SNVs &amp; Indels</td>
<td>Library Preparation</td>
<td>Blood</td>
</tr>
</tbody>
</table>

**Gene Panel**

- **Starting material**: 200 ng DNA
- **Sample type**: Blood
- **Samples per run for >250x coverage depth/Sequencer (Flow Cell)**: 48 for Illumina® MiSeq™ v3 (2x300bp)

**Analysis time from FASTQ**: < 6 hours

- **Sensitivity**: 100% Lower 95% CI
- **Specificity**: 99.99
- **Accuracy**: 99.99
- **Precision**: 99.86
- **Repeatability**: 99.98
- **Reproducibility**: 99.93
- **Average on-target rate**: 79.39
- **Coverage uniformity**: 99.72

**All third party trademarks listed by SOPHiA GENETICS™ remain the property of their respective owners. Unless specifically identified as such, SOPHiA GENETICS™’ use of third party trademarks is to identify the corresponding third party goods and/or services and shall be considered nominative fair use under the trademark law.**

**One Simple Intuitive Platform: Beyond Analytics**

**Accelerated assessment and reporting of genomic variants**

The SOPHiA DDM™ Platform provides the users with a web-based portal and workspace to upload and analyze genomic sample data for our CE-IVD marked products. It enables a fully CE-IVD compliant workflow, from library preparation to variant identification (Figure 1). Once the samples are analyzed, IVD reports are created and can be downloaded from the web portal to support decision-making.

**Product codes:**

- BS0102ILLCGLL01-016, BS0102ILLCGLL01-032
- BS0102ILLCGLL01-048, BS0102ILLCGLL01-096

**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.