A new era for better patient outcomes

Introducing
TruSight™ Oncology Comprehensive (EU)

illumina®

Imagine a better oncology

diagnostic environment

Current oncology patient care relies on multiple biomarker tests. This requires strict management of a limited patient biopsy sample as the iterative single-gene testing approach can lead to tissue depletion and repeat biopsies.[1-3] TruSight Oncology Comprehensive (EU) is a comprehensive genomic profiling (CGP) solution that consolidates numerous individual tests into a single panel, minimizing the amount of sample needed and maximizing the ability to potentially identify an actionable alteration for better patient outcomes.

Comprehensive coverage
Clinical confidence

Conventional oncology testing approaches supply limited information that does not address all biomarkers for approved and emerging targeted therapies and immunotherapies. When treatment-relevant biomarkers are not evaluated, patients may only receive traditional, nonmatched regimens due to a lack of better options. With TruSight Oncology Comprehensive (EU), patients can receive a CGP test that may increase their chances of being genomically matched with a potentially more effective therapy, leading to an improved outcome.[4-9]

A single CGP test can identify more clinically relevant variants than conventional tests, such as single-gene tests and hotspot NGS panels,[2,9-12] while saving time and preserving biopsy specimen. CGP enables detection of DNA plus RNA variants and complex biomarker signatures, such as tumor mutational burden (TMB) and microsatellite instability (MSI), generating a comprehensive genomic profile of the patient's tumor and increasing confidence in ensuring the right treatment decisions.

The biomarker content of TruSight Oncology Comprehensive (EU) covers:

49 Clinical practice guidelines

117 Drug labels

680 European trials

Help inform targeted therapies for better patient outcomes

TruSight Oncology Comprehensive (EU) content includes critical biomarkers with known cancer associations as indicated in drug labels, European Society For Medical Oncology (ESMO) recommendations, and clinical trials for multiple solid tumor types.[13] The results of TruSight Oncology Comprehensive (EU) can help inform therapy decisions according to clinical guidelines.

In addition, TruSight Oncology Comprehensive (EU) is indicated as a companion diagnostic (CDx) test to identify cancer patients with solid tumors who are positive for *NTRK1*, *NTRK2*, or *NTRK3* gene fusions for treatment with VITRAKVI® (larotrectinib) in accordance with the approved therapeutic labeling.[14,15] An extensive pipeline of additional CDx indications that will help identify patients most likely to respond to specific targeted and immunotherapies is currently under development.[14-16]

One test for multiple solid tumor types

Key actionable biomarkers covered for multiple solid tumor types.*

Genes listed are tumor type–specific biomarkers of clinical significance.

Pan-tumor

BRAF
FGFR1
FGFR2
FGFR3
MSI
NTRK1
NTRK2
NTRK3
RET
TMB

Breast

ALK1
BRCA1
BRCA2
ERBB2
ESR1
PALB2
PIK3CA
PTEN

Melanoma

BRAF
KIT
NRAS

Colorectal

BRAF
ERBB2
KRAS
MSI
NRAS
POLE

* The TruSight Oncology Comprehensive (EU) panel includes over 500 genes. To see the full gene list, view the product data sheet at TruSight Oncology Comprehensive (EU).

MSI, microsatellite instability; TMB, tumor mutational burden.

Non-small cell lung cancer

ALK
BRAF
EGFR
ERBB2
KRAS
MET
NGR1
RET
ROS1

Prostate

ATM
BRCA1
BRCA2
PALB2
PTEN

Ovarian

BRCA1
BRCA2

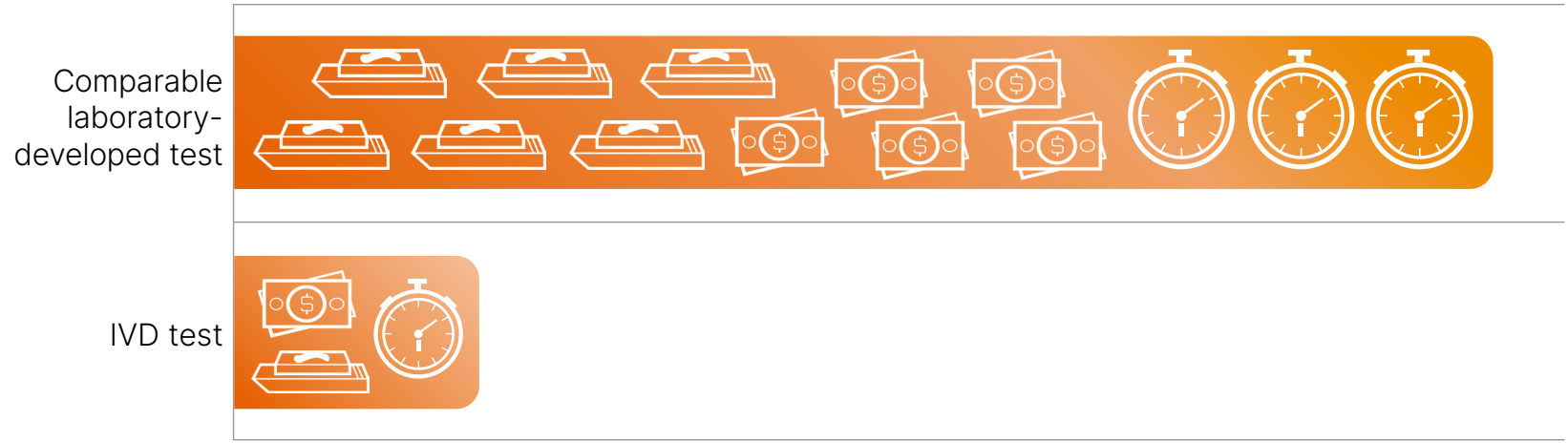
Pancreas

BRCA1
BRCA2
KRAS
NRG1
PALB2

Become a precision medicine provider
Offer CGP testing in your institution

Bring CGP testing into your lab with TruSight Oncology Comprehensive (EU) and enjoy the benefits of being a precision medicine provider. Offering the test in your institution allows you to manage sample logistics better, keep data internally for future studies, and affect sample QC success rates and, ultimately, the rate of biomarker-informed cases.

TruSight Oncology Comprehensive (EU) is a CE-marked IVD solution that is validated by Illumina. It requires ISO 15189 performance verification, which is less burdensome than the validation required by a laboratory-developed test (LDT).



†Illustrative example; not meant to provide a precise comparison of time and resources.

Maximize sample and data

Have more meaningful discussions with the oncologist

Participate more actively in Molecular Tumor Boards

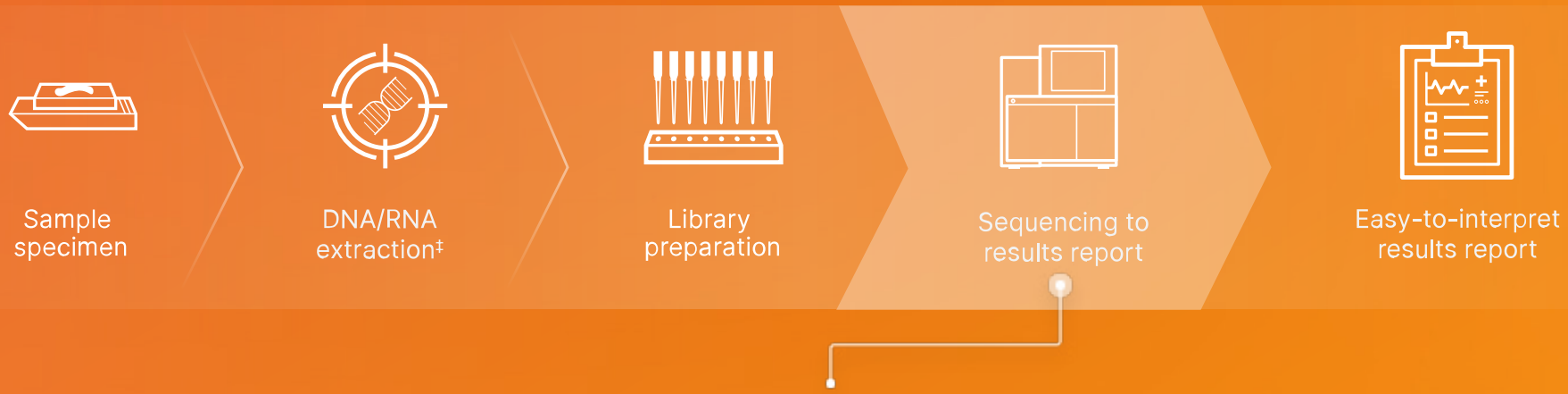
Improve test success rate

Increase number of biomarker-informed cases

From sample to report in just 4 to 5 days

Rely on a CE-marked, IVD, sample-to-answer solution that can be implemented easily, empowering you to generate test results quickly and accurately.

Fully automated sequencing and data analysis



‡ Extraction kits are purchased separately.

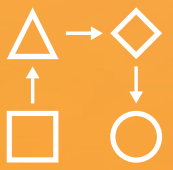
360-degree support from day one

Rest assured that you will receive our comprehensive level of support with TruSight Oncology Comprehensive (EU):

Onboarding plans

Training and certification

Marketing and educational tools through our VIP portal



Verification protocols

Ongoing technical support

Illumina Lighthouse portal

Easily find resources to help you educate your customers on the benefits of comprehensive genomic profiling.

cgplighthouse.illumina.com

TruSight Oncology Comprehensive (EU)
A sample-to-answer solution

Library prep reagents

CE-marked IVD reagents in a kitted format for simple test implementation and reliable results.

NextSeq™ 550Dx System

A CE-marked IVD instrument that delivers the consistency and reliability clinical labs need.

IVD report

Actionable biomarker findings displayed in an easy-to-read IVD report.

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Intended use

TruSight Oncology Comprehensive (EU) is an *in vitro* diagnostic test that uses targeted next generation sequencing to detect variants in 517 genes using nucleic acids extracted from formalin-fixed, paraffin embedded (FFPE) tumor tissue samples from cancer patients with solid malignant neoplasms using the Illumina NextSeq 550Dx instrument. The test can be used to detect single nucleotide variants, multinucleotide variants, insertions, deletions and gene amplifications from DNA, and gene fusions and splice variants from RNA. The test also reports a Tumor Mutational Burden (TMB) score and Microsatellite Instability (MSI) status.

The test is intended as a companion diagnostic to identify cancer patients for treatment with the targeted therapies [see Trusight Oncology Comprehensive (EU) package insert], in accordance with the approved therapeutic product labeling. In addition, the test is intended to provide tumor profiling information for use by qualified healthcare professionals in accordance with professional guidelines and is not conclusive or prescriptive for labeled use of any specific therapeutic product.

Contact your Illumina sales representative to find out more about TruSight Oncology Comprehensive (EU)

TruSight Oncology Comprehensive IVD Solutions

For *In Vitro* Diagnostic Use.
Not available in all regions and countries.

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