



# 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 nextgeneration sequencing (NGS) approach that:

# **Assesses**

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

# **Consolidates**

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

# Increases

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

# 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. ≤ 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 quidelines<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
- 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

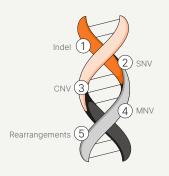
Achieve consistent quality across all three assays:

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

# Extensive coverage of guidelines 14-16

Analyze multiple variant types and key biomarkers in 523 cancerrelevant 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)<sup>†</sup> as measured by GIS<sup>‡</sup>

# Genes with biomarkers of potential clinical significance $^{\scriptscriptstyle o}$

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

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 <sup>‡</sup>	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





# 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

# Scalability\*

Choose from multiple platforms to support a range of 8–192 samples/flow cell for tissue and 8–24<sup>†</sup> samples/flow cell for ctDNA

# **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

# Consistency

Minimize errors with automation options<sup>†</sup> and reduce hands-on time by ~50%<sup>18</sup>

<sup>\*</sup> Throughput doubles for dual flow cell runs.

<sup>†</sup> Automation options and 48-sample ctDNA kits available in 2024.

# Enabling comprehensive genomic profiling

	Specimen	Extraction	Library prep	Sequencing	Variant calling	Insights and reporting
TruSight Oncology 500 Enable CGP from tissue biopsy	FFPE	DNA/RNA extraction kits	TruSight Oncology 500	NextSeq™ 550 or NextSeq550Dx* 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	NovaSeq™ 6000 or NovaSeq 6000Dx* System† 16-192 samples‡	DRAGEN TruSight Oncology 500 Analysis on local DRAGEN server or cloud-based Connected Analytics	Multiple commercial options: Illumina Connected Insights** or Velsera CGW††
3.5–5 day workflow						
TruSight Oncology 500 ctDNA v2 Enable CGP from liquid biopsy	Blood	cfDNA extraction kits	TruSight Oncology 500 ctDNA	NovaSeq 6000 System <sup>§</sup> 8-48 samples	DRAGEN TruSight Oncology 500 Analysis on local DRAGEN server or cloud-based Connected Analytics	Multiple commercial options: Illumina Connected Insights** or Velsera CGW <sup>††</sup>

<sup>\*</sup> NextSeg 550Dx or NovaSeg 6000Dx Instruments in research mode only.

<sup>†</sup> Requires separate, standalone DRAGEN server if local secondary analysis is desired.

<sup>‡</sup> 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.

<sup>§</sup> NovaSeq 6000Dx Instrument in research mode has not been extensively tested with TruSight Oncology 500 ctDNA, but is considered technically compatible. Requires separate, standalone DRAGEN server if local secondary analysis is desired.

<sup>\*\*</sup> Not available in all countries. Illumina Connected Insights supports user-defined tertiary analysis through API calls to third-party knowledge sources.

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# Reduce hands-on time by 50% with automation<sup>15</sup>

TruSight Oncology 500 and TruSight Oncology 500 High-Throughput library preparation automation kits 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>19</sup>
- Optimize lab resources

# Scripts for automating TruSight Oncology 500 High-Throughput

# Biomek i7 Hybrid NGS STAR NGS STAR MOA Illumina Qualified Vendor developed 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.

Learn more about automation options

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



# Innovative library preparation

Library preparation kits offer 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,<sup>†</sup> powered by Myriad Genetics

### Learn more



<sup>†</sup> LOH, loss of heterozygosity; TAI, telomeric allelic imbalance; LST, large-scale state transitions.



# **TruSight Oncology 500 High-Throughput**

Increase throughput by batching up to 192 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

### 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
- Obtain results in ~3.5 days
- Gain inter- and intra-tumor heterogeneity insights
- Use to complement tissue profiling or when tissue samples are unavailable or the quantity is insufficient

### Learn more













	TruSight Oncology 500	TruSight Oncology 500 High-Throughput	TruSight Oncology 500 ctDNA v2	
Content detected				
Small DNA variants (indels, MNVs, SNVs)	<b>✓</b>	<b>✓</b>	<b>✓</b>	
Copy number variants (CNVs)	<b>✓</b>	<b>✓</b>	<b>✓</b>	
Fusions (DNA, RNA)ª	<b>✓</b>	✓	<b>✓</b>	
Splice variants (RNA)	<b>✓</b>	<b>✓</b>	×	
Immuno-oncology biomarkers: TMB/bTMB, MSI	<b>✓</b>	<b>✓</b>	<b>✓</b>	
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)	NovaSeq 6000 System or NovaSeq 6000Dx Instrument (research mode) <sup>c</sup>	NovaSeq 6000 System or NovaSeq 6000Dx Instrument (research mode) <sup>c</sup>	
Automation available	<b>✓</b>	<b>✓</b>	✓d	
Sample types	Tissue (FFPE)	Tissue (FFPE)	ctDNA from blood	
No. samples per flow cell 8		16-192	8-24	
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	
otal assay time (nucleic acid to variant report)	4–5 days	4–5 days	3.5 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.

d. Automation for TruSight Oncology 500 ctDNA v2 will be available in 2024.

# Recognized sequencing power

Powered by proven NGS technology and SBS chemistry, Illumina sequencing systems form the core of an integrated, sample-to-answer workflow. Ongoing developments will lead to compatibility with the latest sequencing systems.

# 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.\*



# 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.\*



<sup>\*</sup> For In Vitro Diagnostic Use. Not available in all regions and countries. Use in RUO mode with TruSight Oncology 500 solutions.











## NextSeq 550 Sequencing System or System NextSeq 550Dx Instrument (RUO mode)ab

# NovaSeq 6000 Sequencing System or NovaSeq 6000Dx Instrument (RUO mode)ac

Assay compatibility  TruSight Oncology 500  TruSight Oncology 500 HRD		TruSight Oncology 500 High-Throughput TruSight Oncology 500 ctDNA v2 TruSight Oncology 500 HRD (SP flow cell only)						
Flow cell	High-output	SP	S1	S2	S4			
Flow cells processed per run	1	1 or 2	1 or 2	1 or 2	1 or 2			
Run time	24 hr	19 hr	19 hr	25–36 hr	36–45 hr			
Clusters passing filter (PF) per flow cell	Up to 400M clusters PF	Up to 800M clusters PF	Up to 1.6B clusters PF	Up to 4.1B clusters PF	Up to 10B clusters PF			
Assay read length	500 and 500 HRD: 2 × 101 bp	500 High-Throughput and 500 HRD: 2 × 101 bp	500 High-Throughput: 2 × 101 bp	500 High-Throughput: 2 × 101 bp 500 ctDNA v2: 2 × 151 bp	500 High-Throughput: 2 × 101 bp 500 ctDNA v2: 2 × 151 bp			
No. samples per flow cell <sup>d</sup>								
TruSight Oncology 500	8	-	-	-	-			
TruSight Oncology 500 HRD	8	16	-	-	-			
TruSight Oncology 500 High-Throughput	-	16	32	72	192			
TruSight Oncology 500 ctDNA	-	-	-	8	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/mm² 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 are indicated for a single flow cell run. Option to run dual flow cells 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

## Illumina Connected Software

Lab Clarity LIMS

Run Instrument software

Analytics DRAGEN secondary analysis

Illumina Connected Insights
Velsera CGW or other commercial options

Insights













# 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<sup>20</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>21</sup> which is critical for high-throughput applications

The DRAGEN TruSight Oncology 500 tissue and ctDNA analysis pipelines are available locally via an oninstrument 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 processspecific 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, quidelines, 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\*\*

<sup>\*</sup> Available as beta features with TruSight Oncology 500 HRD.

<sup>†</sup> GIS algorithm powered by Myriad Genetics is only accessible with TruSight Oncology 500 HRD. Not available in Japan.

<sup>‡</sup> RNA variants not included with TruSight Oncology 500 ctDNA.

<sup>§</sup> Not available in all countries. Illumina Connected Insights supports user-defined tertiary analysis through API calls to third-party knowledge sources.

<sup>\*\*</sup> 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

<sup>\*</sup>For TruSight Oncology 500 bundles on the NextSeq 550Dx instrument, enhanced features apply only to library preparation kits and not to core consumables. CoA will be available for TruSight Oncology 500 ctDNA v2 at the end of 2023. Single-lot shipments for TruSight Oncology 500 ctDNA v2 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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# 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 www.illumina.com/tso500 or contact us today.



We are always available for questions, insights, and conversation. Visit us at illumina.com.

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