The molecular diagnostic application that streamlines the interpretation of complex genomic variants 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 Myeloid Solution is intended to be used to identify variants occurring in **30 genes** involved in myeloid neoplasms by targeting specific mutation-prone positions within the genomic sequence. The function of the product is to be an aid to healthcare professionals to make a clinical decision related to myeloid neoplasms, and to provide molecular rationale for appropriate therapy. The product is intended to be used for in vitro diagnostic and professional use only.

### Gene Panel

<table>
<thead>
<tr>
<th>Gene Panel</th>
<th>Variants Called</th>
<th>Recommendations</th>
<th>Wet Lab</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SNVs, Indels, FLT3-ITDs</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Starting material

- **200 ng DNA**

#### Sample type

- **Blood**

#### Samples per run / Sequencer (Flow Cell)

- **24 for Illumina® MiSeq™ v3 (2x300bp)**

#### Library Preparation

**Day 1:**

- **Capture and Sequencing**
- **Library Preparation**
- **Sample type:** Blood
- **Samples per run / Sequencer (Flow Cell):** 24 for Illumina® MiSeq™ v3 (2x300bp)
- **Total library preparation time:** 2 days

#### Secondary Analysis

**Day 2:**

- **Capture and Sequencing**
- **Library Preparation**
- **Sample type:** Blood
- **Samples per run / Sequencer (Flow Cell):** 24 for Illumina® MiSeq™ v3 (2x300bp)
- **Total library preparation time:** 2 days

### Analytical Performance

The web-based SOPHIA DDM™ Platform analyzes complex NGS data with highly accurate detection of SNVs, Indels and FLT3-ITDs. 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.

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

<table>
<thead>
<tr>
<th>Observed (%)</th>
<th>Lower 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>99.92</td>
</tr>
<tr>
<td>Specificity</td>
<td>99.99</td>
</tr>
<tr>
<td>Accuracy</td>
<td>99.99</td>
</tr>
<tr>
<td>Precision</td>
<td>99.52</td>
</tr>
<tr>
<td>Reproducibility</td>
<td>99.30</td>
</tr>
<tr>
<td>Average on-target rate</td>
<td>87.41</td>
</tr>
<tr>
<td>Coverage uniformity</td>
<td>99.88</td>
</tr>
<tr>
<td>Mean % of target region &gt; 1000x</td>
<td>&gt; 99</td>
</tr>
<tr>
<td>Limit of detection</td>
<td>2.5</td>
</tr>
</tbody>
</table>

*CDS results are not part of the CE-IVD claim.
**Performance values are based on SNVs and Indels in 237 samples processed on Illumina® MiSeq.***

### 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 set up 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.

This CE IVD-marked product is For In Vitro Diagnostic Use in Europe, Turkey and Israel markets. This product has not been cleared and approved by the U.S. FDA and may not be approved in some countries/regions. The CDS features are for Clinical Decision Support only and are not to be used as a primary diagnostic tool. Please contact SOPHIA GENETICS’ local Sales representatives to obtain the appropriate product information for your country of residence.

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