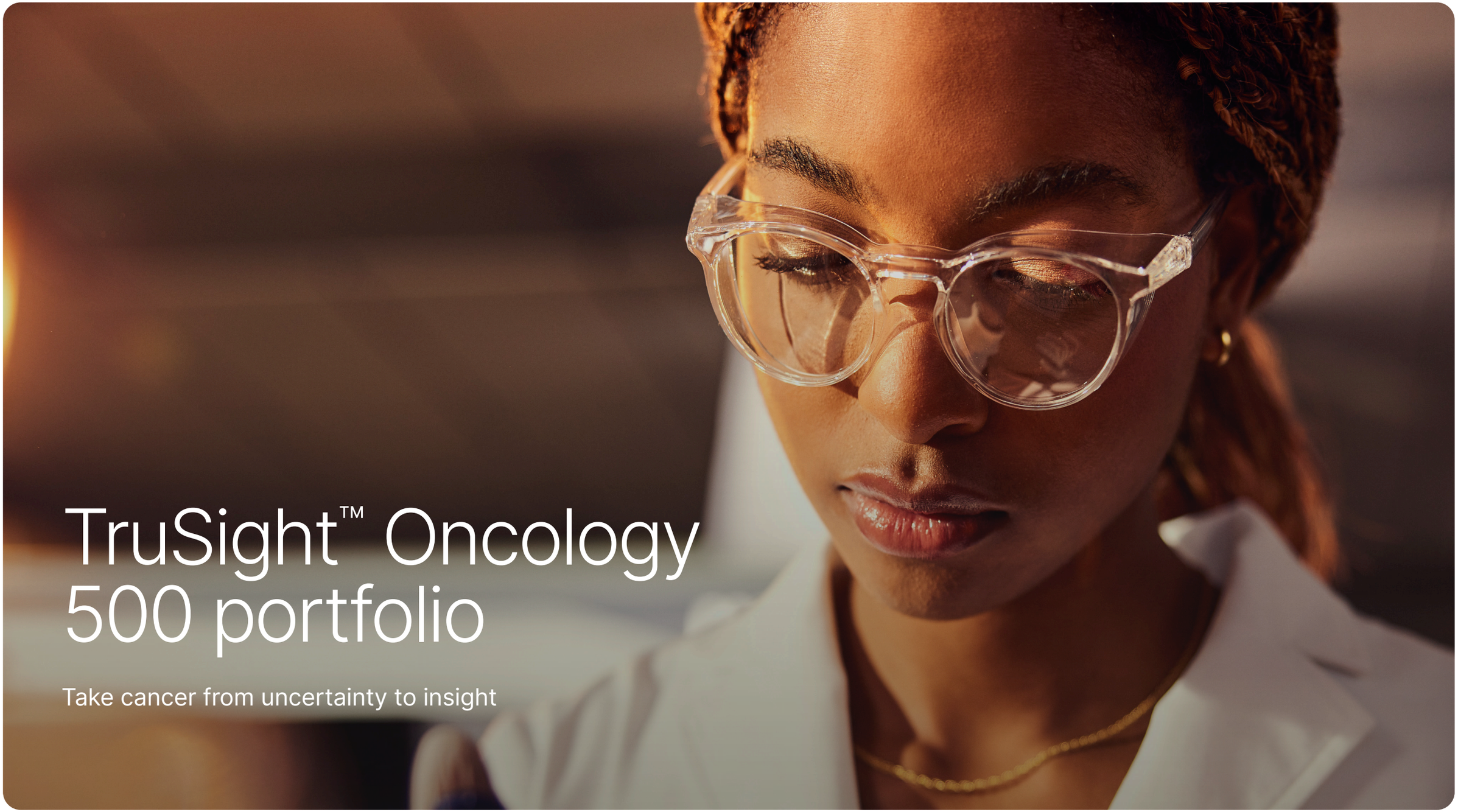


TruSight™ Oncology 500 portfolio

Take cancer from uncertainty to insight

M-GL-01925 v4.0

illumina®

Maximize value from limited sample

Enacting precision oncology studies to move potential therapies beyond today's standard of care requires a comprehensive view of a tumor's underlying genomic landscape.

One method meeting this challenge is comprehensive genomic profiling (CGP), a next-generation sequencing (NGS) approach that:

Assesses

500+ genes simultaneously in a single assay, preserving precious sample

Consolidates

testing, **saving critical time** to inform next steps[6]

Increases

the ability to **find cancer-relevant biomarkers** relative to single-gene tests or multigene panels[1–5]

Generates

one comprehensive analysis report for concise review

Identify genetic alterations in 90% of samples

Large-cohort studies show that comprehensive genomic profiling has the potential to identify relevant genetic alterations in up to 90% of samples.[2,7–11]

TruSight Oncology 500

1 streamlined portfolio. 500+ genes. ≤ 5 days.[12-13]

Enabling in-house comprehensive genomic profiling from tissue and liquid biopsy samples

With the TruSight Oncology 500 portfolio, you can:

Enable CGP

A single, pan-cancer NGS panel covers:

- All main variant classes
- Key guidelines[14–16]
- Clinical trials
- IO biomarkers: TMB, MSI, plus genomic signature HRD*

Implement in house

Offer precision oncology in your institution:

- Retain data and samples in house
- Return results in a relevant timeframe to support decision making
- Use an assay with comprehensive, pan-cancer content designed with the future in mind

Simplify your workflow

Streamline implementation:

- Integrated workflows go from sample to report in ≤ 5 days
- Flexible input types (FFPE or cfDNA from blood)
- Scalable batch sizes enabled with automation
- Local and cloud-based bioinformatics options

Obtain reliable results

Achieve consistent quality across all three assays:

- 99.999% analytical specificity[17]
- > 95% analytical sensitivity[17]
- Robust hybrid-capture chemistry
- Proven SBS sequencing
- Sophisticated bioinformatics

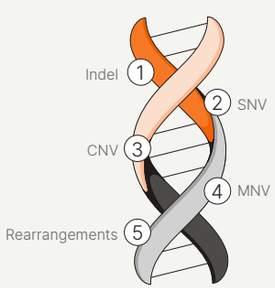
* HRD is only available with the addition of the TruSight Oncology 500 HRD kit to TruSight Oncology 500.

cfDNA, cell-free DNA; FFPE, formalin-fixed paraffin-embedded; GIS, genomic instability score; HRD, homologous recombination deficiency; IO, immuno-oncology; MSI, microsatellite instability; SBS, sequencing by synthesis; TMB, tumor mutational burden.

Extensive coverage of guidelines[14-16]

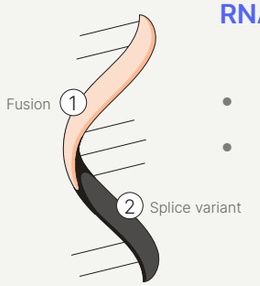
Analyze multiple variant types and key biomarkers in 523 cancer-relevant genes across DNA and RNA* in a single assay with the TruSight Oncology 500 portfolio and DRAGEN™ secondary analysis.

Variant types detected by TruSight Oncology 500 solutions



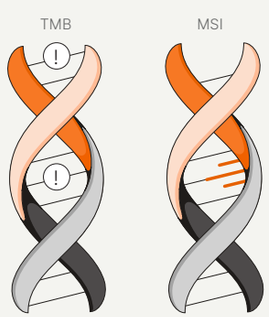
DNA variants

- Insertions/deletions (indel)
- Single nucleotide variants (SNV)
- Copy number variations (CNV)
- Multi-nucleotide variants (MNV)
- Gene rearrangements



RNA variants*

- Fusions
- Splice variants



Genomic signatures

- Tumor mutational burden (TMB from tissue, bTMB from blood)
- Microsatellite instability (MSI)
- Homologous recombination deficiency (HRD)† as measured by GIS‡

* RNA variants are included with the TruSight Oncology 500 and TruSight Oncology 500 High-Throughput tissue-based assays only.
† HRD is only available with the addition of the TruSight Oncology 500 HRD kit to TruSight Oncology 500.
‡ GIS, Genomic instability score.

A large, comprehensive panel ensures broad biomarker coverage across many solid tumor types*

		Genes with 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
Prostate	*AR* *ATM* *BARD1* *BRCA1* *BRCA2* *BRIP1* *CDK12* *CHEK1* *CHEK2* *FANCL* *FGFR2* *FGFR3* *PALB2* *PTEN* *RAD51B*	151
Thyroid	*HRAS* *KRAS* *NRAS* *TERT*	165
Uterine and 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

Find a list of all 523 genes included in the TruSight Oncology 500 portfolio.

A subset of genomic tumor profiling biomarkers for multiple cancer types. Content analysis provided by Velsera based on IVD software Knowledge Base v8.5 (February 2023). * Genes listed contain biomarkers of known significance linked to drug labels or guidelines. † Numbers indicate additional genes in the TruSight Oncology 500 panel that contain biomarkers of potential significance based on their presence in clinical trials. ‡ CNS, central nervous system.

Integrated workflow for timely results

The TruSight Oncology 500 portfolio provides a streamlined workflow using proven NGS technology that enables rapid, reliable CGP.

Insights

Uncover meaningful insights from genomic data with TruSight Oncology 500 software solutions, available on-premises or in the cloud

Flexibility

Use FFPE samples or minimally invasive circulating tumor DNA (ctDNA) from liquid biopsy to complement tissue studies or if sufficient tissue is not readily available

Scalability

Choose from multiple platforms to support a range of 8–960 samples/run for tissue and 4–48 samples/run for ctDNA

Leverage dual flow cells and independent run parameters on the NovaSeq™ X Series to sequence tissue and liquid biopsy samples simultaneously

Consistency

Minimize errors with automation options and reduce hands-on time by ~50%[17]

Enabling comprehensive genomic profiling

	Specimen	Extraction	Library prep	Sequencing	Variant calling	Insights and reporting
	4–5 day workflow					
TruSight Oncology 500 Enable CGP from tissue biopsy	 FFPE	 DNA/RNA extraction kits	 TruSight Oncology 500	 NextSeq™ 550 or NextSeq 550Dx* System Up to 8 samples	 DRAGEN TruSight Oncology 500 Analysis on local DRAGEN server or cloud-based Connected Analytics	 Multiple commercial options: Illumina Connected Insights** or Velsera CGW††
TruSight Oncology 500 High-Throughput Enable high-throughput CGP from tissue biopsy	 FFPE	 DNA/RNA extraction kits	 TruSight Oncology 500 High-Throughput‡	 NextSeq 1000 and 2000† 8–36 samples NovaSeq 6000 or NovaSeq 6000Dx* System† 16–192 samples NovaSeq X Series† 32–960 samples	 DRAGEN TruSight Oncology 500 Analysis on local DRAGEN server or cloud-based Connected Analytics	 Multiple commercial options: Illumina Connected Insights** or Velsera CGW††
	3–4 day workflow					
TruSight Oncology 500 ctDNA v2 Enable CGP from liquid biopsy	 Blood	 cfDNA extraction kits	 TruSight Oncology 500 ctDNA v2	 NovaSeq 6000 System† 8-48 samples NovaSeq X Series†§ 4-48 samples	 DRAGEN TruSight Oncology 500 Analysis on local DRAGEN server or cloud-based Connected Analytics	 Multiple commercial options: Illumina Connected Insights** or Velsera CGW††

* NextSeq 550Dx or NovaSeq 6000Dx Instruments in research mode only.
† Requires separate, standalone DRAGEN server if local secondary analysis is desired.
‡ TruSight Oncology 500 High-Throughput is also compatible with the NextSeq 550 System and NextSeq 550Dx Instrument (in research mode) for up to 8 samples.
§ Compatibility requires DRAGEN TruSight Oncology 500 ctDNA v2.6+.
** Not available in all countries. Illumina Connected Insights supports user-defined tertiary analysis through API calls to third-party knowledge sources.
†† CGW, Clinical Genomics Workspace.

Reduce hands-on time by 50% with automation[17]

Automation kits for TruSight Oncology 500 and TruSight Oncology 500 High-Throughput library preparation are specifically formulated for use with liquid-handling robots, providing optimized volumes to maximize lab efficiency.*

- Minimize errors and wasted reagent
- Increase scalability
- Generate more consistent results[18]
- Optimize lab resources

*Illumina has preferred partnerships with Beckman Coulter Life Sciences and Hamilton to develop scripts specifically for use with the TruSight Oncology 500 portfolio.

Automation scripts

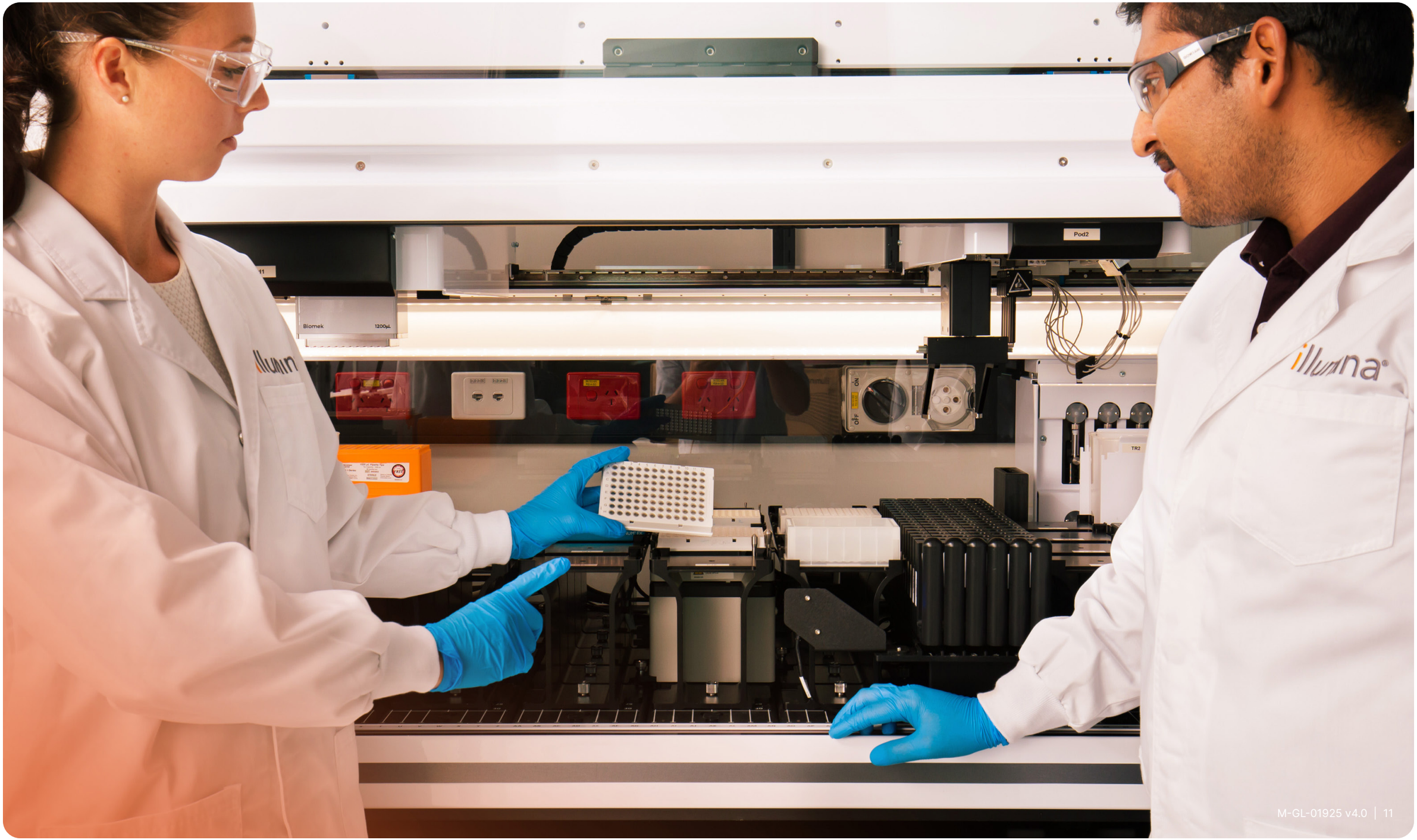
	TruSight Oncology 500	TruSight Oncology 500 High-Throughput	TruSight Oncology 500 ctDNA v2
Beckman Coulter Life Sciences Biomek i7	Illumina Qualified	Illumina Qualified	Available 2025
Beckman Coulter Life Sciences Biomek NGeniuS	Illumina Qualified	N/A	N/A
Hamilton NGS STAR	Illumina Qualified	N/A	N/A
Hamilton NGS STAR MOA	Illumina Qualified	Illumina Qualified	Illumina Qualified

Illumina Qualified methods are developed by the vendor with input from Illumina. The vendor is responsible for testing the method, with produced data reviewed by Illumina. Equipment is supplied and installed by the vendor. Illumina is available for secondary support to the vendor.

Vendor-developed methods are developed and tested by the vendor. Equipment is supplied and installed by the vendor.

N/A, not applicable.

Learn more about automation options


Biomek
1200µL
Pod2
TR2
ON
OFF

Innovative library preparation

Library preparation kits provide shared future-proof content while offering flexibility in sample input type and throughput.

TruSight Oncology 500

Enable CGP studies in house with a mid-throughput, streamlined assay

- Target DNA and RNA variants from 523 cancer-relevant genes, plus MSI and TMB
- Obtain results in 4-5 days

Learn more

Add HRD assessment

Obtain CGP and HRD insights from one sample and one workflow

- Include TruSight Oncology 500 HRD as an add-on to TruSight Oncology 500 for comprehensive assessment of HRD*
- Measure LOH, TAI, and LST together in one GIS,† powered by Myriad Genetics

Learn more

TruSight Oncology 500 High-Throughput

Increase throughput by batching up to 960 solid tumor samples for CGP studies

- Use the same proven content as TruSight Oncology 500
- Choose an automation option to increase scale while reducing hands-on time by 50%[17]

Learn more

TruSight Oncology 500 ctDNA v2

Use minimally invasive blood samples to assess circulating tumor DNA (ctDNA)

- Target DNA variants across 523 cancer-relevant genes, plus MSI and TMB
- Obtain results in 3–4 days
- Leverage manual or automated workflows across a broad range of batch sizes (4-48 samples)

Learn more

* TruSight Oncology 500 HRD is not available for sale in Japan.

† GIS, genomic instability score; LOH, loss of heterozygosity; LST, large-scale state transitions; TAI, telomeric allelic imbalance.

	TruSight Oncology 500	TruSight Oncology 500 High-Throughput	TruSight Oncology 500 ctDNA v2
Content detected			
Small DNA variants (indels, MNVs, SNVs)	✓	✓	✓
Copy number variants (CNVs)	✓	✓	✓
Fusions (DNA, RNA)[a]	✓	✓	✓
Splice variants (RNA)	✓	✓	✗
Immuno-oncology biomarkers: TMB/bTMB, MSI	✓	✓	✓
HRD (genomic instability and causal genes)	✓ Requires TruSight Oncology 500 HRD	✗[b]	✗
Assay-specific information			
System	NextSeq 550 System or NextSeq 550Dx Instrument (research mode)	NextSeq 1000 and 2000 Systems[c] NovaSeq 6000 System or NovaSeq 6000Dx Instrument (research mode)[c] NovaSeq X Series[c]	NovaSeq 6000 System or NovaSeq 6000Dx Instrument (research mode)[c] NovaSeq X Series[c]
Automation available	✓	✓	✓
Sample types	Tissue (FFPE)	Tissue (FFPE)	ctDNA from blood
No. samples per run	8	NextSeq 1000/2000: 8–36 NovaSeq 6000/6000Dx: 16–192 NovaSeq X Series: 32–960	4–48
Panel size	1.94 Mb DNA, 358 kb RNA	1.94 Mb DNA, 358 kb RNA	1.94 Mb DNA
DNA input requirement	40 ng	40 ng	20 ng cfDNA
RNA input requirement	40 ng	40–80 ng	N/A
Total assay time (nucleic acid to variant report)	4–5 days	4–5 days	3–4 days

a. Fusions only detected with RNA using TruSight Oncology 500 or TruSight Oncology 500 High-Throughput.
b. Contact your local Illumina sales representative for options.
c. Requires separate, standalone DRAGEN server if secondary analysis with on-premises server is desired.

Recognized sequencing power

Powered by proven NGS technology and SBS or XLEAP-SBS™ chemistry,* Illumina sequencing systems form the core of an integrated, sample-to-answer workflow.

NextSeq 550 and NextSeq 550Dx† Sequencing Systems

- Benchtop, mid-throughput system
- Push-button controls
- Load-and-go reagents
- Streamlined bioinformatics

The NextSeq 550Dx Instrument is an FDA-regulated, CE-marked *in vitro* diagnostic (IVD) version of the NextSeq 550 System.†

NextSeq 1000 and 2000 Systems

- Benchtop systems enabling a broad range of applications, from targeted panels to whole-genome sequencing
- XLEAP-SBS chemistry enables faster, more economical, and higher quality sequencing
- Multiple flow cell offerings for flexibility

NovaSeq X Series

- Highest throughput of any Illumina sequencing platform
- Flexible sample batching with dual flow cell capability and independent run parameters
- Groundbreaking sustainability improvements
- Transformational economic and productivity gains

NovaSeq 6000 and NovaSeq 6000Dx† Sequencing Systems

- Production-scale system adopted by leading hospital, commercial, and academic labs
- Scalable to adapt to your needs
- Flexible sequencing workflow for advanced applications

The NovaSeq 6000Dx Instrument is an FDA-regulated, CE-marked IVD version of the NovaSeq 6000 System.†

* XLEAP-SBS chemistry is a faster, higher quality, and more robust SBS chemistry available on the NovaSeq X Series.
† For *In Vitro* Diagnostic Use. Not available in all regions and countries. Use in RUO mode with TruSight Oncology 500 solutions.

System	NextSeq 550 Sequencing System or NextSeq 550Dx Instrument (RUO mode)[ab]	NextSeq 1000 and 2000 Systems			NovaSeq 6000 Sequencing System or NovaSeq 6000Dx Instrument (RUO mode)[ac]				NovaSeq X Series[c]		
Assay compatibility	TruSight Oncology 500 TruSight Oncology 500 HRD	TruSight Oncology 500 High-Throughput			TruSight Oncology 500 High-Throughput TruSight Oncology 500 ctDNA v2 TruSight Oncology 500 HRD (SP flow cell only)				TruSight Oncology 500 High-Throughput TruSight Oncology 500 ctDNA v2		
Flow cell	High-output	P2	P3	P4	SP	S1	S2	S4	1.5B	10B	25B
Flow cells processed per run	1	1	1	1	1 or 2	1 or 2	1 or 2	1 or 2	1 or 2	1 or 2	1 or 2
Run time	24 hr	19 hr	31 hr	34 hr	19 hr	19 hr	25–36 hr	36–45 hr	TruSight Oncology 500 High-Throughput 18.5 hr	20 hr	33 hr
									TruSight Oncology 500 ctDNA v2 22 hr	25 hr	
Clusters passing filter (PF) per flow cell	Up to 400M	Up to 400M	Up to 1.2B	Up to 1.8B	Up to 800M	Up to 1.6B	Up to 4.1B	Up to 10B	Up to 1.6B	Up to 10B	Up to 26B
Assay read length	TruSight Oncology 500 and TruSight Oncology 500 HRD	TruSight Oncology 500 High-Throughput			TruSight Oncology 500 High-Throughput and TruSight Oncology 500 HRD	TruSight Oncology 500 High-Throughput 2 × 101 bp	2 × 101 bp	2 × 101 bp	TruSight Oncology 500 High-Throughput 2 × 101 bp	2 × 101 bp	2 × 101 bp
	2 × 101 bp	2 × 101 bp	2 × 101 bp	2 × 101 bp	2 × 101 bp		TruSight Oncology 500 ctDNA v2 2 × 151 bp	2 × 151 bp	TruSight Oncology 500 ctDNA v2 2 × 151 bp	2 × 151 bp	
No. samples per flow cell[d]											
TruSight Oncology 500	8	-	-	-	-	-	-	-	-	-	-
TruSight Oncology 500 HRD	8	-	-	-	16	-	-	-	-	-	-
TruSight Oncology 500 High-Throughput	-	8	24	36	16	32	72	192	32	192	480
TruSight Oncology 500 ctDNA	-	-	-	-	-	-	8	24	4	24	-

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

b. Install specifications are based on Illumina PhiX control library at supported cluster densities (between 129 and 165 k/mm^2 clusters passing filter). Actual performance parameters may vary based on sample type, sample quality, and clusters passing filter. The percentage of bases > Q30 is averaged over the entire run.

c. Output and read number specifications are based on a single flow cell using Illumina PhiX control library at supported cluster densities; the NovaSeq 6000 System can run one or two flow cells simultaneously.

d. Samples per run listed for the NovaSeq 6000 System and NovaSeq X Series are indicated for a single flow cell run. Option to run dual flow cells to double the output for TruSight Oncology 500 High-Throughput and TruSight Oncology 500 ctDNA v2.

Accurate, easy-to-use analysis reduces touchpoints, accelerates insights

Illumina Connected Software streamlines genomics workflows and helps reduce bioinformatics bottlenecks, getting you to reliable data sooner.

Flexible

Local and cloud-based analysis allows labs to choose an option that best suits their needs

Scalable

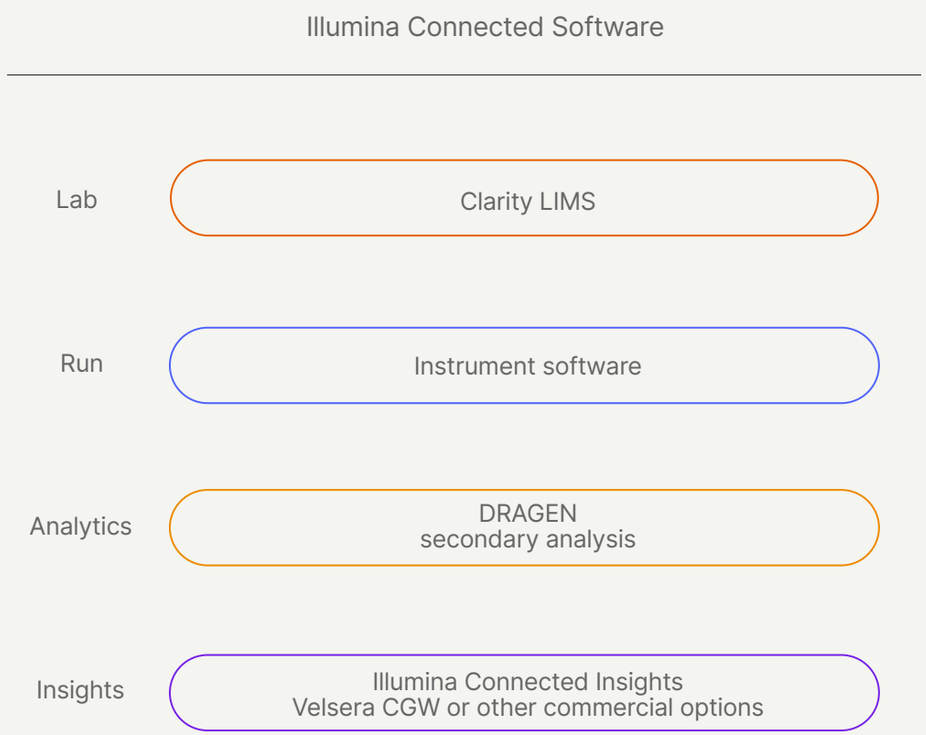
Cloud-based analysis enables scaling without additional hardware investments

Secure and compliant

Seamless data management and a no-touch workflow meet the most stringent security requirements; data sharing security and governance, audit trails, and encryption ensure data are safe and secure

User-friendly

Intuitive interface with automated data transfer and analysis kickoff reduces touchpoints to make software accessible to general users and bioinformatics professionals alike



Simplified lab optimization

Clarity LIMS™ software

- Preconfigured workflows streamline sample tracking and workflow management
- Automated reagent and sample volume calculations, step transitions, sample placement, and quality control save time on workflow configuration and script creation

Learn more

Streamlined run planning

Local and cloud-based tools

- User-friendly software for configuring the sequencing run and analysis steps
- Automated data transfer and analysis eliminate or reduce the need to interact with the workflow until analysis is complete
- Choose between BaseSpace™ Run Planner and a growing number of on-instrument apps

Accurate secondary analysis

DRAGEN secondary analysis

- Provides award-winning[19] accuracy and comprehensive support across multiple variant types
- Calls DNA variants (SNVs, indels, CNVs, absolute CNVs,* LOH,* tumor purity* and ploidy,* MSI, TMB, and GIS†) and RNA variants (fusions and splices)‡
- Runs analysis 2–10× faster than other pipelines,[17] which is critical for high-throughput applications

The DRAGEN TruSight Oncology 500 tissue and ctDNA analysis pipelines are available locally via an on-instrument app and an on-premises DRAGEN server or in the cloud via Illumina Connected Analytics.

Learn More

Powerful insights

Illumina Connected Insights§

- Enables labs to implement and automate process-specific steps, from variant prioritization to report generation
- Streamlines variant interpretation to address this bottleneck and move precision medicine forward
- Harnesses 45+ external knowledge sources to identify relevant biomarkers, clinical trials, drug labels, and guidelines

Learn More

Velsera Clinical Genomics Workspace (CGW)

- Enables variant classification in tiers by clinical relevance based on the most current literature, guidelines, drug labels, and clinical trials information
- Outputs an evidence-based final interpretation report with clear, visual results that adhere to AMP, CAP, ASCO, and ACMG reporting guidelines**

* Available as beta features with TruSight Oncology 500 HRD.
† GIS algorithm powered by Myriad Genetics is only accessible with TruSight Oncology 500 HRD. Not available in Japan.
‡ RNA variants not included with TruSight Oncology 500 ctDNA.
§ Not available in all countries. Illumina Connected Insights supports user-defined tertiary analysis through API calls to third-party knowledge sources.
** AMP, Association of Molecular Pathology; CAP, College of American Pathologists; ASCO, American Society of Clinical Oncology; ACMG, American College of Medical Genetics.

Enhanced product attributes

To enable greater laboratory efficiency, TruSight Oncology 500 products feature:*

Certificate of Analysis

Every TruSight Oncology 500 product is issued with a certificate of analysis (CoA) by the Illumina Quality Assurance Department that ascertains the product has met its predetermined product release specifications and quality

Extended shelf life

The minimum guaranteed shelf life for TruSight Oncology 500 reagents is extended to six months, reducing the risk of product expiration and enabling labs to use reagents according to current testing needs

Advanced change notification

Illumina notifies laboratories six months before any significant changes are made to a product in the TruSight Oncology 500 portfolio

*For TruSight Oncology 500 bundles on the NextSeq 550Dx instrument, enhanced features apply only to library preparation kits and not to core consumables. SIngle-lot shipments for TruSight Oncology 500 ctDNA v2 manual kits are available now. SIngle-lot shipments for TruSight Oncology 500 ctDNA v2 automation kits will be available in 2024.

Welcome to a world of support

Illumina service and support begin when your Illumina instrument is delivered. Our scientists and engineers are ready to assist with instrument installation and laboratory setup. In addition to onsite support, courses are available to train users on various workflows. Illumina scientists are available 24 hours a day, five days a week globally to answer questions every step of the way.

Illumina Evaluation and Verification Service

Expedite analytical evaluation with tools and protocols intended to guide you in aligning with the latest CAP, AMP, and European standards.*

Illumina training

Get high-quality results on Illumina technology even faster with instructor-led, hands-on courses and web-based training options on various topics.

Contact Illumina

Contact your Illumina sales representative to find out more about our solutions.

Contact us

* Available only for TruSight Oncology 500 on the NextSeq 550 or NextSeq 550Dx Systems.

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