Strategies for a Changing Laboratory Landscape

California Clinical Laboratory Association
2015 Annual Conference
About G2 Intelligence
www.g2intelligence.com

• **Advancing the Business of Diagnostic Medicine**
• Our mission is to deliver relevant, meaningful, and actionable findings on diagnostic industry markets, related regulatory changes, and laboratory operations.
• We’ve covered and reported on the diagnostic industry for over 30 years.
• We deliver topical and analytical periodicals, proprietary research studies, and through live and virtual events, facilitate industry meetings and information exchanges.

@g2intelligence
Overview

- Market snapshot
- Market shift
- Value-driven offerings
- Game changers?
From: U.S. Clinical Laboratory and Pathology Testing 2013-2015: Market Analysis, Trends, and Forecasts

**Laboratory Industry Revenue 2010-2015P ($ Billions)**

- 2010: $66.9
- 2011: $70.3
- 2012: $76.1
- 2013P: $74.0
- 2014P: $73.4
- 2015P: $73.0

P = Projected
Midpoint estimates are displayed for 2014 and 2015
Source: G2 Intelligence, Truven Health Analytics, CMS, American Hospital Directory®
From:
U.S. Clinical Laboratory and Pathology Testing 2013-2015: Market Analysis, Trends, and Forecasts

![Bar chart showing revenue growth rates from 2010 to 2015](image.png)

- 2011: 5.1%
- 2012: 8.2%
- 2013P: -2.8%
- 2014P: -0.8%
- 2015P: -0.5%

P = Projected
Midpoint estimates are displayed for 2014 and 2015
Source: G2 Intelligence, Truven Health Analytics, CMS, American Hospital Directory®
From:
**U.S. Clinical Laboratory and Pathology Testing 2013-2015: Market Analysis, Trends, and Forecasts**

![Pie chart showing market share of laboratory and pathology testing in the U.S. in 2013-2015](chart.png)

- **Independent**: 33.0%
- **Hospital**: 63.1%
- **POL (2.9%)**
- **Other (1.0%)**

*Source: G2 Intelligence, Truven Health Analytics*
From: *U.S. Clinical Laboratory and Pathology Testing 2013-2015: Market Analysis, Trends, and Forecasts*

- **Drug Testing (2.1%)**
- **Molecular (9.9%)**
- **Anatomic Pathology (26.1%)**
- **Immunology (7.1%)**
- **Routine (54.3%)**
- **Other (0.5%)**

*Source: G2 Intelligence, Truven Health Analytics, CMS, American Hospital Directory®*
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- Game changers?
How did we get here?

- Precision medicine > need for new services
- Healthcare market reforms
- Lab reimbursement declining

Lab Value Models
A Critical Juncture

• Providers under pressure
• Value-based case for pathology and labs
  – Optimally informed care decisions
• Challenges—and opportunities—abound
What do you mean by “value”?

- Patient health outcomes generated per unit of resources expended
- New industry currency, metric, and business objective
What makes a value-based healthcare model?

• Managing patient populations
• Delivering coordinated care by integrating primary and specialty networks
• Focusing on patient outcomes
• Requiring evidence-based practice
• Implementing health IT for quality measure managing and reporting
• Focusing on overall healthcare cost, rather than itemized fee reduction
Hospitals and Health Systems Facing Serious Threats

- Projections for government reimbursement cuts + increasing expenses imply significant profit declines for hospitals / health systems over the next decade
  - 19 percentage points drop in operating margins over 10 years, according to The Advisory Board
  - 15 to 25 percent declines in hospital revenue yields over next 10 years, according to Booz & Company

- Factors contributing to margin erosion:
  - Expense increases due to nursing shortages, IT investment, more complex care
  - Case mix shifting toward less profitable medical admissions
  - Payer mix shifting toward Medicare and Medicaid
Desperately Seeking New Delivery Models

- Need **double-digit reductions in costs** – not possible using traditional levers
  - “Most of the CEOs agreed on the need to get 20 to 40 percent of costs out of the system to operate at anticipated future reimbursement levels.” (Huron Healthcare CEO FORUM, 2012)

- Majority of hospital executives pursuing **new models of care delivery** as key cost reduction strategy
  - Redesign care delivery processes to remove waste:
    - consolidate or decommission underutilized operations,
    - ensure everyone is working "top of license"
  - Reduce unnecessary care and costs:
    - avoid unnecessary or redundant diagnostic tests and therapies
Physicians can increase their episode payment by improving their results. Either improving patients’ survival or decreasing the total cost of care from one year to the next will trigger UnitedHealthcare to increase the episode payment.

Physicians and UnitedHealthcare’s oncology team together assess the value for each scenario, using more than sixty measures such as survival and complications rates and total cost. The program does not mandate a maximum amount of dollars to be spent for a year of life gained. However, it does allow clinicians to assess the true impact of adding new drugs and potentially to stop prescribing drugs with no value—those that confer no survival benefit or improvement in quality of life.

When comparing multiple regimens with similar response rates, physicians could use these data to select the most cost-effective therapies. Best practices are not limited to drugs alone: Radiology, radiation therapy, laboratory testing, and other services can also be evaluated.
New (Value) Math: Profit = Someone Else’s Revenue

Avg. Episode of Care Costs – Bundling Program

- Testing
- Procedures
- Providers

**ILLUSTRATIVE**

<table>
<thead>
<tr>
<th>Year</th>
<th>Testing</th>
<th>Procedures</th>
<th>Providers</th>
<th>Total Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>$4K</td>
<td>$7K</td>
<td>$12K</td>
<td>$23K</td>
</tr>
<tr>
<td>2014</td>
<td>$3K</td>
<td>$5K</td>
<td>$12K</td>
<td>$20K</td>
</tr>
</tbody>
</table>

- $3K in Cost Savings = Bundle Profit
- **12** in 2013
- **5** in 2014
- **3** in 2014
Decision Time: Is Your Lab a Savings Generator or a Source of Savings?

Savings generator: path and lab medicine services generate clinical value and share in savings

Source of savings: diagnostic testing is cost cutting (profit) opportunity for other providers
On the Table or At the Table?

• Manage testing overutilization
• Lab operations efficiency

Lab testing $ only
3-4% of costs and encourages commoditization

Lab testing drives most clinical decisions and thus most outcomes and costs
• Clinicians overwhelmed and need help making decisions
• Lab info = powerful risk predictor and therapy personalizer

Lab influence $ is multiplied many fold by impacting downstream clinical costs and outcomes
On the Table: Commodity

Status Quo > Providers seek lowest cost lab services

At the Table: Value Services

Provide services beyond test reports for downstream, value

Negotiate compensation based on value

Opportunity
**ACOs and Lab Contracting**

### Commoditization

**Percent of ACO Executives Surveyed**

- Change in lab contracts since ACO:
  - Switch to lower cost labs: 22%
  - Greater % capitated or bundled: 21%
  - Labs received lower reimbursement rates: 18%

### Value Opportunities

**Percent of ACO Executives Surveyed**

- Changes to lab contracts since ACO:
  - Path contracts have ACO success bonuses: 17%
  - Lab contracts have ACO performance payments: 12%
  - Labs received lower reimbursement rates: 19%
More Experienced ACOs Report Better “Lab Value Relations”

<table>
<thead>
<tr>
<th>Description</th>
<th>ACOs less than 18 Mos</th>
<th>ACOs more than 18 Mos</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labs Pursuing Value Initiatives</td>
<td>42%</td>
<td>61%</td>
</tr>
<tr>
<td>Labs Contracts Have ACO Success Payments</td>
<td>6%</td>
<td>19%</td>
</tr>
<tr>
<td>Pathologist Contracts Have ACO Success Payments</td>
<td>5%</td>
<td>26%</td>
</tr>
<tr>
<td>Labs Have Vendors Providing Services Supporting ACOS</td>
<td>9%</td>
<td>30%</td>
</tr>
</tbody>
</table>
Care Decision-Making: A Problematic Process

“The pace at which new knowledge is produced outstrips the ability of any individual clinician…” – Institute of Medicine, 2012

- Provider Shortages + More Complex Patients
- Medical Info Overload + More Complex Science
- Multiple conditions and co-morbidities
- Value Care Decisions Even More Challenging
- Costs, patient preferences, quality measures

Need Next Gen Decision Informing
Key Source of Poor Performance?
Information Overload

“For more than a decade, reports of the Institute of Medicine (IOM) have focused attention on a persistent set of problems within the American health care system that urgently need to be addressed, including poor quality; lax safety; high cost; questionable value; ... The committee identified two reasons for the above problems that grow more urgent every year. One is the increasingly unmanageable complexity of the science of health care. ... the systems by which health care providers are trained, deployed, paid, and updated cannot usefully digest this deluge of information.” – IOM, 2012, “Best Care at Lower Cost”
What is the Return on Decision (ROD)?

Information services

DECISION INVESTMENT

Personnel

Provider care decision

DECISION RETURN: VALUE PAYMENTS

Quality measures
Clinical outcomes
Downstream care savings
The Value of Pathology & Lab Medicine: Optimally Informing Care Decisions

- **Decision Need**
  - Overload of complex info, tests
    - Path / Lab Services
      - Dx Pathways, Clinical Decision Support – Dx EBM to POC
      - Expert teams – patient-specific solutions
  - Predict risk and costs
    - Lab informatics – identify high risk patients, biomarkers
    - Personalized medicine testing services – MDx, PGx
  - Efficiencies and coordination
    - Test tracking and integrated presentation services
    - “Dx test management” resource for high risk patients
  - Error reduction
    - Hospital resistant pathogen services
    - Adverse drug events – pharmacy-lab monitoring, PGx
Claim Your Rightful Role as The Decision Expert

- Personalized Medicine
- Quality analytics
- Disease across levels
- Informatics
- Digital convergence
- Point of care and patient engagement
So What’s the Difference?

**Current Dx Services**
- Transactional – data transfer
- Service is report with test results, from lab or office
- Consults and alerts only by request

**Value-Gen Dx Services**
- Partnering with clinician to achieve outcomes
- Service is knowledge delivery, integrated at point of care
- Proactive, regular outreach to support decision making
Can Dx-Informing Services Add Significant Value? Let’s See

- Estimated path and lab value: used well-regarded model for bundling healthcare costs -- the Prometheus Payment model. Selected by Medicare for their bundling program.
- Prometheus’ financial model details the costs of potentially avoidable complications (“PACs”) for 21 conditions and procedures.
  - 21 conditions and procedures comprise about 45% of healthcare spending, PACs comprise anywhere from 20-50% of costs.
- PACs represent gaps in care that providers can reasonably control
- Reducing PACs = Generating Value
PACs = Source of ACO Savings

- A PAC is any event that negatively impacts the patient and is potentially controllable by all the physicians and hospitals that manage and co-manage the patient.
- Most PACs can be turned into potential savings to all (divvy up the pie):
  - To providers – as bonus
  - To payers – as decreased outlays
  - To patients – as better health
G2 Prometheus Study: Key Findings

Path and lab services could reduce these addressable PAC costs by 30% ... i.e., help generate 30% of a health system’s or payer’s value
Examples of Value Generation

<table>
<thead>
<tr>
<th>Test Decision Support</th>
<th>MDx for ABx</th>
<th>Biomarkers + Other Services</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Fluid and Electrolyte PACs = 42% decrease</td>
<td>• Decub Ulcer PACs = 17% decrease</td>
<td>• Acute Renal Failure PACs = 32% decrease</td>
</tr>
<tr>
<td>• PE and DVT PACs = 18% decrease</td>
<td>• UTI PACs = 17% decrease</td>
<td>• Pneumonia PACs = 31% decrease</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Stroke PACs = 46% decrease</td>
</tr>
</tbody>
</table>
Overview

• Market snapshot
• Market shift
• Value-driven offerings
• Game changers?
Why Should Labs Adopt a Value-Driven Approach?

• To claim a place at the center of clinical care, despite the ancillary nature of offerings
• To build new positions for laboratories in market value chains
• To escape the current path of commoditization and ongoing budget cuts
Why Should Labs Adopt a Value-Driven Approach?

• Ask a pharmacist
  – From shopkeepers and order fulfillers (1980s-90s) to clinical care partners (present)
  – Conscious decision to provide knowledge services, consult with clinicians
  – Inserted themselves into the care continuum
Why Should Labs Adopt a Value-Driven Approach?

Value-driven Laboratory Financial Model Spectrum

- Increased market share
- Higher negotiated rates with payers
- Value-based pricing for new LDT
- Channel deals—license, milestones, revenue shares
- Shared savings, share of bundle or capitated contract
The Value-Driven Laboratory: How Is It Different?

• Change in offerings/services to:
  – Address emerging needs of physicians and payers
  – Optimally assist in improving clinical value
  – Support argument for a new laboratory business model
The Value-Driven Laboratory: How Is It Different?

Business Model Framework for Value-driven Laboratory

- **Offerings**: Performing test and service offerings
- **Channel**: Delivering test and service offerings
- **Financial Model**: Obtaining financial remuneration
Types of Value-Driven Labs

Evolving according to degree of market/clinical reforms:

- Recognition of value delivered by lab’s offerings
- Payment for that value
- Channel used to deliver that value
Value-Driven Laboratory Reform Spectrum

1. System Recognition of Lab Value
   - Value recognized
   - Value in demand
   - Value qualified in currency

2. Lab Payments received
   - CPT at higher rate from payer
   - Non-CPT – e.g., revenues
   - Part of payment reform – e.g., bundling, etc.

3. Lab Channel
   - Payer and lab contracts
   - New entrants – e.g., PBM, pharmas
   - Part of delivery reform – integrated health systems, ACOs, etc.
Value-Driven Laboratory Reform Spectrum
Value Offerings Status

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- Payer and lab contracts - e.g., PBMs, pharmas
- New entrants - e.g., integrated health systems, ACOs, etc.
- Part of delivery reform - integrated health systems, ACOs, etc.
From Data to Knowledge

**Test Data**
- Analytic results

**Test Information**
- Interpretation of results in context of patient info/clinical setting
- Recommendations regarding other tests/diagnoses

**Test Knowledge**
- Tools and diagnostic solutions
- Integration with other patient tests-full diagnostic profile
- Evidence-based diagnostic probability
- Evidence-based treatment algorithms
Framework for Value-Based Laboratory Offerings

<table>
<thead>
<tr>
<th></th>
<th>Typical Status Quo Laboratory Offering</th>
<th>1st Level Value-based Lab Offering</th>
<th>2nd Level Value-based Lab Offering</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tests</strong></td>
<td>Current tests</td>
<td>New, value-targeted LDTs</td>
<td>Novel panels/“packages”</td>
</tr>
<tr>
<td><strong>Diagnostic Information</strong></td>
<td>Data</td>
<td>Information – explanation or interpretation</td>
<td>Knowledge – integrate with other findings, recommendations</td>
</tr>
<tr>
<td><strong>Tools</strong></td>
<td>Few Offered</td>
<td>Ordering and decision support, IT connectivity</td>
<td>Algorithms, protocols, informatics, digital pathology</td>
</tr>
<tr>
<td><strong>Services</strong></td>
<td>Laboratorian available for consult - passive</td>
<td>Proactive clinician outreach</td>
<td>Disease management, patient services, clinical trials</td>
</tr>
</tbody>
</table>

G2 INTELLIGENCE
Value-Driven Laboratory Offerings: Some Examples

- **Test Menu**
  - Status quo - lists of tests with descriptions
  - New e.g. - introduce new, higher value tests
  - New e.g. - evidence base regarding test value

- **Test Ordering**
  - Status quo - test menu only, electronic but without algorithmic guidance
  - New e.g. - test optimization tool for clinicians - recommends optimal tests in different settings
  - New e.g. - services - proactive consult services to educate

- **Test Results**
  - Status quo: report with data and analytics
  - New e.g. - reports with interpretation of results and suggestion of diagnoses; reports with suggestions for treatments
  - New e.g. - patient counseling services
Applications of Value-Driven Offerings

- Test ordering and utilization
  - Identified by physicians as major unmet need
- Test reporting
  - Facilitating comprehension and diagnosis
- Diagnostic support
  - Avoiding diagnostic errors
- Condition management
  - Information services for managing a particular condition/population
- Population management
- Digital pathology
  - Driven by integration of health systems
Application: Utilization Management for Cost Avoidance

- Identify tests with high ordering variation and high downstream spending consequences
- By analyzing lab ordering patterns, looking for tests with high ordering variation and which are known to have a costly impact if results are positive
- Example: CA 125
  - High ordering variation, 10% false positive rate, imaging workup (estimated 100x more downstream radiology spending for every dollar spent on lab testing)
  - Lab implements electronic order lock on CA 125 that popped up a reminder of how the test is most appropriately used
  - Test utilization dropped by 65%, resulting in “huge procedural savings”
Clinicians’ decisions overwhelmed

- Clinician diagnostic errors average 15% of cases - delayed, missed and inaccurate diagnoses

Lab partners clinically on testing

- Algorithms, services
- Improved and faster diagnoses
- Fewer errors, less PACS

Lab viewed as value partner

- Provider of knowledge, not just test results
- Expertise – right tests for right patients at right time for right treatment
Application: Coagulation

Venous Thrombo-Emboli (VTEs)
- Prophylaxis / risk assessment
- Diagnostic services

Advanced Blood Management
- Transfusion restrictions
- Patient blood management
**Application:**

**Coagulation – Restrictive Transfusions**

(trigger of Hgb 7-8 g/dL or less)

1. **Mortality Reduction**
   - 23% decrease in inpatient mortality
     - Anesth and Intens Care 41(2), 2013
   - Relative risk for in-hospital mortality reduced by 26%
     - Am J Med 127(2), 2014

2. **Length Of Stay Reduction**
   - LOS reduction of 17% for hip replacement and 33% for knee
     - Anesth and Intens Care 41(2), 2013
   - LOS reduction of 20% for cardiac patients
     - Premier Healthcare, Oct 2012

3. **Complication Reductions**
   - 28.6% decrease in complications
     - Am J Med 126(10), 2013
   - Decreased rel. risk of acute coronary syndrome (-56%), pulm edema (-52%), bacterial infect. (-14%)
     - Am J Med 127(2), 2014
## Application: Coagulation – Restrictive Protocols

<table>
<thead>
<tr>
<th>Hospital Size 400-500 Beds</th>
<th>Cost</th>
<th>Savings $$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rebleed</td>
<td>$131,721</td>
<td>$60,592</td>
</tr>
<tr>
<td>ACS</td>
<td>$455,544</td>
<td>$255,105</td>
</tr>
<tr>
<td>Pulmonary Edema</td>
<td>$1,101,120</td>
<td>$572,582</td>
</tr>
<tr>
<td>Bacterial Infection</td>
<td>$989,333</td>
<td>$138,507</td>
</tr>
<tr>
<td>Total</td>
<td>$2,677,719</td>
<td>$1,026,786</td>
</tr>
</tbody>
</table>

Source: HCUP Reports, AHD, Shelley R. Salpeter et al. 2014 meta-analysis and G2 Intelligence
## Patient blood management lab value services

| Pre-Operative | • Clinical and laboratory based anemia diagnosis  
• Anemia correction through alternative options to transfusion  
• Patient engagement, prescreening services for high risk conditions, and patient transfusion education including informed consent |
| Intra/post Operative As Well As Non-operative | • Identify potential surgical risks which could increase likelihood of blood loss  
• Computerized physician order entry (CPOE) with algorithm for ordering blood for clinical decision support and "flagging" or "alerts" using established restrictive protocols |
| Improved Resource Utilization /Coordination | • Multi-disciplinary teams (e.g. pathologists, all surgical depts., intensivists, etc.) to develop PBM programs and restrictive protocols  
• Multi-modal interventions such alternatives to transfusion for anemia correction, cell salvage, reducing bedside phlebotomy blood loss, improved surgical technologies that reduce blood loss |
| Monitoring | • Monitoring by blood bank for the laboratory evidence supporting transfusions  
• Post transfusion or PBM intervention evaluative process to review clinical evidence on a per patient case basis  
• Establish the role of Transfusion Safety Officer |
| Big Data/LIS/IT Solutions | • Optimize lab informatics for physician utilization rates, individual case studies, and hospital level versus national performance rates  
• Hospital outcomes research to monitor results of PBM interventions across departments and business lines |
“PBM contributes to driving up revenue for the hospital as patient education and awareness efforts in addition to word of mouth is driving patients into the hospital seeking care with safe, transfusion-free or well-managed, limited blood options”

-Northern U.S. Hospital
Application: Condition Management

• Information services that provide laboratory test-driven solutions for clinically managing a particular condition
• Frequently generate savings in downstream cost avoidance, improve quality and potentially outcomes
• Example: MRSA screening programs
  – Offered for either all inpatients or selected high-risk groups with generally excellent results—e.g., savings from avoided costs due to lowered rates of MRSA infections, lower rates of adverse events
  – Asymptomatic MRSA colonization has been shown to be a risk factor for poor clinical outcomes and is associated with higher patient cost
  – One medical director estimates that MRSA program has cost $2.4 million (including $495,000 in testing costs) and generated $4.9 million in cost savings
Application: Population Management

- Facilitates implementation of evidence-based care, standardization of clinical practice, chronic condition management, prevention and wellness
- May draw upon longitudinal and cross-population lab results, connectivity with hospitals and providers
- Example: Identify “spending time bombs” (approx. 3% of population)
  - Uncover rich clinical targets for laboratory value offerings by selecting conditions or populations with high volume of clinical services, high cost of clinical services, and high variability in clinical service usage
  - Manage conditions like diabetes and HIV by longitudinally tracking test values, then automatically sending clinicians monthly reports indicating patients to be targeted for potential treatment interventions
  - Patient reminders, linkage of lab and pharmacy databases
  - Pay cardiologists and radiologists to join laboratory teams that develop these types of offerings
Overview

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Game Changer: Precision Medicine

Research
Identifies molecular marker (mutation, etc.) and clinical implications

Test Development
With demand comes need to improve test effectiveness and efficiency
• New tests and technologies
• Personalized medicine
• Demand from specialists, patients
• Influx of newly insured
• Value-based healthcare
• Aging population

• Reimbursement cuts
• Payer utilization management, coverage denials
• Lower patient healthcare utilization due to unemployment, high costs
• Interpretability
Many doctors have little or no formal training in genetics and frequently order the wrong test, misinterpret results, or fail to refer the patient to a genetic counselor.

<table>
<thead>
<tr>
<th>I am confident I can...</th>
<th>PCP</th>
<th>Cardiologist</th>
<th>Oncologist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Explain test results to my patients</td>
<td>46%</td>
<td>61% ▲ P</td>
<td>84% ▲ P, C</td>
</tr>
<tr>
<td>Identify appropriate patients for testing</td>
<td>45%</td>
<td>57% ▲ P</td>
<td>85% ▲ P, C</td>
</tr>
<tr>
<td>Understand and interpret the test results</td>
<td>42%</td>
<td>52% ▲ P</td>
<td>83% ▲ P, C</td>
</tr>
<tr>
<td>Choose the right test</td>
<td>35%</td>
<td>50% ▲ P</td>
<td>83% ▲ P, C</td>
</tr>
<tr>
<td>Choose which lab to send tests to</td>
<td>30%</td>
<td>35%</td>
<td>56% ▲ P, C</td>
</tr>
<tr>
<td>Determine if the test is covered by insurance</td>
<td>24%</td>
<td>30%</td>
<td>39% ▲ P, C</td>
</tr>
<tr>
<td>Determine the right insurance codes</td>
<td>23%</td>
<td>25%</td>
<td>34% ▲ P, C</td>
</tr>
</tbody>
</table>

▲ P = Significantly higher than Primary Care.
▲ P, C = Significantly higher than Primary Care and Cardiology

Source: Coamey, Jerry. “MDx and MDs: Is a dose of knowledge the prescription for adoption.” CAHG Physicians Landmark Study.
MDx Sector's Increasing Share of Clinical Lab Market

<table>
<thead>
<tr>
<th>Year</th>
<th>MDx</th>
<th>Rest of Clinical Lab Market</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>$62 Billion</td>
<td>8%</td>
</tr>
<tr>
<td>2015</td>
<td>$79 Billion</td>
<td>12%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sector</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>HemOno</td>
<td>Solid tumors, hematological cancers, hematological disease</td>
</tr>
<tr>
<td>Women’s Health</td>
<td>Sexually transmitted diseases (HPV, Herpes, GC/Chlamydia, Trichomonas), Cystic Fibrosis, Prenatal FISH</td>
</tr>
<tr>
<td>General Infectious</td>
<td>HIV, HBV/HCV, HAI’s, respiratory, other microbacteria</td>
</tr>
<tr>
<td>Inherited</td>
<td>Birth defects (e.g., chromosomal abnormalities), rare genetic diseases, genetic diseases detected at screening (e.g., Fragile X)</td>
</tr>
</tbody>
</table>
| Pharmacogenomics     | Germline genetic variations affecting drug metabolism, efficacy and/or toxicity  
Examples: P450 enzyme tests (e.g., Cytochrome P450), CYP genotyping (e.g., CYP2C9), Vitamin K (e.g., VKORC1), UGA1T1|
| Transplant           | HLA tissue typing                                                                                                                            |
| Blood Screening      | Screening transfusion units for viral infections—e.g., HIV and HCV, mutually exclusive of general infectious sector                          |
### G2 Intelligence MDx Market Driver Profiles: 2013-2015

<table>
<thead>
<tr>
<th>Category</th>
<th>Driver Score</th>
<th>Payer Value</th>
<th>Assay Technology</th>
<th>Therapeutics</th>
<th>Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>HemOnc</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Womens</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Infectious</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Pharmacogenomics</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

Source: G2 Intelligence, U.S. Molecular Diagnostic and Genomic Testing 2013 - 2015: Laboratory Industry Analysis, Trends, and Forecasts, © 2013 Kennedy Information, LLC

**Payer Value**: Attractive in a value-based purchasing world?
**Assay Technology**: Moving toward “game-changing” technology?
**Therapeutics**: Impacting prescribing decisions?
**Population**: Growing patient population?
• Integration with other areas of the laboratory while continuing to play a complementary and/or replacement role?
• Progress across full range of disease testing:
  – Diagnostics, screening, therapy response, risk/relapse prediction
• Specific tests (particular disorders) → broader assays (variants)
• Focus on defining clinical significance of findings
  – Effects of single gene on common diseases generally small
  – Labs clarify how they will assist physicians with the complex interpretation of clinical data generated
    • What do genotypes mean? Will pharmacist be involved in final recommendation to physician?
• Moving to a point-of-care orientation
Game Changer: NGS

• Early applications: Multigene panels to address specific medical situations where clinical utility has been more adequately substantiated
  – Prenatal screening, inherited-disorder carrier screening, identification of rare genetic conditions involving defined genes, tumor characterization to guide targeted therapeutic choices, panels for identifying drug metabolism status

• Multigene panels create foundation for more comprehensive whole-genome testing

• Expansion of available phenotype–genotype correlative data will accelerate application

• Platform manufacturers, software developers designing applications to meet rigor, standards of clinical diagnostics
Opportunities for New Lab Models

<table>
<thead>
<tr>
<th>CURRENT LABORATORY MODEL</th>
<th>RESULTS OF LABORATORY TESTS</th>
<th>CONTRACTS WITH PAYERS, OTHER LABS, PROVIDERS</th>
<th>REIMBURSEMENT BY CPT CODES FEE-FOR-SERVICE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lab Offerings</td>
<td></td>
<td></td>
<td>Lab Revenues</td>
</tr>
</tbody>
</table>

FORCES IMPACTING MODEL
- Precision Medicine, MDx, Market Reforms
- Precision Medicine, MDx, Market Reforms
- MoPath Code Changes, CMS Payment Reform, Value-based Pricing, Sequestration

NEW DEMANDS/OPPORTUNITIES CREATED BY DISRUPTIVE FORCES
- Market demand for more and new types of diagnostic and genetic profile information to personalize medicine
- New types of entrants to laboratory industry—e.g., pharmacy benefit managers, genetic benefit managers, pharmaceuticals, cross industry partnerships, ACO's
- Payment based on strong evidence of clinical utility as the overall market drives towards bundling, risk and cost sharing

Game Changers: PBMs and PGx

<table>
<thead>
<tr>
<th>PBM PGx Options</th>
<th>CVS Caremark/Generation Health</th>
<th>Express Scripts/Medco</th>
</tr>
</thead>
<tbody>
<tr>
<td>Offers companion MDx</td>
<td>✅</td>
<td>✅</td>
</tr>
<tr>
<td>Lab network with testing services</td>
<td>✅</td>
<td>✅</td>
</tr>
<tr>
<td>Collaborations on research/pilot studies (e.g., clinical utility)</td>
<td>✅</td>
<td>✅</td>
</tr>
</tbody>
</table>

- Funding research/pilot studies
- Establishing lab networks
- Facilitating “turn-key” testing through contracts with Genetic Benefit Managers
- Educating clinicians, payers, and patients
- Key access point for information: clinical, economic, and educational
- Linked to patient treatment adherence; potential for expanded models of liaison between physician, hospital, lab, and the patient
Game Changer: Theranos
Theranos
Phase 1

• Syringeless sampling
• Decrease sample volume to a few drops of blood
• Automate testing
• Decrease TAT
• Do it cheaper
Theranos
Phase 2

• Market/data access for patients
• Early detection/prevention
• User experience
• FDA clearance
Patient engagement is the blockbuster drug of the twenty-first century.”

-Leonard Kish
Thank you

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