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) (TSO 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 TSO 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

TSO 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 TSO Comprehensive (EU) can help inform therapy decisions according to clinical guidelines.

In addition, TSO 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. Numbers indicate additional genes in TSO Comprehensive (EU) that are biomarkers of potential clinical significance.

PAN-CANCER: *BRAF*, *NTRK1*, *NTRK2*, *NTRK3*, *RET*, MSI, TMB

Breast

BRCA1
BRCA2
ERBB2
ESR1
PALB2
PIK3CA

180

Colorectal

ERBB2
KRAS
NRAS

166

Bone

EGFR
ERG
ETV1
ETV4
EWSR1
FEV
FLI1
FUS
H3F3A
HEY1
IDH1
MDM2
NCOA2
SMARCB1

140

Lung

ALK
EGFR
ERBB2
KRAS
MET
NUTM1
ROS1

223

Melanoma

KIT
NRAS
ROS1

172

Ovarian

BRCA1
BRCA2
FOXL2

149

CNS†

APC
ATRX
CDKN2A
CDKN2B
EGFR
H3F3A
HIST1H3B
HIST1H3C
IDH1
IDH2
MYCN
PTCH1
RELA
TERT
TP53

140

* The TruSight Oncology Comprehensive (EU) panel includes over 500 genes. To see the full gene list, view the product data sheet on www.illumina.com/products/by-brand/trusight-oncology/ivd-solutions.html

Prostate

AR
ATM
BARD1
BRCA1
BRCA2
BRIP1
CDK12
CHEK1
CHEK2
FANCL
FGFR2
FGFR3
PALB2
PTEN
RAD51B
RAD51C
RAD51D
RAD54L

151

Thyroid

HRAS
KRAS
NRAS
TERT

165

Uterine & cervical

BRCA2
EPC1
ERBB2
ESR1
FOXO1
GREB1
JAZF1
NCOA2
NCOA3
NUTM2A
NUTM2B
PAX3
PAX7
PHF1
POLE
SMARCA4
SUZ12
TP53
YWHAE

138

Other solid tumors

ALK
APC
ARID1A
ASPSCR1
ATF1
ATIC
BAP1
BCOR
BRCA1
BRCA2
CAMTA1
CARS
CCNB3
CDK4
CDKN2A
CIC
CITED2
CLTC
COL1A1
COL6A3
CREB1
CREB3L1
CREB3L2
CSF1
CTNNB1
DDIT3
DDX3X
DNAJB1
DUX4
EED
EGFR
ERBB2
ERG
ETV1
ETV4
ETV6
EWSR1
FEV
FGFR2
FGFR3
FLI1
FOXL2
FOXO1
FOXO4
FUS
GLI1
HEY1
HGF
HMGA2
IDH1
KRAS
LEUTX
MAML3
MDM2
MYB
MYOD1
NAB2
NCOA2
NF1
NFATC2
NFIB
NR4A3
NRAS
NUTM1
NUTM2A
NUTM2B
PALB2
PATZ1
PAX3
PAX7
PDGFB
PDGFRA
PRKACA
PRKD1
RANBP2
ROS1
SDHA
SDHB
SDHC
SDHD
SMARCB1
SS18
SSX1
SSX2
SSX4
STAT6
SUZ12
TAF15
TCF12
TERT
TFE3
TFEB
TFG
TP53
TPM3
TPM4
TRAF7
TSPAN31
VGLL2
WT1
WWTR1
YAP1
YWHAE
ZC3H7B

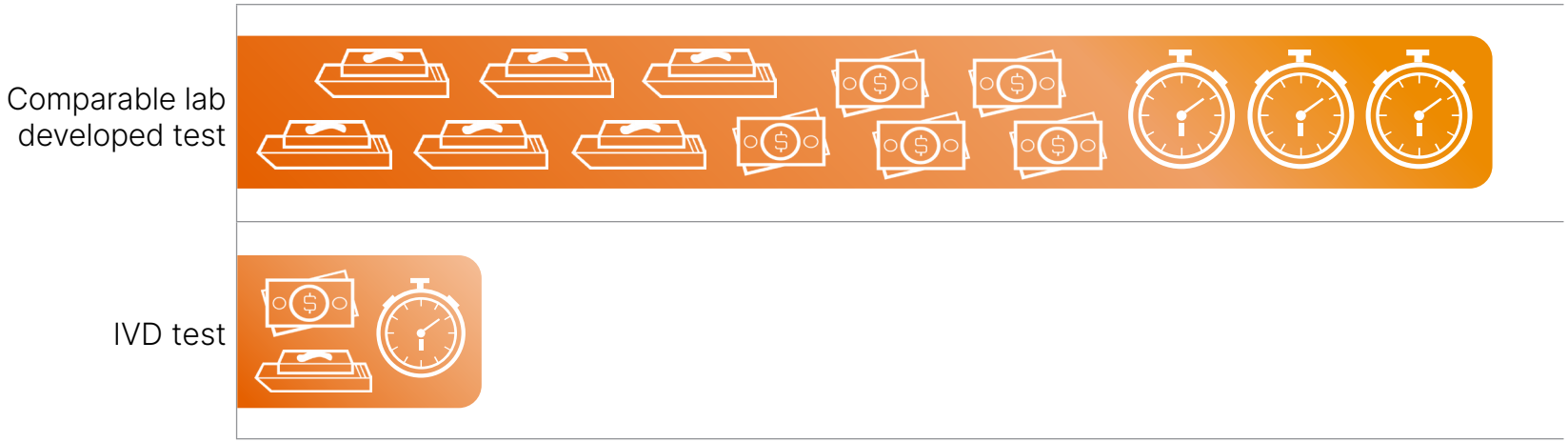
152

† Central nervous system.

Become a precision medicine provider
Offer CGP testing in your institution

Bring CGP testing into your lab with TSO 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.

TSO 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 test developed in the lab.



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

Maximize sample and data

Have more meaningful discussions with the oncologist

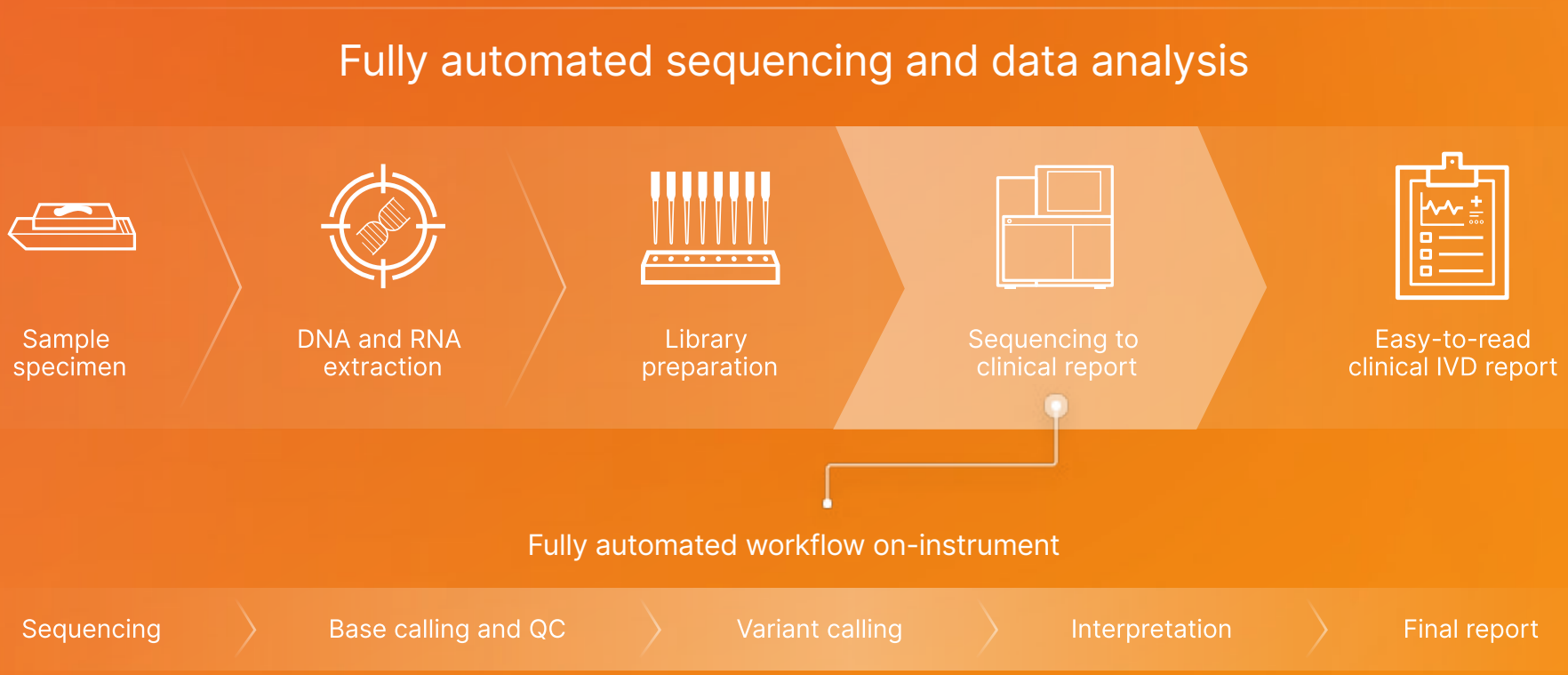
Participate more actively in Molecular Tumor Boards

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.



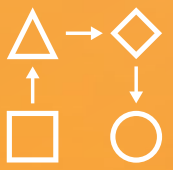
360-degree support from day one

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.

Clinical IVD report

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

References

1. Lim C, Tsao MS, Le LW, et al. Biomarker testing and time to treatment decision in patients with advanced nonsmall-cell lung cancer. *Ann Oncol*. 2015;26(7):1415-1421. doi:10.1093/annonc/mdv208
2. Drilon A, Wang L, Arcila ME, et al. Broad, Hybrid Capture-Based Next-Generation Sequencing Identifies Actionable Genomic Alterations in Lung Adenocarcinomas Otherwise Negative for Such Alterations by Other Genomic Testing Approaches. *Clin Cancer Res*. 2015;21(16):3631-3639. doi:10.1158/1078-0432.CCR-14-2683
3. Yu TM, Morrison C, Gold EJ, Tradonsky A, Layton AJ. Multiple Biomarker Testing Tissue Consumption and Completion Rates With Single-gene Tests and Investigational Use of Oncomine Dx Target Test for Advanced Non-Small-cell Lung Cancer: A Single-center Analysis. *Clin Lung Cancer*. 2019;20(1):20-29.e8. doi:10.1016/j.cllc.2018.08.010
4. Soumerai TE, Donoghue MTA, Bandlamudi C, et al. Clinical Utility of Prospective Molecular Characterization in Advanced Endometrial Cancer. *Clin Cancer Res*. 2018;24(23):5939-5947. doi:10.1158/1078-0432.CCR-18-0412
5. Gutierrez ME, Choi K, Lanman RB, et al. Genomic Profiling of Advanced Non-Small Cell Lung Cancer in Community Settings: Gaps and Opportunities. *Clin Lung Cancer*. 2017;18(6):651-659. doi:10.1016/j.cllc.2017.04.004.
6. Singal G, Miller PG, Agarwala V, et al. Association of Patient Characteristics and Tumor Genomics With Clinical Outcomes Among Patients With Non-Small Cell Lung Cancer Using a Clinicogenomic Database [published correction appears in JAMA. 2020 Feb 4;323(5):480]. *JAMA*. 2019;321(14):1391-1399. doi:10.1001/jama.2019.3241
7. Kato S, Kim KH, Lim HJ, et al. Real-world data from a molecular tumor board demonstrates improved outcomes with a precision N-of-One strategy. *Nat Commun*. 2020;11(1):4965. Published 2020 Oct 2. doi:10.1038/s41467-020-18613-3
8. Rozenblum AB, Ilouze M, Dudnik E, et al. Clinical Impact of Hybrid Capture-Based Next-Generation Sequencing on Changes in Treatment Decisions in Lung Cancer. *J Thorac Oncol*. 2017;12(2):258-268. doi:10.1016/j.jtho.2016.10.021
9. Zehir A, Benayed R, Shah RH, et al. Mutational landscape of metastatic cancer revealed from prospective clinical sequencing of 10,000 patients [published correction appears in Nat Med. 2017 Aug 4;23 (8):1004]. *Nat Med*. 2017;23(6):703-713. doi:10.1038/nm.4333
10. Reitsma M, Fox J, Borre PV, et al. Effect of a Collaboration Between a Health Plan, Oncology Practice, and Comprehensive Genomic Profiling Company from the Payer Perspective. *J Manag Care Spec Pharm*. 2019;25(5):601-611. doi:10.18553/jmcp.2019.18309
11. Kopetz S, Mills Shaw KR, Lee JJ, et al. Use of a Targeted Exome Next-Generation Sequencing Panel Offers Therapeutic Opportunity and Clinical Benefit in a Subset of Patients With Advanced Cancers. *JCO Precis Oncol*. 2019;3:PO.18.00213. Published 2019 Mar 8. doi:10.1200/PO.18.00213
12. Ali SM, Hensing T, Schrock AB, et al. Comprehensive Genomic Profiling Identifies a Subset of Crizotinib-Responsive ALK-Rearranged Non-Small Cell Lung Cancer Not Detected by Fluorescence In Situ Hybridization. *Oncologist*. 2016;21(6):762-770. doi:10.1634/theoncologist.2015-0497
13. Analysis provided by Velera based on the TruSight Oncology Comprehensive software knowledge base v8.5. Current as of February 2023.
14. Illumina and Loxo Oncology to Partner on Developing Next-Generation Sequencing-Based Pan-Cancer Companion Diagnostics. 2018. Available at https://www.businesswire.com/news/home/20180410005649/en/. Accessed February 22, 2021.
15. As Lilly deal closes, Bayer secures full rights to Loxo's Vitrakvi. 2019. Available at https://www.biopharmadive.com/news/as-lilly-deal-closes-bayer-secures-full-rights-to-loxos-vit-rakvi/548584/. Accessed February 22, 2021.
16. Illumina Announces New and Expanded Oncology Partnerships with Bristol Myers Squibb, Kura Oncology, Myriad Genetics, and Merck to Advance Comprehensive Genomic Profiling. 2021. Available at https://www.illumina.com/company/news-center/press-releases/press-release-details.html?newsid=c8606ce8-c9ec-4c7f-9659-270952ae7bba. Accessed February 22, 2021.

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)

www.illumina.com/products/by-brand/trusight-oncology/ivd-solutions.html

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

M-EMEA-00202 v4.0

illumina®