

# 56G ONCOLOGY SOLUTION

The 56G Oncology Solution is a molecular diagnostic application that bundles the analytical power of SOPHiA™ AI with the Accel-Amplicon™ target enrichment kit and full access to SOPHiA DDM® platform.



Accel-Amplicon™ 56G Oncology Panel v2



SaaS Analytical Platform

The Accel-Amplicon 56G Oncology Panel v2 offers an optimal amplicon design for very low input FFPE, fresh-frozen and ccfDNA plasma samples. Contiguous and overlapping coverage paired with high on-target reads percentage guarantees excellent SNVs and Indels detection in 56 genes associated with solid tumors (e.g. lung and colorectal cancers) and hematological malignancies (e.g. acute myeloid leukemia and acute lymphoblastic leukemia).



## Gene panel

\**ABL1* (4-7), \**AKT1* (3,6), \**ALK* (23,25), \**APC* (14), \**ATM* (8,9,12,17,26,34-36,39,50,54,56,61,63), \**BRAF* (11,15), \**CDH1* (3,8,9), \**CDKN2A* (2), \**CSF1R* (7,22), \**CTNNB1*(3), \**DDR2* (18), \**DNMT3A* (23), \**EGFR* (3,7,15,18-21), \**ERBB2* (8,19-21), \**ERBB4* (3,4,6,7,8,9,15,23), \**EZH2* (16), \**FBXW7* (5,8-11), \**FGFR1* (4,5,7), \**FGFR2* (5,7,8,11), \**FGFR3* (7,9,12,14,16), \**FLT3* (11,14,16,20), \**FOXL2* (1), \**GNA11* (4,5), \**GNAQ* (4,5), \**GNAS* (8,9), \**HNF1A* (3,4), \**HRAS* (2,3), \**IDH1* (4), \**IDH2* (4), \**JAK2* (14,16), \**JAK3* (4,13,16), \**KDR* (6,7,11,19,21,26,27,30), \**KIT* (2,9-11,13-15,17,18), \**KRAS* (2,3,4), \**MAP2K1* (2,3,6,7,11), \**MET* (2, 11, 14,16,19), \**MLH1* (12), \**MPL* (10), \**MSH6* (5), \**NOTCH1* (26,27,34), \**NPM1* (11), \**NRAS* (2-4), \**PDGFRA* (12,14,15,18), \**PIK3CA* (2,5,7,8,10,14,19,21), \**PTEN* (1-9), \**PTPN11* (3,13), \**RB1* (4,6,8,10,11,14,17,18,20-23), \**RET* (10,11,13,15,16), \**SMAD4* (3,4-6, 8,9,10-12), \**SMARCB1* (2,4,5,9), \**SMO* (3,5,6,9,11), \**SRC* (14), \**STK11* (1,4,6,8), \**TP53* (1-10), \**TSC1* (15), \**VHL* (1-3)

\*Hotspot panel

## Recommendations

**Starting material:** 10-25 ng per Multiplex PCR (1 plex)

**Sample source:** FFPE tissue, fresh-frozen tissue and plasma

**Samples per run:** Depending on sequencing platform<sup>(1)</sup>

## Wet lab

**Day 1:** DNA Quantification, Multiplex PCR & Indexing

**Day 2:** Library Quantification & Sequencing

Total hands-on time: 5 hours

SOPHiA analyzes complex genomic NGS data by detecting, annotating and pre-classifying genomic variants to help clinicians better diagnose their patients. SOPHiA accurately detects SNVs and Indels in all the genes of the panel.

SOPHiA leads to excellent clinical grade analytical performance:

|                               | Observed<br>FFPE | Observed<br>ctDNA |           |
|-------------------------------|------------------|-------------------|-----------|
|                               |                  | Single            | Replicate |
| <b>Sensitivity</b>            |                  |                   |           |
| <b>2ng</b>                    | N/A              | 98,9%             | 97,9%     |
| <b>5ng</b>                    | N/A              | 99,9%             | 99,7%     |
| <b>10ng</b>                   | 99%              | 100%              | 100%      |
| <b>Precision</b>              |                  |                   |           |
| <b>2ng</b>                    | N/A              | 80,1%             | 97,9%     |
| <b>5ng</b>                    | N/A              | 87,4%             | 96,5%     |
| <b>10ng</b>                   | 93%              | 93,3%             | 100%      |
| <b>Coverage uniformity</b>    | > 90%            | > 98%             | > 98%     |
| <b>Average on-target rate</b> | > 70%            | > 95%             | > 95%     |
| <b>Limit of detection</b>     | 5%               | 0,5%              | 0,5%      |

## Analysis time from FASTQ files: 4 hours<sup>(2)</sup>

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(1) Sequencing recommendations and specifications for sequencing kits and instruments available upon request

(2) Analysis time may vary depending on the number of samples multiplexed and server load

The results are presented in SOPHiA DDM, the platform of choice for clinicians performing routine diagnostic testing. Thanks to its intuitive user interface and integrated features, variants visualization and interpretation are facilitated, while assuring protection of clinical genomic data.

## Dedicated features

Dedicated features in SOPHiA DDM reduce the complexity of determining the clinical significance of genomic variants.

- **Replicate Interpretation Mode:** Easily check SNVs and Indels across replicates for consistency
- **Global View:** Quickly screen all samples from a single sequencing run for hotspots and variants

## OncoPortal

SOPHiA DDM integrates the OncoPortal, providing actionable information on solid tumors and hematological malignancies. Leveraging on precision medicine intelligence and combining curated content from professional association guidelines and publicly available databases, it contains relevant somatic classifications, based on variant-drug-disease association, best available treatments and relevant ongoing clinical trials.

## Access to the World's Largest Clinical Genomics Community

Through SOPHiA DDM, experts from hundreds of healthcare institutions can easily interpret the variants and flag them with the appropriate level of pathogenicity. This highly valuable information feeds the variant knowledge base and is anonymously and safely shared among the members of the community.



SOPHiA™

The AI Democratizing Data-Driven Medicine

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