The Future of Clinical Chemistry and Laboratory Medicine, The Diagnostics Industry View

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Abbott Diagnostic Division (ADD)
Agenda

- Lack of perceived value of laboratory medicine
- Informatics: A solution for addressing laboratory and health system challenges
- Immunoassay diagnostics is still a main and fast growing segment in Diagnostics
- Molecular diagnostics: companion diagnostics play a key part of personalized medicine
- Point-of-Care (POC)
- IVD market in emerging nations
Central Role of Laboratory Medicine

70% of clinical decisions are informed by data from laboratory medicine

4% spend
Reimbursement Reduction Trend for IVD in Japan

-2% -3% -5% -3% -7% -7% -14% -11% -11%

$ Billion


Medical Expense Reimbursement Level $ = $95

Put science on your side.
IVD Product Approval Period (Reviewer Time)

TARGET APPROVAL TIME DEFINED BY REGULATOR: 180 DAYS

SPECIAL CONSULTATION

<table>
<thead>
<tr>
<th>Special Consultation</th>
<th>Number of Cases</th>
<th>PMDA</th>
<th>Within 6 months (184 days)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Reviewer Time</td>
<td>Number of Cases</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Average</td>
<td>Minimum</td>
</tr>
<tr>
<td>With</td>
<td>5</td>
<td>549</td>
<td>346</td>
</tr>
<tr>
<td>Without</td>
<td>58</td>
<td>313</td>
<td>71</td>
</tr>
</tbody>
</table>

Source: IVD Approval Cycle Time Survey 2010, Analyzed by LEK
Collaboration Opportunities for Laboratory Professional Associations and Industry

**IMPROVE RECOGNITION OF VALUABLE CONTRIBUTIONS OF IVD TO HEALTHCARE**

**ASSOCIATIONS AND INDUSTRY WORK TOGETHER WITH LABORATORY PROFESSIONALS, CUSTOMERS AND GOVERNMENT TO INFLUENCE HEALTH POLICIES AND THE REIMBURSEMENT SYSTEM IN ORDER TO IMPROVE HEALTHCARE AND PATIENT’S QOL.**
IFCC-Abbott Visiting Lecturer Programme

Put science on your side.
2012 Turning Science Into Caring (TSIC) Symposium on Oct 15-16, Shanghai, China

PARTNERING WITH IFCC AND CSLM

Symposium Theme:
“To Be”: Healthcare Industry

<table>
<thead>
<tr>
<th>Relative Offering Level</th>
<th>Price/Cost</th>
<th>Quality of Life</th>
<th>Clinical Outcome</th>
<th>Career Attractiveness</th>
<th>Public Perception</th>
<th>Government Perception</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Blue Diamond</td>
<td>Purple Square</td>
<td>Green Circle</td>
<td>Blue Diamond</td>
<td>Purple Square</td>
<td>Green Circle</td>
</tr>
<tr>
<td>Low</td>
<td>Orange Triangle</td>
<td>Purple Square</td>
<td>Green Circle</td>
<td>Blue Diamond</td>
<td>Purple Square</td>
<td>Green Circle</td>
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</table>
Informatics is a solution for addressing laboratory and health system challenges.
Medical Informatics at the Hospital

- **Radiology Information System**
- **Pharmacy Information System**
- **Laboratory Information System**
- **Clinical Information System on Physician’s Workstation**
- **Picture Archiving & Communication System (PACS)**
- **Administrative & Financial System**
- **Nursing Information System**
- **ADT System**
- **Clinical Information System on Physician’s Workstation**
- **Pictorial Representation of Hospital Departments**
Laboratory Informatics

- Aims to expedite the exchange of laboratory data using data networks.
- The field involves developing systems and standards to facilitate and expedite the acquisition, retrieval and communication of test results and other laboratory data.
Abbott’s OneLab Informatics Solutions

A SINGLE PLATFORM AND LOGIN

INVENTORY MANAGER
KEEP TRACK OF THE REAGENTS AND SUPPLIES

DECISION CENTER TAKES LABORATORY DATA AND GENERATES STATISTICS AND REPORTS

SMART CENTER INTERFACE MULTIPLE INSTRUMENTS

Scorecards – Dashboards – Graphs

Action Triggers

Visual Alerts

Stoplights

Measure
Actual
Target
Achievement
Turnaround
Collection Errors
Lab Reporting Errors
Proficiency Testing
Analytic Systems Quality

24.8
25
100%
10.1
12
100%
7.3
10
100%
26.1
25
97.6%
22.1
25
100%

10.1
12
100%
10
100%
12
25
97.6%
25
100%
Immunoassay Diagnostics: a main and fast growing segment in Diagnostics

- IVD market grew by 6% from 2008 to 2009, putting the total worldwide market at $42 billion
- A 5% annual growth rate will put the total worldwide IVD market at $54.5 billion by 2014
- Compared with a 3% growth rate for clinical chemistry and a 5% growth rate for hematology, Immunoassay Diagnostics is expected to grow at 9%, driven by technology advances such as ultrasensitive detection system, assays and novel biomarkers
Project Q is a full-scale revisioning next generation of integrated Diagnostic systems and services covering Hematology, core IACC testing and blood screening, plus informatics.
Concept Development, Review and Prototypes

Inventory Management

The instrument will be designed to accept and process samples in a random and continuous manner, allowing for efficient use of resources like the Architect.

With a steady stream of samples, STATs will be prioritized with priority.

As inventory reaches pre-defined levels, the operator is notified. A variety of verification methods can be used.

Vertical layout

The system enables inventory management with a software solution that monitors and maintains an inventory list.
### Ultrasensitive Detection Assays - hsTnI

<table>
<thead>
<tr>
<th></th>
<th>ARCHITECT TnI*</th>
<th></th>
<th>ARCHITECT hsTnI**</th>
<th></th>
</tr>
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<tbody>
<tr>
<td></td>
<td>µg/L (ng/mL)</td>
<td>ng/L (pg/mL)</td>
<td>µg/L (ng/mL)</td>
<td>ng/L (pg/mL)</td>
</tr>
<tr>
<td>LoD</td>
<td>0.010</td>
<td>10</td>
<td>0.002</td>
<td>1.9</td>
</tr>
<tr>
<td>10%CV</td>
<td>0.032</td>
<td>32</td>
<td>0.005</td>
<td>4.5</td>
</tr>
<tr>
<td>99%ile</td>
<td>0.028</td>
<td>28</td>
<td>0.026</td>
<td>26.2</td>
</tr>
<tr>
<td>% Detectable</td>
<td>&lt;50% of normals</td>
<td>&gt;50% of normals</td>
<td></td>
<td></td>
</tr>
<tr>
<td>above LoD</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</table>

*Representative data from package insert  **Internal R&D Final Verification Data

- ~7x improvement in precision
- Better LoD, enable 2 hours rule out rather than 3 serial troponins over 8-12 hours- quicker and more accurate diagnosis of ACS, as it is able to read below the 99th percentile (rule in or out by 2 hr TnI delta)
Molecular Diagnostics: Personalized Medicine and Companion Diagnostics

“THE RIGHT MEDICINE, AT THE RIGHT DOSE, TO THE RIGHT PATIENT, AT THE RIGHT TIME”

- Personalized Medicine involves co-development of drugs/devices and specialized diagnostic tests… also referred to as “Companion Diagnostics”
- Companion Diagnostic opportunities may be identified at any point in the IVD development life cycle

<table>
<thead>
<tr>
<th>DISCOVERY</th>
<th>RESEARCH PHASE</th>
<th>DESIGN CONTROL</th>
<th>VALIDATION/VERIFICATION REGULATORY APPROVALS</th>
<th>MARKET LAUNCH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collaborations leading to biomarker identification</td>
<td>Products in development may be identified with Companion Dx potential (eg., PIGF)</td>
<td></td>
<td>Products on market may have Companion Dx potential (eg., NGAL, other cancer markers)</td>
<td></td>
</tr>
</tbody>
</table>
COMPANION DIAGNOSTIC ASSAY CAN BE EFFECTIVELY USED FOR:

- Patient stratification
- Toxicity studies
- Selecting dose
- Segregating responders vs non-responders
- Monitoring patient response
Gene-based test for determining HER-2 status in breast cancer

Pioneer in pharmacogenomics, first example of a gene-based diagnostic linked to a therapeutic outcome in clinical practice

Using FISH [Fluorescence In-Situ Hybridization] technology, PathVysion can detect amplification of the HER-2 gene, an aggressive form of breast cancer

A result of “HER-2 Amplified” indicates patients that are candidates for Herceptin “targeted” antibody therapy

Accurate, reliable HER-2 results

Enables physicians to make appropriate treatment decisions

Improves clinical benefit and extends patient survival
<table>
<thead>
<tr>
<th>CANCER TYPE</th>
<th>MARKERS</th>
<th>TECHNOLOGY</th>
<th>APPLICATION</th>
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<tbody>
<tr>
<td>Lung</td>
<td>ALK</td>
<td>FISH</td>
<td>Break Apart</td>
</tr>
<tr>
<td>Breast, Gastric</td>
<td>HER2</td>
<td>FISH</td>
<td>Amplification</td>
</tr>
<tr>
<td>Colon, Lung, Melanoma</td>
<td>KRAS</td>
<td>Real-time PCR</td>
<td>SNP</td>
</tr>
<tr>
<td>Lung</td>
<td>ROS1</td>
<td>FISH</td>
<td>Break Apart</td>
</tr>
<tr>
<td>Lung</td>
<td>PRAME</td>
<td>Real-time PCR</td>
<td>mRNA Expression</td>
</tr>
<tr>
<td>Melanoma, Lung</td>
<td>MAGEA3</td>
<td>Real-time PCR</td>
<td>mRNA Expression</td>
</tr>
<tr>
<td>NSCLC</td>
<td>ALK</td>
<td>FISH</td>
<td>Break Apart</td>
</tr>
<tr>
<td>Colon, Bladder, Kidney, Lung</td>
<td>PIK3CA</td>
<td>FISH, PCR</td>
<td>Amplification, SNP</td>
</tr>
<tr>
<td>Melanoma, Colon</td>
<td>BRAF</td>
<td>Real-time PCR</td>
<td>SNP</td>
</tr>
<tr>
<td>CLL, SLL</td>
<td>TP53</td>
<td>FISH</td>
<td>Deletion</td>
</tr>
<tr>
<td>Melanoma</td>
<td>GNAQ, GNA11</td>
<td>Sequencing</td>
<td>SNP</td>
</tr>
<tr>
<td>Melanoma</td>
<td>cKIT</td>
<td>Sequencing</td>
<td>SNP</td>
</tr>
<tr>
<td>MDS</td>
<td>EGFR/D5S23</td>
<td>FISH</td>
<td>Amplification</td>
</tr>
<tr>
<td>Lung, Gastric, Breast</td>
<td>FGFR1, FGFR2</td>
<td>FISH</td>
<td>Amplification</td>
</tr>
<tr>
<td>Lung, Gastric, Ovarian</td>
<td>cMET</td>
<td>FISH</td>
<td>Amplification</td>
</tr>
</tbody>
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Patient self-testing/OTC products
Rapid tests used in a professional setting—Physician Office Laboratory (POL), home care, clinic, etc.
Rapid tests performed in the hospital
The trends of consolidations/automation and decentralization/POC co-exist
After many years of little growth, the professional POC test market is beginning to come alive
- Blood gases
- Electrolytes
- Activated clotting times
- Glucoses
- Dipstick & automated urinalysis
- Flu A&B
- Gastric and fecal occult blood
- Nitrazine paper
- (amniotic fluid detection)

- Hemoglobin A1c
- Pregnancy (hCG)
- RSV
- Hemoglobin & hematocrit
- Strep A
- PT (prothrombin)
- Microalbumin
- Creatinine
Testing Process Errors

PROBABLE CAUSES OF TESTING PROCESS ERRORS AT THE POINT-OF-CARE INCLUDED:

- Incomplete standardization of patient, staff training and lab procedures
- Inconsistency in following good laboratory practice
- Random and isolated occurrences of patient identification errors
- Less than optimal availability of information on point-of-care lab procedures, supplies and regulations
Advantages of Point-of-Care

- Provides rapid, actionable results
- Expands testing beyond the traditional laboratory setting
- Increased testing and diagnoses in at-risk populations
- Improves diagnostic efficiency in populations that could be lost to follow-up
- Emergency room, public health clinics, incarcerated populations

TWO CRITICAL POINTS ARE NECESSARY FOR POC TO BECOME MORE PREVALENT:

- Data communication – data management linking software and devices are common now
- Correlation with lab-based results – it is still not weak
IVD market in emerging nations is expected to grow from $2.9 billion in 2009 to $5 billion in 2014 at a growth rate of 12%, due to new health consciousness and growing demands for quality medical care resulting from rising incomes and standards of living.
Clinical laboratory professional associations such as IFCC and IVD industry need to work together to improve perceived value of laboratory medicine.

Informatics is a solution for addressing laboratory and health system challenges.

Immunoassay diagnostics is still a main and fast growing segment in Diagnostics driven by ultrasensitive detection system, assays and novel biomarkers.

Companion diagnostics play a key part of personalized medicine.

Demand for Point-of-Care tests are increasing.

IVD market in emerging nations are rapidly growing.
Thank You!