How Automation, Informatics, and Process Improvement Enabled the Achievement of Six-Sigma Quality in a Clinical Laboratory

Charles D. Hawker, PhD, MBA, FACB
Professor (Adjunct) of Pathology
University of Utah School of Medicine
Scientific Director, Automation & Special Projects
ARUP Laboratories, Salt Lake City, UT
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ARUP LABORATORIES

UNIVERSITY OF UTAH SCHOOL OF MEDICINE | Department of Pathology

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Charles D. Hawker, PhD, MBA

Introduction

- Everyone has heard many times that:
  - Clinical labs are under increasing economic pressure…
  - which creates demands for improved productivity.
  - In addition, the laboratory workforce is aging, with…
  - an inadequate pipeline of trained replacements.
  - Improving patient safety is a very important goal...
  - which requires continuous improvement in both non-analytic and analytic quality.
- Lean and Six-Sigma, continuous quality improvement, and process re-engineering in addition to written processes, training, checklists, vigilance, etc., are needed to improve quality.
- Adding automation, robotics, enhanced software, and advanced processes to the above is necessary to push non-analytic quality to the next quality level.
- However, each lab can implement certain activities to improve non-analytic metrics without an investment in expensive automation. Some examples will be provided.

Realistic Error Rates: It is difficult to have better than a 1/1000 error rate without advanced design and technology

Best Rate	Method of Ensuring Accuracy	Example
1/1,000	Clear processes, reliance on education, training, vigilance	Hand washing
1/10,000	The above plus reminders, checklists, communication, retraining, competency testing, processes reflecting human behavior	Requisition order errors Sub-optimal specimens
1/100,000	The above plus standardization, error-proofing, elimination of fatigue & distractions	Mislabeled specimens Corrected reports
1/1,000,000	The above plus automation, robotics, software enhancements, advanced process design	Lost specimens Interfaced result entry Bar code reading

Source: Michael Astion, Univ. of Washington, based on a report by Resar, RK: Making noncatastrophic health care processes reliable: learning to walk before running in creating high-reliability organizations. *Health Serv. Res.* 2006;41:1677-1689

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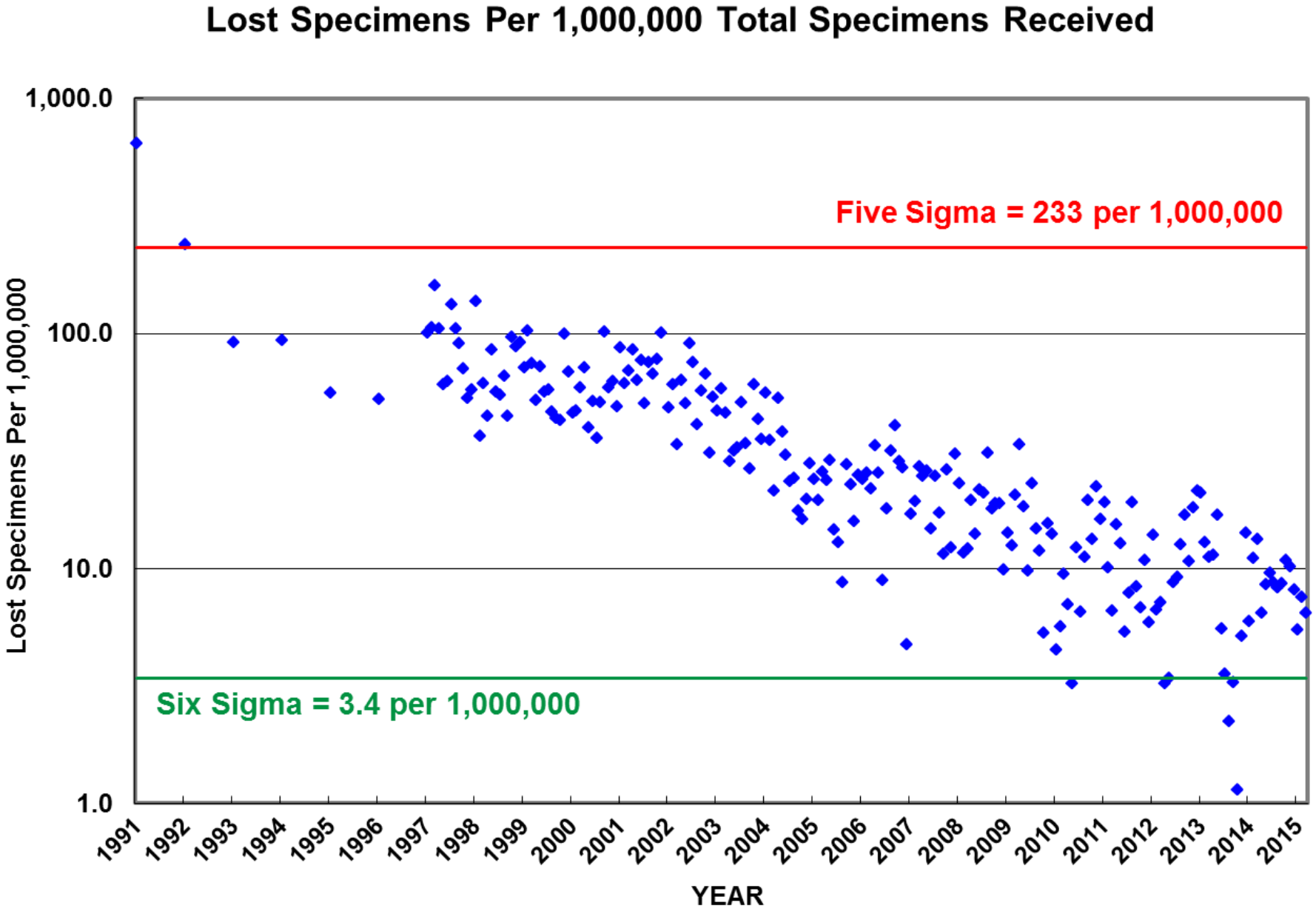
Lost Specimens Per 1,000,000 Total Specimens Received
1,000.0
100.0
10.0
1.0
Lost Specimens Per 1,000,000
Five Sigma = 233 per 1,000,000
Six Sigma = 3.4 per 1,000,000
1991
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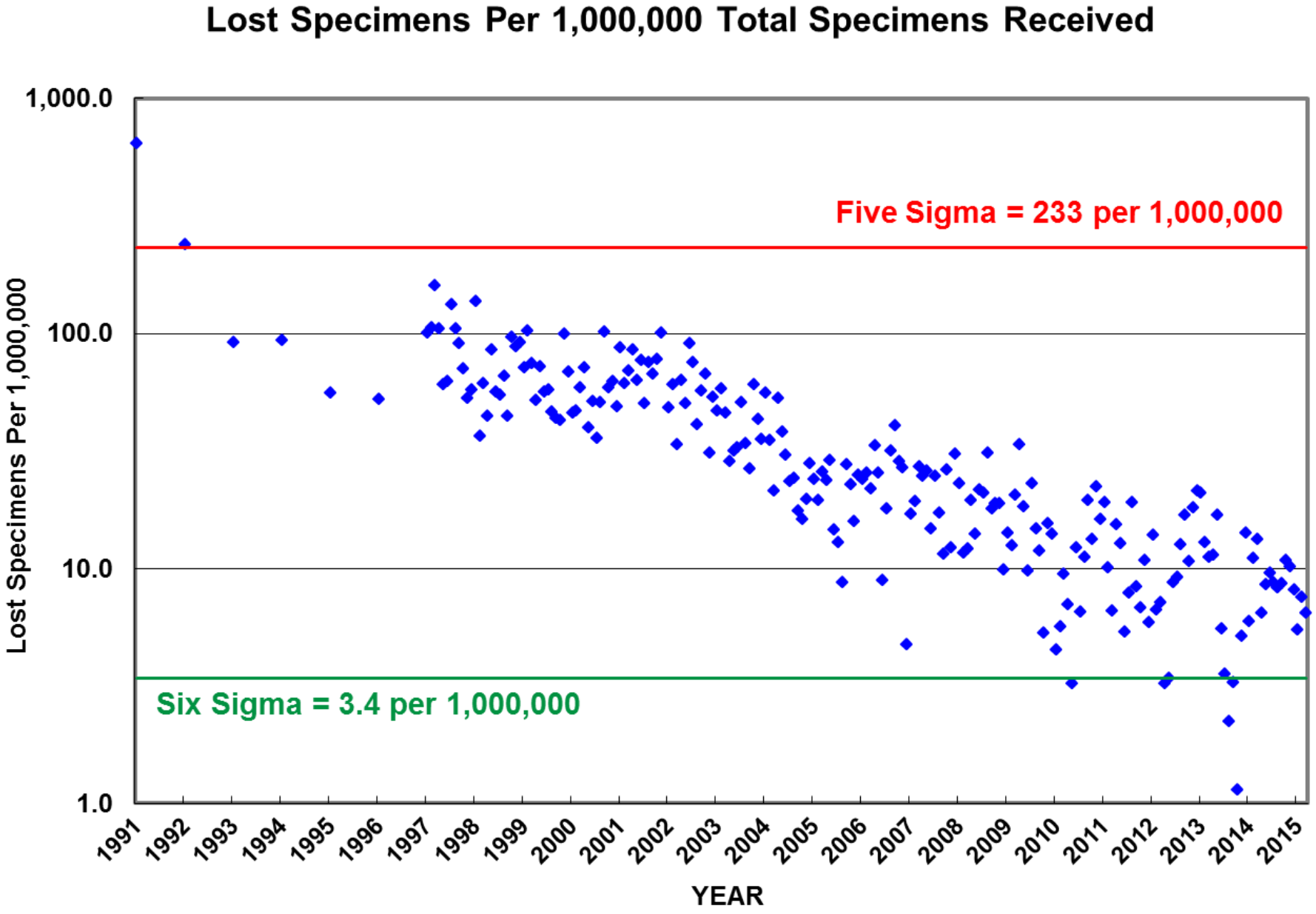
Six-Sigma Analysis

- The definition of Six-Sigma is 3.4 defects per million opportunities (DPMO).
- In the case of lost specimens, each time a specimen is handled represents an opportunity to lose the specimen.
- Although we know that each specimen at ARUP has an average of 1.6 billed units (tests), we don't actually know how many times each specimen was handled. It varies from test to test, client to client.
- Our estimate is that each specimen is handled 5-6 times on average. If we could accurately estimate the number of touches, the lost specimen metric would have many more points in the Six-Sigma range.


Lost Specimens Per 1,000,000 Total Specimens Received
1,000.0
100.0
10.0
1.0
Lost Specimens Per 1,000,000
Five Sigma = 233 per 1,000,000
Six Sigma = 3.4 per 1,000,000
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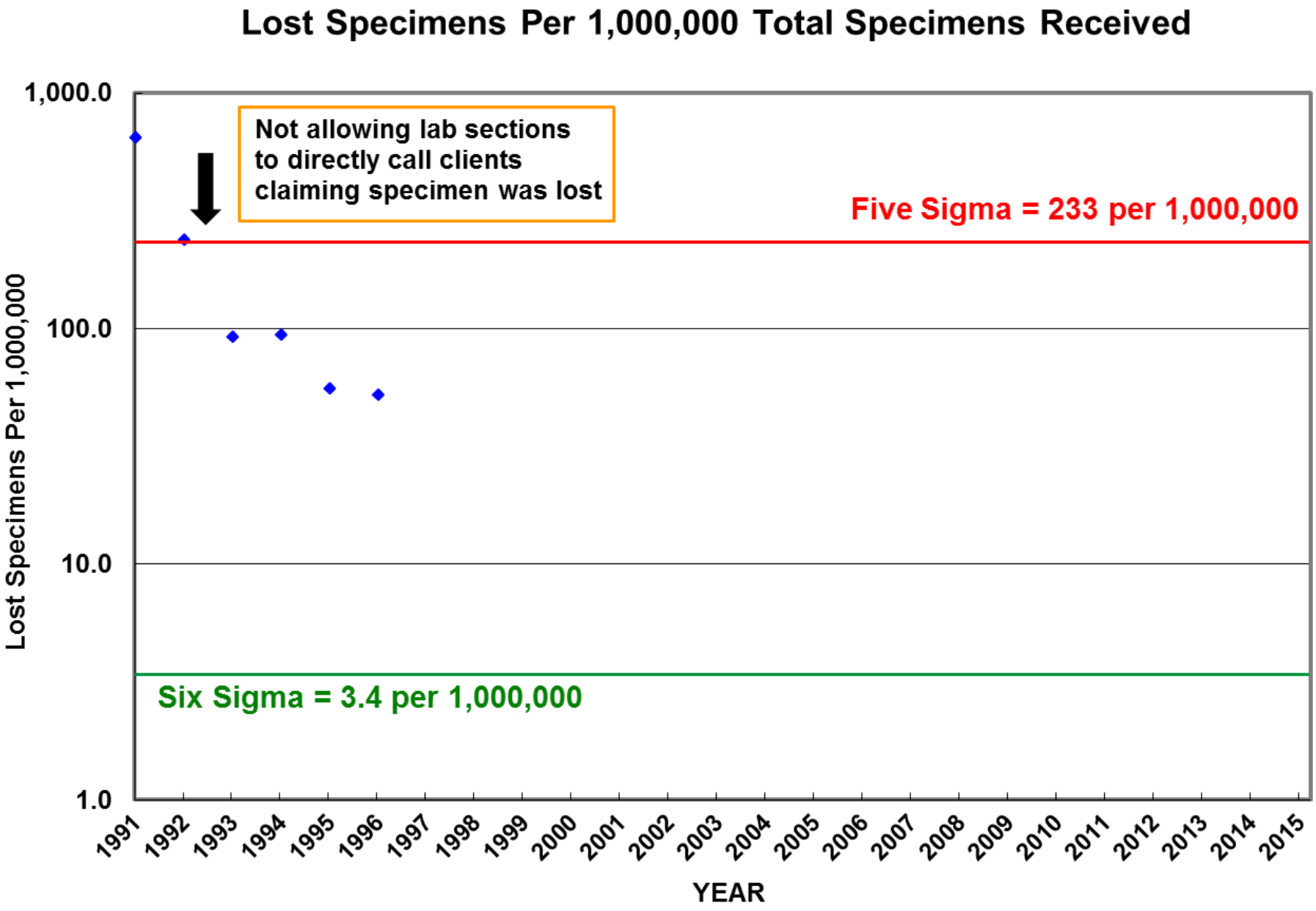
Lost Specimens Per 1,000,000 Total Specimens Received
1,000.0
100.0
10.0
1.0
Lost Specimens Per 1,000,000
Not allowing lab sections to directly call clients claiming specimen was lost
Five Sigma = 233 per 1,000,000
Six Sigma = 3.4 per 1,000,000
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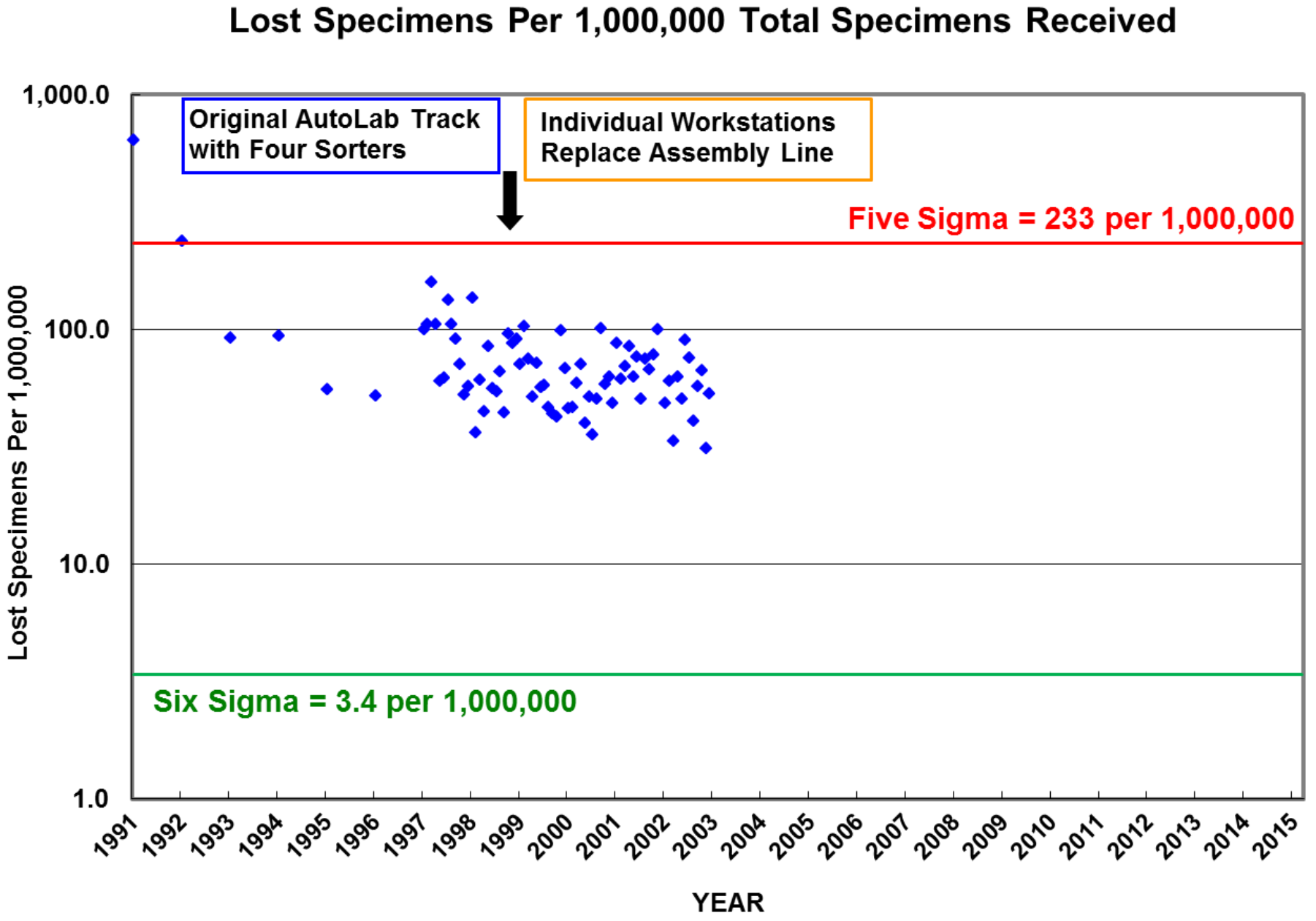
Lost Specimens Per 1,000,000 Total Specimens Received
1,000.0
100.0
10.0
1.0
Lost Specimens Per 1,000,000
Original AutoLab Track with Four Sorters
Individual Workstations Replace Assembly Line
Five Sigma = 233 per 1,000,000
Six Sigma = 3.4 per 1,000,000
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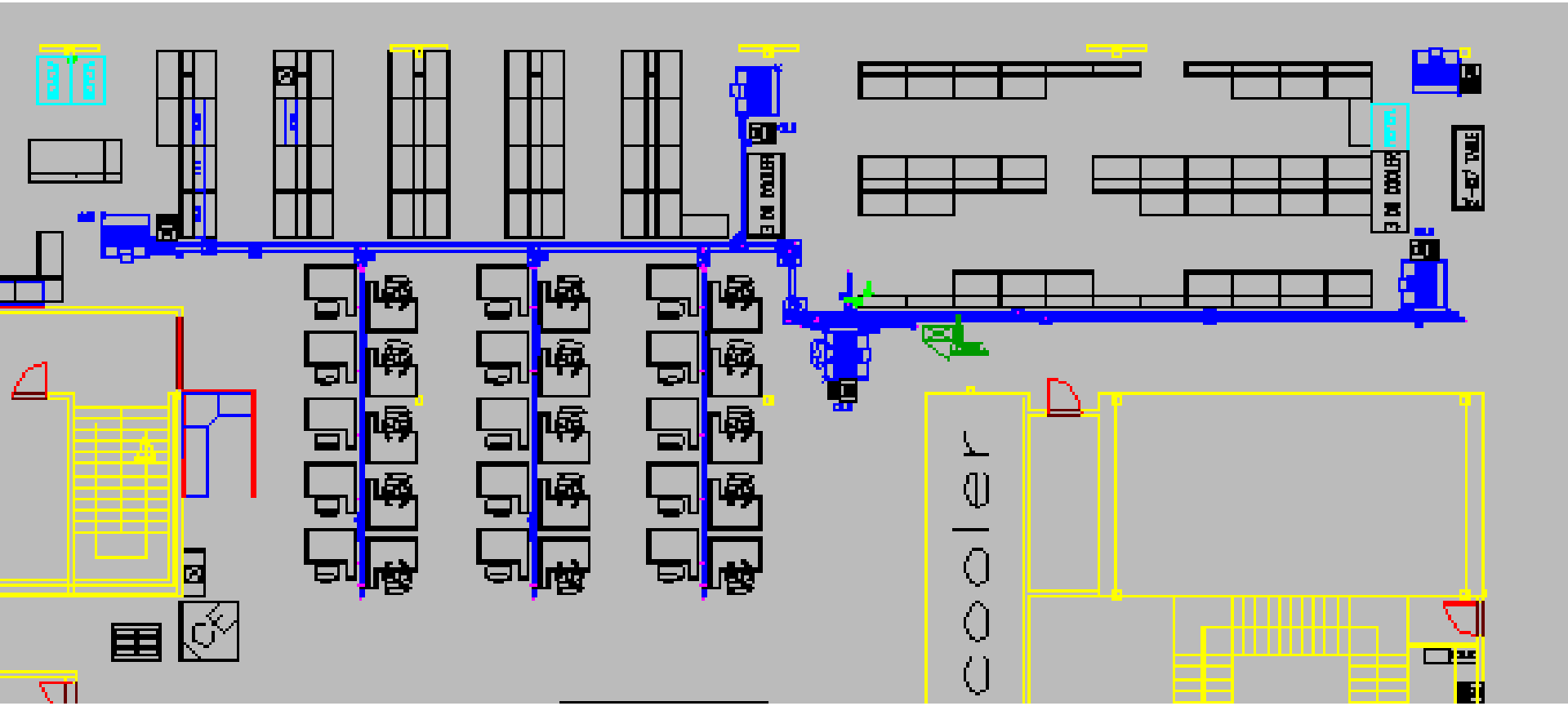
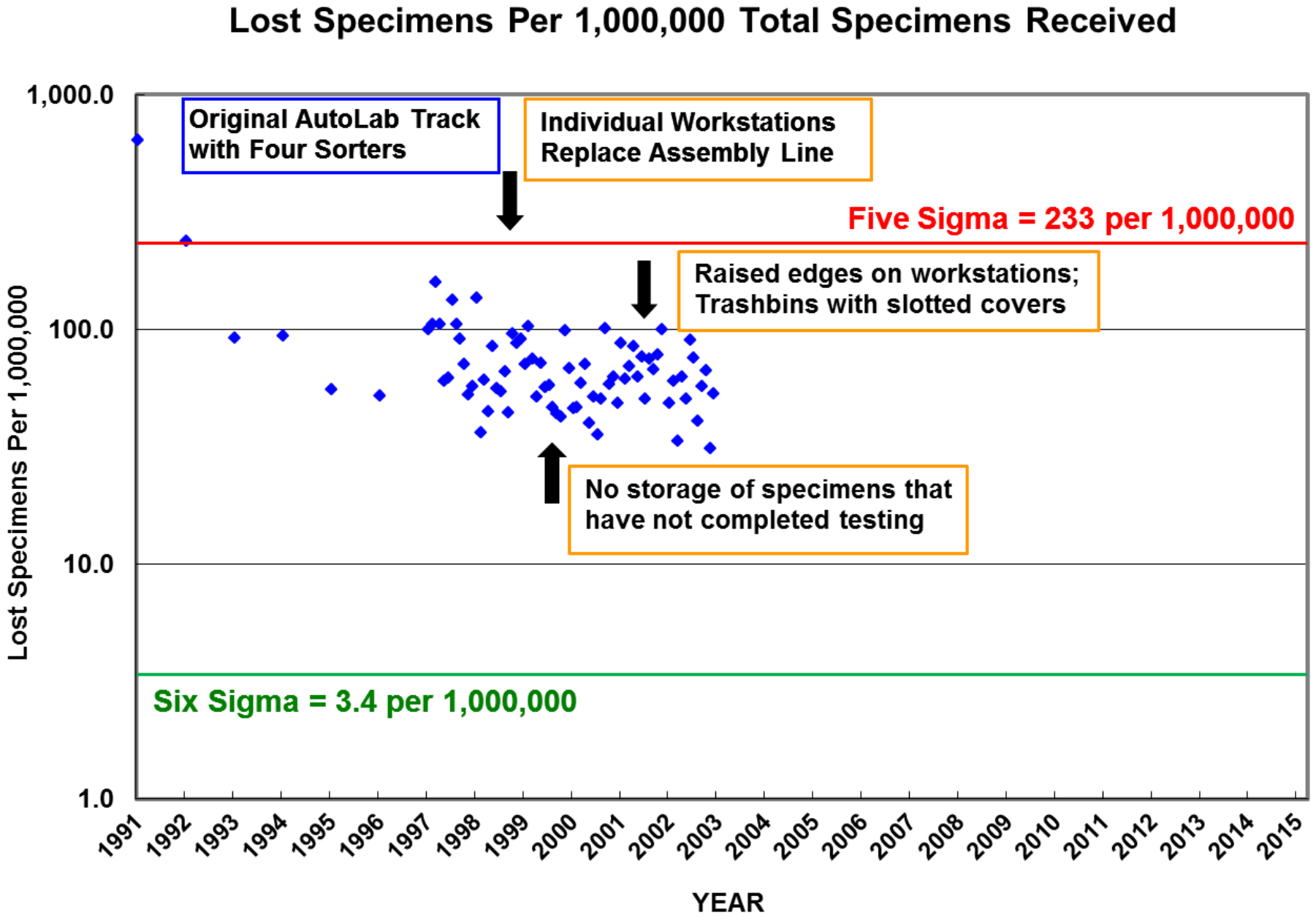
ARUP Automation, November 17, 1998
2000 specimens/hour, 30 workstations, 4 sorters




Lost Specimens Per 1,000,000 Total Specimens Received
1,000.0
100.0
10.0
1.0
Lost Specimens Per 1,000,000
Original AutoLab Track with Four Sorters
Individual Workstations Replace Assembly Line
Five Sigma = 233 per 1,000,000
Raised edges on workstations; Trashbins with slotted covers
No storage of specimens that have not completed testing
Six Sigma = 3.4 per 1,000,000
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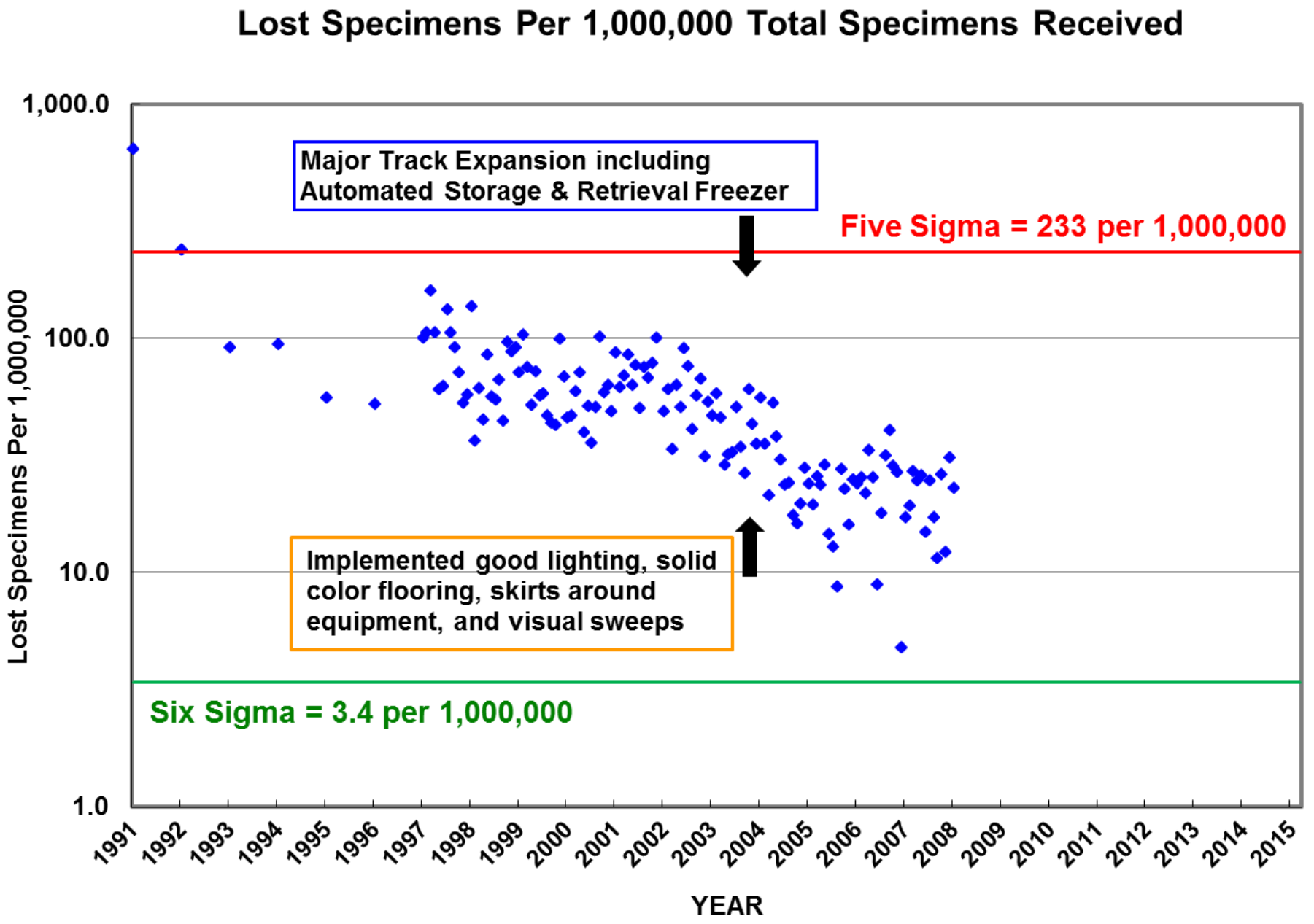
Lost Specimens Per 1,000,000 Total Specimens Received
1,000.0
100.0
10.0
1.0
Lost Specimens Per 1,000,000
Major Track Expansion including
Automated Storage & Retrieval Freezer
Five Sigma = 233 per 1,000,000
Implemented good lighting, solid
color flooring, skirts around
equipment, and visual sweeps
Six Sigma = 3.4 per 1,000,000
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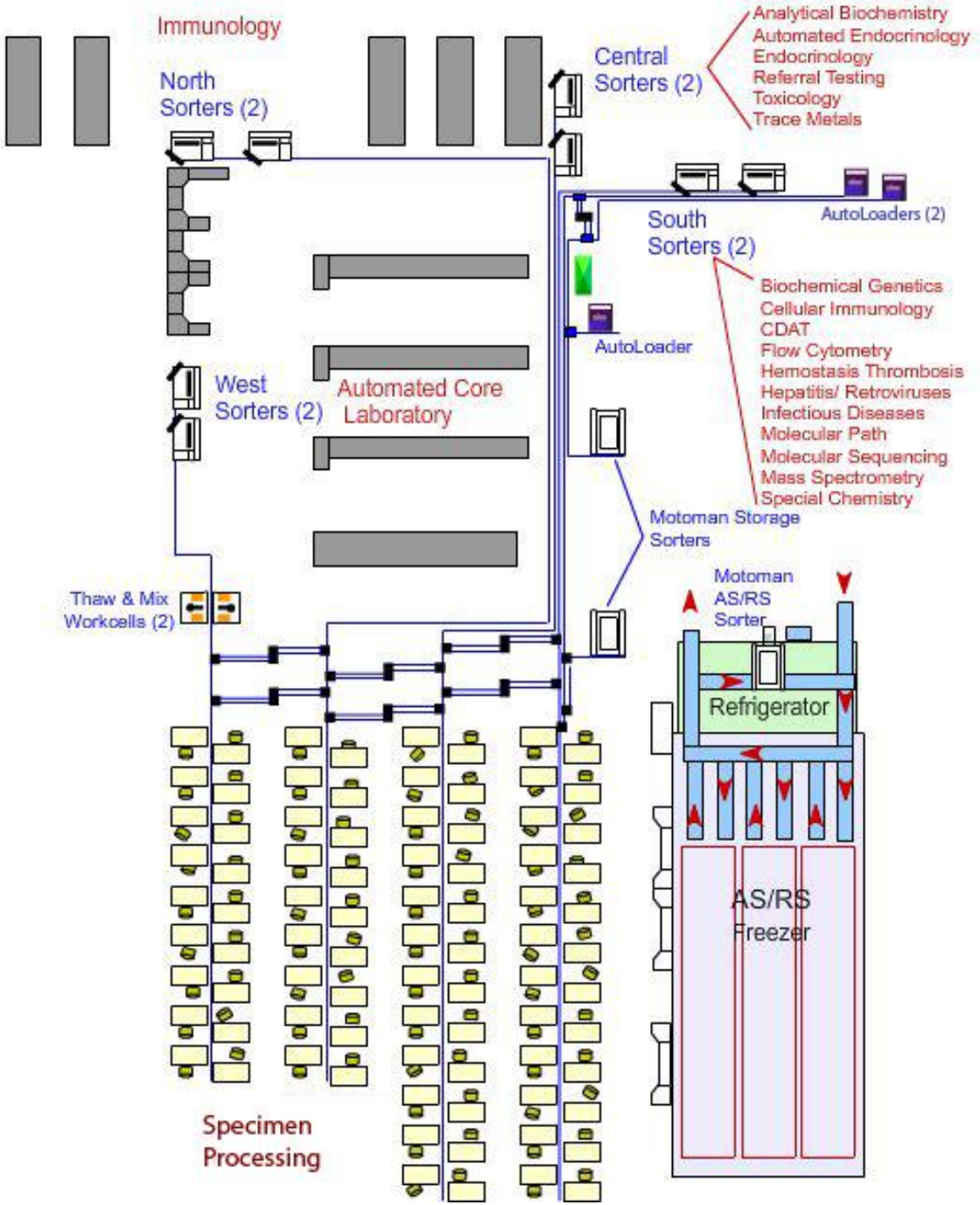
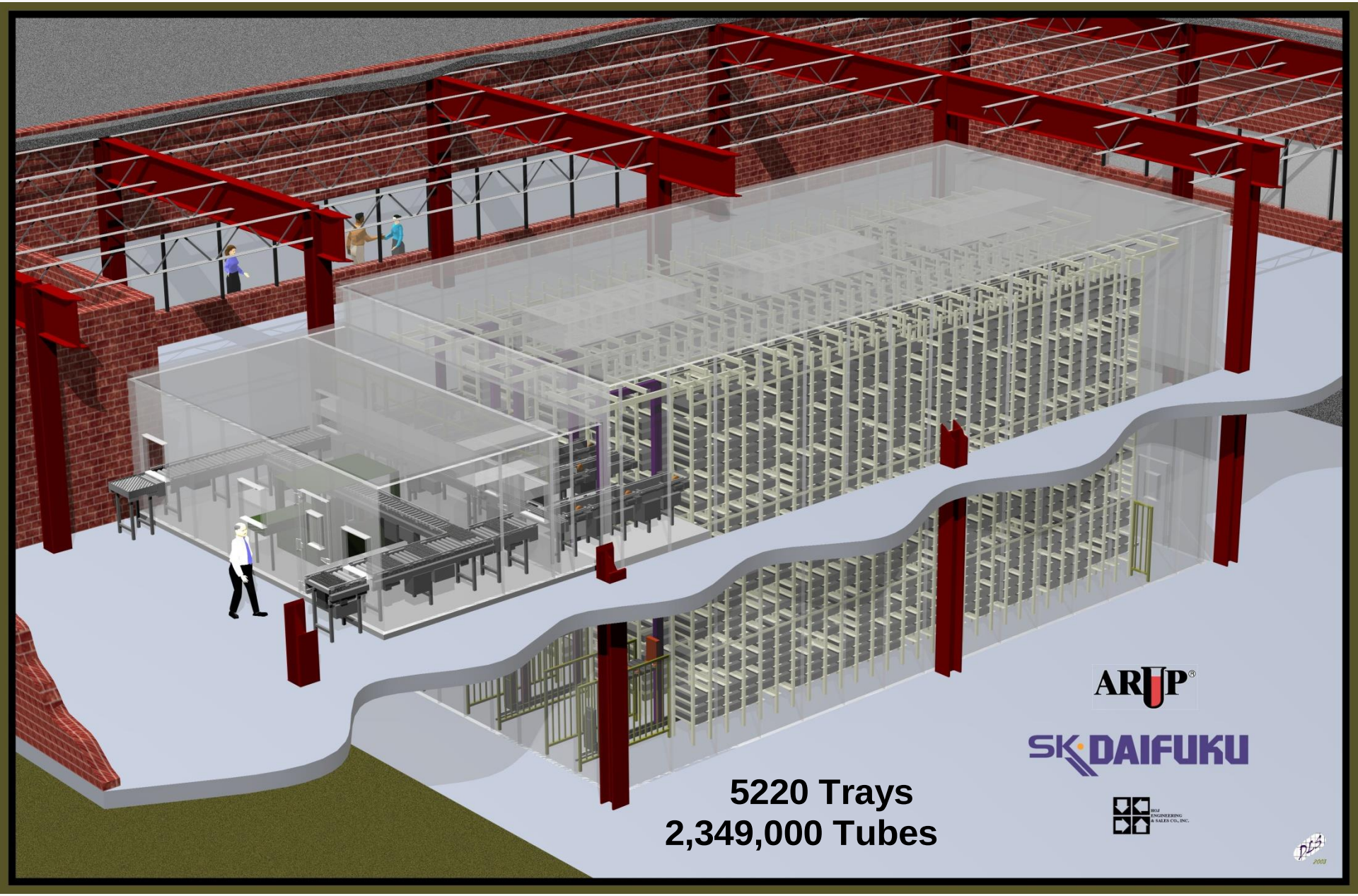
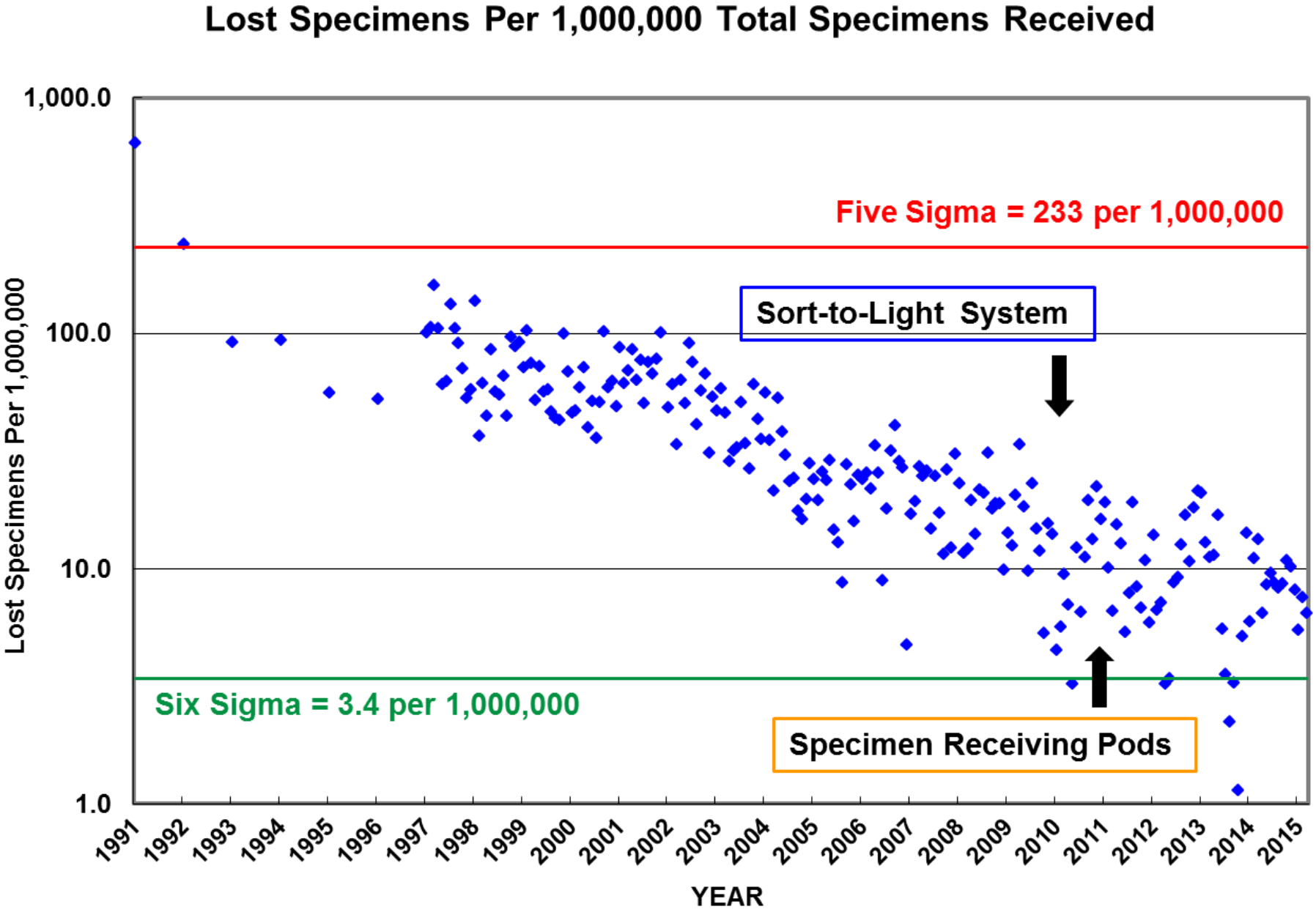

Immunology
North Sorters (2)
Central Sorters (2)
Analytical Biochemistry
Automated Endocrinology
Endocrinology
Referral Testing
Toxicology
Trace Metals
AutoLoaders (2)
South Sorters (2)
Biochemical Genetics
Cellular Immunology
CDAT
Flow Cytometry
Hemostasis Thrombosis
Hepatitis/ Retroviruses
Infectious Diseases
Molecular Path
Molecular Sequencing
Mass Spectrometry
Special Chemistry
AutoLoader
West Sorters (2)
Automated Core Laboratory
Motoman Storage Sorters
Thaw & Mix Workcells (2)
Motoman AS/RS Sorter
Refrigerator
AS/RS Freezer
Specimen Processing


ARUP
SK DAIFUKU
5220 Trays
2,349,000 Tubes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1,000.0
100.0
10.0
1.0
Lost Specimens Per 1,000,000
Five Sigma = 233 per 1,000,000
Sort-to-Light System
Six Sigma = 3.4 per 1,000,000
Specimen Receiving Pods
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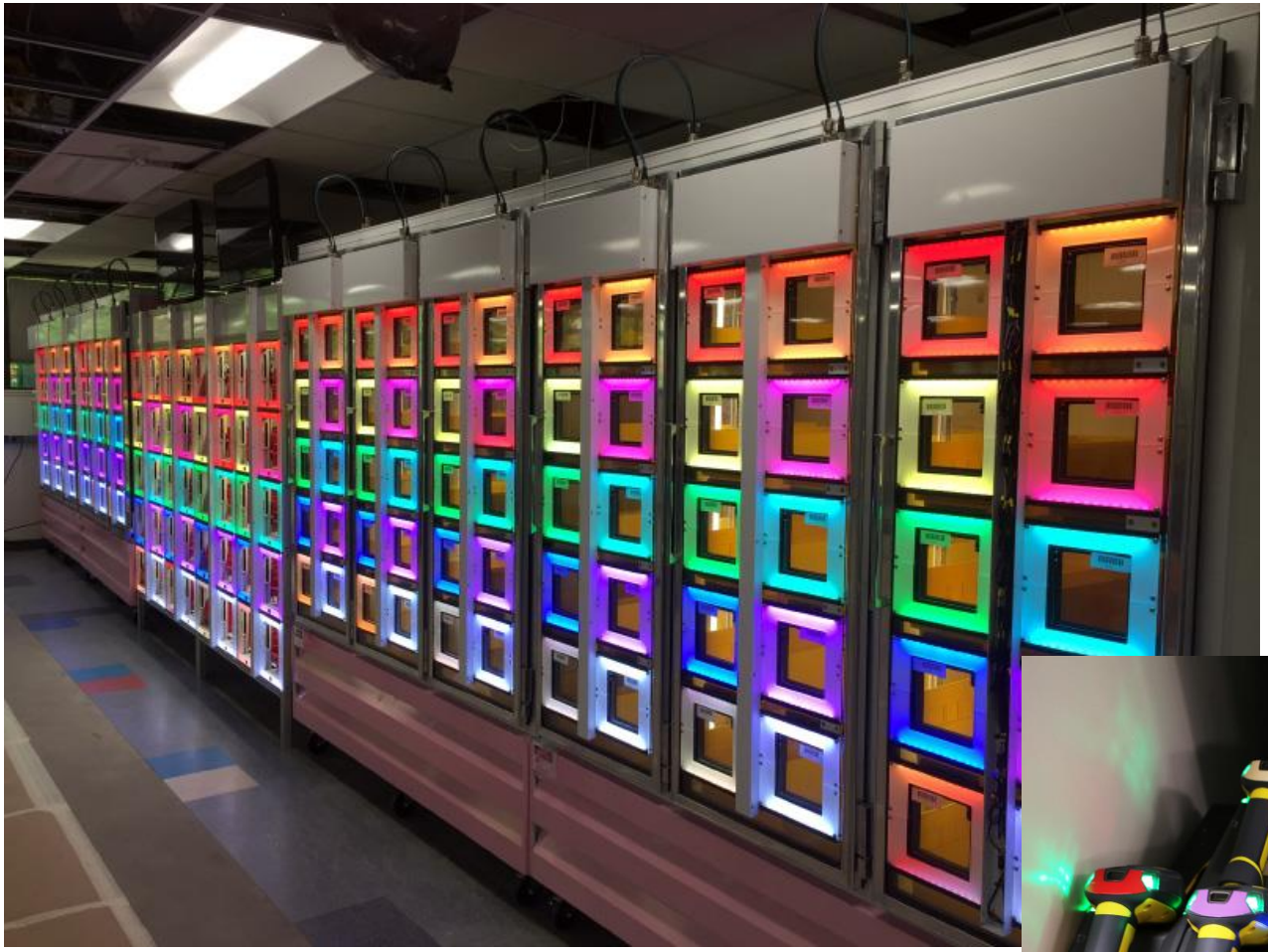
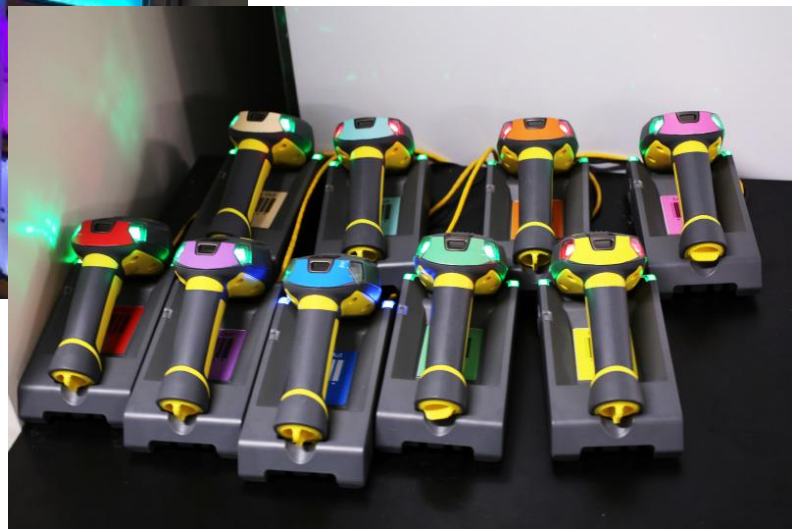
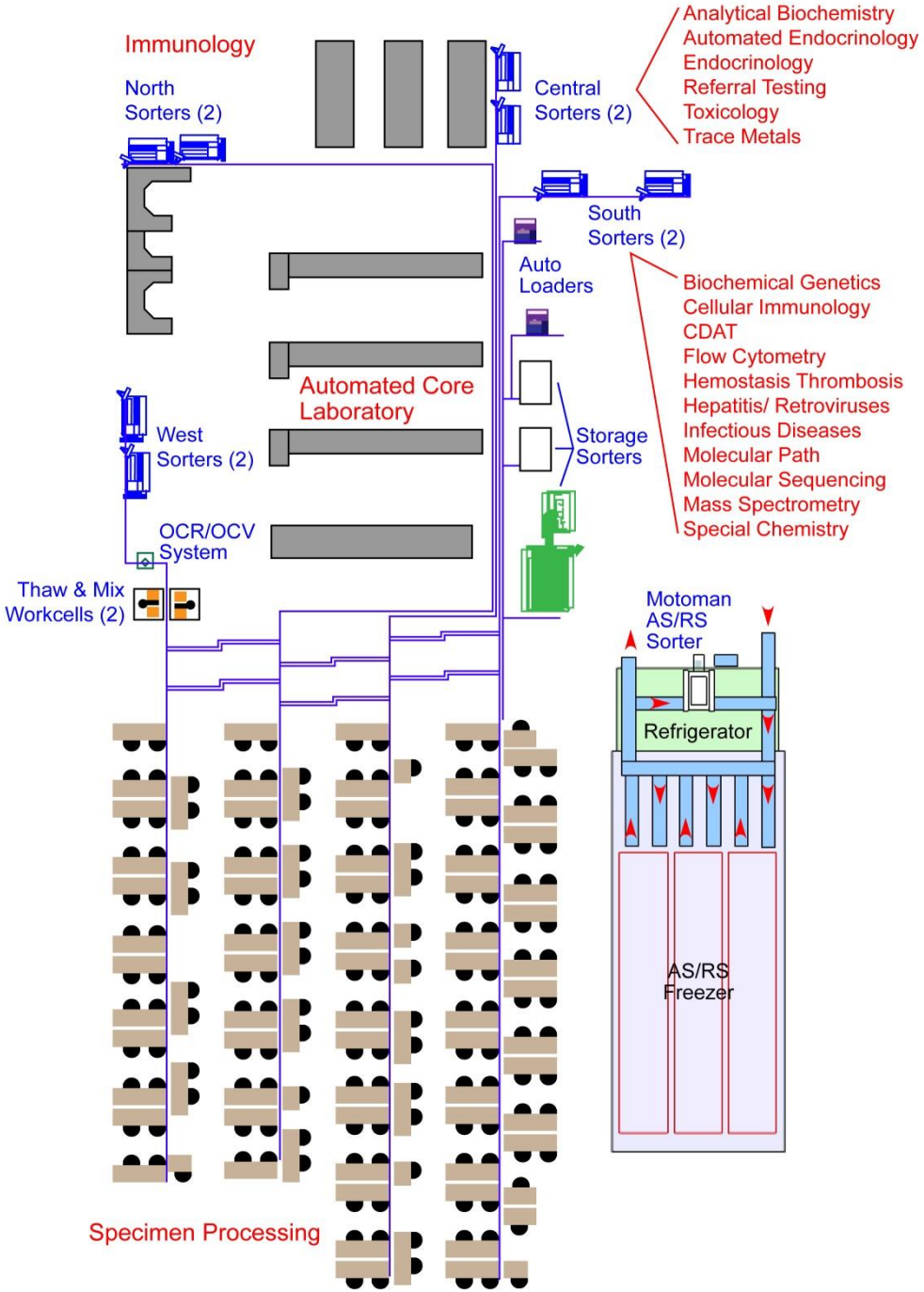
YEAR

ARUP's Sort-To-Light System



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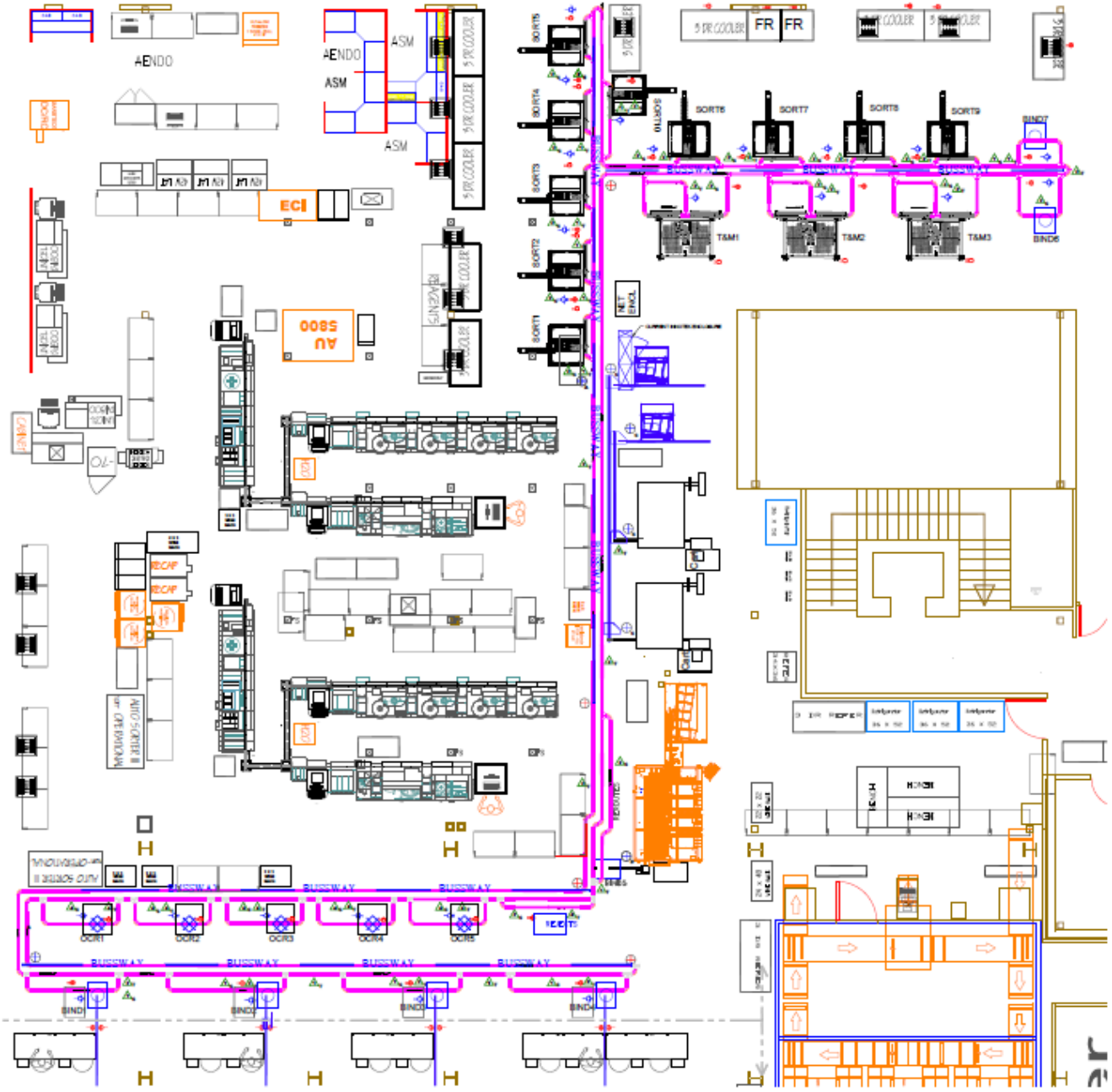
Biochemical Genetics
Cellular Immunology
CDAT
Flow Cytometry
Hemostasis Thrombosis
Hepatitis/ Retroviruses
Infectious Diseases
Molecular Path
Molecular Sequencing
Mass Spectrometry
Special Chemistry
Automated Core
Laboratory
West
Sorters (2)
Storage
Sorters
OCR/OCV
System
Thaw & Mix
Workcells (2)
Motoman
AS/RS
Sorter
Refrigerator
AS/RS
Freezer
Specimen Processing

ARUP's new MagneMotion automation went live in April, 2015. The total layout includes more than 20 custom robotic systems. The MagneMotion conveyor is shown in **pink**.



Summary of Process Improvement Actions (1)

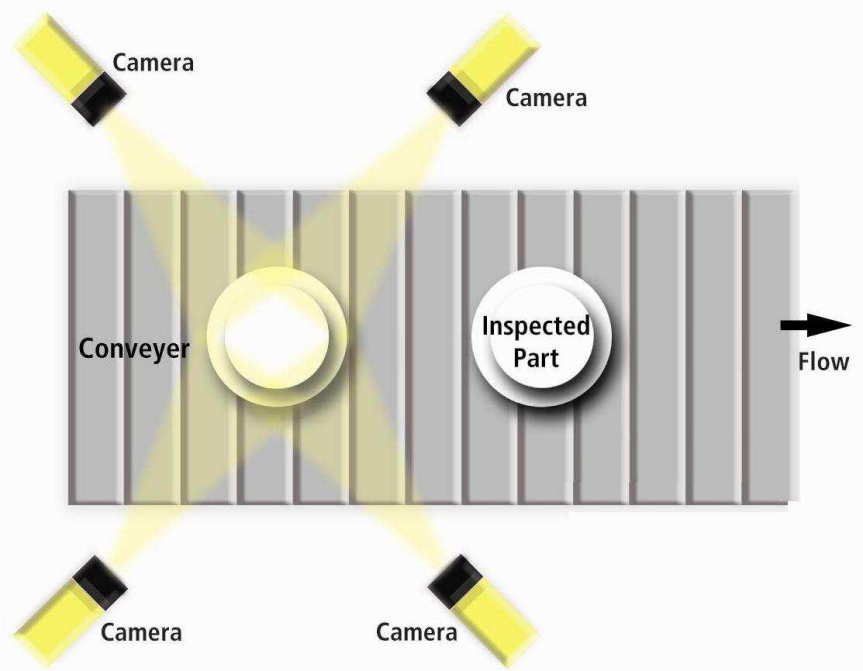
- Used Lean and CQI techniques to identify idling time, bottlenecks, and other similar waste.
- Replaced assembly line approach to specimen processing with individual workstations to give single technicians ownership of all accessioning and labeling steps.
- Standardized processing procedures to reduce hand-offs and total handling steps.
- Reduced/eliminated non-value added handling and sorting.
- Eliminated “running around” to find shared specimens – let automation track and route specimens.
- Implemented IT rule for specimen archive to not store specimens that have not completed testing.

Summary of Process Improvement Actions (2)

- Implemented good lighting (no shadows) and solid color (black) flooring with clean lines of sight to enable easy visual detection of dropped tubes, even small items such as calculi.
- Implemented raised edges on all worktops and counters so specimens less likely to roll on the floor.
- Trash bins covered with plastic covers with slits to prevent tubes from falling in the trash.
- Skirts installed around all equipment, sorters, analyzers, etc., to prevent specimens from rolling beneath them.
- Scheduled visual sweeps in areas of concern at end of each shift.

The Next Phase for Our Lab: Using Automated Camera Systems and OCR to Identify Patient Name Mislabeled Specimens

Cognex Omniview System



The Cognex Omniview system has four 5-megapixel high speed cameras which photograph the tube's exterior from all sides after it is robotically lifted out of the transport carrier. The software stitches the four images together into a two dimensional image. A sophisticated OCR engine analyzes the label content, comparing the patient name on the client label to the patient name in the ARUP LIS.

Label Inspection Result is “Pass”

ARUP Vision Inspection Application

LogMeIn - Remote Session

Status: PROCESSING

Unwrap and Crop | Unwrap Orig | Restitch | Main Vision | Label Angle | Raw | Tube Angle

Auto | Manual | ABBYY OCR | Train OCR

Reset Statistics

Automatic

- Auto
- By-Pass
- Part Train

Stop

Heartbeat: True

Statistics | OCR | DataMan

Inspection Time: **2535** Diameter: **16**

Statistics

Total	1	
Singles Pass:	0	0
Match Pass:	1	100.00
Total Fail:	0	0
Total Pass:	1	**100.00**

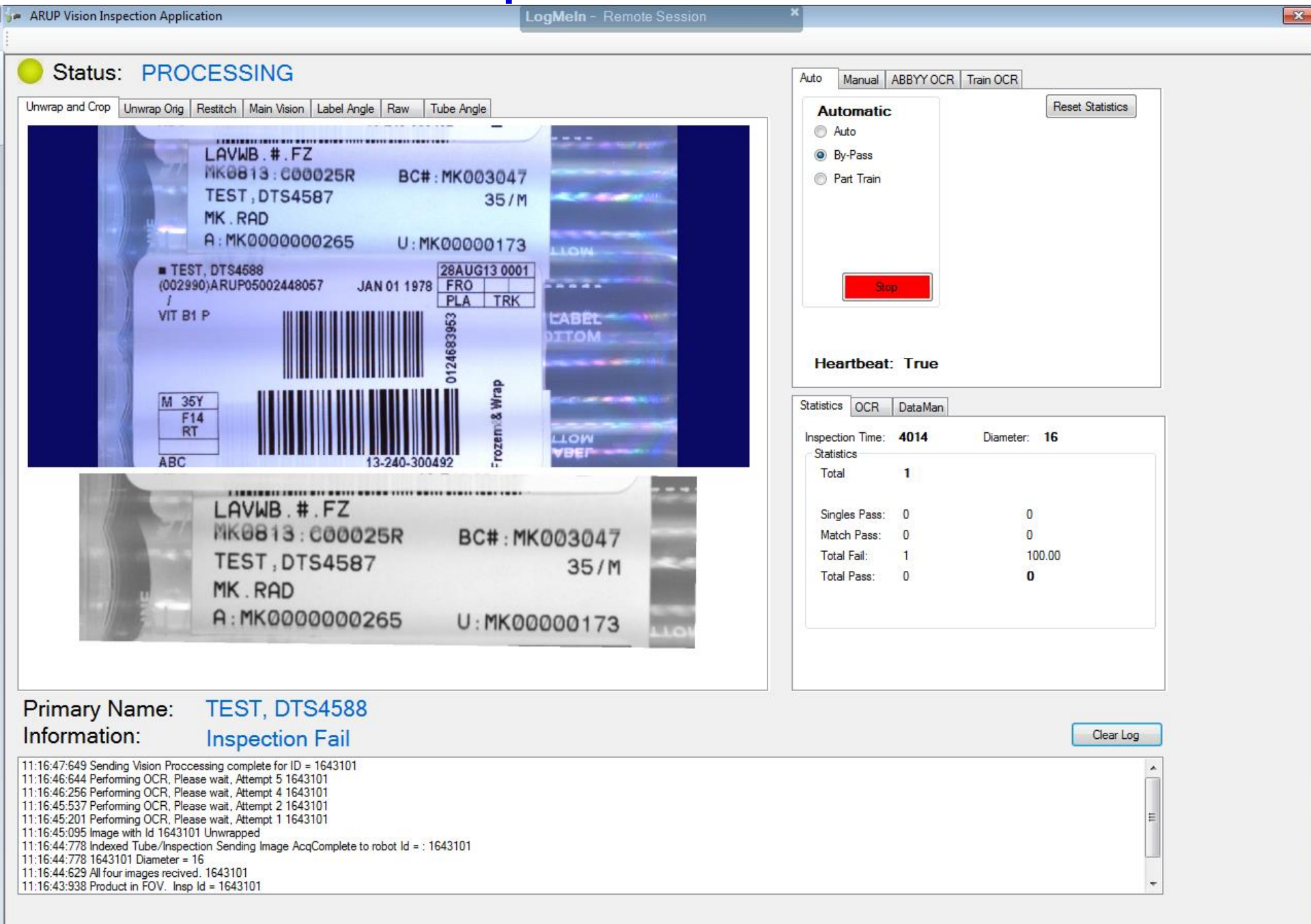
Primary Name: TEST, JODI DND

Information: Pass by Name MATCH

Clear Log

```
11:07:33:001 Sending Vision Proccessing complete for ID = 1643048
11:07:32:253 Performing OCR, Please wait, Attempt 1 1643048
11:07:32:131 Image with Id 1643048 Unwrapped
11:07:31:806 Indexed Tube/Inspection Sending Image AcqComplete to robot Id = : 1643048
11:07:31:806 1643048 Diameter = 16
11:07:31:726 All four images recived. 1643048
11:07:31:035 Product in FOV.  Insp Id = 1643048
11:07:30:168 Sending NewInspectionId = 1643048 For Trans Id = 635133712468766250
11:07:29:952 Tube at carrier with Trans Id = 635133712468766250 Dia = 16
```

Label Inspection Result is “Fail”



Results with Prototype System

- From October, 2012 to October, 2014, 3,308,776 images were collected. Approximately 75% were passed by the system. Images can fail due to label quality, fonts, etc.
- The OCR system found 424 mislabeled specimens, a ratio of 1 per 7800 specimen images. Of these, 228 (56%) were found by the testing lab or S.P. employees prior to testing.
- The prototype results were published in *Clinical Chemistry* in March 2014 (Vol. 60, No. 3, pp 463-470)
- Four new OCR systems are being built, to be installed on our new automation system. All “fail” OCR images will be reviewed in real time, by a centralized team of assigned technicians, potentially reducing corrected reports due to mislabeled specimens to near zero.

Summary

- 25 years of implementing process improvement and automation gave a steady reduction in lost specimens to a level consistently below 10 per 1,000,000 specimens and, in some months, in the Six-Sigma region (≤ 3.4/1,000,000).
- Automation is far more effective when accompanied by good informatics designs.
- New OCR technology for identifying possible mislabeled specimens also has the prospect of achieving Six-Sigma quality levels when fully implemented on our automation.
- Several improvement suggestions were provided that offer opportunities for laboratories to achieve meaningful reductions in error rates, even if not to Six-Sigma levels, without the cost of expensive automation projects.

Thank you!

Questions?