TruSight[™] Oncology Comprehensive (EU)

Clinical report example

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Clinically actionable report

TruSight Oncology (TSO) Comprehensive (EU) makes comprehensive genomic profiling (CGP) accessible to laboratories and health care professionals, 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 (EU) clinical report. This report is automatically generated on the NextSeq[™] 550Dx System during the TSO Comprehensive (EU) workflow. The resulting streamlined clinical report:

- Is easy to read, clearly indicating patient sample information and genomic findings
- Identifies variants that have evidence of clinical significance (therapeutic, prognostic, or diagnostic) based on information in EMA-approved drug labels, FDA-approved drug labels, ESMO Clinical Practice Guidelines, NCCN Guidelines, or ASCO Clinical Practice Guidelines for the patient's tumor type, as specified by the Knowledge Base¹ and supporting rules engine
- Provides clinically actionable data that can help inform therapy decisions according to clinical guidelines

Important facts and benefits of the expertly curated Knowledge Base¹ supporting the TSO Comprehensive (EU) clinical report



Content evaluated and approved by expert oncologists and pathologists



ISO 13485-compliant evidence curation workflow produces IVD-compliant Knowledge Base

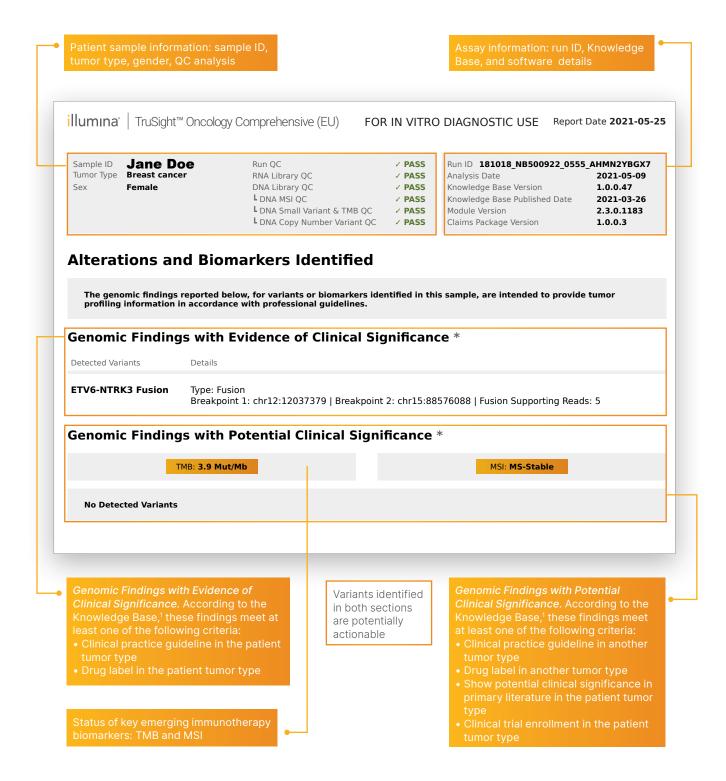


Inclusive data scope and maintenance provide comprehensive coverage

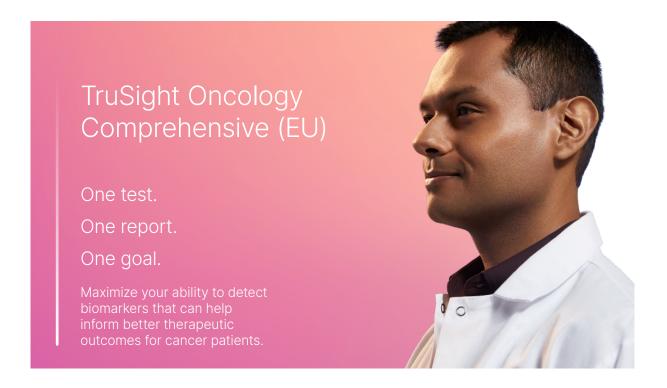


Expertly curated Knowledge Base, with rules engine, accurately identifies and tiers variants in report

The TSO Comprehensive (EU) clinical report



The remainder of the report includes test and informatics details. Not shown.



Learn more

TruSight Oncology Comprehensive (EU), illumina.com/tsocomprehensive

Reference

1. Analysis provided courtesy of PierianDx based on the TSO Comprehensive (EU) Knowledge Base. Current as of July 2021.

Intended use statement

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, multi-nucleotide 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 to provide tumor profiling information for use by qualified health care professionals in accordance with professional guidelines, and is not conclusive or prescriptive for labeled use of any specific therapeutic product.

Abbreviations: ASCO, American Society of Clinical Oncology; EMA, European Medicines Agency; ESMO, European Society for Medical Oncology; FDA, Federal Drug Administration; ISO, International Organization for Standardization; IVD, in vitro diagnostic; NCCN, National Comprehensive Cancer Network

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