Institute for Learning

UNIVERSITY OF UTAH
SCHOOL OF MEDICINE

Department of Pathology

Clinical Laboratory Automation

Evaluating and Selecting an Automation System

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Presented by Charles D. Hawker, PhD, MBA, FACB

Dr. Charles Hawker is the scientific director for automation and special projects at ARUP and an adjunct professor of pathology at the University of Utah School of Medicine. While at ARUP, Dr. Hawker has installed several major automation and robotic systems that have made ARUP one of the country's most automated laboratories. He is a past president of three professional societies and has received several distinguished awards. He is also an author or co-author of several book chapters on automation and a frequent lecturer on laboratory automation to national and international audiences.

Outline

- What is automation?
- Recommended process for a clinical lab to evaluate their need for automation and to determine what solution(s) will work best.
- Examples of automation activities not involving track and robotics
- How to measure the benefit of what you did.
- Cost justification
- Summary and take home messages
- Examples of modular pre- or post-analytic and task-targeted automation systems
- Examples of total lab automation systems

What is Automation?

- Generally speaking, it is automation of manual processes and involves automated or robotic equipment.

- However, for purposes of this presentation and especially for smaller laboratories with limited capital funds, re-engineering of manual processes is part of the definition.

- Process re-engineering, using continuous quality improvement methods such as Lean and Six-Sigma, provides significant improvements with minimal costs, improves quality, and reduces manual labor, repetitive handling, and errors, paving the way for automation.

Automation is Here to Stay

- According to Sept., 2010 CAP TODAY, more than 1100 U.S. labs have total or sub-total automation systems, not including ~575 hematology systems.
- U.S. users of automation are generally satisfied with their automation decisions (see next slide).
- Over the next several years, options for automated systems can be expected to increase along with the technical sophistication of these systems.
- The shortage of qualified medical technologists is only going to get worse. Automation and process re-engineering are the chief ways to address this.

Has Lab Automation Lived Up to the Expectations of U.S. Users ?

Survey from Diagnostic Testing & Technology Report (Washington G-2 Reports) October, 2005

	Task-Targeted Automation	TLA	Combined
Absolutely Yes	37%	41%	39%
Mostly Yes	37%	34%	36%
Satisfactory	22%	22%	22%
No	4%	3%	3%

At the time of the survey an estimated 525 U.S. labs had automation (~2/3 of had Total Lab Automation (TLA) and ~1/3 had task-targeted or sub-total automation). Of 188 total respondents, 32% had automation. Another 25% planned to add automation in the next 12 months.

Ten Reasons Why Automation Projects are Not Successful

- Incomplete understanding of current environment...processes, costs, customer expectations
- Loss in flexibility due to fixed processes and limited throughput
- Unrealistic expectations of system...cost reduction, throughput, return on investment
- Unplanned and poorly developed ‘workarounds’ required to interface automation with manual processes
- Unclear expectations of system functionality
- Overbuilt and unnecessarily complicated system design
- Inadequate technical support
- Credible and realistic impact analysis never conducted
- Hidden costs...labor, supplies, maintenance
- Failure to optimize current processes prior to automation
  →never automate a poor process!

Source: Argent Global Services, Solutions Newsletter, page 4, April 2003, Oklahoma City, OK

Systematic Approach to Automation

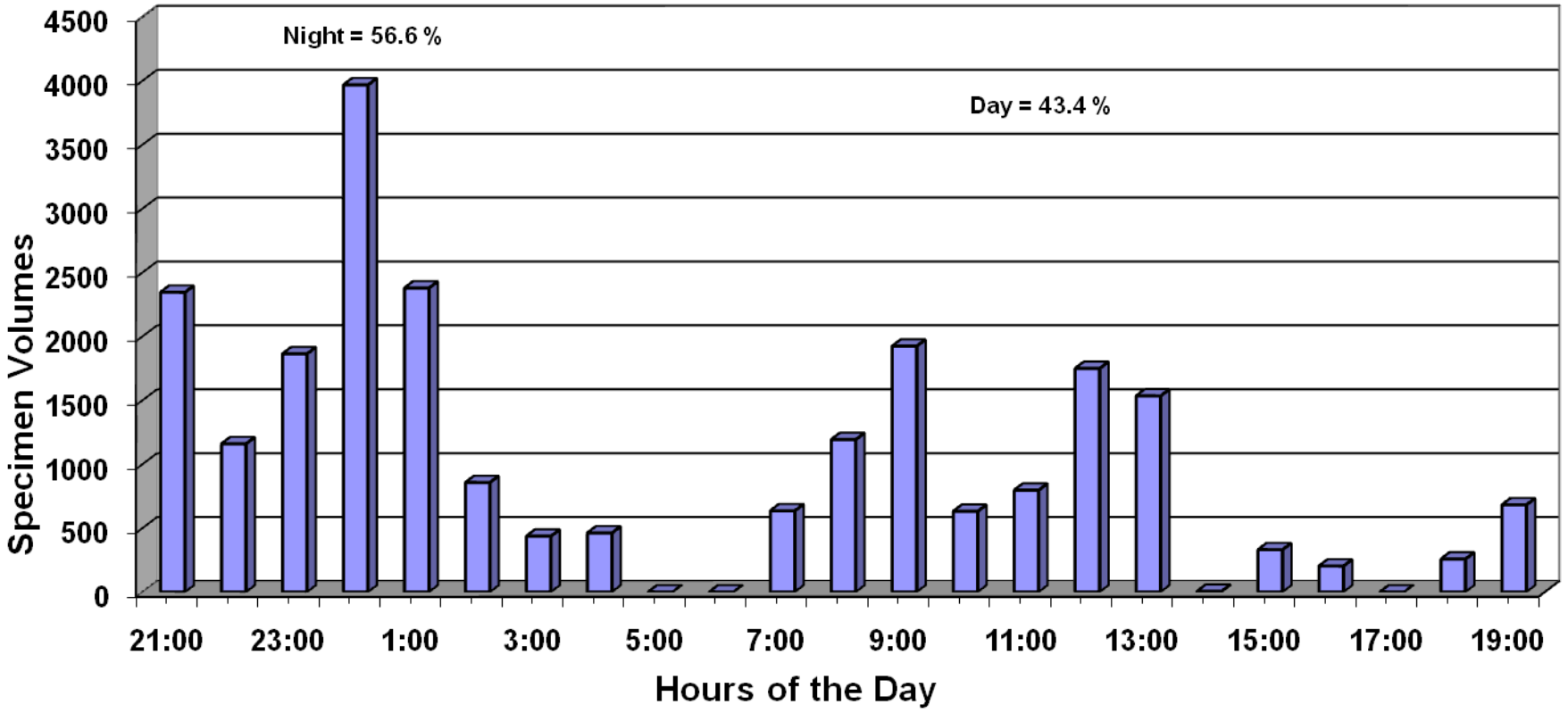
- Evaluation of needs (move current state to desired state)
- Logistics and handling issues
- Facilities and space considerations
- Temperature considerations
- **Mapping workflow, timing workflow**
- Finding bottlenecks and time wasters
- Identify possible solutions to meet needs
- Evaluation of alternatives
- Progress measures
- Cost justification

DETERMINING THE LABORATORY'S NEEDS

Specimen Volumes and Workload

- What is laboratory's specimen volume?
- Chart specimen count by hour of day and day of week
- What percentage are centrifuged?
- What percentage are aliquotted?
- What percentage of specimens are shared between two lab sections?
- What percentage of specimens are refrigerated or frozen?

Average Number of Specimens Received per Hour



Handling Considerations (1)

- How and where do specimens arrive?
  Courier vehicles, tube system, dumb waiter, window, phlebotomists, patient walk-ins, nurse delivery? Are these near each other or in separate areas?

- Patient registration - is it required, is it before or after processing, where is it located, who does it - lab personnel or hospital personnel?

- Patient identification: is there a wrist band bar code system linked to the LIS?

- How do phlebotomists verify patient ID?

Handling Considerations (2)

- Do nurses or patient care assistants (i.e., employees not under lab control) draw or collect specimens?
- For tests ordered on the floors, do LIS labels print on the floors or in the lab?
- Where are tubes centrifuged? Specimen Processing or Chemistry?
- Pour-offs and aliquotting – what is the workload?
- Sorting - how much sorting of specimens occurs - in Specimen Processing and in lab sections?
- Transport - delivery by Specimen Processing or pick-up by labs? What are the distances covered?

Handling Considerations (3)

- How, where, and for how long are archived specimens stored?
- Centralized or decentralized?
- Manual system or using bar codes ?
- What is the percentage of repeat testing?
- What is the percentage of additional testing requested to be added to archived specimens?

Facilities and Space

- If there is the opportunity to design a new facility, great. Whether yes or no, here are several worthwhile ideas:
- Arrange the facilities in a manner that follows the flow of the specimens.
- Position highest volume testing (Chemistry, Hematology, etc.) closest to Specimen Receiving and lowest volume testing furthest away.
- Avoid having all lab traffic go through a key area such as Specimen Receiving.
- Position client service and exception handling activities in or close to Specimen Receiving.

Workflow Mapping

- Material flows (specimens)
- Process flows
- Data flow diagram
  - done at different layers of detail
- Workload map
  - can be used in simulation studies

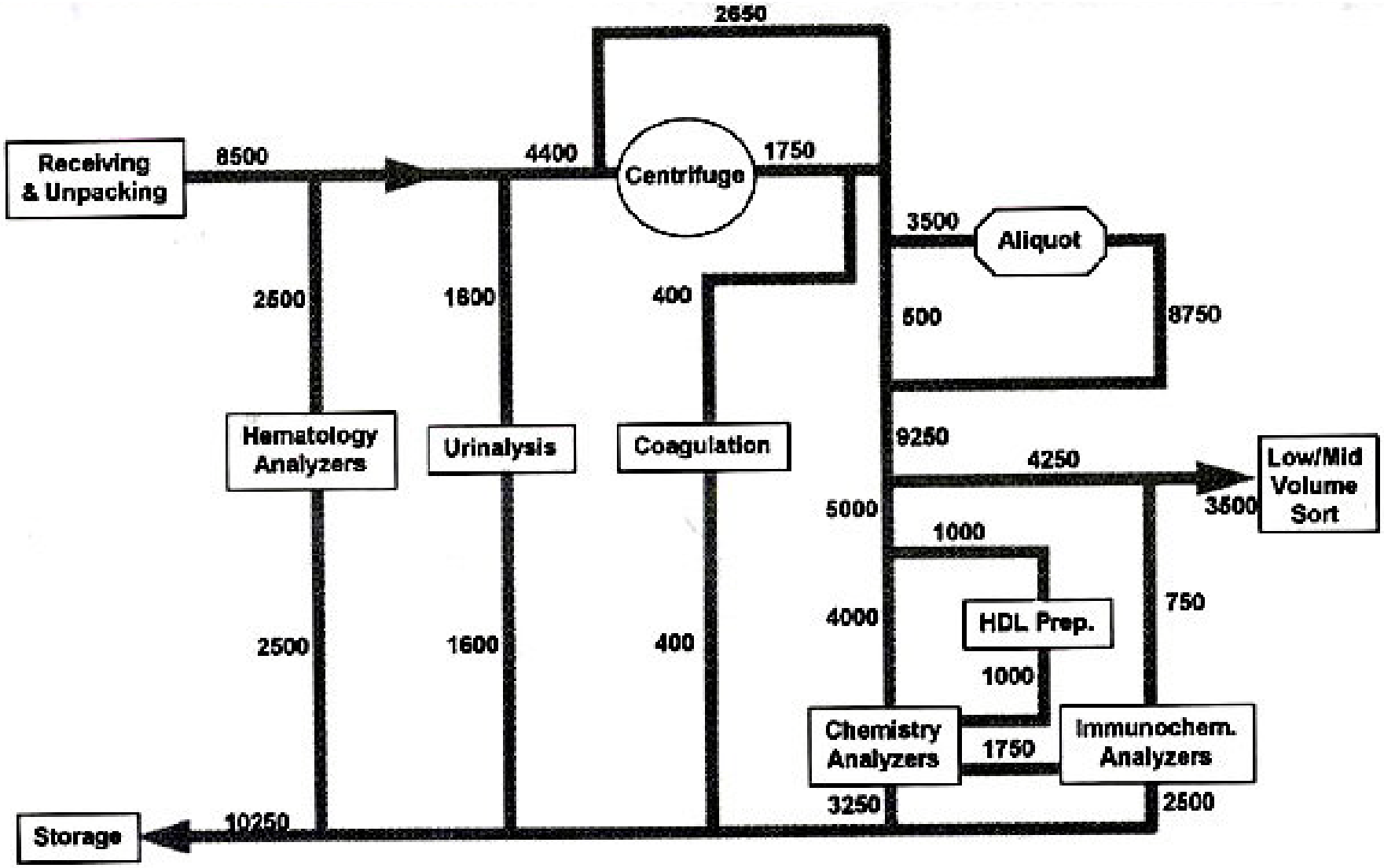


Figure 20.5. Workload map.

From Middleton & Mountain, Ch. 20 in GJ Kost, Ed., Handbook of Clinical Automation, Robotics, and Optimization, Wiley-Interscience, NY, 1996

Timing Studies

- Purpose is to count and time everything in relation to the workflow map.
- One idea: use pre-printed slips taped to tubes, racks, etc. to note the date & time of each step, number of tubes in each batch, employee ID at that step, etc.
- Analysis of data leads to elapsed times each step takes at different times of day.
- Identifies bottlenecks, idling time, and time wasters.

Tracking Category	ARRIVAL TIMES 21:30	23:30	1:30	3:30	7:00	8:00	9:00	10:00	10:30	12:00	Local & Airborne	14:30	Totals
No. of Boxes	20	41	9	36	10	6	3	6	18	6	3	4	162
Specimens	299	1418	475	1305	402	409	50	279	53	200	12	86	4988
No. of Tracking Slips	22	92	37	106	16	9	3	8	8	12	4	3	320
Median Interval Times													
Arrival to Unpack	0:21	0:25	0:03	0:30	0:05	0:00	0:00	0:03	0:10	0:07	0:00	0:00	
Unpacking Time Per Box	0:04	0:06	0:25	0:09	0:16	0:10	0:07	0:10	0:02	0:03	0:03	0:06	
Arrival to Manifest	0:20	0:45	0:03	0:33	0:15	0:06	0:02	0:04	0:16	0:13	0:00	0:03	
Manifest to ROE	0:16	0:37	0:35	0:41	0:26	1:34	1:04	0:22	0:33	0:28	0:27	0:32	
ROE to Labeled	0:24	0:41	0:22	0:26	0:47	1:33	1:56	2:13	2:21	1:14	0:23	0:50	
Labeled to Sort	0:31	0:18	0:25	0:28	0:29	0:21	0:00	0:40	0:16	0:45	0:30	0:53	
ARRIVAL to SORT by ROE	1:17	2:37	1:30	2:28	2:19	3:20	4:00	3:19	3:19	2:48	2:05	1:56	
Manifest to SPR	0:10	1:43	1:35	1:50	1:15	0:30	NA	0:32	NA	1:16	1:15	NA	
SPR Start to Finish	0:09	0:05	0:05	0:07	0:03	0:02	NA	1:30	NA	0:05	0:05	NA	
SPR Finish to Sort	0:59	0:19	0:10	0:37	1:19	1:09	NA	0:04	NA	0:17	0:10	NA	
ARRIVAL to SORT by SPR	1:35	3:08	1:53	3:18	2:52	2:40	NA	2:12	NA	1:57	1:30	NA	
MEDIAN DELAY or (GAIN) for SPR	0:17	0:30	0:22	0:50	0:33	(0:40)	NA	(1:07)	NA	(0:51)	(0:35)	NA	
ARRIVAL TO SORT, OVERALL	1:30	2:42	1:43	2:28	2:19	2:40	4:00	2:50	3:19	2:00	2:05	1:56	
Pour Off Start to Finish	4:12	NA	4:11	5:20	NA	4:50	NA	NA	NA	NA	NA	NA	
Pour Off Start to Sort	4:25	NA	4:16	5:35	NA	5:24	NA	NA	NA	NA	NA	NA	
Pour Offs Arrival to Sort	5:40	NA	13:01	10:40	NA	8:04	NA	NA	NA	NA	NA	NA	
Sort to Lab Pick Up	6:40	3:55	3:05	0:40	0:20	0:15	1:15	0:31	1:24	0:21	1:19	0:02	
Sort to Log Out Table	0:00	NA	NA	NA	NA	0:01	NA	0:12	NA	NA	NA	NA	
Time to Wait for Pick Up	6:25	NA	NA	1:32	NA	0:14	NA	0:41	NA	NA	NA	NA	
Pick Up to UHSC Receipt	0:14	NA	NA	0:23	NA	0:57	NA	NA	NA	NA	NA	NA	
Label to ROU	3:46	1:59	2:19	4:01	NA	NA	8:25	7:02	6:16	5:30	NA	3:58	
ROE to ROU	4:16	2:35	2:40	4:33	NA	NA	10:21	8:40	7:42	7:05	NA	4:36	
ROU to Document Scan	8:09	5:43	5:21	20:23	NA	NA	7:38	8:14	8:23	8:25	NA	8:20	

Identifying Possible Solutions to Meet Needs

- Use quality and turn-around time measures, workflow, and timing studies to find bottlenecks and potential areas for re-engineering.
- Re-engineering of processes should precede introduction of automation.
- Not all solutions need to involve automation
- Several seemingly small, low-cost re-engineering projects sometimes have more impact on laboratory performance than an expensive automation project.
- “Automating a poor process still leaves one with a poor process.”

Re-Engineer Processes

- Use continuous quality improvement (CQI) tools such as Lean and Six Sigma to foster process improvements
- Standardize processing procedures to “best practice” solutions with fewest “hand-offs.”
- Reduce or eliminate non-value added handling and sorting.
- Eliminate “running around” to find shared specimens.
- Redesign workstations so that individuals process orders from start to finish.
- Maximize the number of specimens at test run start times.

Evaluation of Alternatives

- Define and rank objectives (needs to be filled).
- Identify alternative solutions, some of which may not involve automated equipment.
- Match the key features of alternative solutions to the most important needs of your lab that are solved by those solutions.
- Emphasis in any solution that is selected should be on process control and process improvement.
- A solution with several small steps sometimes is better than a major implementation of automation.

Non-Track Automation Possibilities

- Wristband bar code systems for phlebotomy
- Document management systems
- Autoverification, middleware, and QC software
- PC or LIS-based specimen storage and retrieval

Wristband Bar Code Systems for Phlebotomy

Linking patient wristbands to the LIS to portable phlebotomy label printers

• Cardinal Health Care Fusion	www.cardinal.com/us/en/brands/carefusion
• Cerner Bridge Medical	www.cerner.com
• DataRay	www.datarayusa.com
• Endur ID	www.endurid.com
• General Data Co.	www.general-data.com/healthcare
• Intellidot Corp.	www.intellidotcorp.com
• Korchek Technologies, LLC	www.korchek.com
• Lattice	www.lattice.com
• McKesson Horizon	www.mckesson.com
• Olympus Osiris	www.olympusosyris.com
• Precision Dynamics	www.pdcorp.com/healthcare
• Siemens Medical (PIK and BD.id)	www.siemens.com
• St. John Companies – Bio-Logics	www.patientidexpert.com
• Sunquest Collection Manager	www.sunquestinfo.com
• Ultra-Scan Corp. TouchLink	www.ultra-scan.com
• Zebra Technologies Corp.	www.zebra.com

Document Management

- www.bmiassociates.com (801) 546-7642
- www.freeimage.com (734) 327-5600
- www.laserfiche.com (800) 985-8533
- www.medplus.com (800) 444-6235
- www.mesacorp.com (800) 628-5977

Autoverification, Middleware, & QC

- www.beckmancoulter.com (714) 961-4810
- www.datainnovations.com (802) 658-2850
  (also available via Abbott and Roche)
- www.dawning.com (800) 332-0499
- www.fletcher-flora.com (800) 777-1471
- www.orchardsoft.com (800) 856-1948
- www.pathagility.com (501) 327-7700
- www.pvtlabsystems.com (877) 788-5227
- www.qcnet.com/urt2 (800) 224-6723
- www.siemens.com/diagnostics (914) 524-3827
- www.sysmex.com/usa/ (847) 996-4500
- www.technidata-web.com (520) 577-2872

Specimen Storage & Retrieval

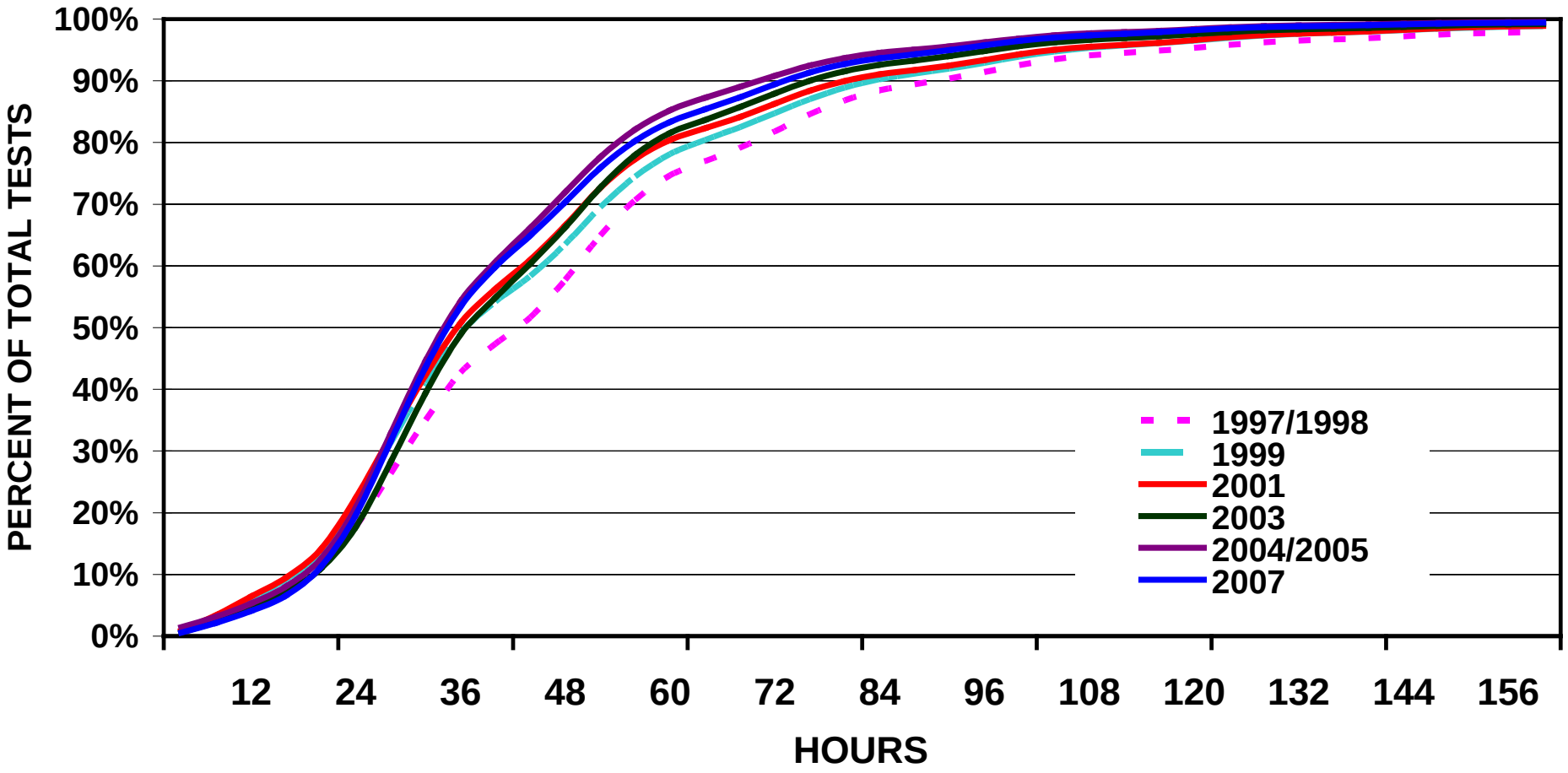
PC-Based Systems

- SpecTRACK II system (Solution Consulting Service)
  (803) 789-3086 www.solutionconsult.net
- www.tubetracker.com
  (570) 558-4580
- SLS
  (708) 870-0759 email: brose@roseinfo.net
- Data Innovations
  (802) 658-2850 www.datainnovations.com
- Legacy Systems
  http://legacysystems.cc

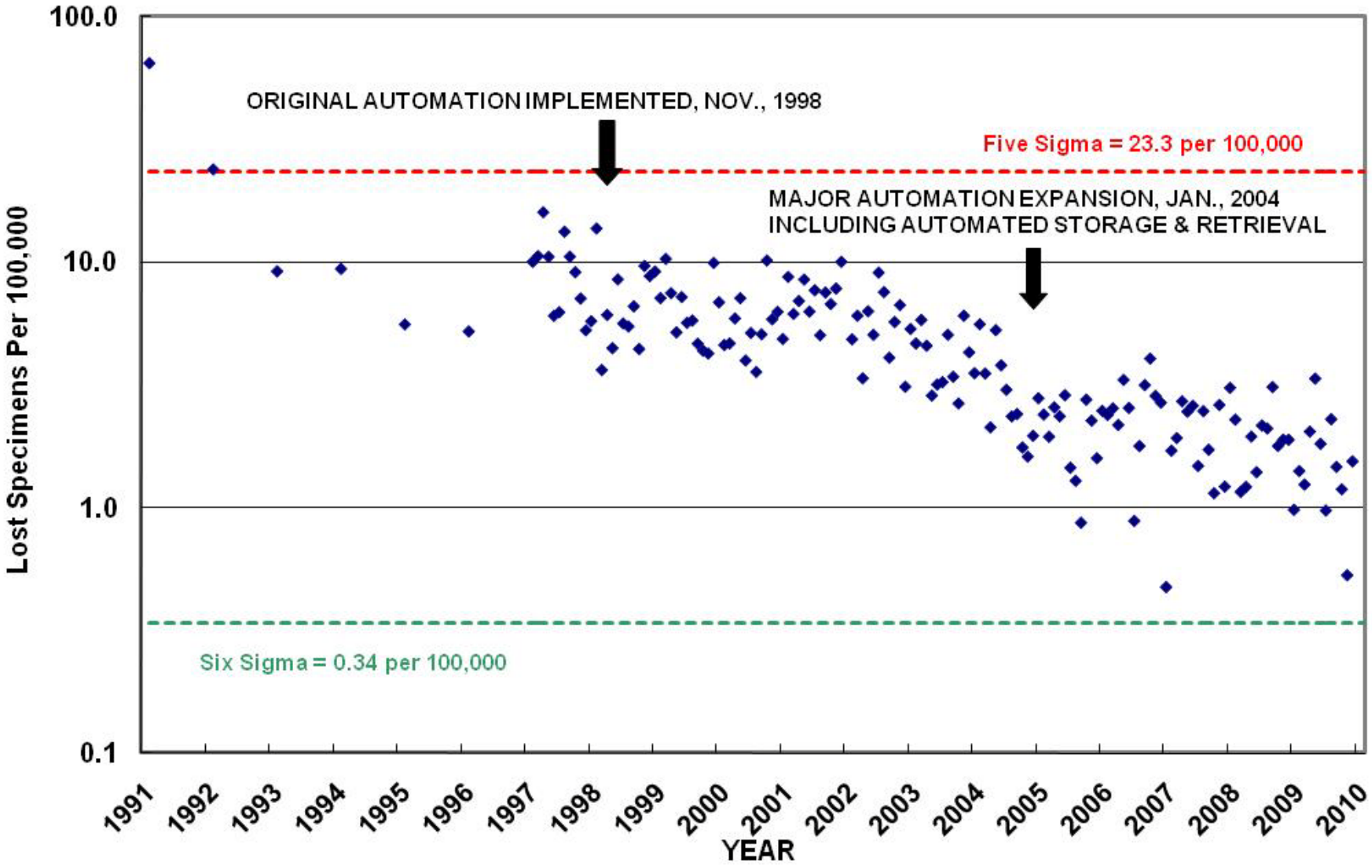
Potential Progress Measures

- Median turn-around time
- 95th percentile turn-around time
- Stat turn-around time
- Lost specimens
- Mislabeled specimens
- Billed units per FTE
- Rate of hiring of technical employees

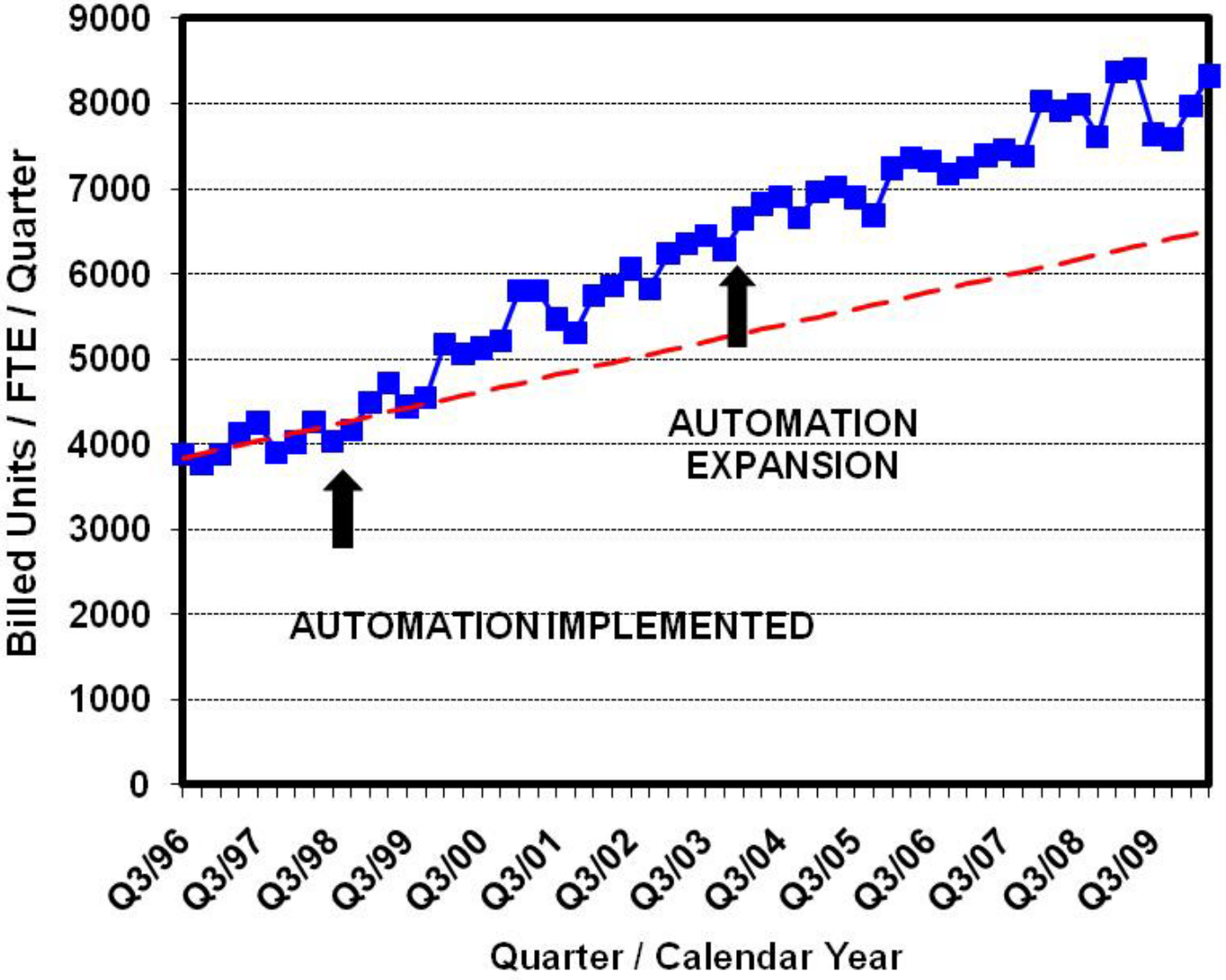
Cumulative Percentages of Total Tests



Lost Specimens Per 100,000 Total Specimens Received (Log Scale)



Actual versus Predicted Productivity in 12 Lab Sections Served by the Automation System



ACTUAL:
8325 BU/FTE/Q
472.6 FTEs

PREDICTED:
6515 BU/FTE/Q
603.9 FTEs

Est. 131.3 FTEs saved

COST JUSTIFICATION

Does TLA Have a Reasonable Return on Investment in North America?

- North Shore – Long Island Jewish Health (USA)
  - 49 FTE's saved (15% of total employees)
- Centralized Laboratory Services, Inc., Long Island City, NY (USA)
  - 3 year pay-back (7.2 million tests/year)
- ARUP Laboratories, Salt Lake City (USA)
  - 131 FTEs saved in 12 lab sections served by automated system as volume increased five fold over 12 yrs
  - 5.4 year pay-back on investment in automation, facility improvement, and new software system
- St Mary's Hospital, Montreal (Canada)
  - 27% decrease in worked hours despite a 73% increase in volume

Case Study: UMass Memorial Med. Ctr.

- Primary reference lab for integrated health care system with >275 hospitals and providers in MA, NH, RI, and northern CT
- Workload: 5 million tests (2002) ↑ to >10 million tests (2007); ~ 4300-4500 chemistry & hematology specimens per day, with 80-85% going on the automation system
- Outreach work increased from 33% to 54% (2002 to 2007)
- Automation (2002, expanded in 2004) Beckman Coulter Power Processor
- Currently: Inlet Unit, Hematology Outlet, 2 Centrifuges, Decapper, 4 LX-20 Analyzers (1 off-line), 2 DxI Analyzers (1 off-line), Recapper, 2 Refrigerated Stockyards, Secondary Decapper
- Core Lab productivity: 71,000 ↑ to 86,000 tests/FTE/year; with chemistry productivity (no heme) = 152,000 tests/FTE/year
- Potassium TAT improved by 50% (routines) and 25% (stats)
- Immunoassay TAT improved by 80%

Data courtesy of Dr. L.V. Rao, Core Lab Director, U. Mass. Memorial Medical Center

Case Study: Medical Center Laboratory (Jackson Madison Co. General Hospital)

- Tenth largest publicly owned health care system in the U.S., serving more than 500,000 west Tennessee residents.
- Workload: 4 million tests per year (2001) increased to 5 million (2004) – approximately 45% inpatient, 55% outpatient.
- Automation (2001): Lab InterLink
- Automation (2002): Ortho (Thermo) enGen system with rack entry module, 2 centrifuges, decapper, rack entry/exit module, buffer module, and exit module. Connected analyzers include: 1 Vitros 950, 2 Vitros Fusion 5.1's, 2 Centaurs.
- Core Lab productivity: 33,000 tests/FTE/year.
- CMP TAT immediately decreased 25 minutes; after one year decreased by 44 minutes despite a reduction of 5 FTEs in lab.
- Automated all HIV, hepatitis testing, and proteins plus several tests previously sent to a reference lab.

Data courtesy of Debra Robinson, Lab Manager II, Core Lab, Medical Center Lab.

Case Study: John T. Mather Memorial Hosp.

- Provides lab services for a 248 bed community hospital, 2 acute skilled nursing centers, 1 assisted living, a wellness center, a 250 bed hospital, 3 IVF centers, 2 wound care centers
- Workload: 1.2 million tests (2000) increased to 1.9 million tests (2006)
- Outreach work increased from 33% to 54% (2000 to 2006)
- Automation (2001, expanded in 2002 and 2006) Beckman Coulter Power Processor
- Currently: Inlet Unit, Hematology Outlet, 1 Centrifuge, Primary Decapper, 2 DXc-800-Analyzers, 1 DxI Analyzer, Recapper, Refrigerated Stockyard, Secondary Decapper, 1 Generic Outlet
- TAT to ED decreased by 46%, while number of ED visits increased by 80%

Data courtesy of Dr. Denise Geiger, Lab Director, John T. Mather Memorial Hospital

Case Study: San Francisco Gen. Hospital

- Workload: 2.1 million tests increased to 2.3 million over 4 yrs, 1000 – 1200 specimens per day
- 25% inpatient, 10% ED, 60% outpatient, 5% Research / Misc.
- Automation (2003) Siemens (Bayer) Advia Workcell
- Sample Manager, 2 Advia 1650's (later 1800's), 2 Centaurs
- Replaced 2 Vitros (88% of volume), 2 Immuno-1's (3.6%), Cobas Mira (2.8%), other platforms
- 29 analytes on Centaurs, 59 on Advia 1800's
- 96.5% of volume now on Workcell, including 12 new tests
- Eliminated 29% of specimens being manually shared
- Routine TAT improved, depending on test,
  e.g., HDL TAT ↓ from 367 min to 136 min, despite 36% ↑ vol.
- Aliquotting reduced 34%

Data courtesy of Susan Fisher Gross, Sr. Chemistry Supv., San Francisco Gen. Hosp.

Impacts of Automation at ARUP

1992	35,000 specimens per month 65 lost specimens per 100,000
1998	200,000 specimens per month 11 lost specimens per 100,000 4,000 billed units / tech. employee / qtr
2003	450,000 specimens per month 6 lost specimens per 100,000 6,300 billed units / tech. employee / qtr
2009	949,000 specimens per month <2.0 lost specimens per 100,000 8,406 billed units / tech. employee / qtr 30% reduction in median TAT 31% reduction in 95th percentile TAT

SUMMARY: Automation Lessons and Take Home Messages

- Know your laboratory's business!
- Map workflow to find bottlenecks
- Determine your primary and secondary objectives
- Use your workflow map and objectives to authenticate vendor proposals
- Focus on process improvement
- Re-engineering processes may have just as much impact on operations as automation
- Maximize use of information technology
- Consider alternatives
- Justify all costs
- Take your time

Suggested References

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EXAMPLES OF MODULAR PREANALYTICAL OR TASK-TARGETED AUTOMATION SYSTEMS

Beckman Coulter’s AutoMate automation system for labs with daily volumes of 500 – 1500 specimens features an LED machine vision system that inspects tubes through as many as three labels to find the top of the serum and the top of the packed red cells, then calculate the serum volume based on tube diameter.

Motoman AutoSorter III – centrifugation, decapping, and racking into analyzer specific racks

Olympus OLA-2500

Olympus is now part of Beckman-Coulter

PVT Lab Systems

PVT VSII Aliquotter

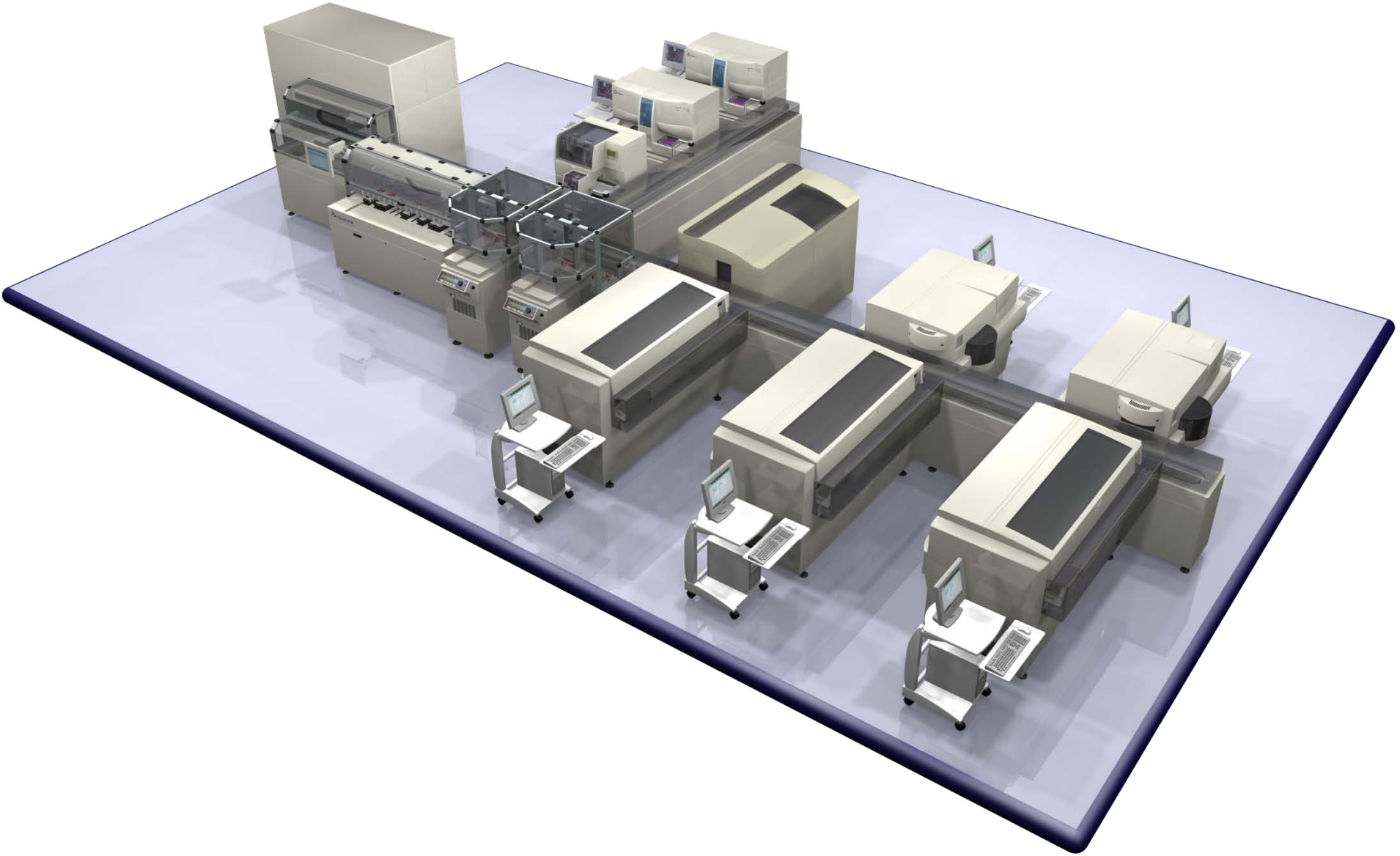
PVT 1000 Sorter

PVT RSA Pro Aliquotting Sorting System

SARSTEDT DC/RC 900 FLEX

Tecan Genesis FE500 Workcell

EXAMPLES OF TOTAL LAB AUTOMATION SYSTEMS



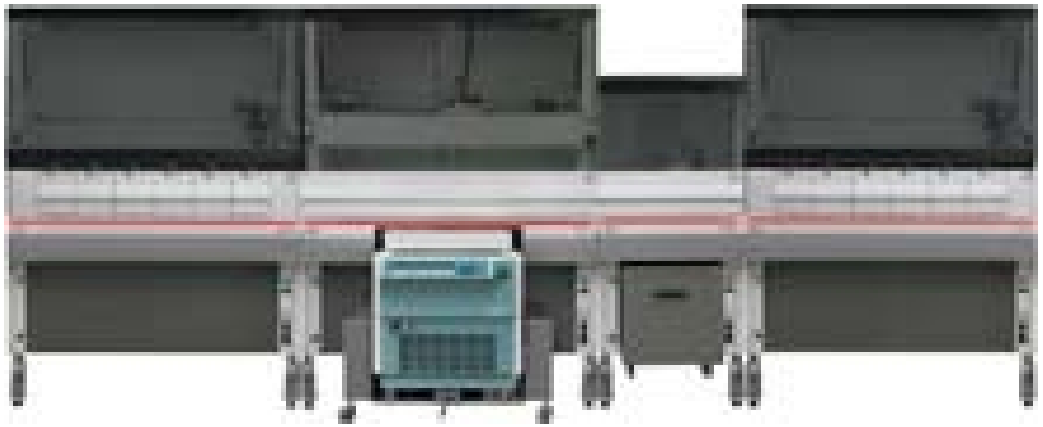
Accelerator ™ Abbott Diagnostics (Inpeco)

Beckman Coulter Power Processor at Ohio State University Hospital

Efficiency Series™ by **Integrated Laboratory Automation Solutions, Inc. (ILAS)** (www.lab-ilas.com) has successfully connected to the Motoman AutoSorter III (as shown here) and has point-in-space sampling connections with the Advia Centaur, Beckman Coulter DxI, Dade Dimension RXL, Ortho Fusion 5.1, Stago STA R, and Tosoh AIA 2000 analyzers.

Ortho-Clinical Diagnostics

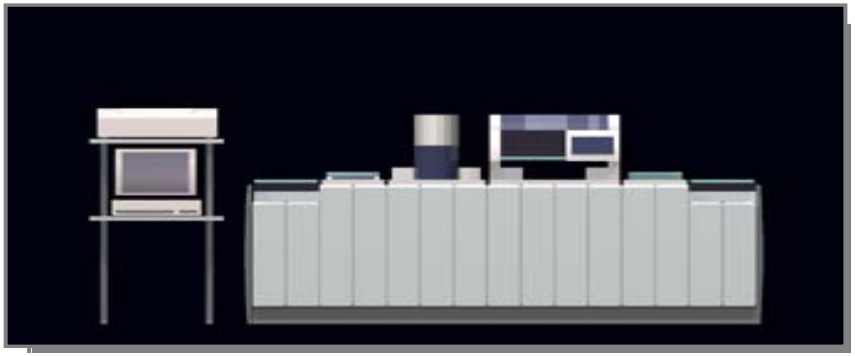
- Single tube carrier
  - ➢ Micro-Chip contains Sample ID, Tube Size, STAT, Route Info
  - ➢ Multiple tube sizes accepted (12/13 x 75/100, 16x 100)
- Centrifuge Module
  - ➢ Up to 300 tubes / hr
- Decapper
  - ➢ Up to 500 samples / hour
- Single Tube Entry-Exit

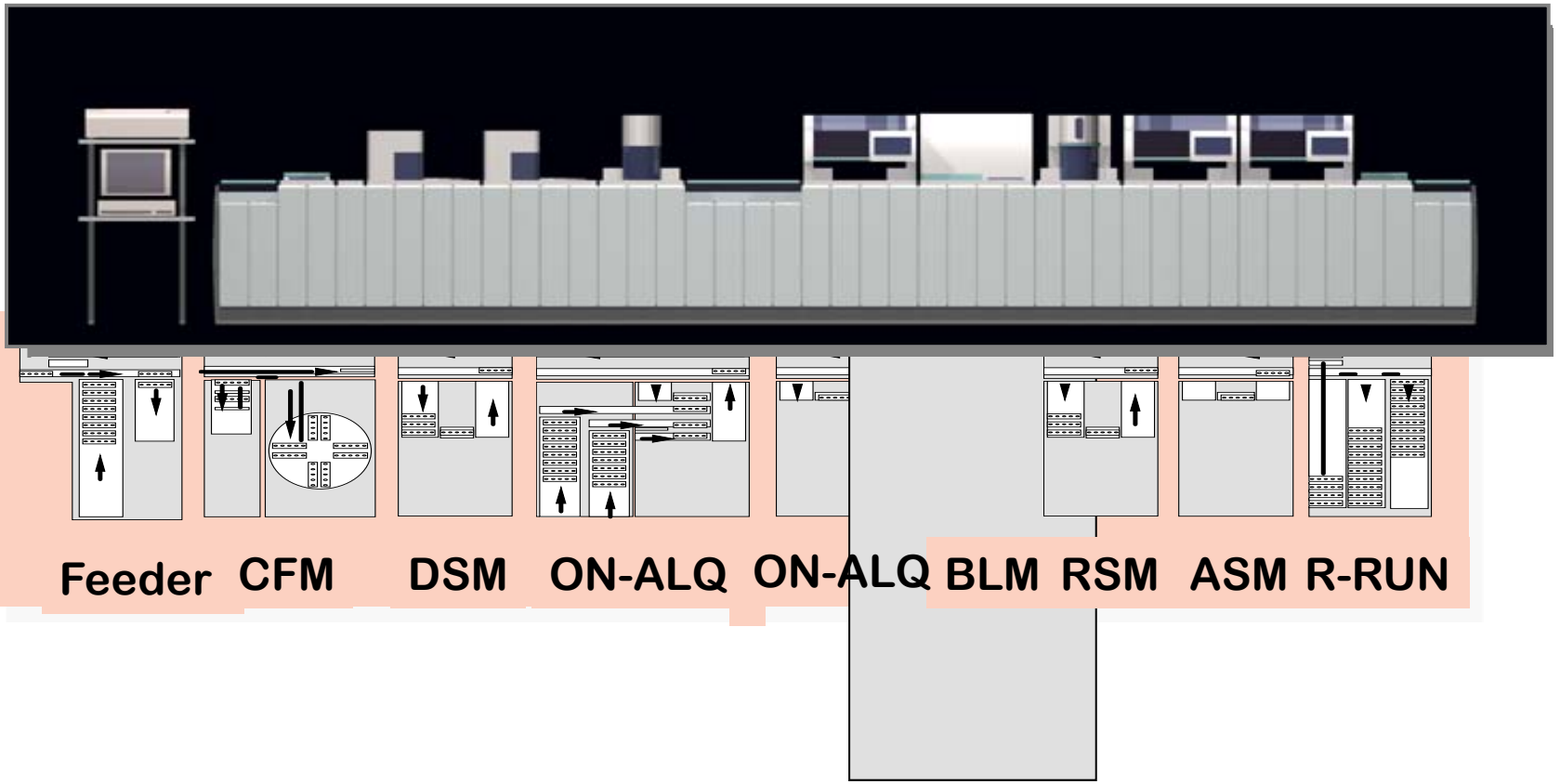


enGen ™

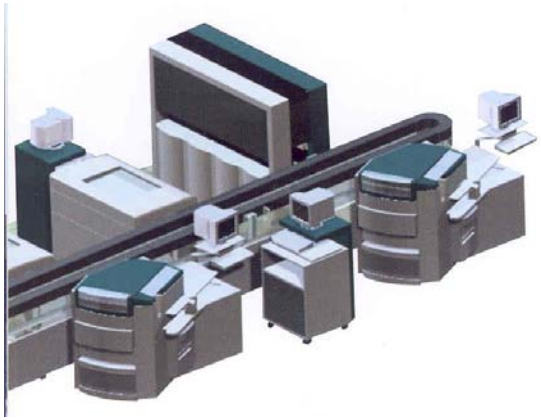
Ortho-Clinical Diagnostics (Raritan, NJ) and Thermo Electron OCD, Finland

Roche/Hitachi Pre-Analytical Modular System





Siemens



(Bayer) ADVIA® LabCell®

(Dade Behring) StreamLAB® Analytical Workcell

The VersaCell™ system merges the Immulite 2000 analyzer with either the ADVIA 1800 or the Centaur XP analyzers

A Peek Into the Future of Clinical Laboratory Automation

New Track Technologies

- FlexLink X45 conveyor system with RFID pucks has capacities (speeds) of up to 3000 pucks per hour (20m/sec)
- MagneMotion's MagneMover™ Lite transport system uses Linear Synchronous Motors (LSM) and magnetic pucks to achieve capacities (speeds) of up to 18,000 pucks per hour (120m/sec)

Automated Inspection Systems (Machine Vision)

- Inspections for clots, hemolysis, lipemia, and icterus
- Inspections for tube type and size and cap color
- Inspections for mislabeled specimens

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