Introducing Ventana Medical Systems

Workflow Optimization and Automated Solutions

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Ventana Medical Systems
Foundation in Anatomic Pathology

- Founded in 1985
- Thomas Grogan, M.D. Professor of Pathology at the University of Arizona
- Born from a relentless search to find a better and faster way to diagnose the patient
- Established a vision for IHC automation & passion for improving pathology
- 6000+ systems installed in 3000+ labs across 35 countries worldwide
- 1000 Employees
Continuous Innovation
Focus on Platform Automation and Superior Technologies

Ventana’s Strategy
Create a Virtuous Cycle of Testing Efficiency and Medical Value

- Continue to improve testing efficiency in the anatomical pathology lab
  - From tissue accessioning and processing through primary and advanced staining to imaging and analysis
  - Enhanced platform efficiency and menu
  - Integrated connectivity solutions to improve patient safety and workflow optimization

- Drive medical value by providing high-value cancer information to patients and physicians
  - From diagnostics to prognostic and predictive tests
  - New technologies enabling more insightful information (Molecular, Qdots®/MIA, Imaging)
Trend toward lean healthcare has held promise, but true solutions for AP have been elusive!

Still...recent CAP Today article reveals that fewer than 50% of labs currently have or planning to launch a Lean project

Today’s Challenges in Anatomic Pathology

Market Pressures
- Increasing regulatory requirements
- Reimbursement and pricing pressures
- Competing technologies overshadowing importance of morphology
- Consolidation resulting in stronger competitors
- Higher test volumes and diverse test mixes
- Need for better service and equipment for latest technologies

Operational Challenges
- More sophisticated testing
- Increased workload demands
- Staffing shortages and workforce challenges
- Commonplace large batching in histology workflow
- Manual and redundant work (labeling, logging, sorting...)
- Manual process controls and lack of reliable information on operational issues

It’s not like it was for Quincy in the 1970s!
Heightened Awareness in AP

Risk Management

Malpractice Claims Against Pathologists Involved “operational errors”

Patient identification errors are the most rapidly growing category ...

Advanced Workflow Team

- Created in 2008 to drive a new level of standardization, automation, and safety across the AP lab
- Lab improvement solutions that optimize your experience with and return from Ventana products
- Lean Six Sigma Consulting expertise
  - > 30 lab assessments completed to date, leveraging Ventana’s 24 years of AP lab expertise
  - Lean and Six Sigma tools used to improve sample, people and information flow
  - Highly collaborative, hands-on approach
- Expand our partnerships with our customers to revolutionize patient care
Why it’s time to implement a lean workflow solution…

Typical savings found in service businesses

• 30 – 60% reductions in cost
• Cycle time improvements of up to 50%
• Capacity recapture of 20% (with no additional staff)

Another data point from 2-week study in histology

• Close to 30% of cases had manual rework totaling 159 hours or 1.3 FTEs
• 89% of defects were made in the analytic phase
• Approx 2% misidentification rate, 67% of those in slide labeling!
• “All misidentifications would have been addressed by an integrated identification system”

1 George Group results, Lean Six Sigma for Service
2 Am J Clin Pathol 2007; 128 p423

A large percentage of activity in your lab adds no value to your customers…

• Current process - 112 activities
• 55 NVA activities identified
• Future process potential - 57 activities or 49% NVA (plus 21% BVA)
VANTAGE is a powerful lab workflow solution fit to your needs by a lean expert.

- The VANTAGE solution begins with a lab workflow and ROI analysis to help you get better and get faster before using any technology.
  - LEAN to reduce waste ("non-value added" or NVA activity)
  - Six Sigma to increase quality and reliability of staining results
- The VANTAGE workflow system uses lean process principles and creates and records information needed for ongoing lab improvement.

First, observe and record...

- Identify actual time for key activities (vs. perceived times)
- Baseline the process for "before and after" measurement
- Identify idle times and opportunities to streamline and smooth work flow

* Currently a 5 Step Process
  - Oven Drying = 25 mins.
  - Wash/Handling time to DRS = 2-6 mins.
  - DRS Staining = 16 mins.
  - Wash/Handling time to SCA* = 2-6 mins.
  - SCA Process = 2-6 mins.
- Total Avg. Time: 85 Minutes
* Each step requires manual intervention and removes histology staff from current activity.
Then reduce or eliminate NVA activity…

“Leaning” your process drives productivity higher, but also leads to fewer, standardized activities that create fewer opportunities for error.

Map the flow of work through the lab…

- Measure the physical movement of work in the lab to find:
  - Bottlenecks
  - Constraints
  - Additional waste - i.e. excessive transport
- Quantify the benefit of a layout that supports continuous flow, works cells, a “pull” system, etc.
**Benefits of Lean Six Sigma**

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Pre-Lean</th>
<th>Post-Lean</th>
<th>Gains/Savings</th>
<th>Percent Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Lead Time (in Minutes)</td>
<td>3767</td>
<td>2828</td>
<td>1139</td>
<td>30.24%</td>
</tr>
<tr>
<td>Turnaround Time (in Minutes)</td>
<td>1217</td>
<td>685</td>
<td>532</td>
<td>43.71%</td>
</tr>
<tr>
<td>Total Cycle Time (in Minutes)</td>
<td>95.95</td>
<td>60.33</td>
<td>35.22</td>
<td>36.86%</td>
</tr>
<tr>
<td>Total Number of NVA and BVA Steps</td>
<td>219</td>
<td>140</td>
<td>79</td>
<td>36.07%</td>
</tr>
<tr>
<td>Total Distance Traveled (in Feet)</td>
<td>773</td>
<td>337</td>
<td>438</td>
<td>56.40%</td>
</tr>
</tbody>
</table>

**Notes:**

- A lot of the opportunity lies reducing the tremendous wait times between steps
  - Cassette Marking to Grossing (2.5 hours)
  - Grossing to Tissue Processing (3.5 hours)
  - Embedding to Microtomy (2.5 hours)
  - Microtomy to H&E Staining (1 hour)
  - H&E Staining to Case Assembly (1.5 hours)

*Simply by cutting these wait times in half, we will save 5.5 hours from the TAT!*
What is VANTAGE?

• **Patient Safety**
  - One label, one time - for tracking, staining, and archiving
  - Improve patient care and mitigate risk of mis-labeling
  - Positive Patient Identification from accessioning to archiving

• **Informatics**
  - Accomplish more with less - lean solution built for histology labs
  - Integration with your Laboratory Information System and Ventana platforms
  - Real-time information to analyze lab productivity and performance metrics

• **Lean Workflow**
  - Increase throughput with streamlined, automated processes
  - Lean sigma workflow experts work with your lab to optimize workflow
  - VANTAGE provides the data that enables you to drive continuous improvement

The Patient Focused Solution

*Improve testing efficiency in the anatomical pathology lab*

*Test Efficiency*
SYMPHONY®
Revolutionizing Automation in Primary Staining

Revolutionizes H&E staining by fully automating every step of slide preparation with one touch operation from drying through cover slipping

• Productivity
  – Walk away automation
  – Continuous access
  – 500 slide capacity
  – Baking through coverslipping

• Safety
  – Xylene free reagents
  – No cross contamination

Test Efficiency

BenchMark® XT
Advanced Staining (IHC / ISH)

• Productivity
  – Walk away automation
  – Complete baking through staining
  – IHC/ISH
  – Multihost capability
  – LIS connectivity

• Quality
  – Bar code driven protocols

• Safety
  – Xylene free reagents

Test Efficiency
*Introducing BenchMark ULTRA
Improving lab efficiency and productivity

- Continuous access, patient case-centric IHC/ISH staining system to enhance laboratory workflow
  - Walk away automation
  - Complete baking through staining
  - True continuous and random access
    - Any test, any time
  - 90+ slides in one 8 hr shift
  - LIS connectivity

NexES Special Stains

- Productivity
  - Workflow benefit
  - Bar coded slides integrate with LIS and VANTAGE providing positive patient id
- Consistency
  - Eliminate tech to tech variability
- Safety
  - Reduce technician exposure to harmful chemicals.

Full Menu of 20 individual stains and new customized protocols allowing greater control over customer staining preferences.
Ventana Image Analysis System
VIAS™

• **Productivity**
  - Integrated with Pathologist’s workflow
  - Real time quantitative image analysis
  - LIS connectivity

• **Quality**
  - 510k cleared for HER-2/neu, ER, PR, Ki-67, p53
  - Integrated patient report

• **Safety**
  - Eliminates subjective interpretation

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Ventana’s solutions to market issues that meet your patient’s needs

– **Workflow solutions:**
  • Automated platforms and lean workflow solutions
  • Connectivity to support continuous improvement, positive patient ID, and electronic patient reporting

– **Information solution:**
  • Bioinformatics and Patient sample tracking

– **Diagnostic solutions:**
  • Innovative diagnostics to enable individualized patient care