

The molecular diagnostic application that detects clinically relevant gene fusions and exon skipping events in lung cancer samples 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 RNAtarget Oncology Solution is intended to be used to identify clinically relevant gene fusions in 11 genes and exon skipping events in *EGFR* and *MET* in RNA extracted from FFPE samples of patients with diagnosed lung cancer by targeting specific transcripts. The function of the product is to provide an aid to healthcare professionals to make clinical decision(s) related to gene fusions/exon skipping events and to provide molecular rationale for the appropriate disease management strategy. The product is a semi-automated, qualitative device intended to be used as an *in vitro* diagnostic for professional use only.

Gene Panel	Recommendations	Wet Lab
Gene fusions: <i>ALK, FGFR1, FGFR2, FGFR3, FGFR4, NRG1, NTRK1, NTRK2, NTRK3, RET, ROS1</i>	Starting material 50 ng RNA	Day 1: Library Preparation
exon skipping: <i>EGFR vIII, MET ex14</i>	Sample type FFPE lung cancer tissue	Day 2: Capture and Sequencing
	Samples per run/Sequencer Up to 86 for Illumina® NextSeq™ 550 Mid Output Kit v2.5	Total library preparation time: 1.5 days

Analytical Performance

Analysis time from FASTQ: Max. 8 hours per 16 samples¹

	Observed (%)	Lower 95% CI
Concordance with comparator NGS assay [*]		
Positive Percent Agreement (PPA)	100	88.65
Negative Percent Agreement (NPA)	100	99.99
Overall Percent Agreement	100	-
Repeatability ^{**}	100	-
Diagnostic sensitivity ^{***}	100	70.09
Diagnostic specificity ^{***}	100	77.19

^{*}Based on analysis of fusion/exon skipping detection in 54 clinical FFPE samples, including 40 lung tumor samples and 14 derived from other solid tumors; status pre-determined by alternative NGS method(s) and compared with SOPHiA DDM™ Dx RNAtarget Oncology Solution outcome.

^{**}Based on measurement of PPA/NPA in 32 replicates of a diluted reference samples, bearing 14 targeted rearrangements.

^{***}Based on analysis of fusion/exon skipping detection in clinical study of 22 RNA FFPE lung tumor samples, performed by external site; status pre-determined by externally validated NGS method and compared with SOPHiA DDM™ Dx RNAtarget Oncology Solution outcome.

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 web portal to support decision-making.

Product codes:
BS0119ILLCSRY07-32

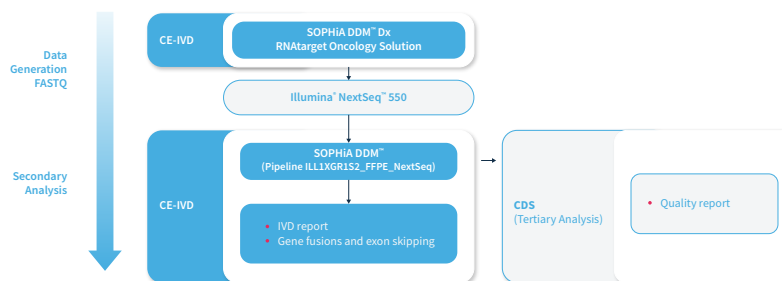


Figure 1. IVD workflow. Clinical Decision Support (CDS) results are not part of the CE-IVD claim.

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.