Building the Specialty Testing Lab Company: Sales and Business Development Strategies that Work

Machaon Diagnostics, Inc.
specialized coagulation testing

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Specialized Coagulation Testing
Oakland, CA
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Machaon Diagnostics operates out of a 3,000 square foot laboratory facility, located at 3023 Summit Street, Oakland, CA.

- Small Business (n=10)
- Self-funded
- Profitable
- Medium growth rate
- Independent
- Specialized services
- 10 year old lab
- MBE
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- The only independent coagulation lab west of the Mississippi

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Testing Capabilities: (*algorithm-based)
• Hypercoagulability Panels*
• Lupus Anticoagulant Work-ups*
• Antiphospholipid Subgroup Panel
• Platelet Aggregation Studies
• von Willebrand Panels with Multimers
• Heparin Levels (UFH, LMWH, ARIXTRA)
• HIT work-ups
• Long aPTT / PT work-ups*
• Bleeding, Clotting work-ups*
• Factor Activities/ Inhibitor Titers*
• Plavix/ Prasugrel Sensitivity
• Warfarin, CYP2C19 Sensitivity
• Recurrent Miscarriage Panels*
• Anticoagulant monitoring (dabigatran)

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US Clinical Lab Testing Market: Competitive Landscape*

- 40% Hospital Labs
- 36% Hospital Outreach
- 20% Commercial Labs
- 4% POLs and others

*Source: Annual Report 2012, Quest Diagnostics, Inc.
Core strategies…

• Be innovative in our test selection.
• Lead the country in TAT.
• Hold limited inventory (JIT).
• Offer a testing service with interpretation that is valuable.
In 2006, the average national Medicare Part B reimbursement was $10.30.
A Rotten Deal…

- Do what you do as fast as you can.
- We’ll pay you at or below your cost.
- Chase the patient for anything else.
  - BTY, 57% are untouchable
The bigger the problem the bigger the opportunity!
1. Fundamental: Patients get sick and doctors need lab testing to treat
90% of all medical decisions are driven by lab test results.

CMS: lab services account for 2.4% of the Medicare Part A and Part B expenditures (2012).
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You can only have two...

The Lab Service Paradigm

Low Price
High Quality
Fast TAT
2. Fundamental: Faster lab testing saves money and lives
Clinical Laboratories have very similar value chain challenges.
Clinical Laboratory Value Chain Analysis

Inbound Logistics → Specimen Analysis → Result Delivery → Marketing and Sales → Client Services

Hidden stakeholders can be leveraged to bend the cost curve.

Primary Activities → Margin
Identification of stakeholders:

1. Who benefits from the result?
2. Who calls asking for the result?
3. Who uses the result?
4. Who pays for the result?

Likely on the list:
- Hospitals
- Doctors
- Pharmacy
- Pharm Co.
- Biotech.
- Patients
- Ins. Co?
Questions to ask yourself about stakeholders:

1. What makes them $?  
2. What saves them $?  
3. How can we link our services to 1 and 2.
Think Entrepreneurially!

- Tease out the Need (unarticulated)
- Use ABC and decision modeling (theirs)
- Find their opportunity first, ours followed
- Building decision tree: cost analysis
- Include financials (test price insensitive)
- Exploit other costs in HC delivery process
- Exploit uncertainty of disease progression
Goals

• Careful cost analysis (vendors and clients)
• Every requisition profitable
• Suffer no losers on menu
• All contracts are money makers
• Provide highest quality at the fastest TAT
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Machaon Diagnostics’ Income Sources

- 60% Inpatient
- 10% Outpatient
- 15% CRO
- 15% Clinical Trials
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Diversify Payor Base: (i.e. insolation)

• Hospitals
• Pharmaceutical firms
• Medical devise companies
• Dietary supplement firms
• Insurance companies (CMS and commercial)
• Patients
• Charities
• Other reference labs
Stakeholder proposals that are financially based

- NPV – net present value
- Decision trees with overlaid financials
- ROI
- Cost up over price down (broken pricing)
- Reimbursement driven
Heparin-induced Thrombocytopenia (HIT) Testing Cost Analysis

Average number of suspected HIT cases per US hospital annually: 120
Expected mortality from diagnosed HIT: up to 30%
Percent of suspected cases that test negative for HIT: 90%
Average number of suspected cases that test negative for HIT: 108
Average wholesale drug cost of heparin: $60
Average wholesale drug cost of argatroban: $1,576

"...generally, when a patient is thought to have HIT, heparin is pulled and argatroban is started until HIT can be ruled out."  
Brad Lewis, MD

<table>
<thead>
<tr>
<th>Drug course:</th>
<th>Day 0</th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
<th>Day 6</th>
<th>Day 7</th>
<th>Day 8</th>
<th>Day 9</th>
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</thead>
<tbody>
<tr>
<td>Heparin spend:</td>
<td>$60</td>
<td>$60</td>
<td>$1,576</td>
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<tr>
<td>Cumulative spend:</td>
<td>$1,636</td>
<td>$3,212</td>
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<td>$7,940</td>
<td>$9,516</td>
<td>$11,092</td>
<td>$12,668</td>
<td>$14,244</td>
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</tbody>
</table>

**Testing approach:** Day 0: HIT suspected and sample sent to national lab
Day 1: Patient transitioned to argatroban
Day 8: On average it takes over 7 days to confirm HIT diagnosis (Clin Appl Thromb Hemost, 2012).
Day 10: Patients without HIT returned to heparin

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<td>$1,816</td>
<td>$1,876</td>
<td>$1,936</td>
<td>$1,996</td>
<td>$2,056</td>
<td>$2,116</td>
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**Testing approach:** Day 0: HIT suspected and sample sent to Machaon
Day 1: Patient transitioned to argatroban
Day 1: Machaon results received in afternoon
Day 2: Patients without HIT returned to heparin

"...ask your pathologist how long it takes your hospital to rule out HIT."

**Savings associated with the use of Machaon Diagnostics. (Savings based on drug cost alone*)**

<table>
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<tr>
<th>Day argatroban pulled:</th>
<th>Day 2</th>
<th>Day 3</th>
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<td>Potential per patient savings:</td>
<td>$1,516</td>
<td>$3,032</td>
<td>$4,548</td>
<td>$6,064</td>
<td>$7,580</td>
<td>$9,096</td>
<td>$10,612</td>
<td>$12,128</td>
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<tr>
<td>Potential annualized savings: (n=108)</td>
<td>$163,728</td>
<td>$327,456</td>
<td>$491,184</td>
<td>$654,912</td>
<td>$818,640</td>
<td>$982,368</td>
<td>$1,146,096</td>
<td>$1,309,824</td>
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*Note: Additional savings will likely be associated with reductions in staffing, ICU bed time and other support services.
Drivers for continued buy-in from stakeholders:

• Re-hospitalization (RAC audits)
• Pharmacy costs
• ACO growth
• SGR
• Hospital competition
• Pressure for better outcomes
• Other CMS cuts
• Many, many other sources of downward pressure
How to build a free sales force…

1. Identify your stakeholders
2. Show them how they benefit
3. Show them the value of that benefit
4. Show them how they can help

Result = as a 10 person lab we’ve built an 80+ person sales force in 2 years.
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How to build a free sales force…
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Metrics of our Success (so far...)

• 2 → 26 states in last 2 years
• CARG ~20%
• 2013 = 1.5 revenues
• Debt < 5%
Things that worked out well:

- Found a core service early, beachhead (and focused)
- Diversified income sources early
- Fluid, flexible business plan (MD ’03 ≠ MD’ ‘13)
- Hiring of smart folks (100+ years of clinical and technical expertise)
- Identification and leveraging of stakeholders
- Growing a sales force at no cost
- Motivated, engaged team
- Recognize limitations
- Contracting strategically
Where we dropped the ball:

- Getting a client contract prior to start-up
- Entered into contracts we could afford (BC, BS, UH)
- Early leverage easier than lean leverage
- Financially investment partner (faster growth)
- Too many other failures to list…
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Lab Staff:

- Michael Ero, MT, CLS, MBA, president, founder
- Brad Lewis, MD, hematologist, medical director
- Walter Jeske, PhD, scientific consultant
- Tim Shurtleff, MPA, laboratory administrator
- Tamara Mihailovski, CLS, MSCLS, lab supervisor
- Sheila Flaherty, CLS, staff scientist
- Connie Ng, CLS, staff scientist
- Jack Harbert, BS, research coordinator
- Jenny Adams, MS
- Denae Heartfield, MPH
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Q & A

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