Paradigm PCDx™
Comprehensive Genomic Profiling, in record time

Accurate.
Clinically Proven.
Fast.
Comprehensive genomic profiling, in record time

PCDx Comprehensive Genomic Profiling (CGP) provides precise information about the targetable cancer pathways in the tumor to allow for more effective clinical decision-making.

Challenges presented by current CGP solutions

Obtaining quality results on small tissue specimens
A large percentage of tumor biopsies that are received by molecular laboratories have either a limited amount of tissue (e.g. FNAs) or low tumor cellularity (e.g. samples with 5-10% tumor). These present practical challenges when attempting to run comprehensive genomic testing for many patients unless an accurate test such as PCDx is run.

Rapid turnaround time
Advanced stage cancer patients typically progress rapidly. Often these patients are unable to obtain their next course of therapy due to worsening of condition.1,2 There is a clinical need to obtain your testing results as fast as possible.

Clinically meaningful results
Tissue should be tested to maximize potential treatment options. A large number of reports are generated citing either unactionable genomic findings or inapplicable clinical trials. This creates practical challenges and frustration to the treating clinician when deciding what to do next.

Comprehensive genomic profiling on small tissue specimens
With only 1/3rd of the sample failure rate of other leading NGS providers, Paradigm’s success rate in profiling tumors with PCDx is 94%.4 Through our proprietary library creation methods and other laboratory techniques that provide us with an average depth of coverage of >5000x, we obtain comprehensive genomic profiling results on small tissue specimens with limited tumor (e.g. 5-10%), including fine needle aspirates (FNAs).

Data on ~2900 sequential samples submitted for PCDx

- 123 PCDx cases Run and Reported with insufficient DNA and mRNA
- 52 PCDx cases cancelled prior to testing due to insufficient tissue
- 94% Sample Success Rate

Fastest turnaround time
Paradigm delivers clinical results to our clients in 4 to 5 business days from receipt of the tissue sample. Our laboratory processes have been engineered to ensure a reduced time to next therapy and continuity of clinical care.

Day 1
Sample is received and pathology confirms initial diagnosis with H&E.

Day 2
Tumor DNA & RNA are extracted, purified and quantified.

Day 3
DNA & RNA library creation.

Day 4
Sequencing and IHC analysis.

Day 5
Clinical interpretation of results, quality assurance performed and clinical report delivered.


4, 6. Paradigm’s sample rejection rate is approximately ~6% vs. 18% as seen for other leading NGS platforms (Mantripragada et al. Journal of Oncology Practice. 2016). Paradigm internal data set and analysis on first 2700 patients run on the PCDx platform where only 175 patients had insufficient tissue for analysis.
Carcinoma of Unknown Primary
Protein BRAF
Assay Type NGS
Positive
Pathologist H&E was performed and Result LII-3
N/A No
Biomarker Result
NGS IHC Assay Type Protein DTT TP (TYMP) Protein Result RNA TOPO IIa High Measure None Detected Protein Expression NGS Pathologist H&E was performed and mRNA Expression hENT1 Ver: PCDx2016.09.13.01 DTT
Next-Generation Sequencing (NGS) assays analyzing BCL-2 Gain No Biomarker Right Supraclavicular region NGS IHC LII-2 HER2 (ERBB2) CCND1 CA IX TOP1 ROS1 NGS

Supported by published clinical data
In an independent clinical study, genomically directed therapy guided by Paradigm PC Dx improved progression free survival as compared to non-genomically guided therapy.\(^2\) Patients treated with genomically guided therapy had a superior median PFS compared to those treated with non-genomically guided therapy (86 days vs. 49 days, \(p<0.005\), H.R.=0.55, 95% C.I.:0.37- 0.84).

Proportion of Patients Achieving a PFS Ratio \(\geq 1.3\)

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<tr>
<th>Percent of Patients</th>
<th>Genomically Directed</th>
<th>Non-Genomically Directed</th>
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<tr>
<td></td>
<td>43.2%</td>
<td>5.3%</td>
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\(p<0.0001\)

PCDx can help identify the best cancer treatment options for you today.

Start getting better results, faster.

For more information, please contact Client Services at 844-232-4719 or visit paradigmmdx.com

Accurate.
- 5000x average depth of coverage
- Low sample rejection (QNS) rates (6% vs. 18%)6

Clinically Proven.
- Analyzes Tumor DNA, RNA & Protein
- Prospective data published showing improvement in Progression Free Survival (PFS)7
- Provides associations to >80 single agent and combination therapies
- Full PCDx results possible from >5% tumor; including FNAs

Fast.
- Results delivered in 4 to 5 business days
- Reduces time to next therapy
- Ensures continuity of clinical care