STRATA ONCOLOGY

StrataNGS™ Test

TECHNICAL INFORMATION & TEST OVERVIEW

METHODOLOGY

The validated StrataNGS Test is a solid tumor, pan-cancer Next Generation Sequencing (NGS) test to detect mutations across 87 genes, copy number variations (amplifications and deep deletions) across 31 genes, and fusion events across 46 driver genes.

The assay utilizes the Ion S5 sequencing workflow, with libraries created using the StrataNGS Assay, incorporating Ampliseq chemistry. The assay runs up to 24 patient samples on one Ion 540 chip, utilizing both DNA and RNA from each sample.

SCOPE AND APPLICATION

The StrataNGS Test is a clinical assay performed in a CLIA-certified laboratory. This test was designed to focus on identification of clinically actionable genetic variants for which there is an approved therapy or clinical trial with established proof of concept.

Tumors may harbor additional alterations outside of the regions targeted by the StrataNGS Test. Likewise, only predefined potentially actionable areas of interest are reported by the StrataNGS Test. Patients may have additional alterations of unknown significance not targeted or reported by the StrataNGS Test .

	Activating				Deleterious		
Technical Information	Base Substitutions	Indels	Copy Number Alterations	Fusion	Base Substitutions	Indels	Copy Number Alterations
Sensitivity at LOD	>99% 5% VAF	>99% 10% VAF	>99% at 6.5 copies	N/A* >99%	>99% 20% VAF	>99% 20% VAF	>80% at 0.2 copies
Specificity	>99%	>99%	>99%	>99%	>99%	>99%	>99%
Reproducibility	>99%	>99%	>99%	>99%	>99%	>99%	>99%
Median depth of coverage	>500 reads						
Sample requirements	FFPE slides or blocks with minimum tissue of 9mm^2 (>0.5mm^3 by volume) and >20% tumor nuclei after microdissection (if required).						
TAT	10 business days or less						

N/A*: LOD was not attempted for gene fusions because of inherent difficulties in extrapolating the meaning of such results (due to non-uniform expression levels across specimens) and there is no competition between the normal and fusion RNA transcripts for this fusion-specific PCR amplification.

v. 07.07.17

CURRENT GENE LIST

Full Genes	Copy Number Variants		Hotspots		Fusions	
ATM	ALK	FGFR4	AKT1	KRAS	ALK	NOTCH1
BRCA1	AR	IGF1R	ALK	MAP2K1	AR	NOTCH4
BRCA2	ATM	KIT	AR	MAP2K2	AXL	NRG1
CDKN2A	BRAF	KRAS	ARAF	MAP2K4	BRAF	NTRK1
MSH2	BRCA1	MDM2	BRAF	MAP2K7	EGFR	NTRK2
MSH6	BRCA2	MET	CDK4	MAPK1	ERBB2	NTRK3
PTEN	CCND1	MSH2	CTNNB1	MET	ERBB4	NUTM1
RB1	CDK4	MSH6	EGFR	MTOR	ERG	PDGFRA
TP53	CDK6	MYC	ERBB2	MYD88	ESR1	PDGFRB
	CDKN2A	MYCN	ERBB3	NRAS	ETV1	PIK3CA
	EGFR	PDGFRA	ERBB4	NTRK1	ETV4	PPARG
	ERBB2	PIK3CA	ESR1	NTRK2	ETV5	PRKACA
	ESR1	PTEN	EZH2	NTRK3	FGFR1	PRKACB
	FGFR1	RB1	FGFR1	PDGFRA	FGFR2	PTEN
	FGFR2	TP53	FGFR2	PIK3CA	FGFR3	RAD51B
	FGFR3		FGFR3	POLE	FGR	RAF1
			GNA11	RAF1	FLT3	RELA
			GNAQ	RET	JAK2	RET
			HRAS	RIT1	KRAS	ROS1
			IDH1	ROS1	MET	RSPO2
			IDH2	SF3B1	MYB	RSPO3
			JAK1	SMO	MYBL1	TERT
			JAK2	SPOP	NF1	
			JAK3	TERT		
			KIT			

STRATA LABORATORY LICENSURE

CLIA ID #: 23D2121068 (MI); Rhode Island (LCO01095); Pennsylvania (ID: 35579); Maryland (#2646); California (ID: COS 00800780) .

EXAMPLE STRATA TEST REPORT

- The report focuses on Strata Partnered Trial match, with instructions for enrollment.
- Reads out and summarizes positive and negative genetic variants, and associated FDA-approved therapies and clinical trials.

STRATA ONCOLOGY

Report Date: 5/22/2017

Physician Information		Patient Information		Specimen Information	
Client	---	**Name**	---, ---	**Date of Collection**	---
Strata Client	---	**Date of Birth**	---	**Date Received**	01/19/2017
Ordering Physician	---	**Gender**	Male	**Cancer Type**	Prostate
		Diagnosis	Prostate	**Specimen Site**	
		Strata Case	---	**Specimen Type**	FFPE Block
		Client MRN	---	**Client Specimen ID**	---
		Subject ID	PH00178		

About the StrataNGS™ Test:

StrataNGS is a next-generation sequencing assay that measures actionable alterations in 88 genes in tumor tissue, including standard of care markers and clinical trial eligibility markers. The StrataNGS test assays for specific predefined single nucleotide variants, multinucleotide variants, small insertions and deletions (indels), gene fusions, exon skipping mutations and copy number changes; the test also assays for de novo deleterious mutations (stop gains and frame shifting indels) in tumor suppressor genes.

STRATA TRIAL MATCH

The patient tested positive for genomic alteration(s) that match to the following clinical trial:

TRITON2: A Multicenter, Open-label Phase 2 Study of Rucaparib in Patients With Metastatic Castration-resistant Prostate Cancer Associated With Homologous Recombination Deficiency

Genomic Alterations: BRCA2 copy number alteration

Local Site: California, Georgia, Nebraska, North Carolina, Ohio | Local PI:

Contact Information: Clovis Oncology Clinical Trial Navigation Service +1 (855) 262-3040 clovistrials@emergingmed.com

STRATA TRIAL MATCH

The patient tested positive for genomic alteration(s) that match to the following clinical trial:

TRITON3: A Multicenter, Randomized, Open Label Phase 3 Study of Rucaparib Versus Physician's Choice of Therapy for Patients With Metastatic Castration Resistant Prostate Cancer Associated With Homologous Recombination Deficiency

Genomic Alterations: BRCA2 copy number alteration

Local Site: California, Georgia, North Carolina, Ohio | Local PI:

Contact Information: Clovis Oncology Clinical Trial Navigation Service +1 (855) 262-3040 clovistrials@emergingmed.com

Positive Test Results

The patient tested positive for the following genomic alteration(s):

- BRCA2 copy number alteration
  Estimated copy number: 0, confidence interval: 0.3 - 0.5, cellularity: 60%
- RB1 copy number alteration
  Estimated copy number: 0, confidence interval: 0.1 - 0.3, cellularity: 60%
- TP53 p.R213X

DRAFT