illumina®

You've always had what it takes. **Now you have what you need.**

Introducing the US FDA–approved IVD

TruSight™ Oncology Comprehensive

Be the change you want to see in cancer care

Current oncology patient care requires optimal 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 (TSO Comprehensive) is a US FDA–approved comprehensive genomic profiling (CGP) solution that takes a hypothesis-neutral approach and consolidates numerous individual tests into a single panel, minimizing the amount of sample needed and maximizing the ability to potentially identify an actionable biomarker for better patient outcomes.

TSO Comprehensive is a kitted solution. This enables testing in house and closer to the patient, potentially reducing the turnaround time to result and empowering pathologists to play a more active role on the patient care team.

As an *in vitro* diagnostic (IVD) test, TSO Comprehensive can optimize time to go-live with an easier verification process and help labs prepare for an evolving regulatory landscape.

Preserve precious biopsy, democratize access

Conventional, iterative oncology biomarker testing approaches may lead to rapid biopsy tissue depletion. As tissue is depleted, the ability to assess additional targetable markers is negatively impacted. With TSO Comprehensive, patients receive comprehensive biomarker testing 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.

As the first distributable US FDA–approved CGP test with pan-cancer companion diagnostics (CDx) claims, TSO Comprehensive is helping democratize access to potentially life-saving diagnostic testing. With a pathway to expanded reimbursement, including coverage under National Coverage Determination (NCD) 90.2[13, 14], more patients may become eligible for testing.

The biomarker content of TSO Comprehensive covers[15]:

53
Clinical practice guidelines

67
FDA-approved drug labels

~820
US clinical trials

Enabling precision medicine for better patient outcomes

TSO Comprehensive content includes critical biomarkers with known cancer associations as indicated in FDA-approved drug labels, major US clinical guidelines, and clinical trials for multiple solid tumor types.[15] The results of TSO Comprehensive can help inform therapy decisions according to clinical guidelines.

In addition, TSO Comprehensive is indicated as a CDx test to identify cancer patients with solid tumors who are positive for *NTRK1*, *NTRK2*, or *NTRK3* gene fusions for treatment with VITRAKVI® (larotrectinib) and cancer patients with non-small cell lung cancer (NSCLC) who are positive for *RET* gene fusions for treatment with RETEVMO® (selpercatinib) in accordance with the approved therapeutic labeling.[16,17] A pipeline of additional tumor profiling and CDx claims is under development.[16-18]

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 (based on presence in FDA-approved drug labels and clinical guidelines). Numbers indicate additional genes in TSO Comprehensive that are biomarkers of potential clinical significance (based on presence in clinical trials).[15]

PAN-CANCER: *BRAF, ERBB2*†, *NTRK1, NTRK2, NTRK3, RET*, TMB

Breast 94

AKT1
BRCA1
BRCA2
ESR1
PALB2
PIK3CA
PTEN

Colorectal 96

KRAS
NRAS
POLD1
POLE

Bone 97

ERG
ETV1
ETV4
EWSR1
FEV
FLI1
FUS
HEY1
IDH1
NCOA2
PATZ1

Central nervous system 69

APC
ATRX
CDKN2A
CDKN2B
CTNNB1
EGFR
H3F3A
HIST1H3B
HIST1H3C
IDH1
IDH2
MYCN
NF1
PTCH1
SMO
TERT
TP53

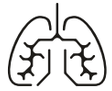
Melanoma 105

KIT
NRAS
ROS1†

Ovarian 177

BRCA1
BRCA2

Lung 120



ALK†
EGFR
KRAS
MET†
MTOR
ROS1†

Prostate 89

ATM
ATR
BARD1
BRCA1
BRCA2
BRIP1
CDK12
CHEK1
CHEK2
FANCA
FANCL
FGFR3
MLH1
MRE11
NBN
PALB2
PTEN
RAD51B
RAD51C
RAD51D
RAD54L
TACC3

Thyroid 96

TERT

Uterine and cervical 124

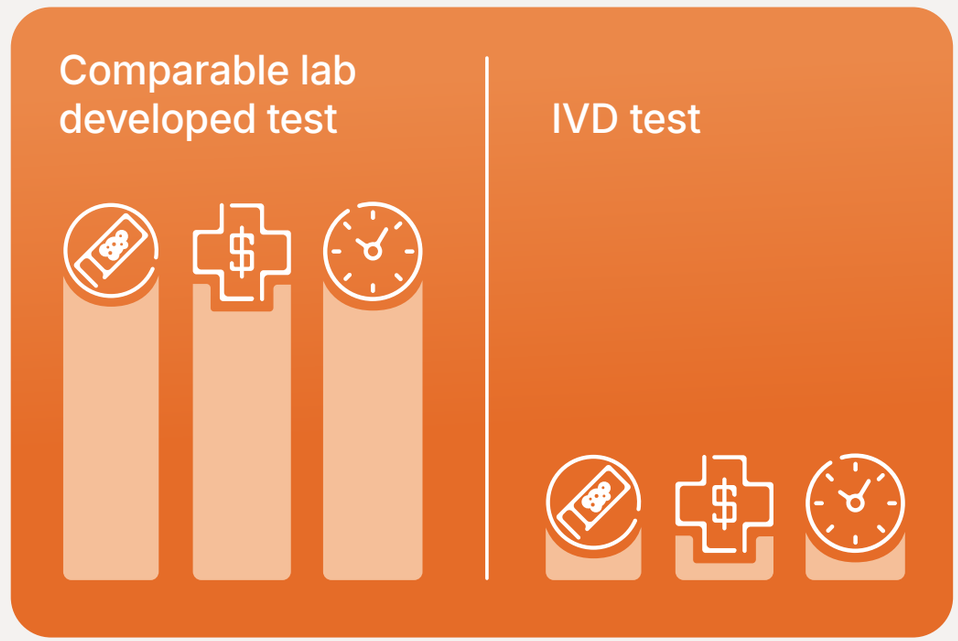
BCOR
BRCA2
ESR1
FOXO1
GREB1
NCOA1
NCOA2
NCOA3
NUTM2A
NUTM2B
PAX3
PAX7
POLE
SMARCA4
TP53
YWHAE
ZC3H7B

* The TSO Comprehensive 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.
† Small DNA variants only.

Become a precision medicine provider by offering CGP testing in your institution

Bring CGP testing into your lab with TSO Comprehensive. Offering NGS testing in your institution allows you to manage sample logistics better, keep data internally for future studies, optimize sample QC success rates, and, ultimately, increase the rate of biomarker-informed cases.[19]

TSO Comprehensive is a US FDA–approved IVD solution that is validated by Illumina. It requires performance verification,[‡] which is less resource-intensive than the validation required by a laboratory-developed test (LDT).



Time and resources to implement test[§]

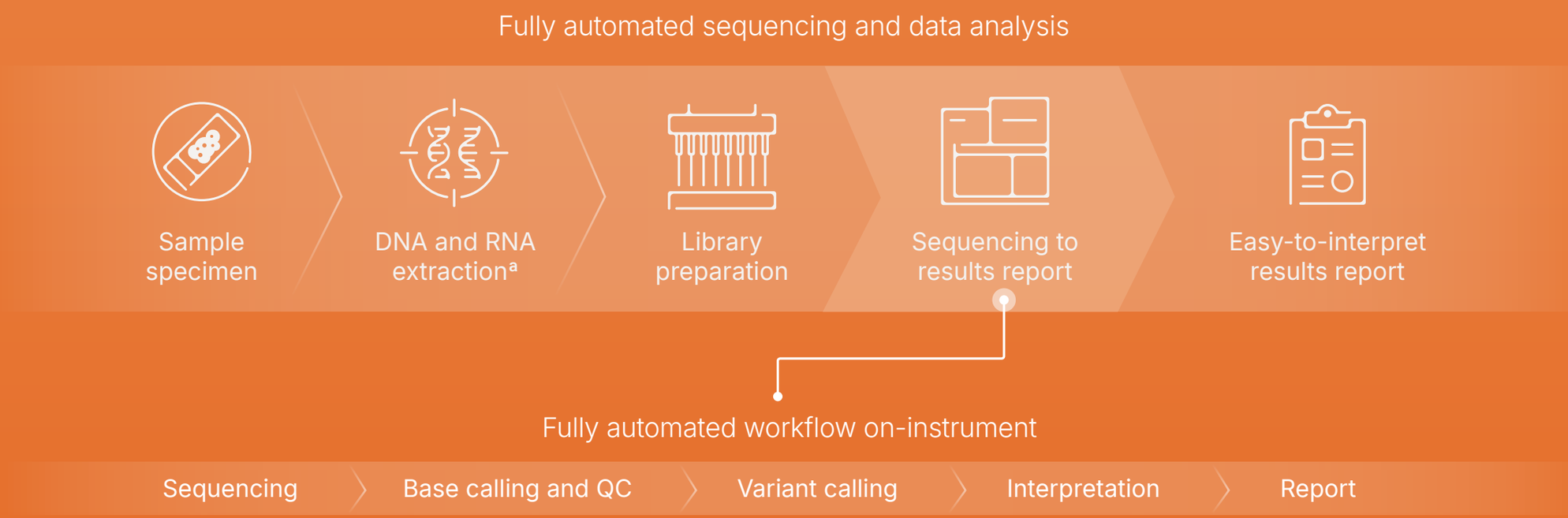
[‡] Per guidelines set in 42 CFR 493.1253.
[§] Illustrative example; not meant to provide a precise comparison of time and resources.

Benefits of offering TSO Comprehensive in your institution

- Maximize sample and data stewardship
- Have more meaningful discussions with Oncologists
- Participate more actively in Molecular Tumor Boards
- Improve test success rate
- Increase number of biomarker informed cases
- Optimize time to go-live
- Prepare for evolving regulatory landscape
- Expand access to testing

From sample to report in just 4 to 5 days

Rely on a US FDA–approved sample-to-result solution that can be implemented easier than an LDT, optimizing your time to go-live and empowering you to generate test results quickly and accurately.



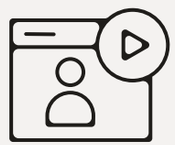
a. Extraction kits must be purchased separately.

360-degree support from day one

Rest assured that you will receive our full support with TSO Comprehensive:

Onboarding plans

Training and certification



Marketing and educational tools through our CGP Lighthouse VIP portal

Verification guidance

Ongoing technical support

CGP Lighthouse portal

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

cgplighthouse.illumina.com

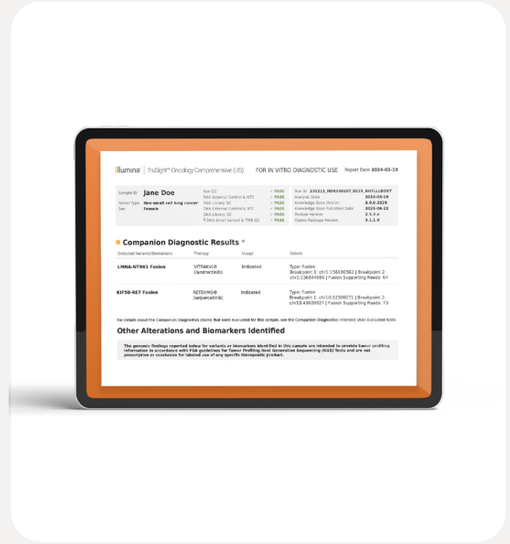
TSO Comprehensive:
A sample-to-report solution

Library prep reagents

US FDA–approved IVD reagents in a kitted format for simple test implementation and reliable results.

NextSeq™ 550Dx System

An IVD instrument that delivers the consistency and reliability clinical labs need.



Results report

Actionable biomarker findings are displayed in an easy-to-interpret results report.

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Intended use statement

TruSight™ Oncology Comprehensive is a qualitative *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, and deletions from DNA, and fusions in 24 genes and splice variants in one gene from RNA. The test also reports a Tumor Mutational Burden (TMB) score.

The test is intended to be used as a companion diagnostic to identify cancer patients who may benefit from treatment with the targeted therapies listed in Table 1, in accordance with the approved therapeutic product labeling.

In addition, the test is intended to provide tumor profiling information for use by qualified health care professionals in accordance with professional guidelines in oncology for patients with solid malignant neoplasms. Genomic findings other than those listed in Table 1 of the intended use statement are not conclusive or prescriptive for labeled use of any specific therapeutic product.

Table 1: Companion Diagnostic Indications

Tumor Type	Biomarker(s) Detected	Therapy
Solid Tumors	*NTRK1/2/3* fusions	VITRAKVI® (larotrectinib)
Non-Small Cell Lung Cancer (NSCLC)	*RET* fusions	RETEVMO® (selpercatinib)

Contact your Illumina sales representative to find out more about TSO Comprehensive

Learn more TruSight Oncology Comprehensive IVD Solutions

illumina®

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

M-AMR-01527 v1.0