The StrataNGS™ Test

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 deletions) across 31 genes, and fusion events across 46 gene drivers.

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. The 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 if unknown significance not targeted or reported by the StrataNGS Test.

<table>
<thead>
<tr>
<th>Technical Information</th>
<th>Base Substitutions</th>
<th>Indels</th>
<th>Copy Number Alterations</th>
<th>Fusion</th>
<th>Base Substitutions</th>
<th>Indels</th>
<th>Copy Number Alterations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity at LOD</td>
<td>&gt;99%</td>
<td>&gt;99%</td>
<td>&gt;99%</td>
<td>N/A*</td>
<td>&gt;99%</td>
<td>&gt;99%</td>
<td>&gt;80%</td>
</tr>
<tr>
<td>Specificity</td>
<td>&gt;99%</td>
<td>&gt;99%</td>
<td>&gt;99%</td>
<td>&gt;99%</td>
<td>&gt;99%</td>
<td>&gt;99%</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>Reproducibility</td>
<td>&gt;99%</td>
<td>&gt;99%</td>
<td>&gt;99%</td>
<td>&gt;99%</td>
<td>&gt;99%</td>
<td>&gt;99%</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>Median depth of coverage</td>
<td>&gt;500 reads</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Sample requirements</td>
<td>FFPE slides or blocks with minimum tissue of 2.9mm² (&gt;0.5mm³ by volume) and &gt;20% tumor nuclei after microdissection (if required).</td>
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<td></td>
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</tr>
<tr>
<td>TAT</td>
<td>10 business days or less</td>
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</tr>
</tbody>
</table>

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.
### StrataNGS Test Overview

#### Current Gene List

<table>
<thead>
<tr>
<th>Full Genes</th>
<th>Copy Number Variants</th>
<th>Hotspots</th>
<th>Fusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATM</td>
<td>ALK, IGF1R</td>
<td>AKT1, GNAQ, NRAS</td>
<td>ALK, JAK2, PRKACA</td>
</tr>
<tr>
<td>BRCA1</td>
<td>AR, KIT</td>
<td>ALK, HRAS, NTRK1</td>
<td>AR, KRAS, PRKACB</td>
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<tr>
<td>BRCA2</td>
<td>ATM, KRAS</td>
<td>AR, IDH1, NTRK2</td>
<td>AXL, MET, PTEN</td>
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<tr>
<td>CDKN2A</td>
<td>BRAF, MDM2</td>
<td>ARAF, IDH2, NTRK3</td>
<td>BRAF, MYB, RAD51B</td>
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<tr>
<td>MSH2</td>
<td>BRCA1, MET</td>
<td>BRAF, JAK1, PDGfra</td>
<td>EGFR, MYB1, RAF1</td>
</tr>
<tr>
<td>MSH6</td>
<td>MSH2</td>
<td>CDK4, JAK2, PIK3CA</td>
<td>ERBB2, NF1, RELA</td>
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<tr>
<td>PTEN</td>
<td></td>
<td>CTNNB1, JAK3, POLE</td>
<td>ERBB4, NOTCH1, RET</td>
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<tr>
<td>RB1</td>
<td></td>
<td>ERBB2, KIT, RAF1</td>
<td>ER, NOTCH4, ROS1</td>
</tr>
<tr>
<td>TP53</td>
<td></td>
<td>ERBB3, MAP2K1, RIT1</td>
<td>ESR1, NRG1, RSPO2</td>
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<tr>
<td></td>
<td>EGFR</td>
<td>ERBB4, MAP2K2, ROS1</td>
<td>ER, NOTCH4, ROS1</td>
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<tr>
<td></td>
<td>PIK3CA</td>
<td>ESR1, MAP2K4, SFI3B1</td>
<td>ETV1, NTRK1, RSPO3</td>
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<td>EZH2, MAP2K7, SMO</td>
<td>ETV5, NTRK3</td>
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<tr>
<td></td>
<td></td>
<td>FGFR1, MAPK1, SPOP</td>
<td>FGR, NUTM1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>FGFR2, MET, TERT</td>
<td>FGR, PIK3CA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>FGFR3, MTOR</td>
<td>FLT3, PPARG</td>
</tr>
<tr>
<td></td>
<td></td>
<td>GNA11, MYD88</td>
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</tbody>
</table>

#### Microsatellite Instability Detection

Results include microsatellite instability (MSI) status, which may help predict response to immunotherapy.

#### Strata Laboratory Licensure

CLIA ID # 23D2121068 (MI), California (ID: COS 00800780), Florida (800028815), Maryland (#2646), Pennsylvania (ID: 35579), Rhode Island (LCO01095).
Sample StrataNGS™ 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

### StrataNGS Test Overview

- **Strata Oncology Test Overview**
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### StrataNGS Test Report

**Physician Information**
- Client: ---
- Strata Client: ---
- Ordering Physician: ---

**Patient Information**
- Name: ---, ---
- Date of Birth: ---
- Gender: Male
- Diagnosis: Prostate
- Strata Case: ---
- Client MRN: ---
- Subject ID: PH00178

**Specimen Information**
- Date of Collection: ---
- Date Received: 01/12/2018
- Cancer Type: Prostate
- Specimen Site: FFPE Block

### 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, well-defined single nucleotide variants, multineucleotide 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

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

### Positive Test Results

**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

**Report Date:** 1/22/2018

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**FOR REFERENCE ONLY**