

The molecular diagnostic application that characterizes the complex mutational landscape of the major solid tumors by combining a capture-based target enrichment kit with the analytical performance and advanced features of the SOPHiA DDM™ Platform.

Main Features

The CE-IVD marked SOPHiA DDM Dx Solid Tumor Solution covers **42 genes** associated with solid tumors, including lung, colorectal, skin, and brain cancers. Probe design is optimized to guarantee high on-target rate and coverage uniformity throughout the entire target regions, delivering clinical-grade analytical performance.

Gene Panel	Variants Called	Recommendations	Wet Lab
<p><i>AKT1</i> (3), <i>ALK</i> (21-25), <i>BRAF</i> (11,15), <i>CDK4</i> (2), <i>CDKN2A</i> (1*,2,3), <i>CTNNB1</i> (3), <i>DDR2</i> (17), <i>DICER1</i> (24,25), <i>EGFR</i> (18-21), <i>ERBB2</i> (8,17,20), <i>ERBB4</i> (10,12), <i>FBXW7</i> (7-11), <i>FGFR1</i> (12,14), <i>FGFR2</i> (7,12,14), <i>FGFR3</i> (7,9,14,16), <i>FOXL2</i> (1*), <i>GNA11</i> (4,5), <i>GNAQ</i> (4,5), <i>GNAS</i> (8), <i>H3F3A</i>(2*), <i>H3F3B</i> (2*), <i>HIST1H3B</i> (1), <i>HRAS</i> (2-4), <i>IDH1</i> (4), <i>IDH2</i> (4), <i>KIT</i> (8-11,13,17,18), <i>KRAS</i> (2-4), <i>MAP2K1</i> (2,3), <i>MET</i> (2,14-20), <i>MYOD1</i> (1), <i>NRAS</i> (2-4), <i>PDGFRA</i> (12,14,18), <i>PIK3CA</i> (2*,3,6*,8,10,21), <i>PTPN11</i> (3), <i>RAC1</i> (3), <i>RAF1</i> (7,10*,12,13*,14*,15*), <i>RET</i> (11,13,15,16), <i>ROS1</i> (38*,41*), <i>SF3B1</i> (15-17), <i>SMAD4</i> (8-12), <i>TERT</i> (promoter*,1*,8*,9*,13*), <i>TP53</i> (2-11)</p> <p><small>*Hotspots only</small></p>	<ul style="list-style-type: none"> • SNVs and Indels in all genes of the panel 	<p>Starting material 50 ng</p> <p>Sample type FFPE</p> <p>Samples per run for 1000x coverage depth / Sequencer (Flow Cell)¹ 24 / Illumina MiSeq™ v3 (2x300bp)*</p> <p><small>*2x150-cycle sequencing run (paired-end) is recommended</small></p>	<p>Day 1: Library Preparation</p> <p>Day 2: Capture and Sequencing</p> <p>Total library preparation time: 1.5 days</p>

Analytical Performance

The web-based SOPHiA DDM™ Platform analyzes complex NGS data with highly accurate detection of SNVs and Indels. The SOPHiA DDM Platform™ desktop access mode 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: < 4 hours²

	Observed (%)	Lower 95% CI
Sensitivity	98.77	93.31
Specificity	100	99.92
Accuracy	99.97	99.85
Precision	100	96.25
Repeatability	96.45	96.41
Reproducibility	89.13	89.05
Coverage uniformity	98.70	92.50***

*CDS results are not part of the CE-IVD claim.
**Performance values have been calculated based on SNVs and Indels only in 150 samples processed on Illumina MiSeq™ using KAPA™ HyperPlus KK8512 library preparation reagents.
***5% quantile

One Simple Intuitive Platform: Beyond Analytics

Accelerated assessment and reporting of genomic variants

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 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 portal to support decision-making.

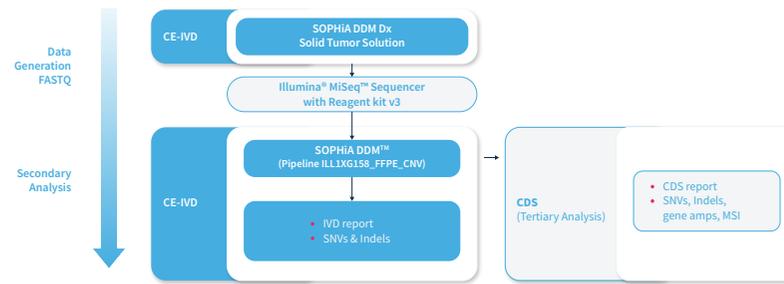


Figure 1. IVD workflow. CDS results are not part of the CE-IVD claim.

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:
BS0105ILLCSML03-016
BS0105ILLCSML03-032
BS0105ILLCSML03-048

amps., amplifications; IVD, in vitro diagnostic; MSI, microsatellite instability; SNV, single nucleotide variation.
1. Sequencing recommendations and specifications for other sequencing kits and instruments available upon request. Delivery time may vary according to the selected sequencing platform.
2. Analysis time may vary depending on the number of samples multiplexed and server load.

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 not for use as a primary diagnostic tool. Please contact SOPHiA GENETICS local Sales representatives to obtain the appropriate product information for your country of residence. 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 does not indicate any relationship, sponsorship, or endorsement between SOPHiA GENETICS and the owners of these trademarks. Any references by SOPHiA GENETICS to 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.