



# TruSight™ Oncology 500 portfolio

Take cancer from uncertainty to insight



# Maximize value from limited sample

Enacting precision oncology research 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:

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## Assesses

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

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## Consolidates

testing, **saving critical time** to inform next steps<sup>6</sup>

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## Increases

the ability to **find cancer-relevant biomarkers** relative to single-gene tests or multigene panels<sup>1-5</sup>

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## 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.<sup>2,7-11</sup>









# TruSight Oncology 500

1 streamlined portfolio. 500+ genes. 3–4 days.<sup>12-13</sup>

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

# With the TruSight Oncology 500 portfolio, you can:



## Enable CGP research

A single, pan-cancer NGS panel covers:

- All main variant classes
- Key guidelines<sup>14-16</sup>
- 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
- Deliver results rapidly to inform timely research decisions
- 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 3–4 days
- Flexible input types (FFPE or cfDNA from blood)
- Scalable batch sizes enabled with automation
- Local and cloud-based bioinformatics options



## Obtain reliable results

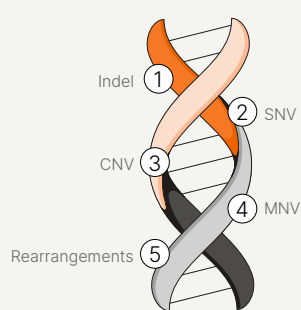
Achieve consistent quality:

- 99.999% analytical specificity<sup>17</sup>
- $\geq 95\%$  analytical sensitivity<sup>17</sup>
- Robust hybrid-capture chemistry
- Proven SBS sequencing
- Sophisticated bioinformatics

# Extensive coverage of guidelines<sup>14-16</sup>

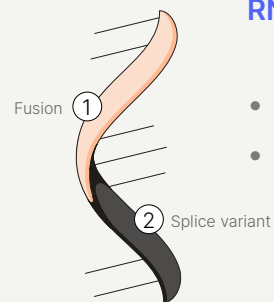
Analyze multiple variant types and key biomarkers in 523 cancer-relevant genes across DNA and RNA\* in a single assay with the TruSight Oncology 500 portfolio and DRAGEN™ secondary analysis.

## 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<sup>†</sup>

\* RNA variants are included with the TruSight Oncology 500 v2 tissue-based assay only.

† GIS, Genomic instability score.

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

Pan-cancer	BRAF NTRK1 NTRK2 NTRK3 RET MSI TMB
Breast	AKT1 BRCA1 BRCA2 ESR1 PIK3CA PTEN
Colorectal	KRAS NRAS POLD1 POLE
Non-small cell lung cancer	ALK BRAF EGFR ERBB2 KRAS MET RET ROS1
Melanoma	KIT NRAS
Ovarian	BRCA1 BRCA2 HRD
Prostate	ATM ATR BARD1 BRCA1 BRCA2 BRIP1 CDK12 CHEK1 CHEK2 FANCL MRE11A NBN PALB2 RAD51B RAD51C RAD51D RAD54L
Uterine	POLE

Download a list of all genes included in the TruSight Oncology 500 assay [here](#) and in the TruSight Oncology 500 ctDNA v2 assay [here](#).

A subset of genomic tumor profiling biomarkers for multiple cancer types is shown.

\* Genes listed contain biomarkers of known significance linked to major guidelines.





# Integrated workflow for timely results

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

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## Insights

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

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## 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

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## Scalability

Choose from multiple platforms to support a range of 8–960 samples/run for tissue and 4–128 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













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## Consistency

Benefit from automation to reduce manual steps, streamline use, and lower the risk of error.<sup>17</sup>



# Enabling comprehensive genomic profiling

	Specimen	Extraction	Library prep	Sequencing	Variant calling	Insights and research reporting
3–4 day workflow						
<b>TruSight Oncology 500 v2*</b> Enable CGP from tissue biopsy	 FFPE	 DNA/RNA extraction kits	 TruSight Oncology 500 v2* (manual or automated)	 NextSeq™ 550 System or NextSeq 550Dx Instrument† 8 samples per run  NextSeq 1000 and 2000 Systems‡ 8–36 samples per run  NovaSeq 6000 System or NovaSeq 6000Dx Instrument 16–384 samples per run  NovaSeq X Series‡ 32–960 samples per run	 DRAGEN TruSight Oncology 500 Analysis on local DRAGEN server or cloud-based Connected Analytics	 Illumina Connected Insights or other options, such as Velsera CGW§ are available
2.5–4 day workflow						
<b>TruSight Oncology 500 ctDNA v2</b> Enable CGP from liquid biopsy	 Blood	 cfDNA extraction kits	 TruSight Oncology 500 ctDNA v2 (manual or automated)	 NextSeq 2000 System† 4 samples per run  NovaSeq 6000 System or NovaSeq 6000Dx Instrument 4–48 samples per run  NovaSeq X Series‡ 4–128 samples per run	 DRAGEN TruSight Oncology 500 Analysis on local DRAGEN server or cloud-based Connected Analytics	 Illumina Connected Insights or other options, such as Velsera CGW§ are available

\* TruSight Oncology 500 v2 is not available for sale in Japan.

† NextSeq 550Dx or NovaSeq 6000Dx Instruments in research mode only.

‡ Requires separate, standalone DRAGEN server if local secondary analysis is desired.

§ CGW, Clinical Genomics Workspace.

# Reduce hands-on time with automation<sup>17</sup>

Automation kits for TruSight Oncology 500 v2 and TruSight Oncology 500 ctDNA v2 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<sup>18</sup>
- 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 v2	TruSight Oncology 500 ctDNA v2
Beckman Coulter Life Sciences Biomek i7	Illumina Qualified Plus	Illumina Qualified Plus
Hamilton NGS STARlet	Illumina Qualified	Illumina Qualified
Hamilton NGS STAR	Illumina Qualified	N/A
Hamilton NGS STAR MOA	Illumina Qualified Plus	Illumina Qualified Plus

**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.

**Illumina Qualified Plus methods** are codeveloped and tested with our automation partners. Our partners own, supply, and install these methods. Illumina provides front-line field and technical support for these methods. Our partners provide secondary support for these methods. Our partners service and support their liquid handler systems.

N/A, not applicable.

[Learn more about automation options](#)





# Innovative library preparation

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



## TruSight Oncology 500 v2\*

### Enable CGP studies in house with a flexible, streamlined assay

- Target DNA and RNA variants from 523 cancer-relevant genes, plus MSI and TMB
- Obtain results in 3–4 days
- Increase throughput by batching up to 960 solid tumor samples
- Choose an automation option to increase scale while reducing hands-on time<sup>17</sup>

### Obtain CGP and HRD insights from one sample and one workflow

- TruSight Oncology 500 v2 includes HRD for optional comprehensive assessment in all samples
- Measure LOH, TAI, and LST together in one GIS, powered by Myriad Genetics

[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 2.5–4 days
- Leverage manual or automated workflows across a broad range of batch sizes (4–128 samples)

[Learn more](#)

\* TruSight Oncology 500 v2 is not available for sale in Japan.

CGP, comprehensive genomic profiling; GIS, genomic instability score; LOH, loss of heterozygosity; LST, large-scale state transitions; MSI, microsatellite instability; TAI, telomeric allelic imbalance; TMB, tumor mutational burden.



	TruSight Oncology 500 v2	TruSight Oncology 500 ctDNA v2
Content detected		
Small DNA variants (indels, MNVs, SNVs)	✓	✓
Copy number variants (CNVs)	✓	✓
Fusions (DNA, RNA) <sup>a</sup>	✓	✓
Splice variants (RNA)	✓	✗
Immuno-oncology biomarkers: TMB/bTMB, MSI	✓	✓
HRD (genomic instability)	✓	✗
Assay-specific information		
System	NextSeq 550 System or NextSeq 550Dx Instrument (research mode) NextSeq 1000 and 2000 Systems <sup>b</sup> NovaSeq 6000 System or NovaSeq 6000Dx Instrument (research mode) NovaSeq X Series <sup>b</sup>	NextSeq 2000 System <sup>b</sup> NovaSeq 6000 System or NovaSeq 6000Dx Instrument (research mode) NovaSeq X Series <sup>b</sup>
Automation available	✓	✓
Sample types	Tissue (FFPE)	ctDNA from blood
No. samples per run	NextSeq 550/550Dx: 8 NextSeq 1000/2000: 8–36 NovaSeq 6000/6000Dx: 16–384 NovaSeq X Series: 32–960	NextSeq 2000: 4 NovaSeq 6000/6000Dx: 4–48 NovaSeq X: 4–128
Panel size	1.94 Mb DNA, 358 kb RNA, ~25K SNPs HRD	1.94 Mb DNA
DNA input requirement	30 ng (as low as 10 ng)	20 ng cfDNA
RNA input requirement	40 ng (as low as 20 ng)	N/A
Total assay time (nucleic acid to variant report)	3–4 days	2.5–4 days

a. Fusions only detected with RNA using TruSight Oncology 500 v2.

b. Requires separate, standalone DRAGEN server if secondary analysis with on-premises server is desired.

bTMB, blood tumor mutational burden; cfDNA, cell-free DNA; CNV, copy number variant; ctDNA, circulating tumor DNA; FFPE, formalin-fixed, paraffin embedded; HRD, homologous recombination deficiency; indels, insertions/deletions; MNV, multinucleotide variant; MSI, microsatellite instability; SNP, single nucleotide polymorphism; SNV, single nucleotide variant.

# 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.



## 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



## 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



## NextSeq 550 and NextSeq 550Dx<sup>†</sup> 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.<sup>†</sup>



## NovaSeq 6000 and NovaSeq 6000Dx<sup>†</sup> 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.<sup>†</sup>

\* XLEAP-SBS chemistry is a faster, higher quality, and more robust SBS chemistry available on the NextSeq 1000 and 2000 Systems and the NovaSeq X Series.

<sup>†</sup> 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) <sup>ab</sup>	NextSeq 1000 and 2000 Systems			NovaSeq 6000 Sequencing System or NovaSeq 6000Dx Instrument (RUO mode) <sup>ac</sup>				NovaSeq X Series <sup>c</sup>		
Assay compatibility	TruSight Oncology 500 v2 <sup>d</sup>	TruSight Oncology 500 v2 TruSight Oncology 500 ctDNA v2			TruSight Oncology 500 v2 TruSight Oncology 500 ctDNA v2				TruSight Oncology 500 v2 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	TruSight Oncology 500 v2	19 hr	19 hr	TruSight Oncology 500 v2		TruSight Oncology 500 v2		
				34 hr			25 hr	36 hr	18.5 hr	20 hr	33 hr
				TruSight Oncology 500 ctDNA v2		TruSight Oncology 500 ctDNA v2			TruSight Oncology 500 ctDNA v2		
				44 hr		25 hr	36 hr	45 hr	22 hr	25 hr	48 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	2 × 101 bp	2 × 101 bp	2 × 101 bp	TruSight Oncology 500 v2	TruSight Oncology 500 v2				TruSight Oncology 500 v2		
				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		TruSight Oncology 500 ctDNA v2			TruSight Oncology 500 ctDNA v2		
				2 × 151 bp		2 × 151 bp	2 × 151 bp	2 × 151 bp	2 × 151 bp	2 × 151 bp	2 × 151 bp
No. samples per flow cell <sup>e</sup>											
TruSight Oncology 500 v2 tissue	8	8	24	36	16	32	72	192	32	192	480
TruSight Oncology 500 ctDNA	-	-	-	4	-	4	8	24	4	24	64

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<sup>2</sup> 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. TruSight Oncology 500 v2 is not available for sale in Japan.

e. 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 v2 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

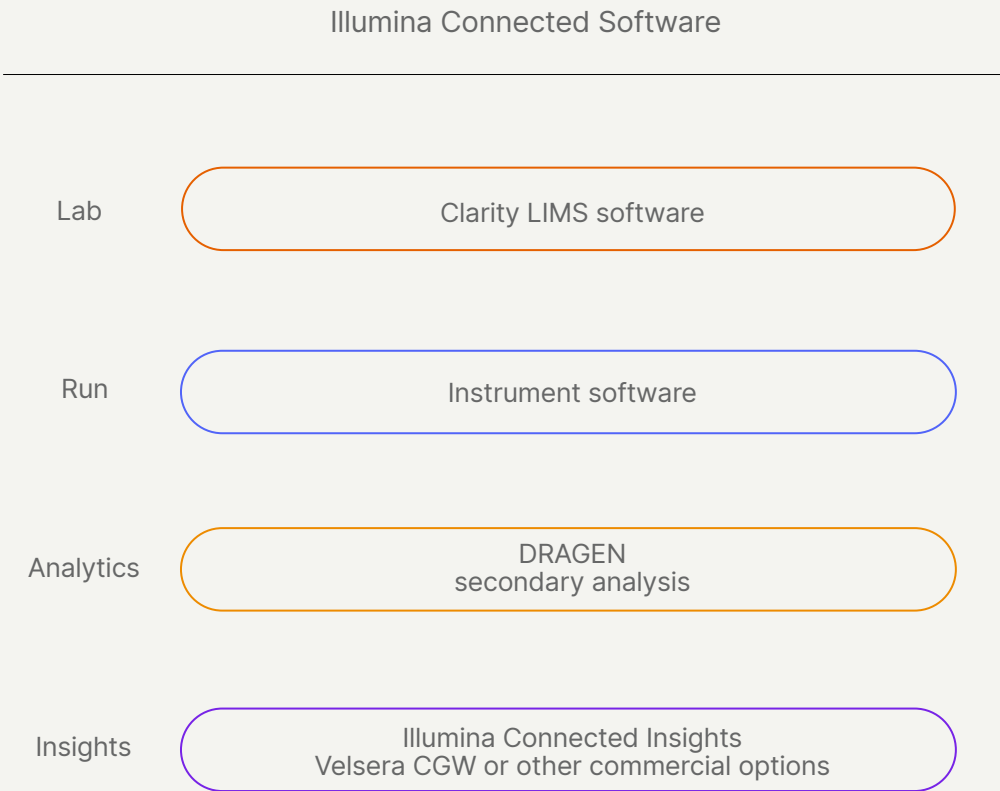
Cloud-based analysis enables scaling without additional hardware investments

## 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

\* Available as beta features with TruSight Oncology 500 v2.

† GIS algorithm powered by Myriad Genetics is only accessible with TruSight Oncology 500 v2 tissue. Not available in Japan.

‡ RNA variants not included with TruSight Oncology 500 ctDNA.

CNV, copy number variant; GIS, genomic instability score; indels, insertions/deletions; LOH, loss of heterozygosity; MSI, microsatellite instability; SNV, single nucleotide variant; TMB, tumor mutational burden.

## Accurate secondary analysis

### DRAGEN secondary analysis

- Provides award-winning<sup>19</sup> 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,<sup>17</sup> 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





# Enhanced product attributes

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

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## Certificate of Analysis

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

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## Extended shelf life

The minimum guaranteed shelf life for TruSight Oncology 500 ctDNA v2 reagents is extended to six months, reducing the risk of product expiration and enabling labs to use reagents according to current testing needs

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## 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. Extended shelf life for TruSight Oncology 500 v2 reagents will be available in 2026.

# 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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## Take cancer from uncertainty to insight

CGP offers a streamlined, faster method for gaining insights into the genomic underpinnings of cancer. With proven solutions and world-class support, the Illumina TruSight Oncology 500 portfolio is ready to enable your CGP efforts. Illumina is committed to investing in the TruSight Oncology 500 portfolio to bring new advancements to oncology researchers.

Together, we can obtain a greater understanding of the genome, propelling precision medicine forward.

Visit [TruSight Oncology 500](#) or contact us today.



We are always available for questions, insights, and conversation.

Visit us at [illumina.com](https://www.illumina.com).

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