CHASING THE NEXT GENERATION OF LAB TEST REVENUE

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There are many environmental changes impacting the laboratory industry and what optimal strategies should look like.

**Technological Innovation**
- Next generation sequencing
- Circulating tumor cell
- Companion Diagnostics
- Decision analytic tools & algorithms
- Patient centered analytics and monitoring

**Evolution in Payment Systems**
- Accountable Care Organizations
- Risk-Shifting from Payer to Providers
- Value-based reimbursement models
- Outcomes based reimbursement
- Medicare payment reform

**Environmental Factors**
- Aging Population and Rising Healthcare costs
- Regulatory & reimbursement reform
- Healthcare Reform
- Coding and Rate Changes
- Parallel Review
We have a choice as to how we react to these changes
Lab revenue models are very different, changing landscape create winners and losers within the industry

<table>
<thead>
<tr>
<th>Medicare Payment Model Changes</th>
<th>Reference Labs</th>
<th>Single Test CLIA Labs</th>
<th>Hospital Labs</th>
<th>Specialty Labs</th>
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<tbody>
<tr>
<td>ACOs</td>
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<td>Bundled Payments</td>
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<td>MDX Coding</td>
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Lab business models have relied on spread between costs and payment, with volume driving many businesses.

Both systems rely on test costs, overhead costs, and volume as main determinants of revenue.

- **Fee for Service Model**
  - Test Reimbursement - Costs
  - Volume of tests
  - **Revenue**
  - Likely to remain the standard for specialty labs or single test CLIA lab providers; payer may shift

- **Capitated Model**
  - Capitated Rate - Costs
  - # of People covered
  - **Revenue**
  - Global payments and bundling start to reflect similar incentives as capitated model; though who holds risk varies
Global payments attempt to incent value driven healthcare and efficient use of services

- New payment systems attempting to bundle diagnostic services within global procedural payments or global care bundles

- Lack of separate payment for diagnostics changes the financial risk of diagnostic utilization from the Payer to the providers/hospitals

- As this occurs, providers/hospitals become more conscious of test ordering and will likely decrease volume and associated costs

- However, appropriate and impactful diagnostics still required to deliver high quality efficient care… providers looking for value

- So what should labs do in response?
Moving from volume driven revenue model to value driven revenue model is challenging

The more you do the more you get.....

Reimbursement and contracting driven by services delivered AND impact of those services to clinical decision-making
Next Generation Sequencing and other methods to provide patients with enormous amounts of information… creates opportunities and risks.

Moving forward, the industry will face tremendous challenges as diagnostics move from binary results, to multi-dimensional risk profilers.

- **Patients’ Ability to Understand Genetics**
- **Patients’ Ability to Understand Risk**
- **Patients’ Role in Cost-Sharing**

- **Number of data points impacting treatment (future)**
- **Ability for majority of information to impact decision-making**
- **Experts in place to help patients navigate results**
Labs, get ready to be part of the solution….

- Educate about options and test implications
- Assess clinical utility
- Provide Genetic counseling
- Contextualize results

You can help providers deliver higher quality and more efficient care

This creates novel revenue opportunities
Additionally, there are ramifications for what services are offered, the type of expertise required, and the relationship that the lab has with clinicians and patients.

Who do you want to be for your customers?

Labs are moving from technical suppliers of results to information partners.

This has an impact on how services are positioned and how results should be shared.
The next generation of lab test revenue may come from areas where little revenue is currently generated.

Increase the Value of Test Results
To prepare for success, Executives have to consider multiple factors, prioritize, and plan accordingly.

Commercial success in diagnostics…..

Strategy and Execution Plan

- Clinical need you address
- Evidence base
- Customer segments
- Understanding of competition
- Financial incentives for use/Reimbursement
- Clinician receptivity
- Environmental context for launch
- Opportunities for education/messaging
- Sales force needs
- Company infrastructure to execute
- Resources needed to execute
- Operational and technical infrastructure or partners
- Visibility on market evolution
- …and more

…starts with taking a realistic inventory of what you have, what you don’t, and what you need to develop
Tomorrow’s revenue will come from understanding **what will change** in this volatile market and **what will stay the same**. Have a clear perspective on variables and stable factors; once identified… strategies, risk mitigation, and tactical implementation will follow.

**What do you know about Customers?**
- Market research with clinicians, patients, and labs can help inform you of unmet need and positioning.

**What do you know about Competition?**
- Competitive landscape assessment is critical to know what your comparators are and what they will evolve to be.

**What do you know about Reimbursement?**
- Payer research critical to understand funding/coding pathways and whether reimbursement is acceptable for business model.

**What do you know about the Market?**
- The clinical, economic, and social context of the market need to be understood to inform all sales and marketing activities.
What to do…
To start, the type of lab you are and the depth and breadth of offerings will determine revenue pathways and strategy.

**What resources do we have and what should I invest?**

<table>
<thead>
<tr>
<th></th>
<th>Single Test Lab</th>
<th>Small Portfolio of Tests</th>
<th>Large Portfolio</th>
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<tbody>
<tr>
<td>Test components</td>
<td></td>
<td>X</td>
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</tr>
<tr>
<td>LDT(s)</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>FDA approved kit(s)</td>
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<td>X</td>
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<tr>
<td>Testing platforms</td>
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**How many customers do I need to reach and who could my partners be?**

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<tr>
<th></th>
<th>Simple Test</th>
<th>Complex Test</th>
<th>Highly Complex</th>
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<tbody>
<tr>
<td>Single source lab</td>
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<td>X</td>
<td>X</td>
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<tr>
<td>Reference labs</td>
<td>X</td>
<td>X</td>
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</tr>
<tr>
<td>Specialty labs</td>
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</table>

**What will I need to demonstrate to get it paid for?**

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<th></th>
<th>Simple Test</th>
<th>Complex Test</th>
<th>Highly Complex</th>
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<tbody>
<tr>
<td>Clinical Evidence</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Economic Evidence</td>
<td>X (?)</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Clinician/Patient Advocacy</td>
<td>X (?)</td>
<td>X</td>
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For complex, high value diagnostics data is the cornerstone of most sales and marketing success.

**Differentiate**
- Position against a standard of care clinically
- For comparable tests, focus on process or efficiency metrics to demonstrate superiority

**Demonstrate Value**
- Target data to different stakeholders, demonstrating value in the terms that impact them most
  - Clinicians will look for clinical utility while payers want both clinical utility and cost-effectiveness

**Support Value based Pricing**
- Impact on clinical outcomes, resource utilization, or physician decision-making drives value based pricing

**Enable Reimbursement**
- Consistent demand for high quality data to enable coverage and payment
- Help payers understand in what populations testing has its greatest value.
Across the testing portfolio, consider how you are answering key questions for customers

- **Who for**
- **What Impact**
- **Do we have the evidence to prove it?**
- **Does use of the test create cost savings or efficiency?**

What value does your offering (test specific or overall portfolio provide?)
Given some of the ACO/Bundled Payments and Risk-Shifting Models, the paradigm of evaluation shifts

- Payers no longer the ones who matter
- Provider groups/ Hospitals/ systems/ ACOs will decide what tests to include in care
- Outcomes based payment shifts the analysis of value
- Evidence development plan must take into account

Consider micro versus macro impact of your test
Value may be derived from how your test impacts outcomes associated with specific areas measured in the agreement

Understand your test’s role in efficiency
While payers have considered budget impact and cost-effectiveness of tests for a while, ACOs and other risk-owners are focused on driving efficiency while maintaining quality
And what if, the potential value doesn’t play out in the real world….

**Actions Taken if Test Said Drug Wouldn’t Work**
(if Diagnosed w/Life Threatening Cancer)

- **71%** would get a second opinion
- **13%** would not get the treatment, accepting the fact that it was not going to work
- **13%** would still want the treatment, regardless of what the doctor said, and discuss with him/her how to get it
- **2%** other actions

Vast majority would seek a second opinion if test indicated therapy would not work
As labs, you need to be flexible and adaptable to the changing context as new models emerge.
Laboratory partners should leverage the value of their data to help stakeholders understand impact of different pathways.

Use big data assets to determine what is working, and what is delivering the most value:

- Demonstrate value of diagnostics or other approaches impacted by diagnostic information.
- Other data sources, from EMRs, Claims data, and other data assets can provide opportunities to demonstrate dimensions of clinical and cost utility.
- Partner with customers to provide data driven decision-support and business insights.
In Conclusion...
Think as part of a system as oppose to test result providers

Your test is a part of a larger diagnostic and treatment cascade

Demonstrate value with larger stakeholder goals in mind….

- Reduction in costs (as a function of?)
- Improvement in outcomes (in association with?)
- Streamlined care (as compared to?)

Understand how your customers are being evaluated, what they care about, and how to align incentives
In these times of rapid change, significant opportunities for labs exist to reposition themselves

- Be a part of the solution
- Help build infrastructure to support roll out of your offerings
- Deliver value beyond a test result, help solve implementation problems
- Act as a true partner
- Share data