TruSight™ Oncology Comprehensive

Results report example

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Results report

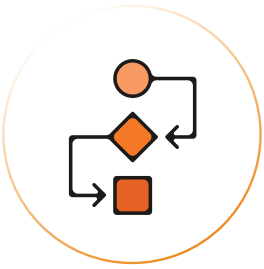
TruSight Oncology Comprehensive (TSO Comprehensive) makes comprehensive genomic profiling (CGP) accessible to laboratories, enabling simultaneous analysis of biomarkers (DNA and RNA variants and complex genomic signatures) with known cancer associations in less time than conventional, iterative testing methods. Integral to the solution is the TSO Comprehensive results report. This report is automatically generated on the NextSeq™ 550Dx System during the TSO Comprehensive workflow. The resulting streamlined results report:

- Is easy to interpret, clearly indicating patient sample information, companion diagnostic (CDx) results, and cancer mutation findings
- Provides companion diagnostics (CDx) indications for current CDx claims
- Identifies cancer mutations with evidence of clinical significance (therapeutic, prognostic, or diagnostic) based on information in US FDA–approved drug labels or major US clinical practice guidelines for the patient's tumor type, as specified by the Knowledge Base[1] and supporting rules engine

The TSO Comprehensive results report is meant to be incorporated into a final clinical report produced by the laboratory and provided to clinicians who make decisions on patient management. The design and content of the final clinical report is up to the discretion of the laboratory.

Important facts and benefits of the Knowledge Base[1] supporting the TSO Comprehensive results report

Content evaluated and approved by expert oncologists and pathologists



ISO 13485–compliant evidence curation workflow produces IVD-compliant knowledge base

Inclusive data scope and maintenance provide comprehensive coverage

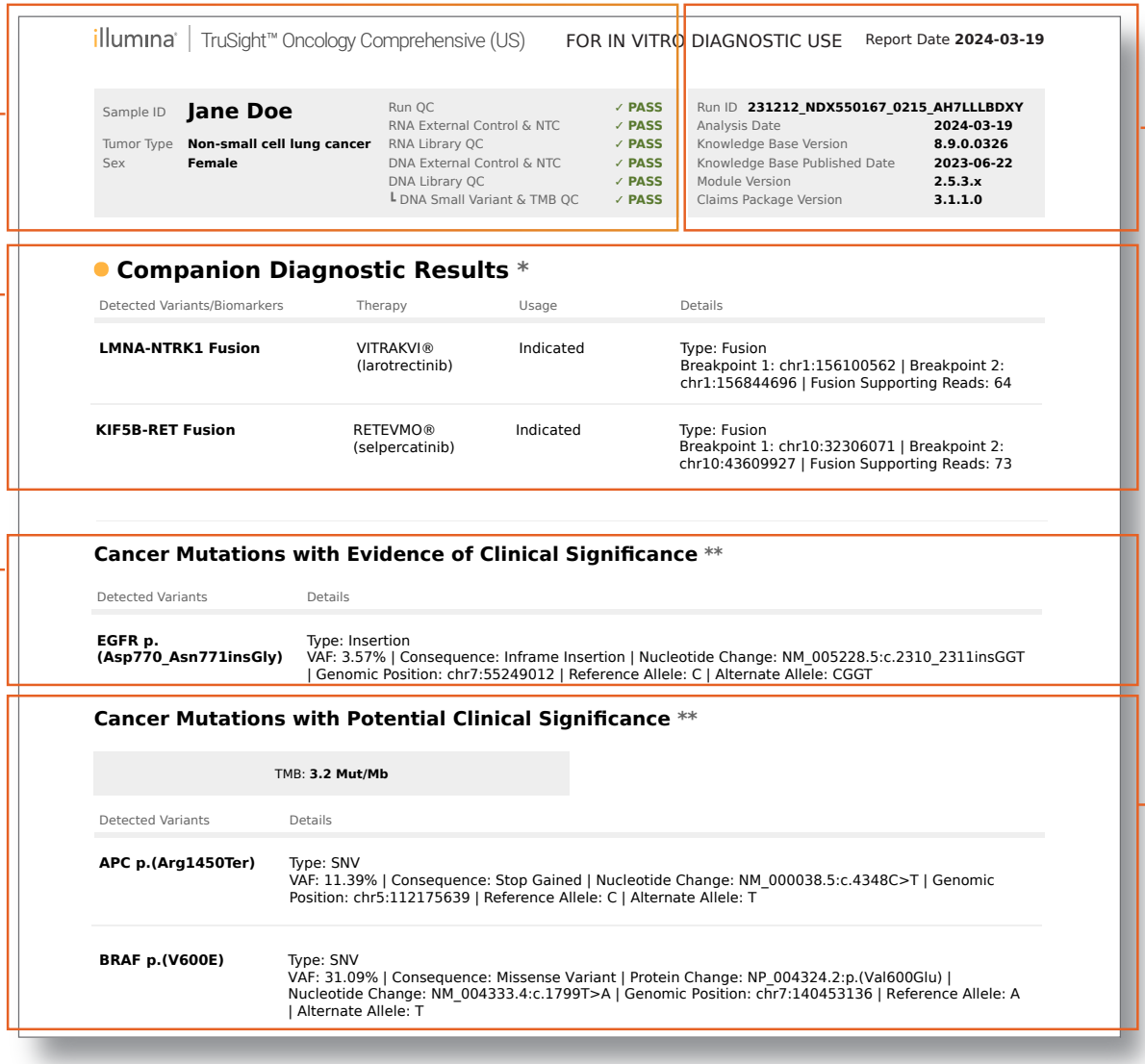
Rules-based Knowledge Base and software engine ensure variants are identified and populated in the correct tier in the report

Abbreviations: ASCO, American Society of Clinical Oncology; FDA, Federal Drug Administration; ISO, International Organization for Standardization; IVD, *in vitro* diagnostic

The TSO Comprehensive results report

Patient sample information: Sample ID, tumor type, gender, QC analysis

Assay information: Run ID, Knowledge Base, and software details



illumina | TruSight™ Oncology Comprehensive (US) FOR IN VITRO DIAGNOSTIC USE Report Date **2024-03-19**

Sample ID	**Jane Doe**	Run QC	✓ PASS	Run ID	**231212_NDX550167_0215_AH7LLLBDXY**
Tumor Type	**Non-small cell lung cancer**	RNA External Control & NTC	✓ PASS	Analysis Date	**2024-03-19**
Sex	**Female**	RNA Library QC	✓ PASS	Knowledge Base Version	**8.9.0.0326**
		DNA External Control & NTC	✓ PASS	Knowledge Base Published Date	**2023-06-22**
		DNA Library QC	✓ PASS	Module Version	**2.5.3.x**
		↳ DNA Small Variant & TMB QC	✓ PASS	Claims Package Version	**3.1.1.0**

Companion Diagnostic Results *

Detected Variants/Biomarkers	Therapy	Usage	Details
LMNA-NTRK1 Fusion	VITRAKVI® (larotrectinib)	Indicated	Type: Fusion Breakpoint 1: chr1:156100562 | Breakpoint 2: chr1:156844696 | Fusion Supporting Reads: 64
KIF5B-RET Fusion	RETEVMO® (selpercatinib)	Indicated	Type: Fusion Breakpoint 1: chr10:32306071 | Breakpoint 2: chr10:43609927 | Fusion Supporting Reads: 73

Cancer Mutations with Evidence of Clinical Significance **

Detected Variants	Details
EGFR p.(Asp770_Asn771insGly)	Type: Insertion VAF: 3.57% | Consequence: Inframe Insertion | Nucleotide Change: NM_005228.5:c.2310_2311insGGT | Genomic Position: chr7:55249012 | Reference Allele: C | Alternate Allele: CGGT

Cancer Mutations with Potential Clinical Significance **

TMB: **3.2 Mut/Mb**

Detected Variants	Details
APC p.(Arg1450Ter)	Type: SNV VAF: 11.39% | Consequence: Stop Gained | Nucleotide Change: NM_000038.5:c.4348C>T | Genomic Position: chr5:112175639 | Reference Allele: C | Alternate Allele: T
BRAF p.(V600E)	Type: SNV VAF: 31.09% | Consequence: Missense Variant | Protein Change: NP_004324.2:p.(Val600Glu) | Nucleotide Change: NM_004333.4:c.1799T>A | Genomic Position: chr7:140453136 | Reference Allele: A | Alternate Allele: T

**Additional information in Informatics Details section*

*** Accuracy of DNA tumor profiling variants below 5% variant allele frequency has not been established. Additional information in Informatics Details section*

Variants identified in both Cancer Mutations sections are potentially actionable

Cancer Mutations with Evidence of Clinical Significance: According to the Knowledge Base,[1] these findings meet at least one of the following criteria:

- Clinical practice guideline in the patient tumor type
- Drug label in the patient tumor type

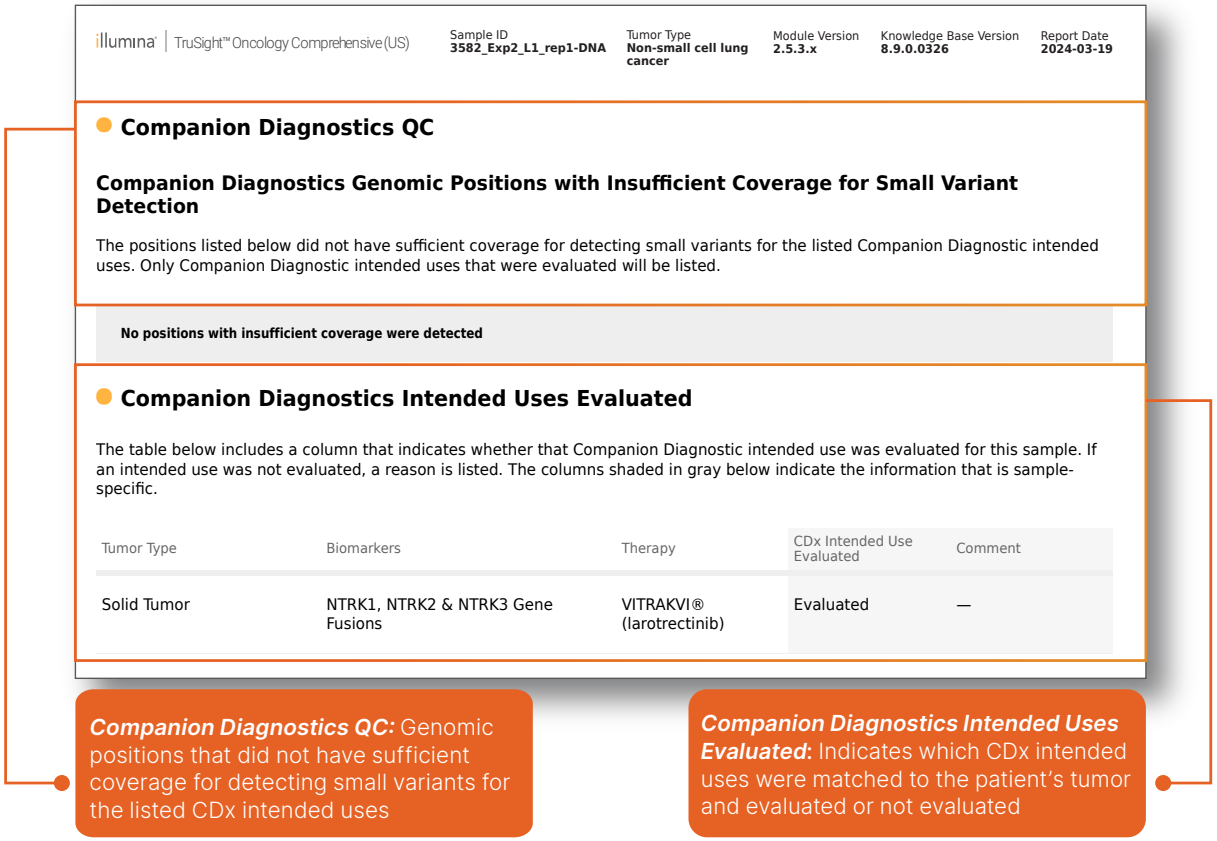
Companion Diagnostic Results: These findings identify variants or biomarkers and associated therapy indications. Example report shows results for a sample that is positive for two CDx indications

Cancer Mutations with Potential Clinical Significance: According to the Knowledge Base,[1] these findings meet at least one of the following criteria:

- Clinical practice guideline in another tumor type
- Drug label in another tumor type
- Show potential clinical significance in primary literature in the patient tumor type
- Clinical trial enrollment in the patient tumor type

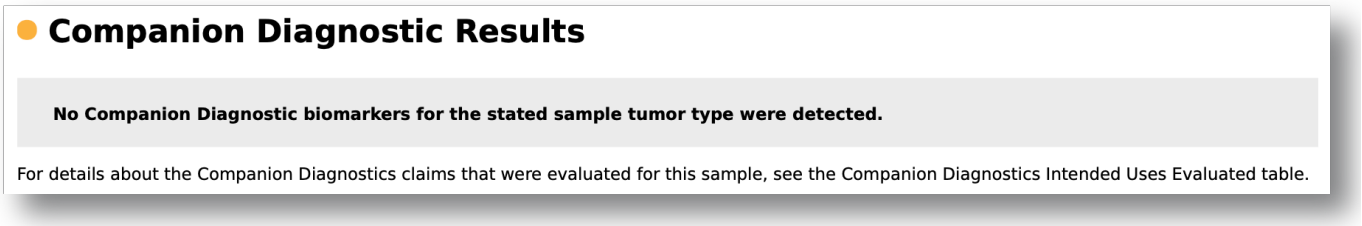
Includes status of immunotherapy biomarker TMB

The TSO Comprehensive results report



The TSO Comprehensive results report when a CDx is not detected

If a companion diagnostic result is not detected, the TSO Comprehensive results report will contain the same reporting fields as described on pages 3 and 4 of this document. Instead of listing a possible CDx, the section entitled "Companion Diagnostic Results" will indicate that "No Companion Diagnostic biomarkers for the stated sample tumor type were detected."



Learn more

TruSight Oncology Comprehensive

Reference

1. Analysis provided courtesy of Velsera based on the TSO Comprehensive Knowledge Base.

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, multi-nucleotide 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)

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