
**Michael S. Manak, PhD, Jonathan S. Varsanik, PhD, David M. Albala, MD, Grannum R. Sant, MD, Ashok C. Chander, PhD**

**Cellanyx, LLC: info@cellanyx.com**

---

**Precision Oncology**

The promise of precision and personalized medicine is rooted in accurate, highly sensitive, and specific disease biomarkers. This is particularly true for cancer—a disease characterized by marked tumor heterogeneity, and diverse genetic and molecular signatures.

**Personalized Treatment Guidance**

It is estimated that 130,000 prostate cancer patients per year received suboptimal treatment in the U.S. due to inadequate clinical tools. Cellanyx’s STRAT-AP platform addresses this unmet need and predicts prostate cancer adverse pathology features important for shared decision making and personalized treatment guidance with >85% sensitivity and specificity. Cellanyx’s live-cell phenotypic approach shows stronger performance than genomic and IHC methodologies.

**Conclusions & Prospective**

1. The ability to rapidly culture primary human biopsy cells enables a powerful new class of live-cell phenotypic biomarkers to advance precision medicine tests and tools.
2. Live-cell phenotypic biomarkers provide dynamic spatiotemporal cell behavior information to discern the inherent heterogeneity of cancers such as a prostate cancer with single cell resolution.
3. Leveraging automated and objective machine vision and machine learning, Cellanyx’s live-cell phenotypic STRAT-AP platform can predict with strong accuracy (*AUCs > 0.85*) adverse pathology features towards personalized treatment guidance.
4. STRAT-AP can risk stratify low- and intermediate-risk patients based on adverse pathology features.*
5. STRAT-AP can predict adverse pathology and risk stratify patients even if biopsy misses the tumor.*
6. Cellanyx's STRAT-AP platform is a next generation patient risk stratification test and drug development tool for precision medicine.

---

**High-Content, Ex Vivo Platform**

First-in-class platform components include a proprietary extra-cellular matrix formulation, paraffin-encapsulated live-cell phenotypic biomarkers, high-content machine vision analysis, and machine learning algorithms to generate clinically relevant predictive scores by interrogating patient biopsy cell behavior with single cell resolution over time in vitro.

**Enhanced Risk Stratification**

There is a significant need for better stratification tools to distinguish indolent from aggressive disease in men with low or intermediate grade prostate cancer—Gleason 6 or Gleason 7. Cellanyx’s clinical scores can risk stratify these patients by predicting the gold-standard of prostate cancer diagnosis—survival adverse pathology features—and determine which Gleason 6 or 7 patients are intermediate-risk or at risk for locally aggressive and / or metastatic disease.

**Live-Cell Phenotypic Biomarkers**

Phenotypic biomarkers have re-emerged to ameliorate the challenges of cancer diagnosis and risk stratification due to the inherent genetic heterogeneity in prostate cancer. Prior attempts to analyze dynamic biomarkers from single cells derived from primary biopsy tissue have been limited, leaving many potentially powerful biomarkers inaccessible.

**Machine Learning Algorithms**

Machine vision and statistical analysis algorithms have the ability to process multiple biomarkers and accurately predict various pathological outcomes. Live cell images are collected on approximately 5000 cells for each of 26 time-points. Each cell is assigned a unique identifier. Phenotypic biomarkers are measured for each cell at multiple time points, leading to an average of 42 million measurements per sample.

**Prognostics From Missed Biopsies**

Roughly 700,000 men undergo repeat biopsies every year in the U.S., with 80% of those men being positively diagnosed upon repeat biopsy. Cellanyx’s STRAT-AP can eliminate the need for repeat biopsies given its ability to predict surgical adverse pathology features from tumor-adjacent tissue found in biopsies that miss the tumor. This capability represents a significant advance in prostate cancer disease management via the reduction of unnecessary diagnostic and treatment procedures.

---

**Ability to predict post radical prostatectomy adverse pathology:**

<table>
<thead>
<tr>
<th>Sensitivity</th>
<th>Specificity</th>
<th>AUC</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 85%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**POWERFUL RISK STRATIFICATION OF CLASSICALLY DEFINED LOW- & INTERMEDIATE RISK PATIENTS**

<table>
<thead>
<tr>
<th>Risk Stratification</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>AUC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>&gt; 85%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intermediate</td>
<td>&gt; 85%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Live-Cell Phenotypic Biomarkers**

- **ABILITY TO PREDICT ADVERSE PATHOLOGY FROM BIOPSIES THAT MISS THE TUMOR:**
  - **88% Sensitivity**
  - **93% Specificity**
  - **AUC = 0.89**
  - **n = 87**

**Conclusions & Prospective**

1. The ability to rapidly culture primary human biopsy cells enables a powerful new class of live-cell phenotypic biomarkers to advance precision medicine tests and tools.
2. Live-cell phenotypic biomarkers provide dynamic spatiotemporal cell behavior information to discern the inherent heterogeneity of cancers such as a prostate cancer with single cell resolution.
3. Leveraging automated and objective machine vision and machine learning, Cellanyx’s live-cell phenotypic STRAT-AP platform can predict with strong accuracy (*AUCs > 0.85*) adverse pathology features towards personalized treatment guidance.
4. STRAT-AP can risk stratify low- and intermediate-risk patients based on adverse pathology features.*
5. STRAT-AP can predict adverse pathology and risk stratify patients even if biopsy misses the tumor.*
6. Cellanyx’s STRAT-AP platform is a next generation patient risk stratification test and drug development tool for precision medicine.

---

**Ability to Predict Post Radical Prostatectomy Adverse Pathology:**

<table>
<thead>
<tr>
<th>Sensitivity</th>
<th>Specificity</th>
<th>AUC</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 85%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Live-Cell Phenotypic Biomarkers**

- **ABILITY TO PREDICT ADVERSE PATHOLOGY FROM BIOPSIES THAT MISS THE TUMOR:**
  - **88% Sensitivity**
  - **93% Specificity**
  - **AUC = 0.89**
  - **n = 87**

---

**Live-Cell Phenotypic Biomarkers**

- **ABILITY TO PREDICT ADVERSE PATHOLOGY FROM BIOPSIES THAT MISS THE TUMOR:**
  - **88% Sensitivity**
  - **93% Specificity**
  - **AUC = 0.89**
  - **n = 87**

**Conclusions & Prospective**

1. The ability to rapidly culture primary human biopsy cells enables a powerful new class of live-cell phenotypic biomarkers to advance precision medicine tests and tools.
2. Live-cell phenotypic biomarkers provide dynamic spatiotemporal cell behavior information to discern the inherent heterogeneity of cancers such as a prostate cancer with single cell resolution.
3. Leveraging automated and objective machine vision and machine learning, Cellanyx’s live-cell phenotypic STRAT-AP platform can predict with strong accuracy (*AUCs > 0.85*) adverse pathology features towards personalized treatment guidance.
4. STRAT-AP can risk stratify low- and intermediate-risk patients based on adverse pathology features.*
5. STRAT-AP can predict adverse pathology and risk stratify patients even if biopsy misses the tumor.*
6. Cellanyx’s STRAT-AP platform is a next generation patient risk stratification test and drug development tool for precision medicine.