Medical Automation Research Center

http://marc.med.virginia.edu

Improving healthcare quality and efficiency through the development of advanced technologies
The Hospital/Laboratory Partnership

• Improving physician efficiency and efficacy by providing rapid definitive diagnostic data
  – Electronic medical records, minimally invasive Point-of-Care diagnostics, efficient sample collection, labeling, and transportation

• Improving overall hospital efficiency
  – Resource tracking, schedule optimization, inventory control, skill level assessment and training, process control

• Allowing patients to self diagnose
  – Internet health portals, home diagnostics

• Creating a partnership between the lab and the physician
Course Objectives

• Describe pre-analytical and analytical molecular diagnostic automation
• Show actual performance data on some of these systems
Smaller laboratories have had few options to improve their competitiveness against larger reference laboratories.

- Improve competitiveness
  - Better service (faster turnaround time, improved consults, better patient education, fewer errors)
  - Reduced costs (eliminate send out costs, reduce labor, reduce tube diversity, reduce inefficient arrival patterns)
Specimen Arrival Rates

60% Centrifugation
30 % 1 Aliquot

70 % Centrifugation
20 % 1 Aliquot

60% Centrifugation
50% 1 Aliquot

60 % Centrifugation
40 % 1 Aliquot

60% Centrifugation
5 % 1 Aliquot

72 % Centrifugation
31 % 1 Aliquot

40 % Centrifugation
23 % 1 Aliquot

Source: Donna Crook, Tecan, Research Triangle Park, NC, USA
Selection of Automation Based on Test Volume and Versatility

- **Total Laboratory Automation**
- **Workcell**
- **Workstation**

### Samples per Year (Millions)

- 0
- 1
- 2
- 3

### Relative Cost
Clinical Laboratory Automation

**Total Laboratory Automation (TLA)**

**Modular Laboratory Automation (MLA)**

**Workcell**

**Workstation**
Benefits of Pre-Analytical Automation

- Pre-analytical workstations installed worldwide are exceeding customer expectations
- Optimized preparation of high quality samples
- Exceptional use of laboratory space
- Significant increases in laboratory productivity
- Predictable return on investment
Standardized Automation

Preanalytical Module

Picture: Courtesy of A&T Corp.
Open LA21 Project

Open LA21 Project Member

A&T
ALOKA
JEOL
HORIBA
TOYOB
NIPPON CHEMIPHAR
ORTHO-CLINICAL DIAGNOSTICS
INTERNATIONAL REAGENTS
TOSOH
Techno Medica

Picture: Courtesy of A&T Corp.
• **Maximizing Analyzer Throughput**
  - Single tube but “high speed” transportation
  - Buffering Module avoids traffic jam
  - Efficient distribution of sample – the number of samples loaded in sampling point will be monitored and controlled
Random Access for Routine, Emergency and Repeat Testing

- All the samples will be dispatched from Buffering Module to the Analyzer with “random access”
- STAT Sample will be fed to Sampling Point with priority
- The sample will be kept in Buffering Module for Retesting
Pre-analytical Workstations

Front End Processor
Pyxis

Power Processor
Beckman Coulter
Brea, CA

Pathfinder
Ai-Scientific,
Scarborough
Australia

MODULAR Preanalytics,
Roche Diagnostics, Indianapolis, IN

GENESIS FE500
Abbott/Tecan, North Chicago,
IL/Durham, NC
• Single point connections for power, modem, network, water, and waste

• LabCell information system
  – ADVIA CentraLink®
  – Process Control
  – Auto verification
<table>
<thead>
<tr>
<th>Pre-analytical Processors</th>
<th>Tube requirements</th>
<th>Throughput Primary/max output/hr</th>
<th>Centrifugation</th>
<th>Aliquots</th>
<th>Recapping</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott/Tecan FE 500</td>
<td>13x75-16x100</td>
<td>288 – 332, (8 -10 min spins)</td>
<td>yes</td>
<td>UL</td>
<td>no</td>
</tr>
<tr>
<td>Bayer ADVIA, Lab Cell</td>
<td>11.5x75-16.2x100</td>
<td>600/module</td>
<td>yes</td>
<td>In development</td>
<td>no</td>
</tr>
<tr>
<td>Beckman Coulter Power Processor</td>
<td>13x75-16x100</td>
<td>300</td>
<td>yes</td>
<td>6</td>
<td>yes</td>
</tr>
<tr>
<td>Roche MODULAR</td>
<td>13x75-16x100</td>
<td>600</td>
<td>yes</td>
<td>5</td>
<td>no</td>
</tr>
<tr>
<td>Lab-Interlink Front-end Processor</td>
<td>13x75-16x100</td>
<td>200 – 425 (300 if aliquotting)</td>
<td>yes</td>
<td>UL</td>
<td>yes</td>
</tr>
<tr>
<td>Ai-Scientific Pathfinder</td>
<td>13x75-16x100</td>
<td>300</td>
<td>no</td>
<td>UL</td>
<td>yes</td>
</tr>
</tbody>
</table>

UL = unlimited
# Time to 1st Tube

<table>
<thead>
<tr>
<th></th>
<th>Time to 1st Tube wo Centrifugation</th>
<th>Time to 1st Tube w Centrifugation</th>
<th>Time to 1st Tube, Centrifugation + 1 Aliquot</th>
<th>Time to 1st Tube, Centrifugation + 2 Aliquots</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FE 500</strong></td>
<td>52 seconds</td>
<td>15 min, Centrifugation (8 min)</td>
<td>17 min, 32 sec</td>
<td>17 min, 40 sec</td>
</tr>
<tr>
<td><strong>Front End Processor</strong></td>
<td>6 sec</td>
<td>10 min, 30 sec, Centrifugation (10 min, 24 sec)</td>
<td>10 min, 55 sec</td>
<td>11 min, 1 sec</td>
</tr>
<tr>
<td><strong>Pathfinder</strong></td>
<td>6 seconds</td>
<td>NA</td>
<td>15 seconds, no centrifugation</td>
<td>20 seconds, no centrifugation</td>
</tr>
</tbody>
</table>
Case Study 1: Clinical Trial FE500

- 4000 specimens over a period of 3 months
- Input rate from 40 to 300 tubes per hour
- Aliquots from 1 to 5
- We measured
  - throughput
  - error rate reduction
  - centrifuge efficiency
  - Labor savings

Tecan GENESIS FE500
Front View of FE500

- Robot Arms
- Decapping Station
- Tube Output Area
- Tube Input Station
- Centrifuge

Dimensions:
- Height: ca 173 cm (68 in.)
- Width: 230 cm (90 in.)
- Minimum clearance: min 40 cm (15.8 in.)
GENESIS FE 500 Layout

Specimen Input
Tube Loading
Centrifugation
Specimen Output
Positive Specimen ID
Installation

Day 1

Site Preparation

Day 2

Delivering, Installation, Testing, Intelligent Routing Programming

Day 12

System Fine Tuning And Training
FE 500 Throughput

Average Time to Complete Primary and Secondary Tubes

Tubes Loaded
- 80% 1 aliquot, 20% direct sort
- 70% 2 aliquots, 30% direct sort
- 80% 1 aliquot, 20% direct sort
- 70% 1 aliquot, 30% direct sort
- 80% 2 aliquots, 20% direct sort

Tubes Unloaded
- 480
- 400
- 340
- 320
- 300
- 240
- 200
- 180
- 100
- 89
- 96
- 100
- 180
- 260
- 170
- 240
- 200
# Error Reduction

<table>
<thead>
<tr>
<th>Error / event classification</th>
<th>Number of Errors / Events per Month**</th>
<th>% Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sorting and routine errors</td>
<td>Pre FE500: 10,192</td>
<td>80.0</td>
</tr>
<tr>
<td></td>
<td>Post FE500**: 2,038</td>
<td></td>
</tr>
<tr>
<td>Pour-off errors</td>
<td>Pre FE500: 3,072</td>
<td>80.0</td>
</tr>
<tr>
<td></td>
<td>Post FE500**: 614</td>
<td></td>
</tr>
<tr>
<td>Labeling errors</td>
<td>Pre FE500: 9,011</td>
<td>80.0</td>
</tr>
<tr>
<td></td>
<td>Post FE500**: 1,800</td>
<td></td>
</tr>
<tr>
<td>Biohazard exposure events</td>
<td>Pre FE500: 3,126</td>
<td>99.3</td>
</tr>
<tr>
<td></td>
<td>Post FE500**: 24</td>
<td></td>
</tr>
</tbody>
</table>

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* Study performed at Milton S. Hershey Medical Center, Pennsylvania State University.

** Estimated for one month’s period of data collection.

*** Errors recorded in this category were from manually-handled samples for STAT testing plus those samples processed for microbiology and virology testing.
Data is expressed as mean ± SD of total platelets (x 10³) / uL of whole blood.

* NOTE: We performed a control run on each specimen according to NCCLS guidelines (e.g., 1500 x g for 10 minutes).
Fiscal Impact of the FE500

Manual Processing

- Manual Processing Steps per month – 75K
- 12 FTEs

Automated Processing

- Manual Processing steps per month 25K
- 8 FTEs (- 33%)
SUMMARY

• Pre-analytical automation provides a cost effective improvement in specimen processing
• Throughput of pre-analytical automation workstations matches the needs of most medium sized laboratories
• Errors are significantly reduced by pre-analytical automation
Case Study 2: CoagAutolink
Automation Reduces Steps

TRANSPORT

INSPECT

BALANCE

LOAD

ALIGN

LOAD
Pre-analytical Processing Time

Times from Central Receiving to Aspiration

Case Study 3: Beckman Coulter

- **Step I**
  - Power Processor
  - 16X100 mm
  - Manual barcode scan
- **Step II**
  - Power Processor II
  - Many size tubes
  - Automated barcode scanning

Dadoun R., Case Study: Automation’s Impact on productivity and turnaround time
Mobile Robots for Medical Deliveries

- Hospital wide delivery using the Helpmate (Pyxis, Inc., Danbury, CT)
- Intra-laboratory delivery using the RoboCart (CCRI, Lake Arrowhead, CA)
PIC & PLACE

- Automated pick up and delivery for medical specimens
- Does not interrupt busy technologists
- Provides high capacity transportation
- Provides greater efficiency than human based delivery methods
- Point of origin to point of need connectivity
Mobile Robots and Delivery Efficiency

**Delivery Time, Robot vs Courier**

- 2 Robots: 40 minutes
- 3 Robots: 30 minutes
- 6 Robots: 20 minutes
- Courier: 35 minutes

30% more efficient

**COSTS, Robot vs Courier**

- 2 Robots: $100,000
- 3 Robots: $150,000
- 6 Robots: $200,000
- Courier: $350,000

$250,000 annual savings
Tecan Freedom EVO

- Modular design to serve genomics, proteomics, and diagnostics
- Modular hardware for detection, separation and storage
- Meets European EU In-Vitro Diagnostics Directive 98/79/EC and FDA’s 21 CFR Part 11 regulations
Gen-Probe Tigris DTS

- Automates all steps related to molecular diagnostic testing (nucleic acid amplification)
  - Sample processing
  - Amplification
  - Detection
  - Data analysis
Molecular Diagnostics

• Fastest growing diagnostic test sector
• Presents new pre-analytical challenges
  – Sample Identification and privacy
  – Cross contamination
  – Sample size
• Analytical techniques
Pre-analytical DNA Processors

• Automated DNA extraction at a rate of 40-96 specimens/day
• Whole blood, buffy coat, packed cells, lysates for compromised samples, buccals, cultured cells
• Cost per test is about $4/specimen
• DNA is suitable for most reactions

Gentra Versapure 1000
Gentra Autopure LS
Single Function MDx Automation

• Completely automated DNA/RNA extraction / purification

Magtration Extractor
Precision System Science Tokyo, Japan.

Magnetic bead based extraction
Multiple Function MDx Automation

- Performs multiple parts of MDx reaction scheme
- Can be programmed for user flexibility
- Thermal cyclers, pipetting automation, and signal detection instruments placed on board
- Ideal for clinical molecular biology method development

TECAN Genesis RSP 150
Relies on bioelectronics—using organic molecules to form electronic circuits.

Allows the simple, rapid, and cost-effective detection of up to 36 DNA or RNA targets simultaneously: SNP, Mutation, Bacterial, Viral, Transgene, and Gene Expression.
Simplified DNA Detection

- Electronic biochip reader
- Custom and catalog biochip cartridges
- Software and protocols
- Designed for use in a commercial lab setting
Molecular Diagnostics Summary

Ideal Small Laboratory Initial Molecular Diagnostic Devices

• Nucleic acid extractor
• Polymorphism detection system
Post Analytical Automation

• Usually a function available on a pre-analytical processor
• Sorting, labeling, capping, organizing
• Automated reflex, repeat, add-on
Automated Low Temperature Storage and Retrieval System
Compact Secure Storage
Goals
• Provide examples of modular automation systems that make sense in smaller laboratories
• Show actual performance data on some of these modular systems

Conclusions
• Modular automation is possibly the best first step in clinical laboratory automation
• Substantial process improvement, error reduction, and cost savings are being realized
• Modular automation is evolving to keep pace with the changing clinical diagnostics market