FREQUENTLY ASKED QUESTIONS

TruSight™ Oncology Comprehensive (EU)

Learn more about this CE-marked *in vitro* diagnostic, next-generation sequencing solution for comprehensive genomic profiling

illumina®

General information

What is TruSight Oncology Comprehensive (EU)?

As a global leader in next-generation sequencing (NGS) and microarray-based solutions, Illumina is dedicated to improving human health by unlocking the power of the genome. Illumina continues to innovate by offering TruSight Oncology Comprehensive (EU), a CE-marked *in vitro* diagnostic (IVD), pan-cancer comprehensive genomic profiling (CGP) panel. TruSight Oncology Comprehensive (EU) can generate a broad molecular profile of solid tumor patient samples, including formalin fixed, paraffin embedded (FFPE) tissue, maximizing a lab's ability to find actionable alterations that can help inform therapy decisions according to clinical guidelines.

Additional key points:

- TruSight Oncology Comprehensive (EU) can be implemented easily in house, features a streamlined workflow that proceeds from sample to final clinical report in 4–5 days, and requires as few as five FFPE slides
- TruSight Oncology Comprehensive (EU) reliably detects all DNA and RNA variant categories, including single nucleotide variants (SNVs), insertions/deletions (indels), amplifications, fusions, and splice variants and enables analysis of genomic signatures such as tumor mutational burden (TMB) and microsatellite instability (MSI)
- A roadmap of Companion Diagnostic claims will add multiple indications, linked to breakthrough therapies that can improve patient outcomes

Generate a CGP report for a patient sample

- Detect DNA plus RNA variants and biomarkers signatures for multiple solid tumor types, generate a CGP report for a patient's tumor, and increase confidence in correct treatment decisions

Enable targeted therapies and clinical trials

- Leverage content that includes key biomarkers associated with drug labels, ESMO guidelines, and clinical trials for multiple solid tumor types
- Deliver results that inform therapy decisions according to clinical guidelines

Perform IVD testing in-house

- Implement a streamlined workflow, going from sample to report in 4–5 days
- Offer precision oncology research, keep data in your institution, and avoid losing samples to send-out services

Who is the target customer?

The target customers for TruSight Oncology Comprehensive (EU) are molecular pathologists and lab directors in European countries, who routinely run solid tumor tissue biomarker tests to aid oncologists with therapy selection for cancer patients. Common qualifiers and details about the locations of target customers:

Types of institutions:

- Academic medical centers
- Large to medium hospitals
- Independent commercial labs

TruSight Oncology Comprehensive (EU) will be available in the following countries:

- Austria
- Belgium
- Bulgaria
- Cyprus
- Czech Republic
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Iceland
- Ireland
- Israel
- Italy
- Liechtenstein
- Luxembourg
- Malta
- Netherlands
- Norway
- Poland
- Portugal
- Qatar
- Romania
- Slovenia
- South Africa
- Spain
- Sweden
- Switzerland
- UAE
- UK

What are the IVD claims?

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, multinucleotide 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 as a companion diagnostic to identify cancer patients for treatment with the targeted therapy listed in Table 1, in accordance with the approved therapeutic product labeling. In addition, the test is intended to provide tumor profiling information for use by qualified healthcare professionals in accordance with professional guidelines and is not conclusive or prescriptive for labeled use of any specific therapeutic product.

Table 1: CDx indication

Tumor type	Biomarkers	Targeted therapy
Solid tumors	*NTRK1*, *NTRK2*, *NTRK3* gene fusions	VITRAKVI® (larotrectinib)

Read the TruSight Oncology Comprehensive Package Insert to learn more, support.illumina.com/sequencing/sequencing_kits/trusight-oncology-comprehensive.html

What gene/biomarker content is included?

TruSight Oncology Comprehensive (EU) includes key biomarkers in clinical guidelines, drug labels, and clinical trials, across multiple solid tumor types and histologies (Figure 1). Content includes small DNA variants (Table 2) as well as fusions (RNA), splice variants (RNA), amplifications (DNA), and complex genomic signatures (Table 3). These lists are based on content that has been validated by Illumina.

Pan-cancer: *BRAF, NTRK1, NTRK2, NTRK3, RET*, MSI, TMB													
		Genes with biomarkers of clinical significance[a]											Genes with biomarkers of potential clinical significance[b]
	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*	**140**
		MDM2	*NCOA2*	*SMARCB1*									
	Lung	*ALK*	*EGFR*	*ERBB2*	*KRAS*	*MET*	*NUTM1*	*ROS1*					**223**
	Melanoma	*KIT*	*NRAS*	*ROS1*									**172**
	Ovarian	*BRCA1*	*BRCA2*	*FOXL2*									**149**
	CNS[c]	*APC*	*ATRX*	*CDKN2A*	*CDKN2B*	*EGFR*	*H3F3A*	*HIST1H3B*	*HIST1H3C*	*IDH1*	*IDH2*	*MYCN*	**140**
		PTCH1	*RELA*	*TERT*	*TP53*								
	Prostate	*AR*	*ATM*	*BARD1*	*BRCA1*	*BRCA2*	*BRIP1*	*CDK12*	*CHEK1*	*CHEK2*	*FANCL*	*FGFR2*	**151**
		FGFR3	*PALB2*	*PTEN*	*RAD51B*	*RAD51C*	*RAD51D*	*RAD54L*					
	Thyroid	*HRAS*	*KRAS*	*NRAS*	*TERT*								**165**
	Uterine and cervical	*BRCA2*	*EPC1*	*ERBB2*	*ESR1*	*FOXO1*	*GREB1*	*JAZF1*	*NCOA2*	*NCOA3*	*NUTM2A*	*NUTM2B*	**138**
		PAX3	*PAX7*	*PHF1*	*POLE*	*SMARCA4*	*SUZ12*	*TP53*	*YWHAE*				
	Other solid tumors	*ALK*	*APC*	*ARID1A*	*ASPSCR1*	*ATF1*	*ATIC*	*BAP1*	*BCOR*	*BRCA1*	*BRCA2*	*CAMTA1*	**152**
		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*							

Figure 1: Key actionable biomarkers—Genes listed represent a subset of all genes present in the panel. Content analysis provided by Velsera, based on IVD software Knowledge Base v8.5 (February 2023).

a. Genes linked to current drug labels or guidelines.
b. Based on evidence in scientific literature, presence in clinical trials, or linked to labels in other histologies..
c. CNS, central nervous system.

Table 2: TruSight Oncology Comprehensive (EU) panel content

Small variants - 517 genes (from DNA)											
ABL1	*BCR*	*CREBBP*	*ERBB4*	*FGFR4*	*HIST1H3G*	*KEAP1*	*MST1*	*PDCD1*	*PTPRS*	*SH2D1A*	*TFRC*
ABL2	*BIRC3*	*CRKL*	*ERCC1*	*FH*	*HIST1H3H*	*KEL*	*MST1R*	*PDCD1LG2*	*PTPRT*	*SHQ1*	*TGFBR1*
ABRAXAS1	*BLM*	*CRLF2*	*ERCC2*	*FLCN*	*HIST1H3I*	*KIF5B*	*MTOR*	*PDGFRA*	*QKI*	*SLIT2*	*TGFBR2*
ACVR1	*BMPR1A*	*CSF1R*	*ERCC3*	*FLI1*	*HIST1H3J*	*KIT*	*MUTYH*	*PDGFRB*	*RAB35*	*SLX4*	*TMEM127*
ACVR1B	*BRAF*	*CSF3R*	*ERCC4*	*FLT1*	*HIST2H3A*	*KLF4*	*MYB*	*PDK1*	*RAC1*	*SMAD2*	*TMPRSS2*
ADGRA2	*BRCA1*	*CSNK1A1*	*ERCC5*	*FLT3*	*HIST2H3C*	*KLHL6*	*MYC*	*PDPK1*	*RAD21*	*SMAD3*	*TNFAIP3*
AKT1	*BRCA2*	*CTCF*	*ERG*	*FLT4*	*HIST2H3D*	*KMT2A*	*MYCL*	*PGR*	*RAD50*	*SMAD4*	*TNFRSF14*
AKT2	*BRD4*	*CTLA4*	*ERRFI1*	*FOXA1*	*HIST3H3*	*KRAS*	*MYCN*	*PHF6*	*RAD51*	*SMARCA4*	*TOP1*
AKT3	*BRIP1*	*CTNNA1*	*ESR1*	*FOXL2*	*HNF1A*	*LAMP1*	*MYD88*	*PHOX2B*	*RAD51B*	*SMARCB1*	*TOP2A*
ALK	*BTG1*	*CTNNB1*	*ETS1*	*FOXO1*	*HNRNPK*	*LATS1*	*MYOD1*	*PIK3C2B*	*RAD51C*	*SMARCD1*	*TP53*
ALOX12B	*BTK*	*CUL3*	*ETV1*	*FOXP1*	*HOXB13*	*LATS2*	*NAB2*	*PIK3C2G*	*RAD51D*	*SMC1A*	*TP63*
AMER1	*CALR*	*CUX1*	*ETV4*	*FRS2*	*HRAS*	*LMO1*	*NBN*	*PIK3C3*	*RAD52*	*SMC3*	*TRAF2*
ANKRD11	*CARD11*	*CXCR4*	*ETV5*	*FUBP1*	*HSD3B1*	*LRP1B*	*NCOA3*	*PIK3CA*	*RAD54L*	*SMO*	*TRAF7*
ANKRD26	*CASP8*	*CYLD*	*ETV6*	*FYN*	*HSP90AA1*	*LYN*	*NCOR1*	*PIK3CB*	*RAF1*	*SNCAIP*	*TSC1*
APC	*CBFB*	*DAXX*	*EWSR1*	*GABRA6*	*ICOSLG*	*LZTR1*	*NEGR1*	*PIK3CD*	*RANBP2*	*SOCS1*	*TSC2*
AR	*CBL*	*DCUN1D1*	*EZH2*	*GATA1*	*ID3*	*MAGI2*	*NF1*	*PIK3CG*	*RARA*	*SOX10*	*TSHR*
ARAF	*CCND1*	*DDR2*	*FAM46C*	*GATA2*	*IDH1*	*MALT1*	*NF2*	*PIK3R1*	*RASA1*	*SOX17*	*U2AF1*
ARFRP1	*CCND2*	*DDX41*	*FANCA*	*GATA3*	*IDH2*	*MAP2K1*	*NFE2L2*	*PIK3R2*	*RB1*	*SOX2*	*VEGFA*
ARID1A	*CCND3*	*DHX15*	*FANCC*	*GATA4*	*IFNGR1*	*MAP2K2*	*NFKBIA*	*PIK3R3*	*RBM10*	*SOX9*	*VHL*
ARID1B	*CCNE1*	*DICER1*	*FANCD2*	*GATA6*	*IGF1*	*MAP2K4*	*NKX2-1*	*PIM1*	*RECQL4*	*SPEN*	*VTCN1*
ARID2	*CD274*	*DIS3*	*FANCE*	*GEN1*	*IGF1R*	*MAP3K1*	*NKX3-1*	*PLCG2*	*REL*	*SPOP*	*WISP3*
ARID5B	*CD276*	*DNAJB1*	*FANCF*	*GID4*	*IGF2*	*MAP3K13*	*NOTCH1*	*PLK2*	*RET*	*SPTA1*	*WT1*
ASXL1	*CD74*	*DNMT1*	*FANCG*	*GLI1*	*IKBKE*	*MAP3K14*	*NOTCH2*	*PMAIP1*	*RHEB*	*SRC*	*XIAP*
ASXL2	*CD79A*	*DNMT3A*	*FANCI*	*GNA11*	*IKZF1*	*MAP3K4*	*NOTCH3*	*PMS1*	*RHOA*	*SRSF2*	*XPO1*
ATM	*CD79B*	*DNMT3B*	*FANCL*	*GNA13*	*IL10*	*MAPK1*	*NOTCH4*	*PMS2*	*RICTOR*	*STAG1*	*XRCC2*
ATR	*CDC73*	*DOT1L*	*FAS*	*GNAQ*	*IL7R*	*MAPK3*	*NPM1*	*PNRC1*	*RIT1*	*STAG2*	*YAP1*
ATRX	*CDH1*	*E2F3*	*FAT1*	*GNAS*	*INHA*	*MAX*	*NRAS*	*POLD1*	*RNF43*	*STAT3*	*YES1*
AURKA	*CDK12*	*EED*	*FBXW7*	*GPS2*	*INHBA*	*MCL1*	*NRG1*	*POLE*	*ROS1*	*STAT4*	*ZBTB2*
AURKB	*CDK4*	*EGFL7*	*FGF1*	*GREM1*	*INPP4A*	*MDC1*	*NSD1*	*PPARG*	*RPS6KA4*	*STAT5A*	*ZBTB7A*
AXIN1	*CDK6*	*EGFR*	*FGF10*	*GRIN2A*	*INPP4B*	*MDM2*	*NTRK1*	*PPM1D*	*RPS6KB1*	*STAT5B*	*ZFHX3*
AXIN2	*CDK8*	*EIF1AX*	*FGF14*	*GRM3*	*INSR*	*MDM4*	*NTRK2*	*PPP2R1A*	*RPS6KB2*	*STK11*	*ZNF217*
AXL	*CDKN1A*	*EIF4A2*	*FGF19*	*GSK3B*	*IRF2*	*MED12*	*NTRK3*	*PPP2R2A*	*RPTOR*	*STK40*	*ZNF703*
B2M	*CDKN1B*	*EIF4E*	*FGF2*	*H3F3A*	*IRF4*	*MEF2B*	*NUP93*	*PPP6C*	*RUNX1*	*SUFU*	*ZRSR2*
BAP1	*CDKN2A*	*ELOC*	*FGF23*	*H3F3B*	*IRS1*	*MEN1*	*NUTM1*	*PRDM1*	*RUNX1T1*	*SUZ12*	
BARD1	*CDKN2B*	*EML4*	*FGF3*	*H3F3C*	*IRS2*	*MET*	*PAK1*	*PREX2*	*RYBP*	*SYK*	
BBC3	*CDKN2C*	*EMSY*	*FGF4*	*HGF*	*JAK1*	*MGA*	*PAK3*	*PRKAR1A*	*SDHA*	*TAF1*	
BCL10	*CEBPA*	*EP300*	*FGF5*	*HIST1H1C*	*JAK2*	*MITF*	*PAK5*	*PRKCI*	*SDHAF2*	*TBX3*	
BCL2	*CENPA*	*EPCAM*	*FGF6*	*HIST1H2BD*	*JAK3*	*MLH1*	*PALB2*	*PRKDC*	*SDHB*	*TCF3*	
BCL2L1	*CHD2*	*EPHA3*	*FGF7*	*HIST1H3A*	*JUN*	*MLLT3*	*PARP1*	*PRKN*	*SDHC*	*TCF7L2*	
BCL2L11	*CHD4*	*EPHA5*	*FGF8*	*HIST1H3B*	*KAT6A*	*MPL*	*PAX3*	*PRSS8*	*SDHD*	*TERC*	
BCL2L2	*CHEK1*	*EPHA7*	*FGF9*	*HIST1H3C*	*KDM5A*	*MRE11*	*PAX5*	*PTCH1*	*SETBP1*	*TERT*	
BCL6	*CHEK2*	*EPHB1*	*FGFR1*	*HIST1H3D*	*KDM5C*	*MSH2*	*PAX7*	*PTEN*	*SETD2*	*TET1*	
BCOR	*CIC*	*ERBB2*	*FGFR2*	*HIST1H3E*	*KDM6A*	*MSH3*	*PAX8*	*PTPN11*	*SF3B1*	*TET2*	
BCORL1	*COP1*	*ERBB3*	*FGFR3*	*HIST1H3F*	*KDR*	*MSH6*	*PBRM1*	*PTPRD*	*SH2B3*	*TFE3*	

Table 3: Additional content in TruSight Oncology Comprehensive (EU)

Fusions: 23 genes (from RNA)					
ALK	*EGFR*	*ETV1*	*FGFR3*	*NTRK2*	*RET*
AXL	*EML4*	*ETV4*	*KIF5B*	*NTRK3*	*ROS1*
BCL2	*ERG*	*FGFR1*	*NRG1*	*PAX3*	*TMPRSS2*
BRAF	*ESR1*	*FGFR2*	*NTRK1*	*RAF1*	
Splice variants: Two genes (from RNA)					
MET				*EGFR*	
Amplifications: Two genes (from DNA)					
ERBB2				*MET*	
Complex genomic signatures					
TMB				MSI	

What are the key attributes of the TruSight Oncology Comprehensive (EU) assay?

- Provides a kitted solution that can be implemented in house by any lab
- Includes both DNA and RNA content and detects all classes of variants, plus genomic signatures such as TMB and MSI; of note fusions are called from RNA, to maximize sensitivity for detection
- Enables CGP test results to be generated in only 4–5 days

How is TruSight Oncology Comprehensive (EU) different from current research use only (RUO)-labeled CGP kit offerings, eg, Oncomine Comprehensive Assay Plus (Thermo Fisher Scientific, Catalog no. A48578)?

- **IVD label**: As a CE-marked IVD test, TruSight Oncology Comprehensive (EU) is compliant with European IVD Directive (IVDD) requirements and is on course to comply with stricter IVD Regulation (IVDR) legislation; the IVD label provides labs with the benefits of IVDR preparedness and reduced liability risk, and enables easier implementation with significantly reduced test validation efforts, as compared to RUO tests.
- **Pipeline of companion diagnostic claims**: Multiple pharmaceutical partnerships have been established around TruSight Oncology Comprehensive (EU), with the goal of having many companion diagnostic claims; these are not in the roadmap for RUO-labeled products.
- **Underlying technology drives a high level of reliability**: TruSight Oncology Comprehensive (EU) is based on proven Illumina technology for library preparation, sequencing, and bioinformatics, maximizing data quality and accuracy; library prep uses hybrid–capture chemistry, enabling full detection and characterization of fusion events not possible with amplicon-based techniques (Figure 2).

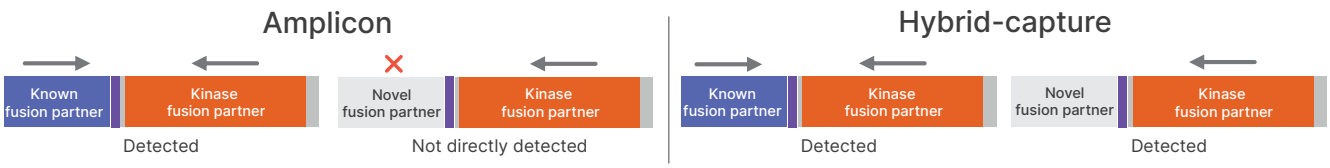


Figure 2: Hybrid–capture chemistry detects novel fusions missed by amplicon-based approaches— Amplicon-based approaches typically require confirmatory testing and do not characterize novel fusion partners. Hybrid–capture chemistry can identify both known and novel fusion partners.

Workflow

What is the recommended sample input?

TruSight Oncology Comprehensive (EU) requires 40 ng RNA and/or 40 ng DNA extracted from FFPE tissue.

What are the workflow steps from sample preparation to final report?

The TruSight Oncology Comprehensive (EU) workflow includes four steps: sample acquisition and processing, DNA and RNA extraction, library preparation, and fully automated sequencing, analysis, and report generation (Figure 3).

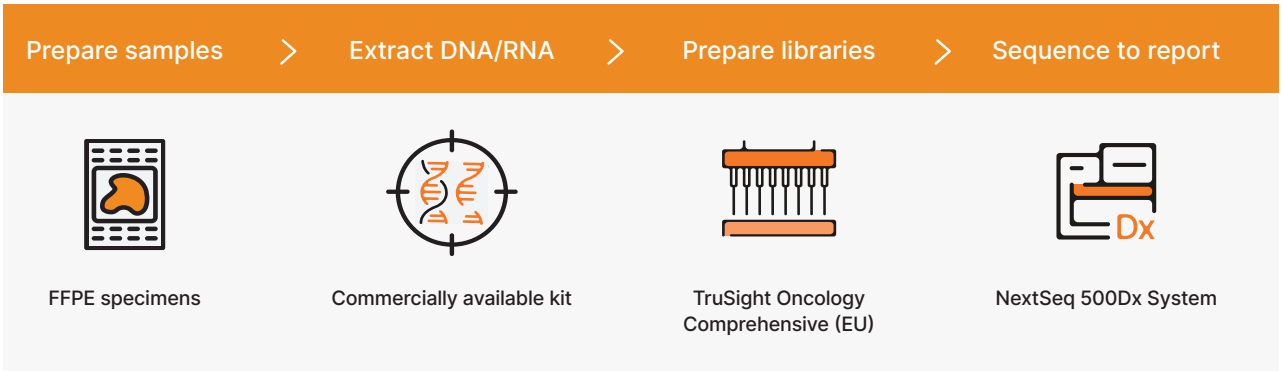


Figure 3: TruSight Oncology Comprehensive (EU) sample to report workflow.

Additional details:

- Specimen tissue should be fixed using formalin fixative suitable for molecular analyses; a minimum of 20% tumor cell content is recommended and ≥ 30% is optimal
- DNA and RNA extraction can be performed using commercially available extraction kits
- Library preparation takes approximately two days
- After loading the libraries on the NextSeq™ 550Dx instrument, the workflow is fully automated, including sequencing, base calling and QC, variant calling, interpretation, and generation of the final clinical report

How long is the turnaround time (TAT) from sample to report?

The TAT is 4–5 days from extracted DNA-RNA to final clinical report

What sequencing platform is needed?

TruSight Oncology Comprehensive (EU) is run on the NextSeq 550Dx instrument, an FDA-regulated and CE-marked, high-throughput sequencing platform

What is the workflow for data analysis?

TruSight Oncology Comprehensive (EU) offers a streamlined, automated workflow from sequencing to final clinical report. Simply set up the sequencing run using Local Run Manager software. After the sequencing run is complete, secondary and tertiary analysis kickoff automatically and are performed on-instrument. The output is a final clinical report.

What is the expected analysis time for a sample batch processed in a sequencing run?

The analysis time is 8–10 hours

What is included in the final clinical report?

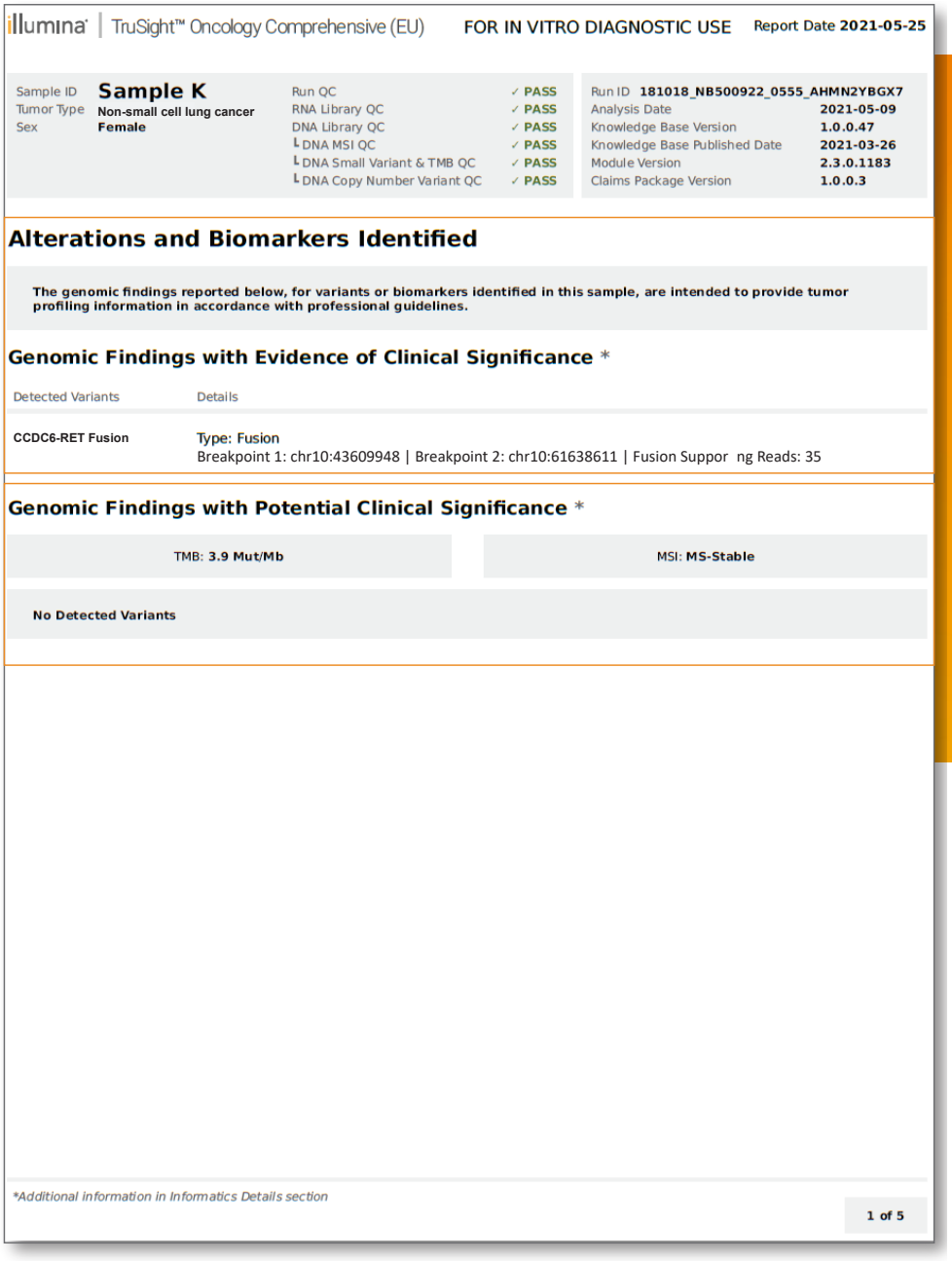
One of the key concerns when using a CGP panel is how to interpret the data and filter nonsignificant variants. TruSight Oncology Comprehensive (EU) software performs analysis and filtering as part of a fully automated workflow. The final report is easy to read and highly actionable.

IVD Clinical Report

The IVD Clinical Report is organized into two main sections (Figure 4):

- Genomic findings with evidence of clinical significance: A list of detected variants that have evidence of clinical significance (therapeutic, prognostic, or diagnostic) based on information in approved drug labels, guidelines, and clinical practice guidelines for the patient's tumor type.
- Genomic findings with evidence of potential clinical significance: A list of detected variants that:

1. Have evidence of potential clinical significance (therapeutic, prognostic, or diagnostic) based on information in drug labels, guidelines, and clinical practice guidelines in another tumor type
2. Match genomic and tumor type eligibility criteria for a clinical trial
3. Have evidence of potential clinical significance in the primary literature for the patient's tumor type


illumina | TruSight™ Oncology Comprehensive (EU) FOR IN VITRO DIAGNOSTIC USE Report Date 2021-05-25

Sample ID Sample K
Tumor Type Non-small cell lung cancer
Sex Female

Run QC ✓ PASS
RNA Library QC ✓ PASS
DNA Library QC ✓ PASS
└ DNA MSI QC ✓ PASS
└ DNA Small Variant & TMB QC ✓ PASS
└ DNA Copy Number Variant QC ✓ PASS

Run ID 181018_NB500922_0555_AHMN2YBGX7
Analysis Date 2021-05-09
Knowledge Base Version 1.0.0.47
Knowledge Base Published Date 2021-03-26
Module Version 2.3.0.1183
Claims Package Version 1.0.0.3

Alterations and Biomarkers Identified

The genomic findings reported below, for variants or biomarkers identified in this sample, are intended to provide tumor profiling information in accordance with professional guidelines.

Genomic Findings with Evidence of Clinical Significance *

Detected Variants	Details
CCDC6-RET Fusion	Type: Fusion Breakpoint 1: chr10:43609948 | Breakpoint 2: chr10:61638611 | Fusion Suppor ng Reads: 35

Genomic Findings with Potential Clinical Significance *

TMB: 3.9 Mut/Mb

MSI: MS-Stable

No Detected Variants

*Additional information in Informatics Details section

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Genomic findings with evidence of clinical significance

Genomic findings with evidence of potential clinical significance

Figure 4: TruSight Oncology Comprehensive (EU) example clinical report—The clinical report includes genomic findings with evidence of clinical significance and genomic findings with evidence of potential clinical significance.

Reimbursement

What reimbursement is available for CGP tests in Europe? How does that vary by country?

National and/or regional funding is available in most Western European countries. Laboratory services are reimbursed in different ways depending on the country in which they are located, the clinical setting in which they work, and the services they provide (Figure 5 and Table 4). Illumina has established a dedicated Market Access team that works with Payers to further expand the reimbursement of CGP across all European countries. In addition, Illumina is working towards opening access to CGP in various major emerging markets of Europe. For further questions about the appropriate coding or reimbursement for cancer testing, we encourage customers to:

- Speak to your respective national medical society for guidance regarding how to manage reimbursement claims for testing and refer to any national or regional budget holders (Payers) for guidance on coding and reimbursement, eg, national pathology societies.
- Contact your local Illumina representative who will connect you with the Illumina Market Access team. The Illumina Market Access team will provide you with guidance on where to find general reimbursement fee schedules, answer general reimbursement queries for diagnostics from customers or point customers to key local institutions they can contact.
  Note: as a manufacturer of IVD products, Illumina will not be able to advise customers on what specific reimbursement codes customers should bill for TruSight Oncology Comprehensive (EU).

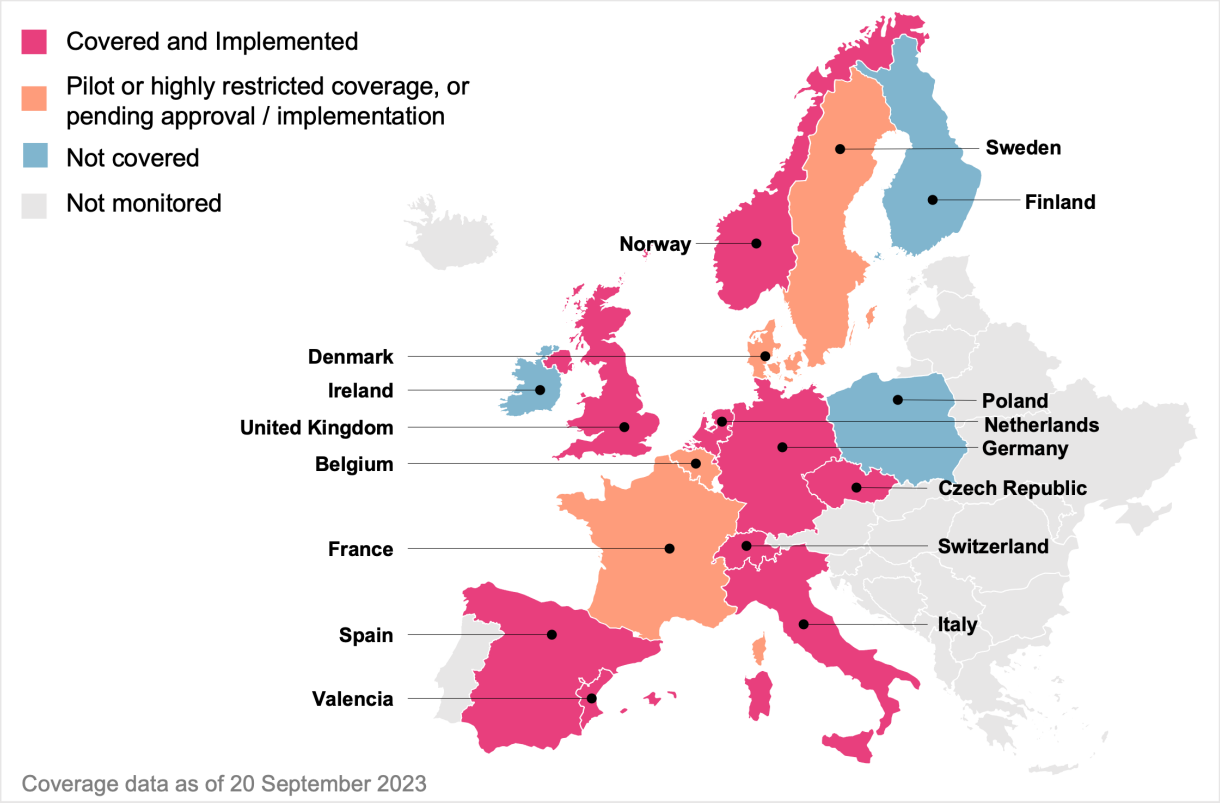

Figure 5: CGP test coverage options across Europe

Table 4: Laboratory fee schedules

Country	Relevant fee schedules
Austria	Not applicable
Belgium	NGS pilot study
Denmark	Not applicable
England	National Genomic Test Directory
Finland	Not applicable
France	National Reimbursement List for Innovative Technologies and National Fee Schedule
Germany	National Fee Schedule Germany
Israel	National Health Basket
Italy[a]	National Fee Schedule
Netherlands[b]	Not applicable
Norway	Not applicable
Scotland	Not applicable
Spain[a]	Not applicable
Sweden	Not applicable
Switzerland	National Fee Schedule for Medical Services

a. For Italy, the national fee schedule is informative only; for Italy and Spain, coverage is defined at the regional level
b. For the Netherlands, coverage is negotiated at the local level between hospitals and health insurers
Not applicable: Not available, ie, no fee schedule for diagnostics in the country; diagnostics are funded through global budget allocation to laboratory customers

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