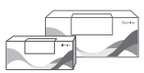
illumina®

Simplifying the process to identify applicable variants in oncology samples

The TruSight™ Oncology 500 product family, the Illumina variant calling pipeline, and PierianDx Clinical Genomics Workspace™ software enable molecular pathology labs to implement comprehensive genomic profiling (CGP) for quick, easy identification of significant biomarkers.

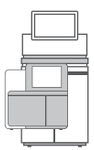


1. Prepare

Analyze 523 cancer-related genes, including biomarkers in key guidelines and clinical trials

Assess CNVs, SNVs, indels, fusions, splice variants, and complex genomic signatures, such as MSI and TMB*

TruSight Oncology 500	TruSight Oncology 500 High-Throughput	TruSight Oncology 500 ctDNA
• Solid tumor samples • DNA and RNA	• Solid tumor samples • DNA and RNA	• Liquid biopsy samples • DNA



2. Sequence

Exceptional data quality

Flexible and scalable

TruSight Oncology 500	TruSight Oncology 500 High-Throughput	TruSight Oncology 500 ctDNA
NextSeq™ 550 and NextSeq 550Dx† Systems • Up to 8 samples per run	**NextSeq 550 and NextSeq 550Dx† Systems** • Up to 8 samples per run **NovaSeq™ 6000 System** • 16-192 samples per run	**NovaSeq 6000 System** • Up to 24 samples per run

3. Call variants

Sophisticated, proprietary algorithms remove errors, artifacts, and germline variants

High-sensitivity variant calling from raw sequencing data

TruSight Oncology 500	TruSight Oncology 500 High-Throughput	TruSight Oncology 500 ctDNA
Local Run Manager • On-instrument analysis **Local Server** • Off-instrument analysis **PierianDx Clinical Genomics Workspace** • Cloud-based analysis (VCF and FASTQ files)	**Local Server** • Off-instrument analysis **PierianDx Clinical Genomics Workspace** • Cloud-based analysis (VCF and FASTQ‡ files)	**DRAGEN™ TruSight Oncology 500 ctDNA Analysis Software** • Off-instrument analysis in ~20 hours **PierianDx Clinical Genomics Workspace** • Cloud-based analysis (VCF files only)

4. Interpret results and produce meaningful reports with PierianDx Clinical Genomics Workspace

pieriandx

Easy
Upload raw data files (BAM, FASTQ, VCF) and let PierianDx Clinical Genomics Workspace do the interpretation and reporting work

Secure and compliant
Follow privacy best practices, including HIPAA, HITRUST, GDPR, CLIA, and CAP§

Scalable
Run data sets from multiple samples in parallel for fast turnaround of results

Relevant
Identify significant variants using the constantly curated, IVD-ready PierianDx Clinical Genomics Knowledgebase

Comprehensive
Learn from a partner sharing network comprised of world-leading cancer centers and health institutions aggregating real-world knowledge

Applicable
Output an evidence-based final interpretation report with clear, visual results in accordance with commonly accepted nomenclature and reporting guidelines

* CNV = copy number variations, SNV = small nucleotide variants, indel = insertions/deletions, MSI = microsatellite instability, TMB = tumor mutational burden

† NextSeq 550Dx System in Research Mode

‡ Additional fee required

§ HIPAA = Health Insurance Portability and Accountability Act, HITRUST = Health Information Trust Alliance, GDPR = General Data Protection Regulation, CLIA = Clinical Laboratory Improvement Amendments, CAP = College of American Pathologists

From sequence to applicable results

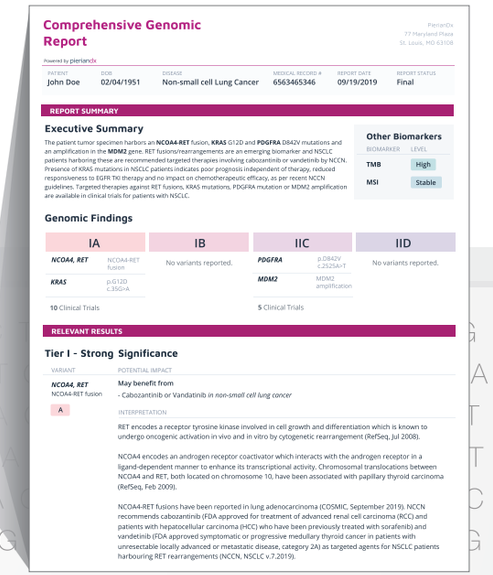
Illumina and PierianDx offer an easy, seamless workflow for turning raw sequence data into an easy-to-understand report.

523
Genes sequenced

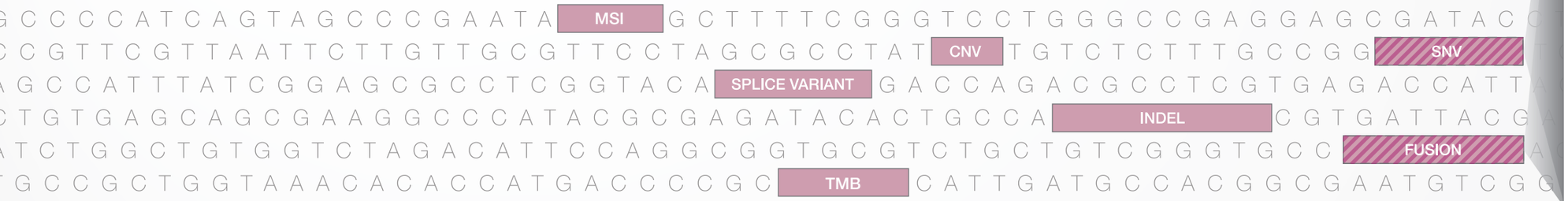
1000+
Variants called

<10
Relevant variants identified

1
Meaningful report



File format:	BAM, FASTQ	VCF	PDF



Variants and signatures identified by variant calling tools

Pathogenic variants identified by PierianDx CGW

TruSight Oncology 500

- Sequence 523 genes in key cancer guidelines and clinical trials

Secondary analysis

- Identify genomic alterations present in sample data
- Call variants with 99.9998% analytical specificity and >95% analytical sensitivity[1]
- Determine multiple variant types, including genomic signatures such as MSI and TMB
- Run Illumina secondary analysis pipeline in the PierianDx cloud, reducing risk, cost, and time

PierianDx Clinical Genomics Workspace

- Determine variant significance using literature, guidelines, drug labels, and trials information
- Filter out variants of uncertain significance or that are benign/likely benign
- Classify variants in tiers by clinical significance
- Map variants to guidelines and clinical trials
- Annotate and interpret relevant variants

Customizable genomic report

- Consolidate relevant information in one, easy-to-read report
- Adhere to AMP, CAP, ASCO, and ACMG guidelines*
- Generate meaningful information for oncologists

Learn more

Enable CGP with TruSight Oncology 500 at www.illumina.com/products/by-brand/trusight-oncology-500
Request a demo of PierianDx Clinical Genomics Workspace at www.pieriandx.com/request-a-demo/

* AMP = Association of Molecular Pathology, CAP = College of American Pathologists, ASCO = American Society of Clinical Oncology, ACMG = American College of Medical Genetics

1. Illumina. (2020) TruSight Oncology 500 and TruSight Oncology 500 High-Throughput. Accessed May 4, 2020.

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