How We Achieved Six-Sigma Performance in Our Automated Lab:
Lessons Learned from our Multi-Year Journey

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October 1, 2013

Disclosure and Objectives

Disclosure: employee of ARUP Laboratories

Objectives:

After completing this activity, the participant will be able to…

- Define various process improvement actions and how they impact non-analytic quality metrics.
- Describe the role of automation in improving non-analytic quality.
- List three activities to improve non-analytic quality in their own laboratory.

Introduction

- To repeat what everyone has heard many times:
  - 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.
- Automation and process re-engineering, as part of a continuous quality improvement program, often utilizing Lean and Six-Sigma processes, are clearly meeting some of these demands on laboratories.

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

Automation, Lean, Six-Sigma, and More

- In addition to written processes, training, checklists, vigilance, etc., continuous quality improvement and process re-engineering, using Lean and Six-Sigma, are needed to reduce errors and improve quality.
- Adding automation, robotics, enhanced software, and advanced processes to written procedures, training, checklists, vigilance, etc., is necessary to push non-analytic quality to Six Sigma levels.
- However, there are certain activities each lab can implement which can improve the lab's non-analytic metrics without an investment in sophisticated automated systems. They may not lead to Six-Sigma levels, but these activities can still improve quality. Some examples will be provided.

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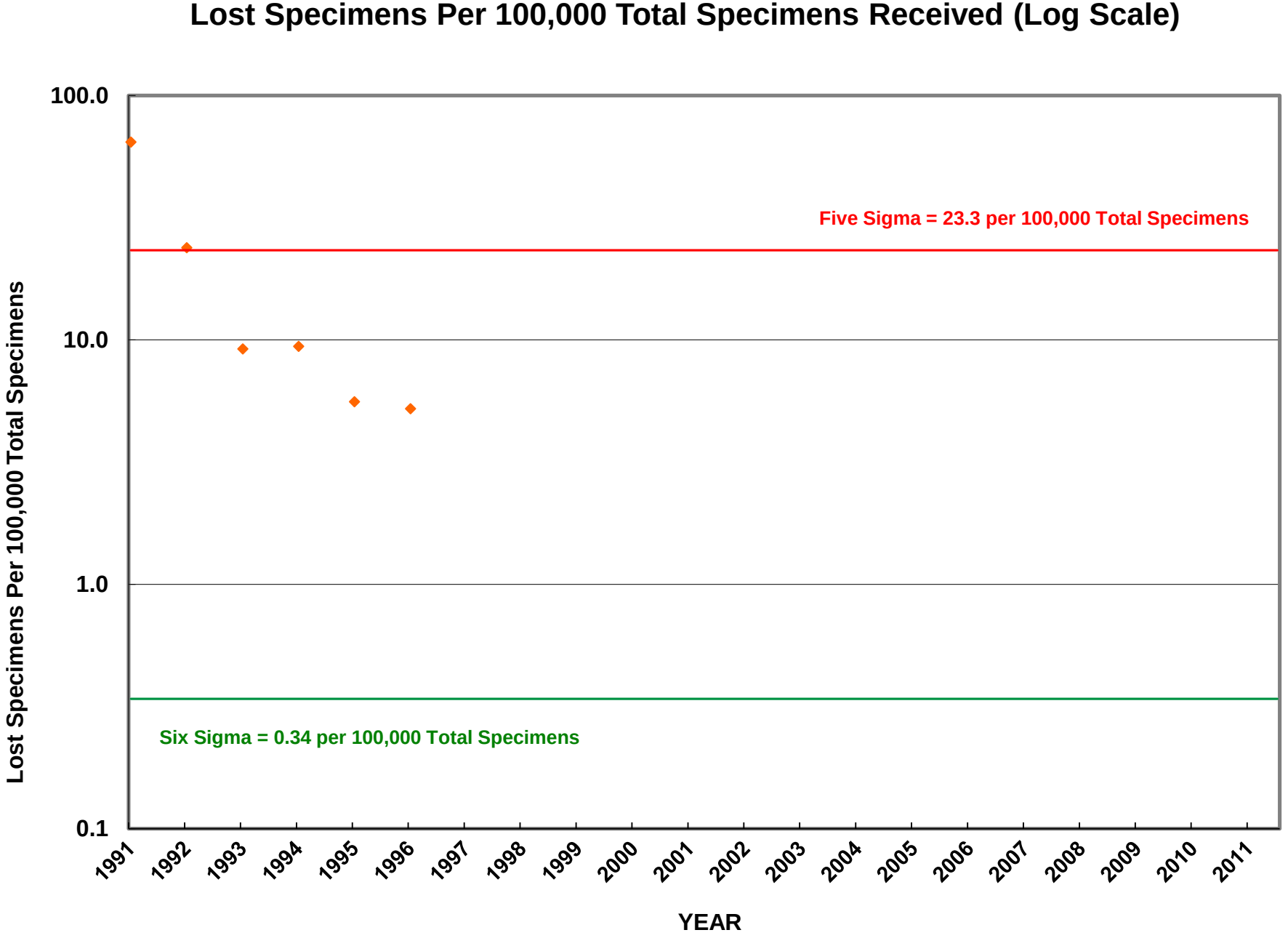
Lost Specimens Per 100,000 Total Specimens Received (Log Scale)
100.0
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Lost Specimens Per 100,000 Total Specimens
Five Sigma = 23.3 per 100,000 Total Specimens
Six Sigma = 0.34 per 100,000 Total Specimens
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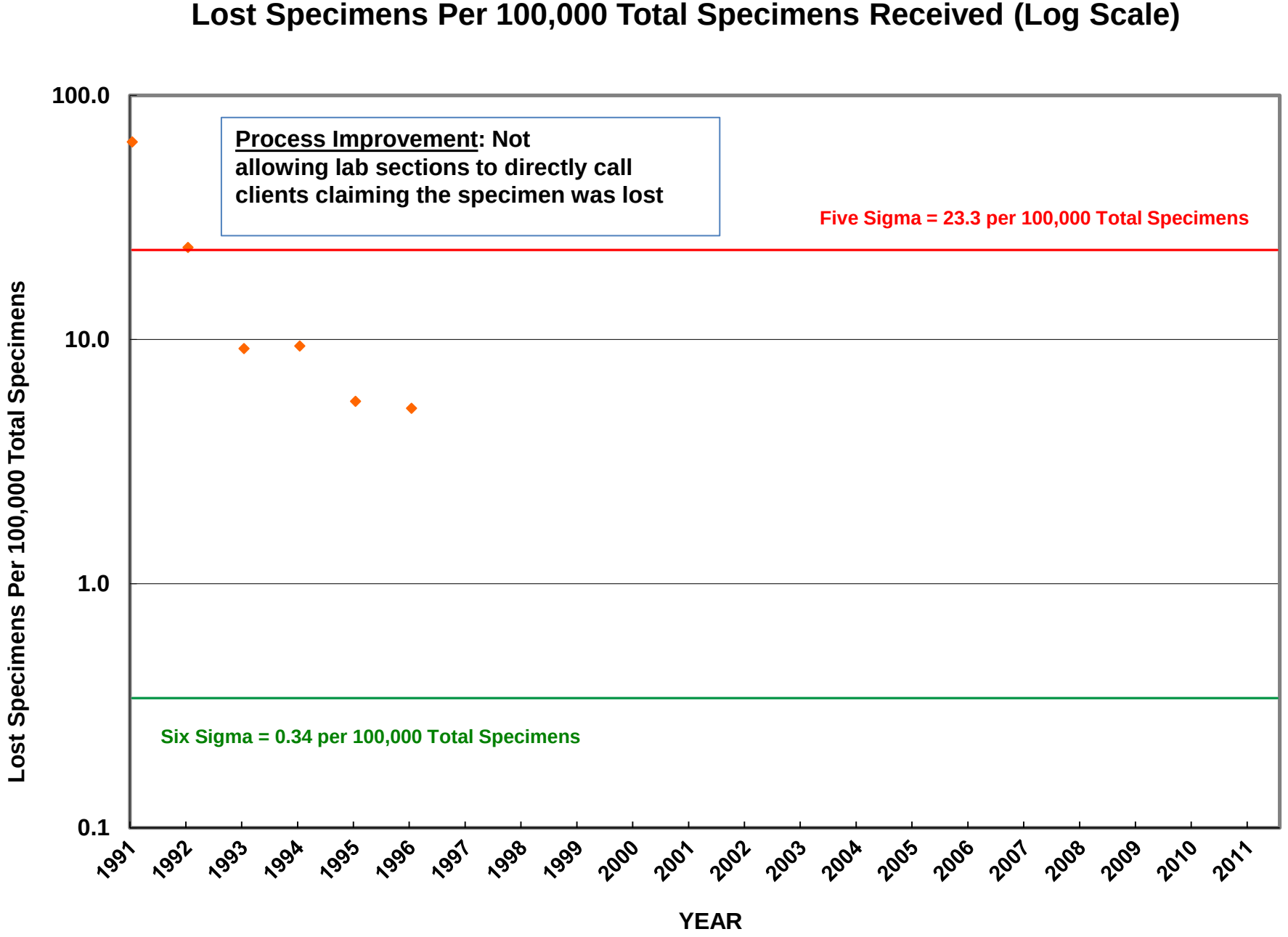
Lost Specimens Per 100,000 Total Specimens Received (Log Scale)
Process Improvement: Not allowing lab sections to directly call clients claiming the specimen was lost
Five Sigma = 23.3 per 100,000 Total Specimens
Six Sigma = 0.34 per 100,000 Total Specimens
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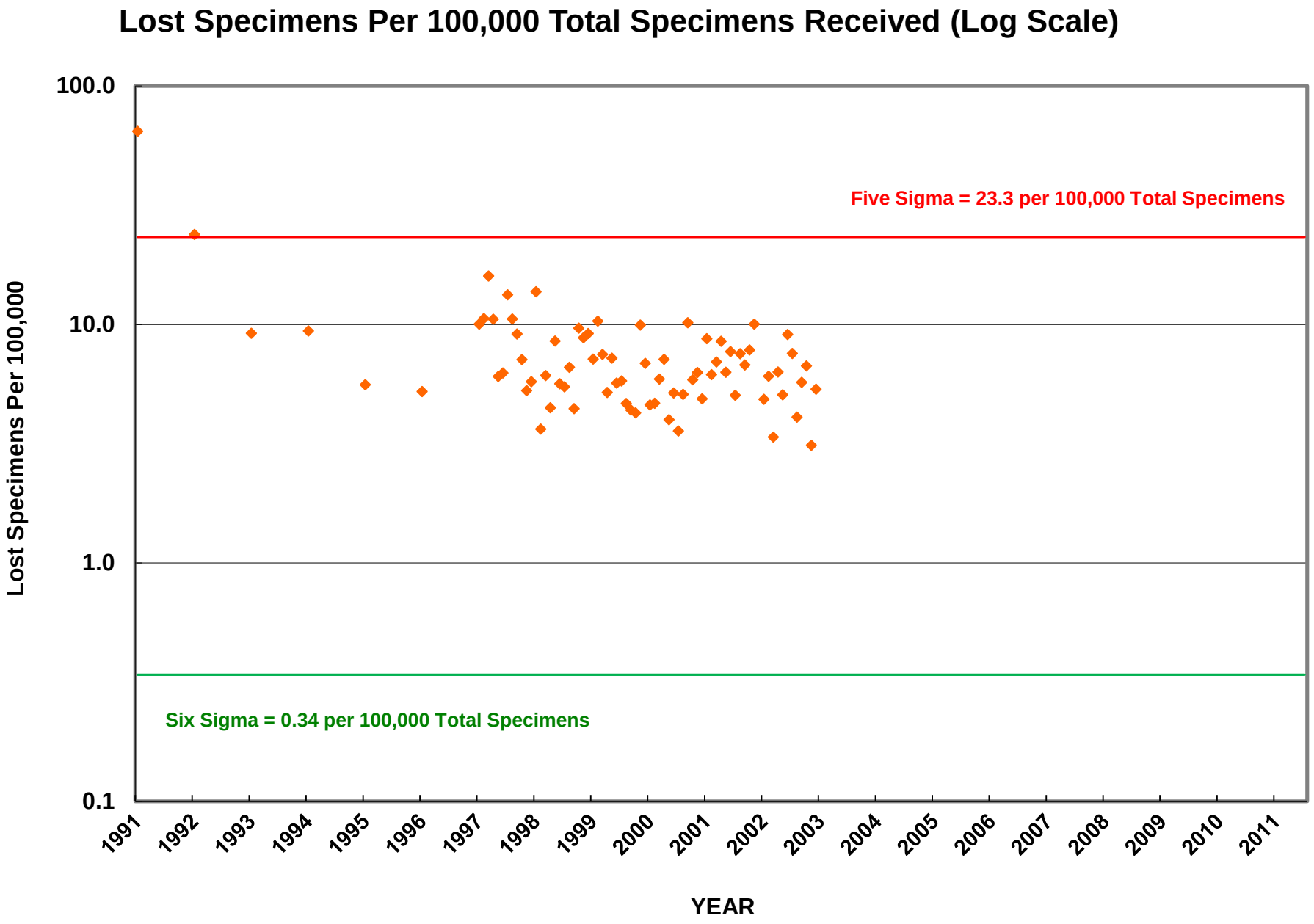
Lost Specimens Per 100,000 Total Specimens Received (Log Scale)
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Lost Specimens Per 100,000
Five Sigma = 23.3 per 100,000 Total Specimens
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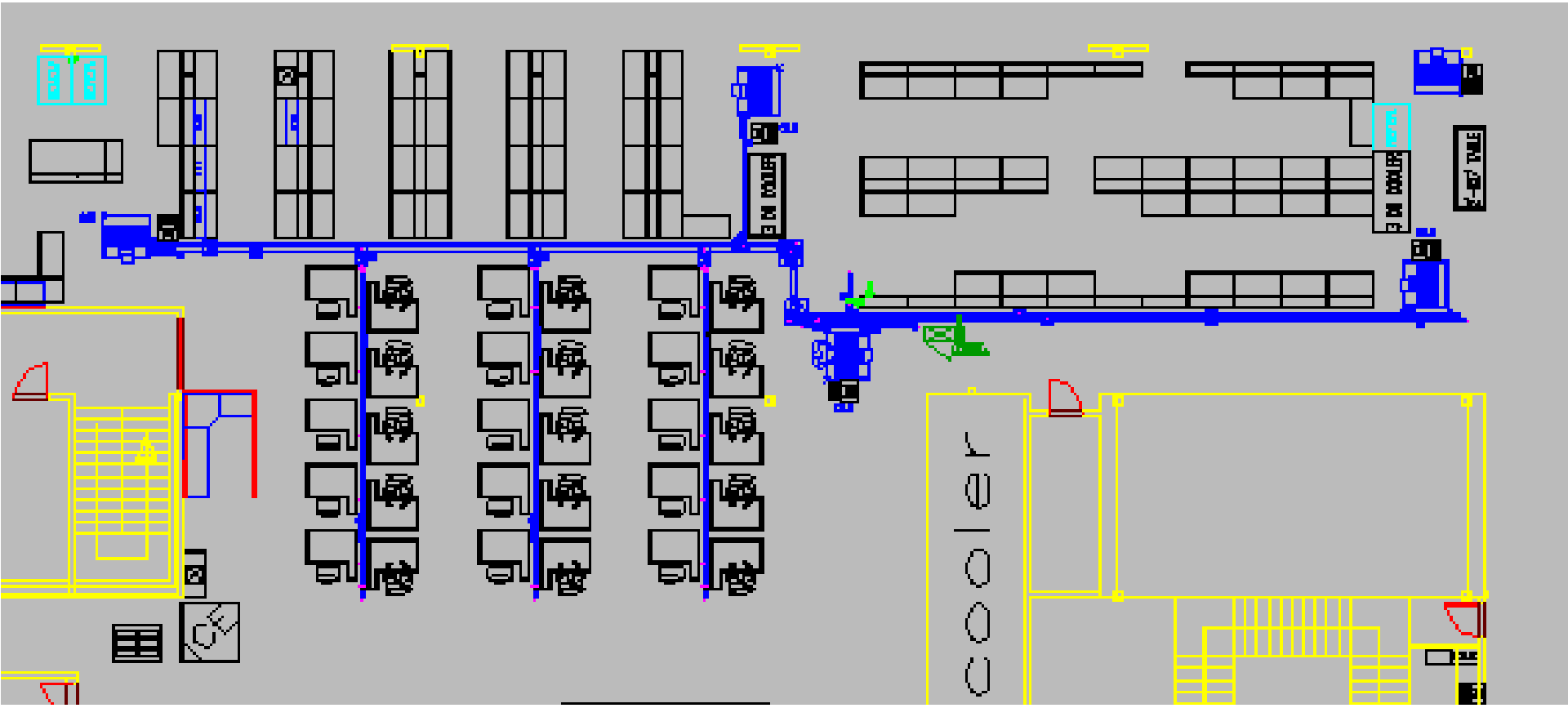
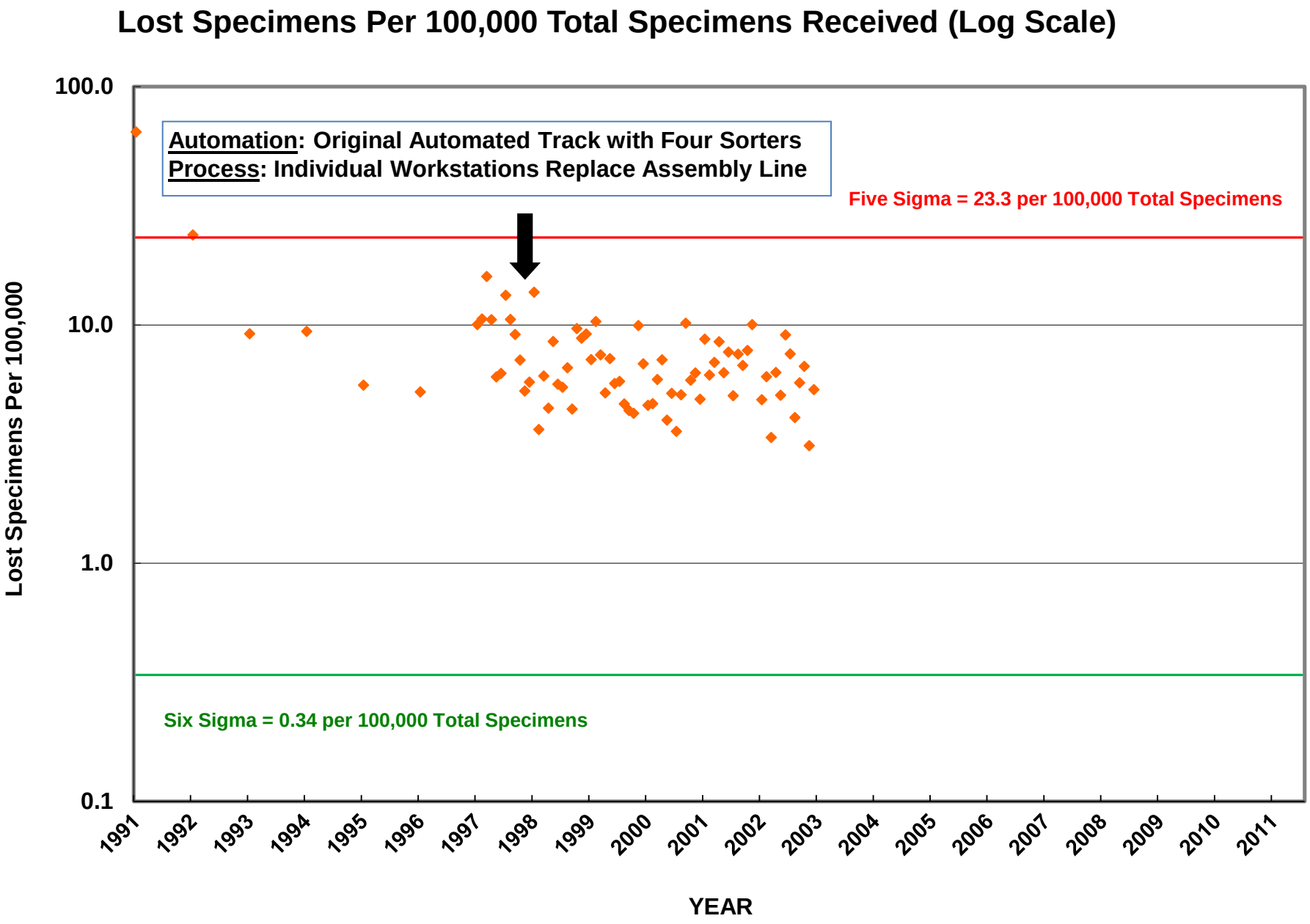
ARUP Automation, November 17, 1998
2000 specimens/hour, 30 workstations, 4 sorters




Lost Specimens Per 100,000 Total Specimens Received (Log Scale)
Automation: Original Automated Track with Four Sorters
Process: Individual Workstations Replace Assembly Line
Five Sigma = 23.3 per 100,000 Total Specimens
Six Sigma = 0.34 per 100,000 Total Specimens
Lost Specimens Per 100,000
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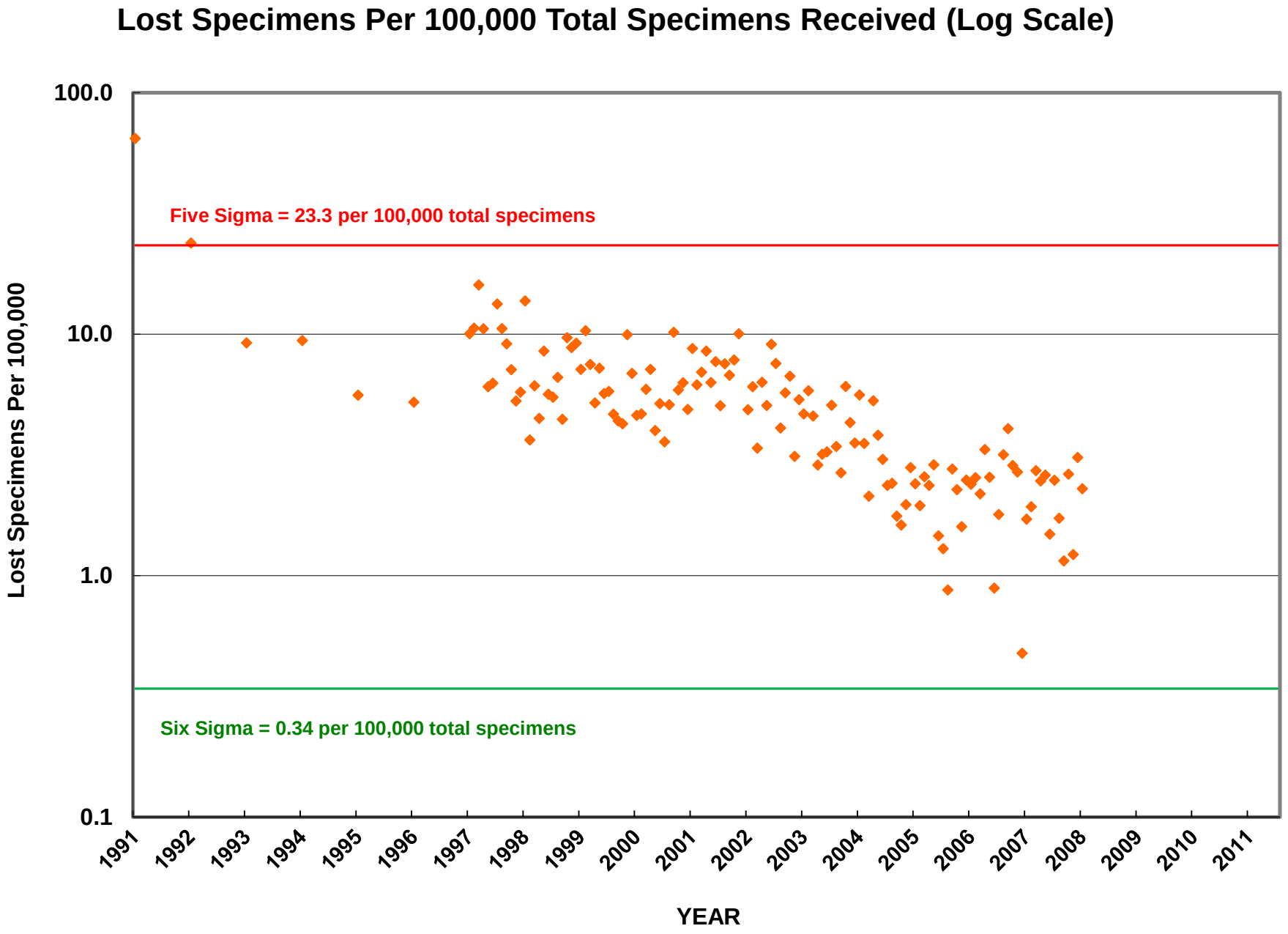
Lost Specimens Per 100,000 Total Specimens Received (Log Scale)
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Lost Specimens Per 100,000
Five Sigma = 23.3 per 100,000 total specimens
Six Sigma = 0.34 per 100,000 total specimens
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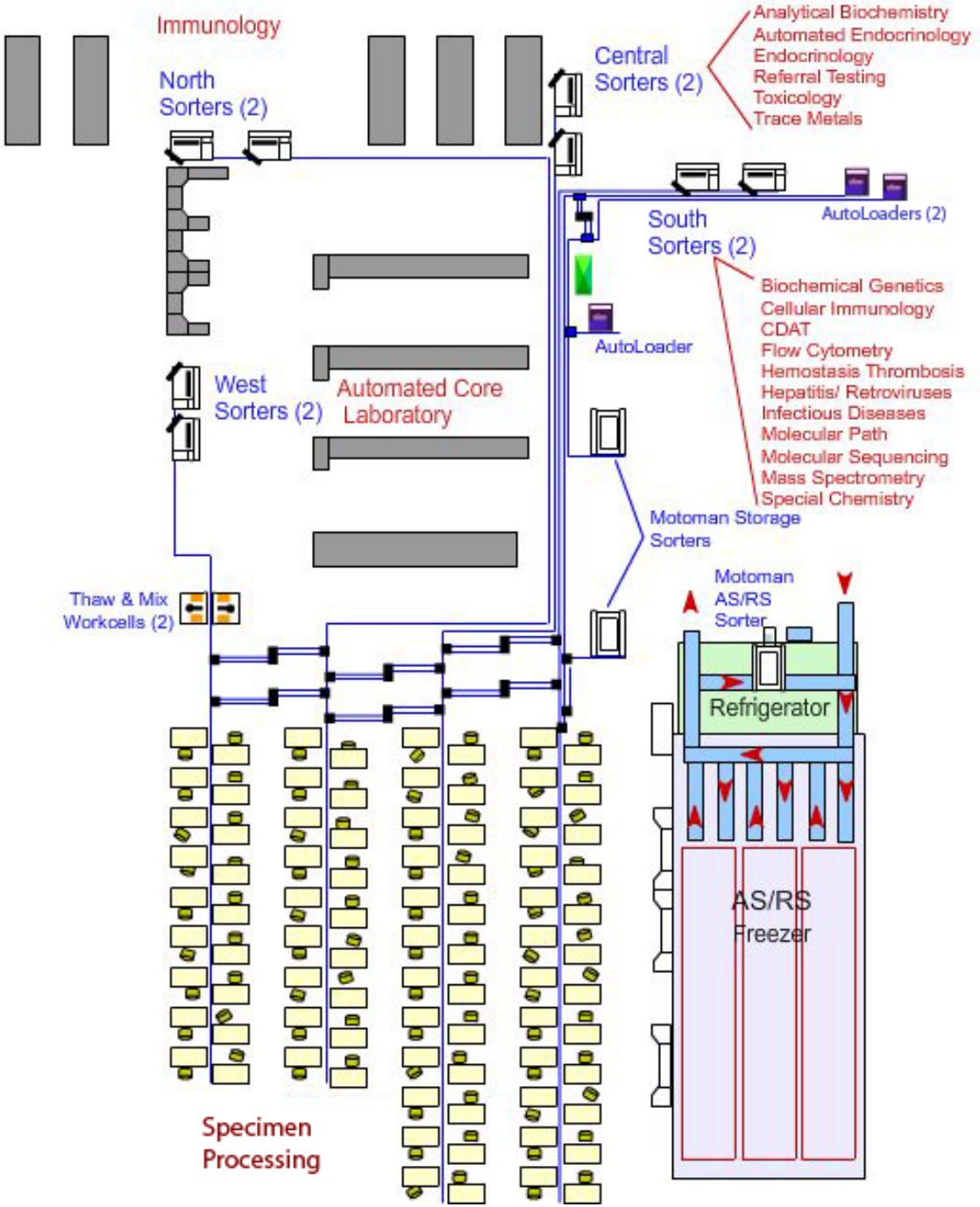
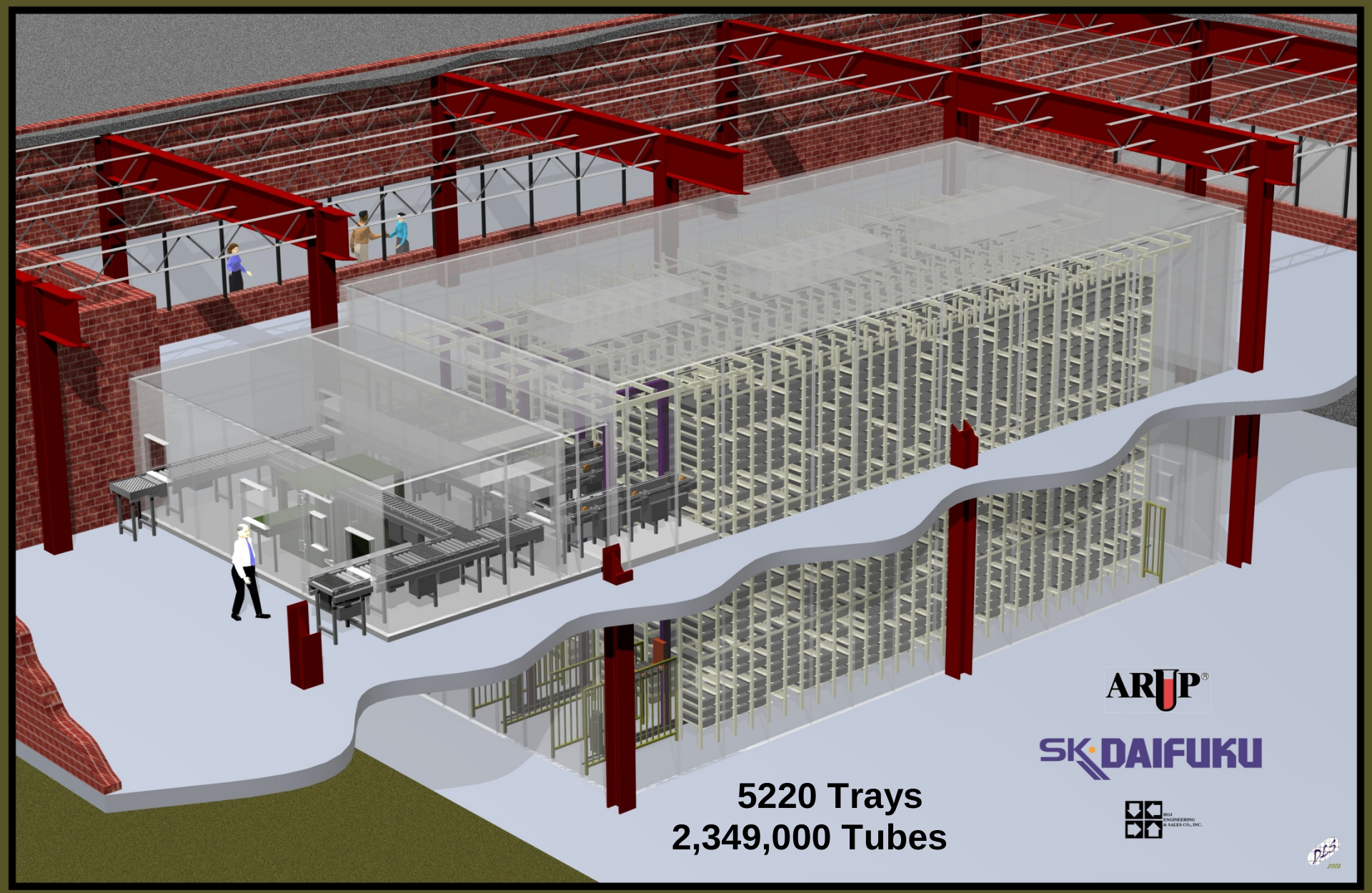
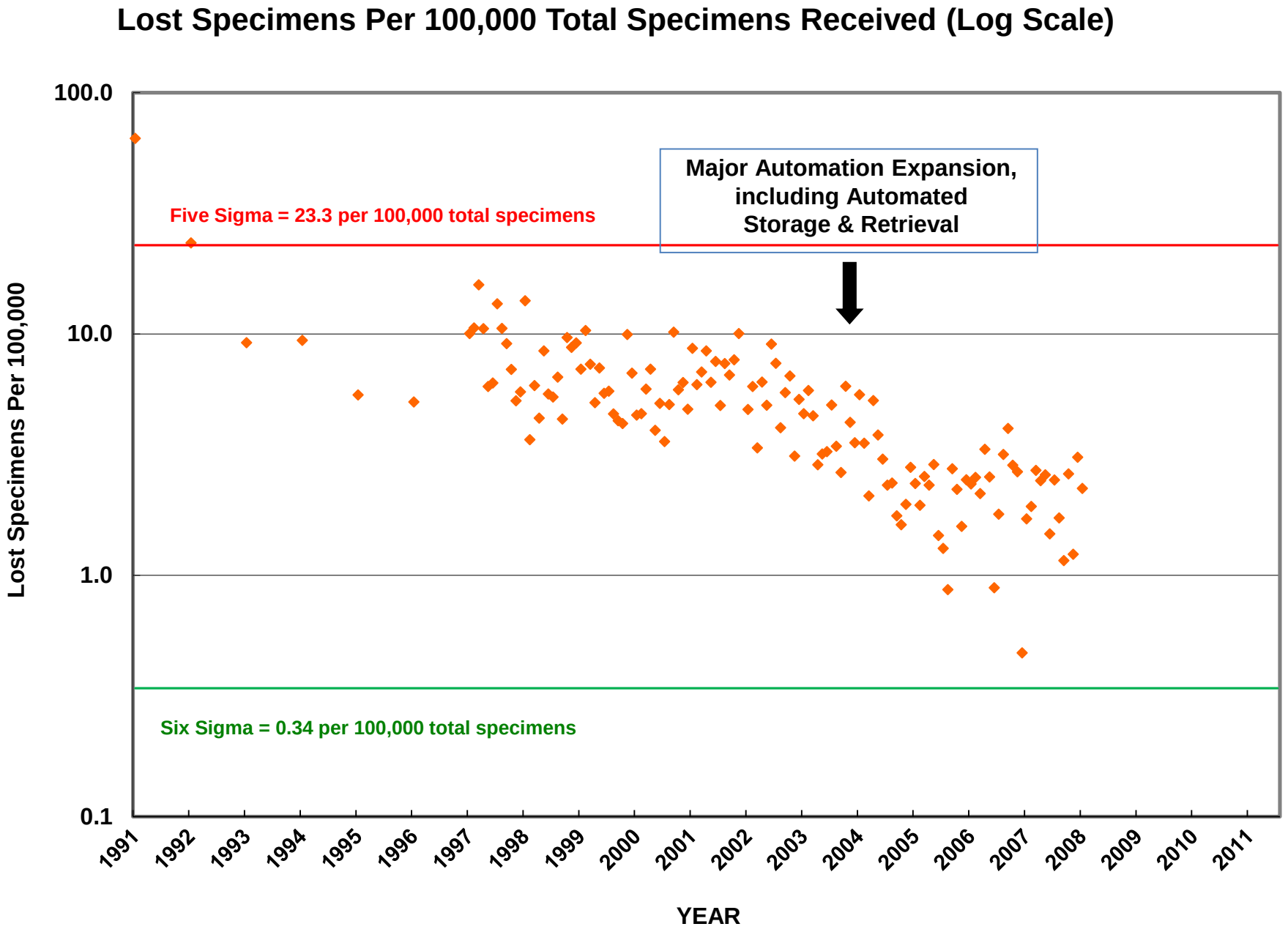

Immunology
North Sorters (2)
Central Sorters (2)
Analytical Biochemistry
Automated Endocrinology
Endocrinology
Referral Testing
Toxicology
Trace Metals
AutoLoaders (2)
South Sorters (2)
Biochemical Genetics
Cellular Immunology
CDAT
Flow Cytometry
Hemostasis Thrombosis
Hepatitis/ Retroviruses
Infectious 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


Lost Specimens Per 100,000 Total Specimens Received (Log Scale)
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Lost Specimens Per 100,000
Five Sigma = 23.3 per 100,000 total specimens
Major Automation Expansion, including Automated Storage & Retrieval
Six Sigma = 0.34 per 100,000 total specimens
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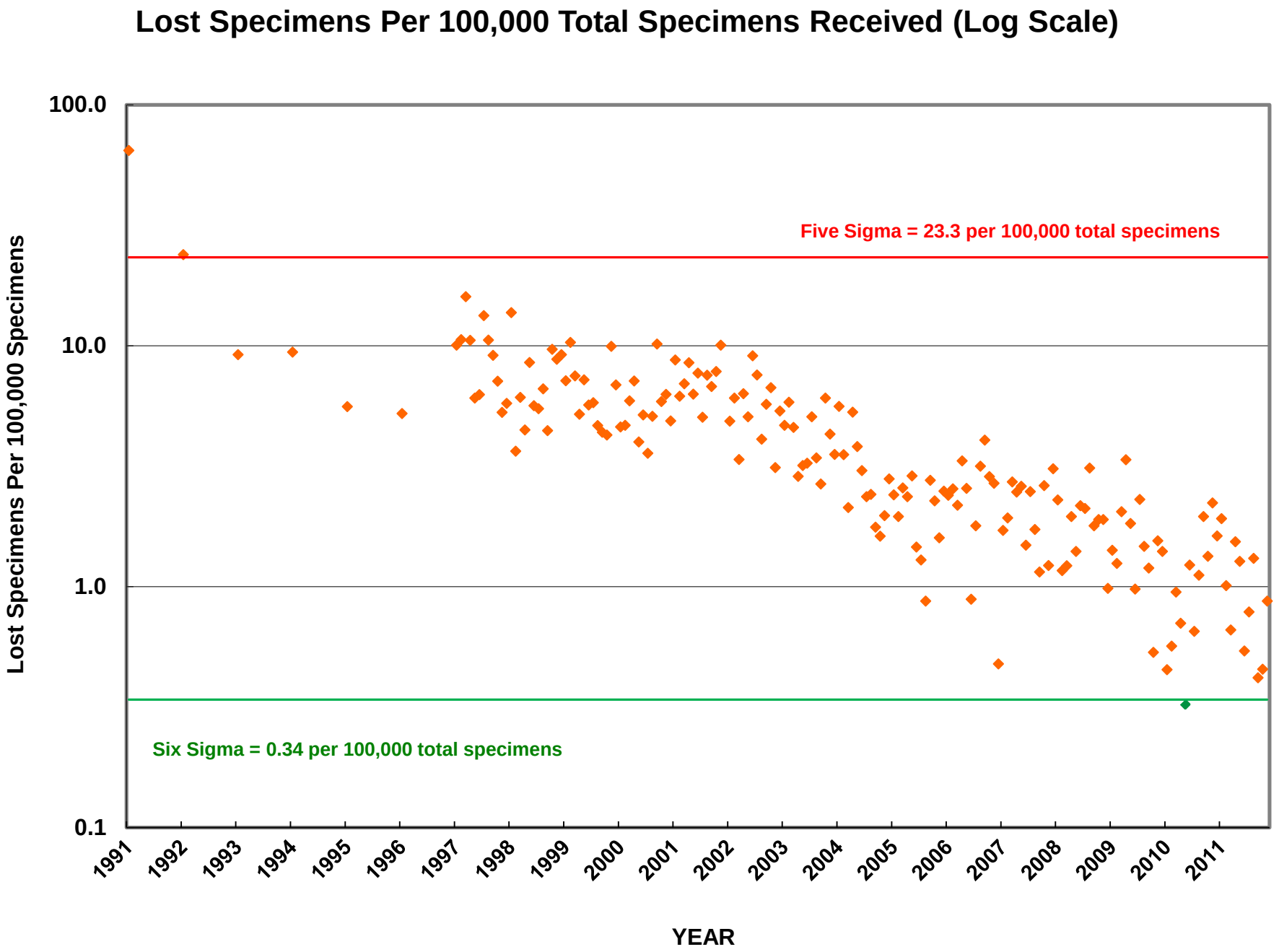
Lost Specimens Per 100,000 Total Specimens Received (Log Scale)
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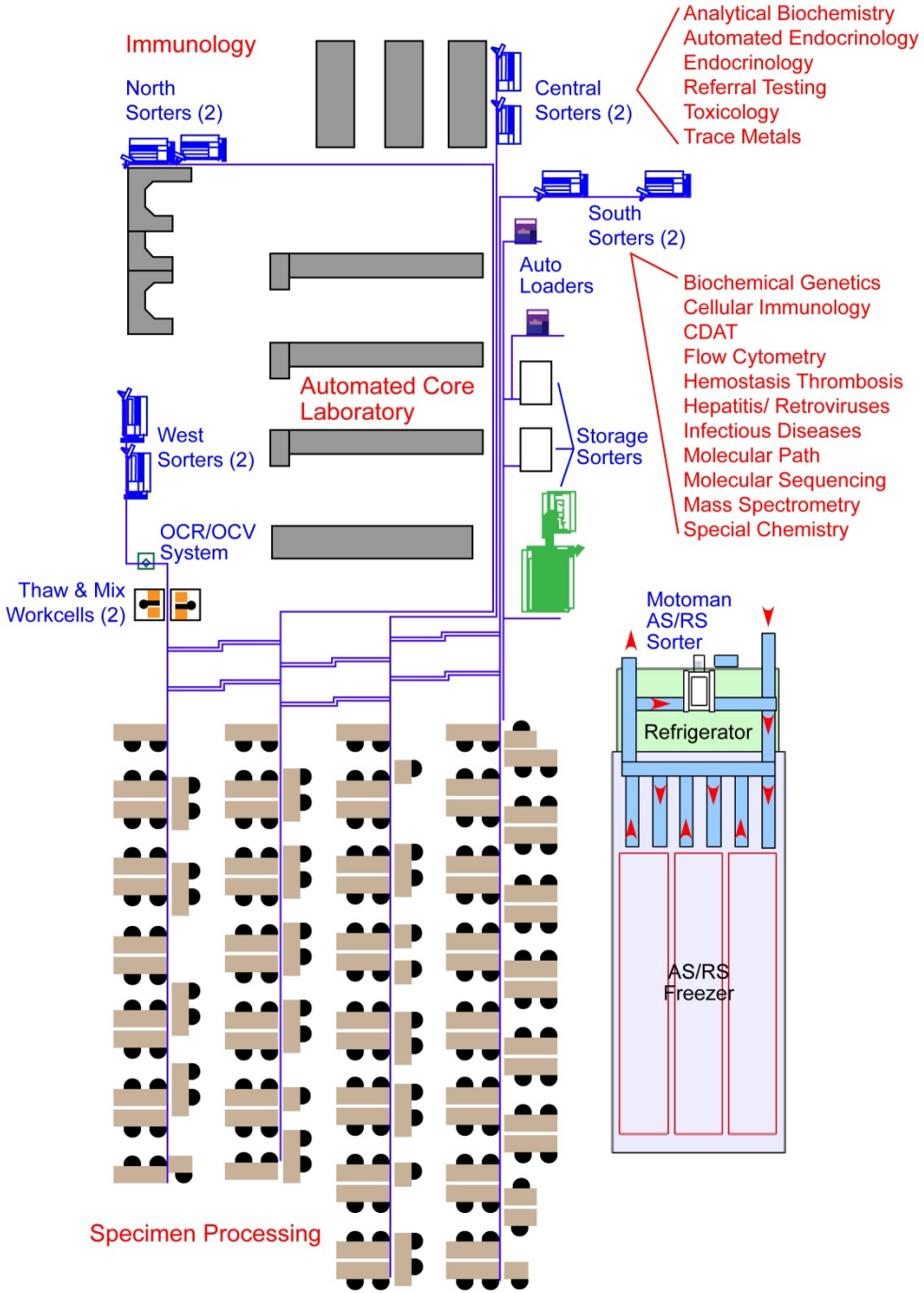
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Trace Metals
South
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Auto
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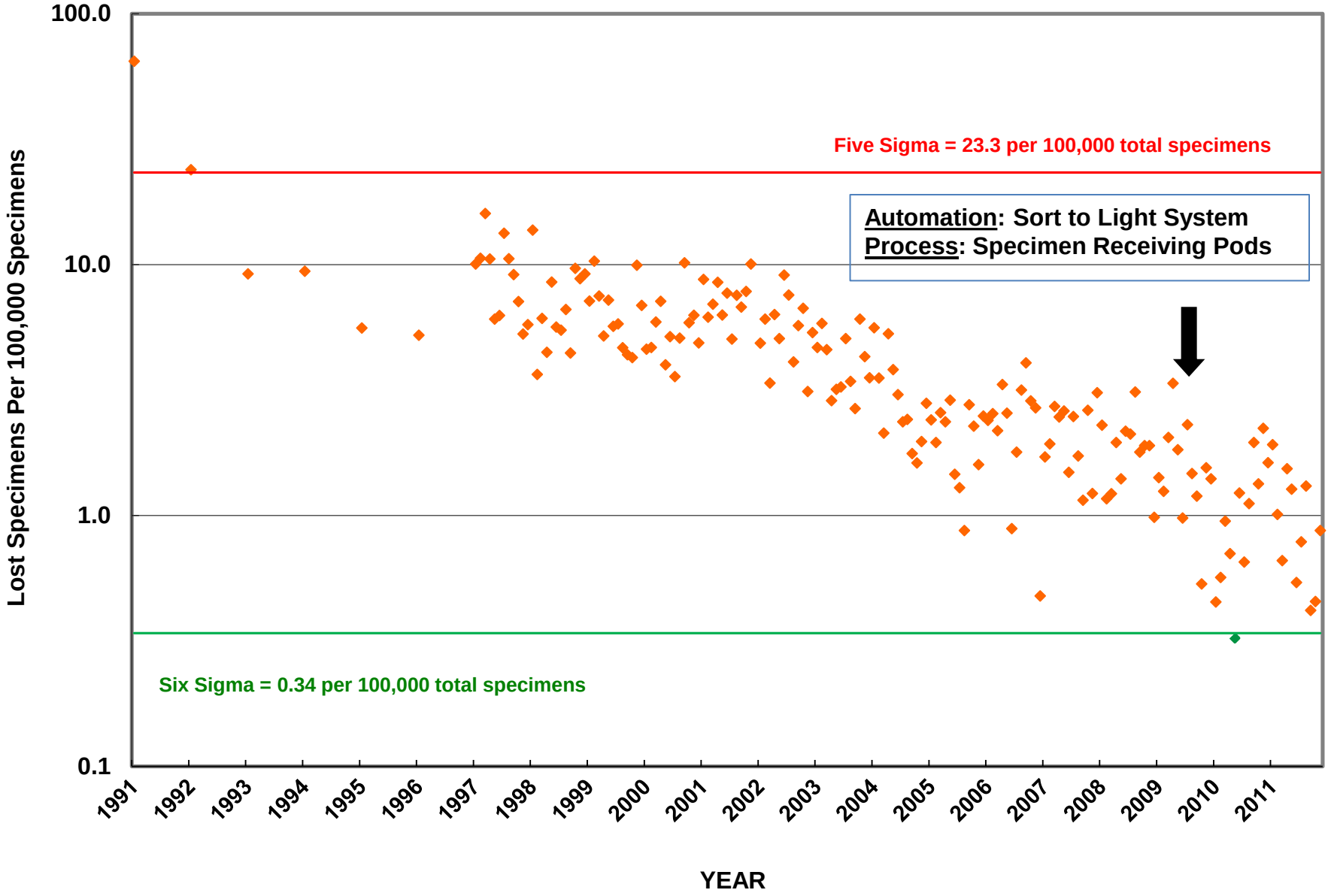
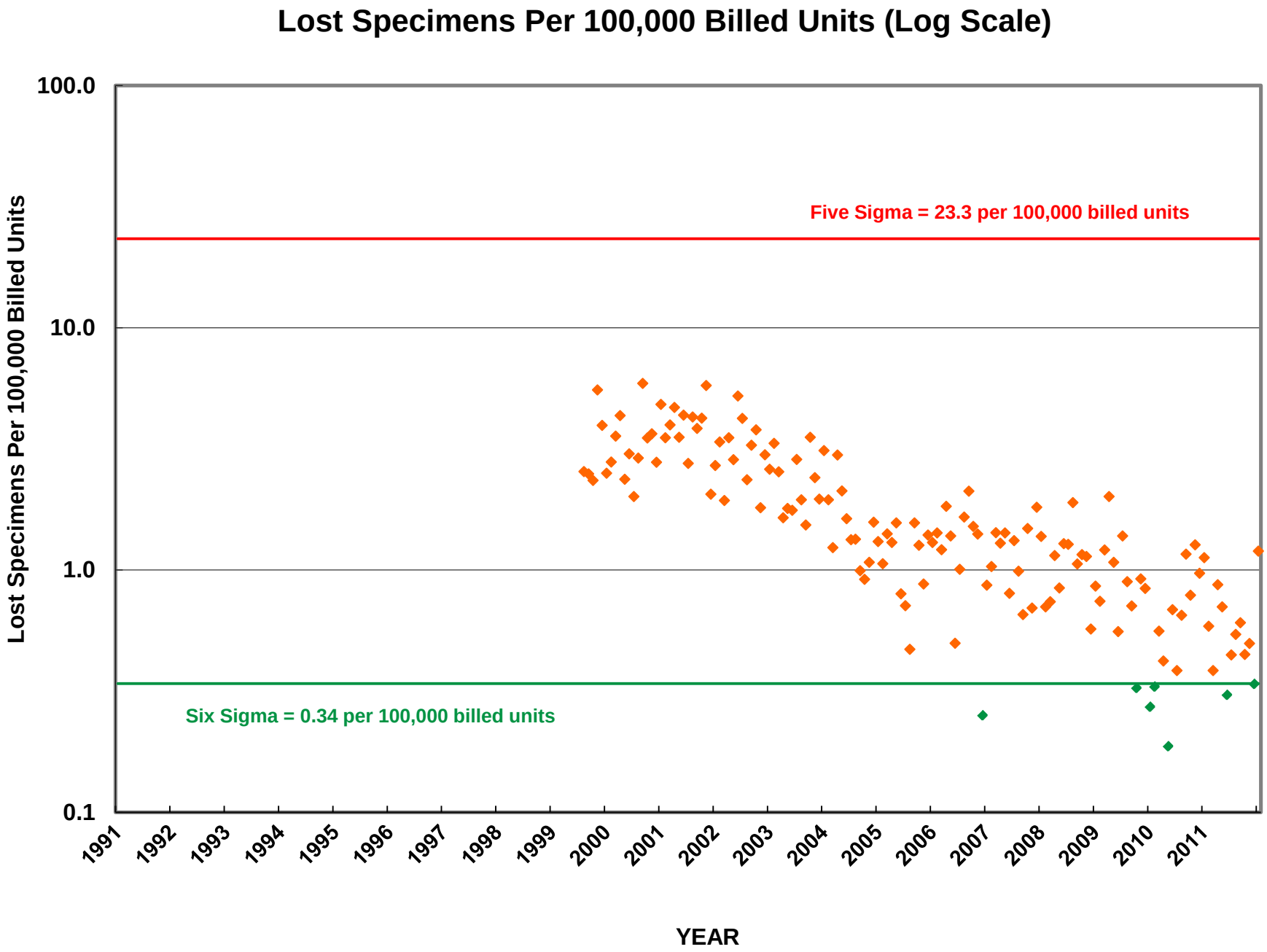
Biochemical Genetics
Cellular Immunology
CDAT
Flow Cytometry
Hemostasis Thrombosis
Hepatitis/ Retroviruses
Infectious Diseases
Molecular Path
Molecular Sequencing
Mass Spectrometry
Special Chemistry
Automated Core
Laboratory
West
Sorters (2)
Storage
Sorters
OCR/OCV
System
Thaw & Mix
Workcells (2)
Motoman
AS/RS
Sorter
Refrigerator
AS/RS
Freezer
Specimen Processing

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



Six-Sigma

- 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.
- At ARUP, each specimen has an average of 1.6 billed units (or tests). Each test represents a separate handling of the specimen and is thus an opportunity to lose the specimen.
- Therefore, for Six-Sigma assessment of lost specimens, using total billed units as a denominator is more correct than using total specimens.


Lost Specimens Per 100,000 Billed Units (Log Scale)
Lost Specimens Per 100,000 Billed Units
100.0
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Five Sigma = 23.3 per 100,000 billed units
Six Sigma = 0.34 per 100,000 billed units
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Mislabeled Specimens in the US and ARUP

- Mislabeled lab specimens are a significant element of US patient errors, ranging from 0.04% to 5% in different studies.
- In an early CAP Q-Probe study of 120 reporting institutions, Valenstein and Raab, et al, [*Arch Pathol Lab Med*. 2006;130:1106–1113] reported a median incidence of mislabeled specimens of 0.39 per 1000.
- Another CAP Q-Probe study of 147 reporting US clinical labs showed an average incidence of mislabeled specimens of 0.9 per 1000 [Wagar, et. al., *Arch Pathol Lab Med* 2008; 132(10):1617-22].
- A third CAP Q-Probe study of 122 reporting US blood banks showed an average incidence of 1.12% mislabeled specimens [Grimm, et. al., *Arch Pathol Lab Med* 2010; 134(8):1108-15].
- At ARUP, our historic measured error rate in Specimen Processing has been ~1 per 10,000, or about 1/4 to 1/10 the above published US error rates. Of those, we believed that our “down stream” inspections in the lab sections were finding and correcting ~95%.

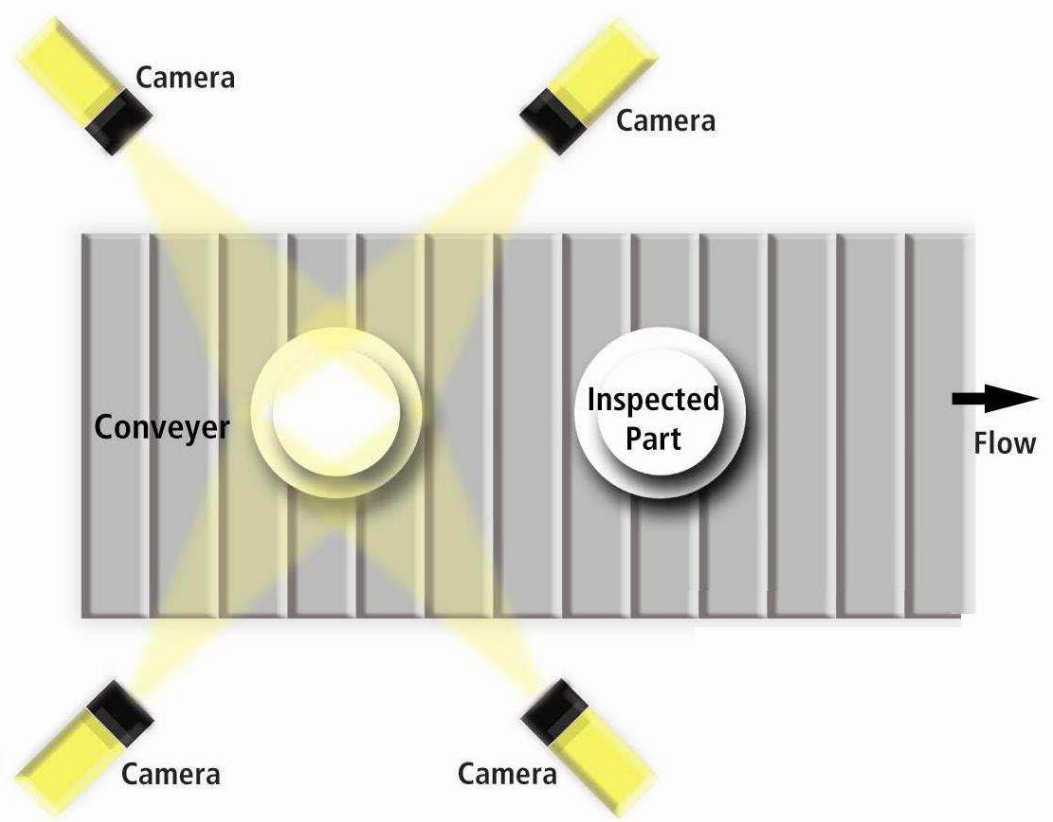
The Cost of A Mislabeled Specimen

- According to a published citation (Kahn, et al 2005*), the average total of hypothetically incurred charges of a mislabeled specimen is $712 at 2005 cost levels, not including patient anxiety and discomfort and delays in diagnosis and treatment, had the patients or payers been billed for any required additional charges to resolve the mislabeled specimen. They were not actual incurred costs.
- Per the CAP website cited below, if the median estimate of Valenstein and Raab (previous slide) of 0.39 mislabeled specimens per 1000 is multiplied by the $712 in hypothetical costs, misidentified specimens can add as much as $280,000 in costs to the healthcare system for each million specimens tested.

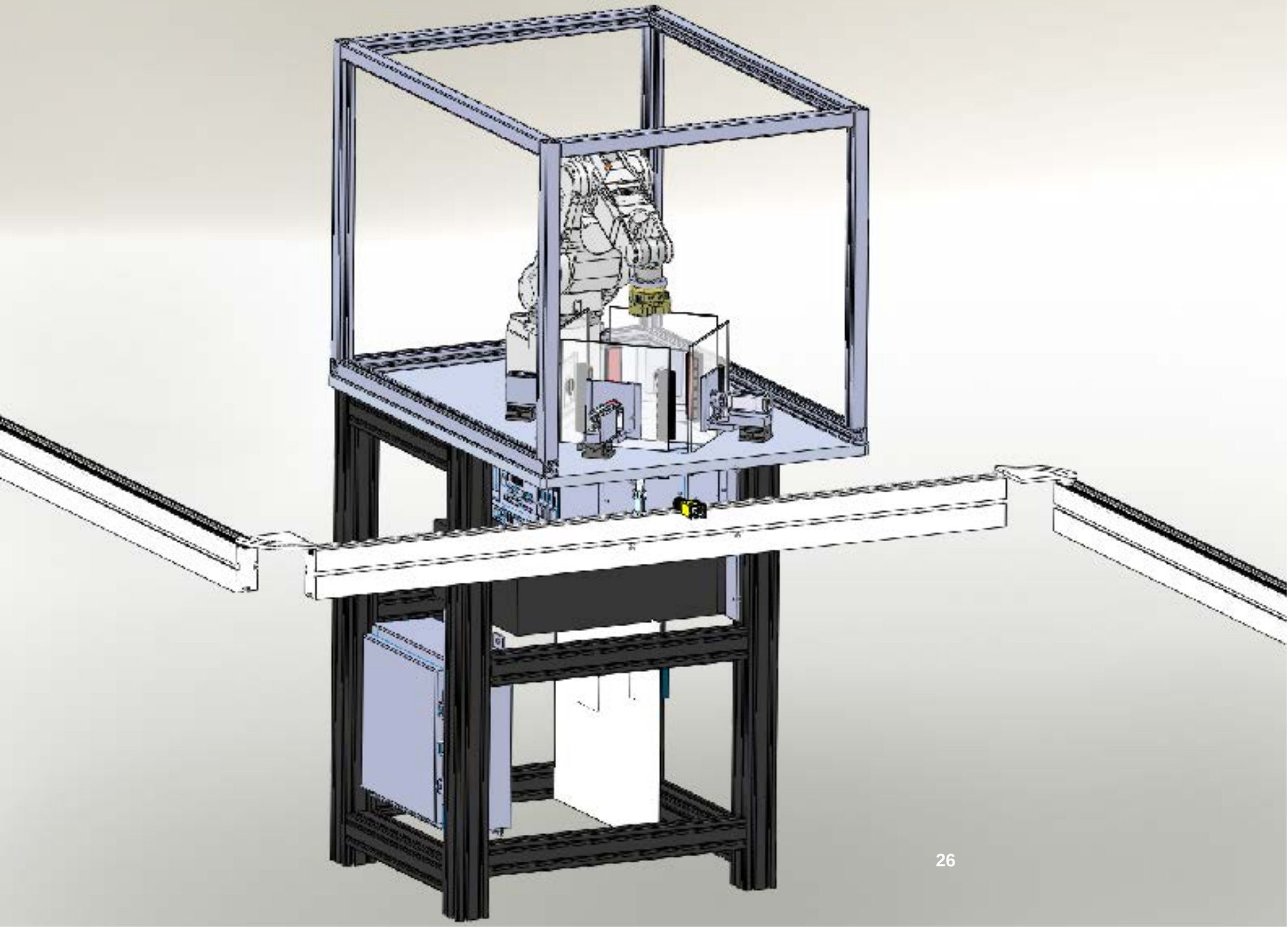
*http://www.cap.org/apps/portlets/contentViewer/show.do?printFriendly=true&contentReference=practice_management%2Fdirectips%2Fmislabeled_specimens.html

Or: *Laboratory Medical DirecTIPs*, February 23, 2010, The Problem of 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.



How the OCR System Classifies Images

- If a character string is found on the client label that is an exact match for what is in the patient name field in the LIS, the image is a “pass.”
- If there is only a single label on the specimen tube, the image is an automatic pass (pass as a single).
- If no exactly matching character string can be found on the client label, the image is a “fail.”
- There are many reasons for fails – poor label quality, unusual fonts, name partially covered by handwriting or by the ARUP label, truncations, names turned 90°, colored labels, striped labels, etc.
- Human inspection of all fails is required.

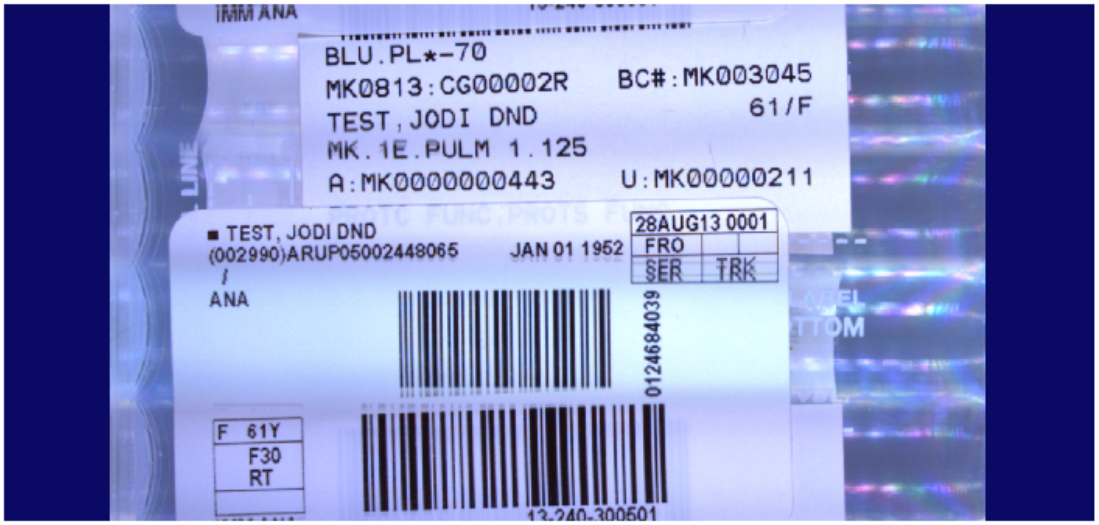
Label Inspection Result is “Pass”

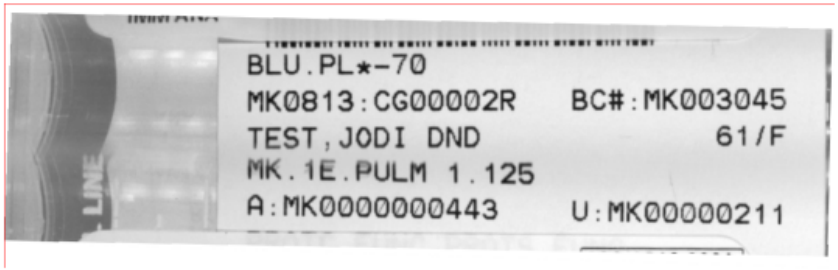
ARUP Vision Inspection Application

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
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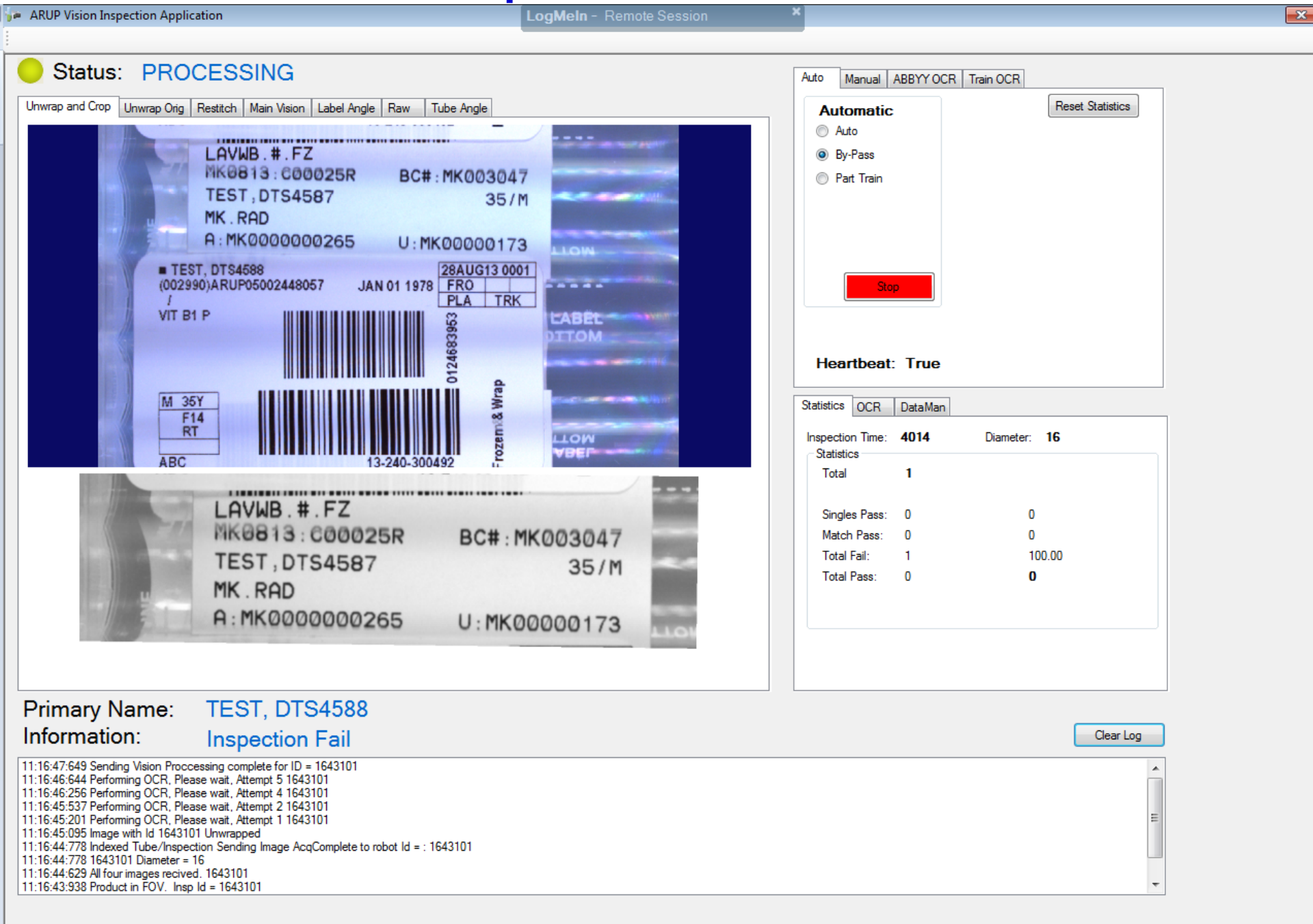
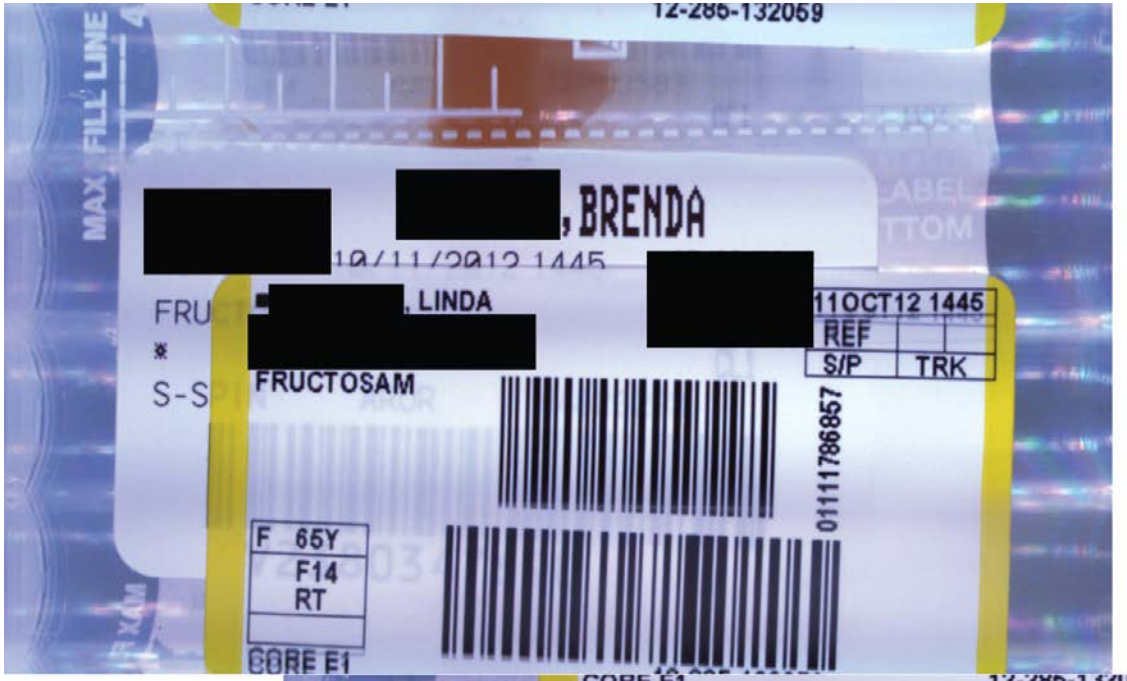
Label Inspection Result is “Fail”



First Mislabeled Specimens Caught by the OCR System



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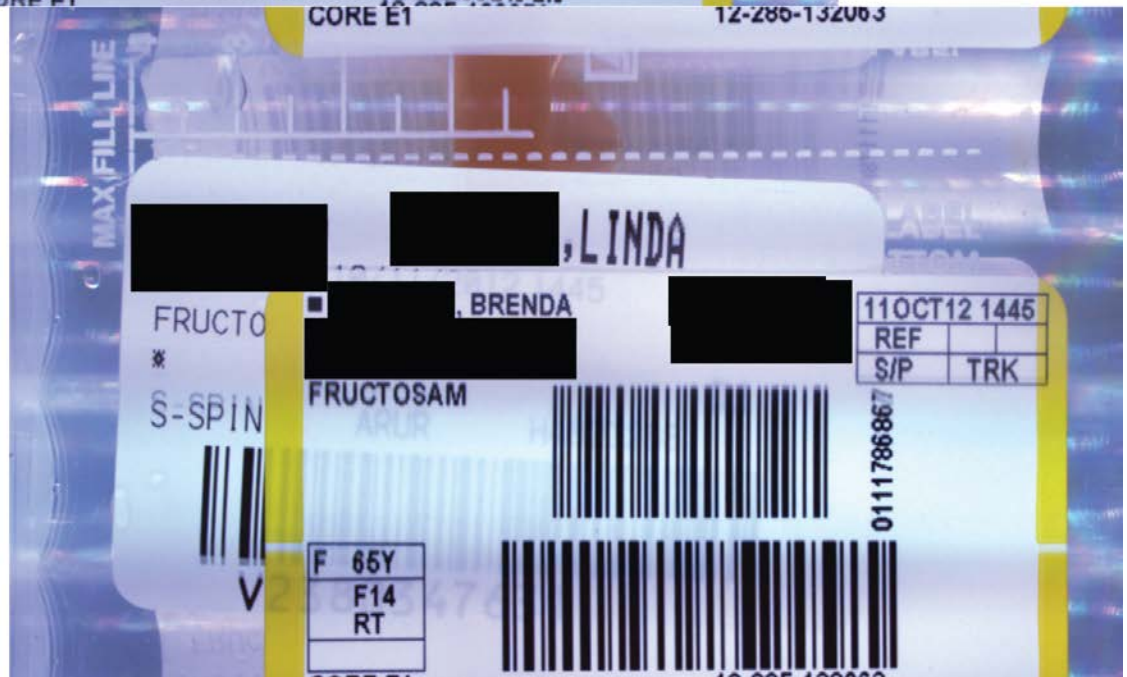


B

Objectives of Validation Study

- Minimize the total number of tubes that fail due to label quality, font training, incorrect positioning of ARUP label over client label, etc. (FALSE FAILS). All fails require human inspection (manual work). Target 20%
- In other words, maximize the correctly labeled tubes that are that are passed by the system (TRUE PASSES). Target 80%
- Guarantee that all mislabeled tubes will be failures (TRUE FAILS) and manually inspected. Target 100%
- Guarantee that no mislabeled tubes will ever be automatically passed (FALSE PASSES). Target 0%

Validation Study

- Images for 1,009,830 specimens (the goal was one million) were obtained as of May 31. **Every image was reviewed**.
- The OCR system's "pass" rate of specimen labels on which the patient name can be optically read and verified by the system is ~75%. Long term we expect to achieve >80%.
- **No false passes** i.e., no mislabeled specimens were passed by the system out of 742,977 passes.

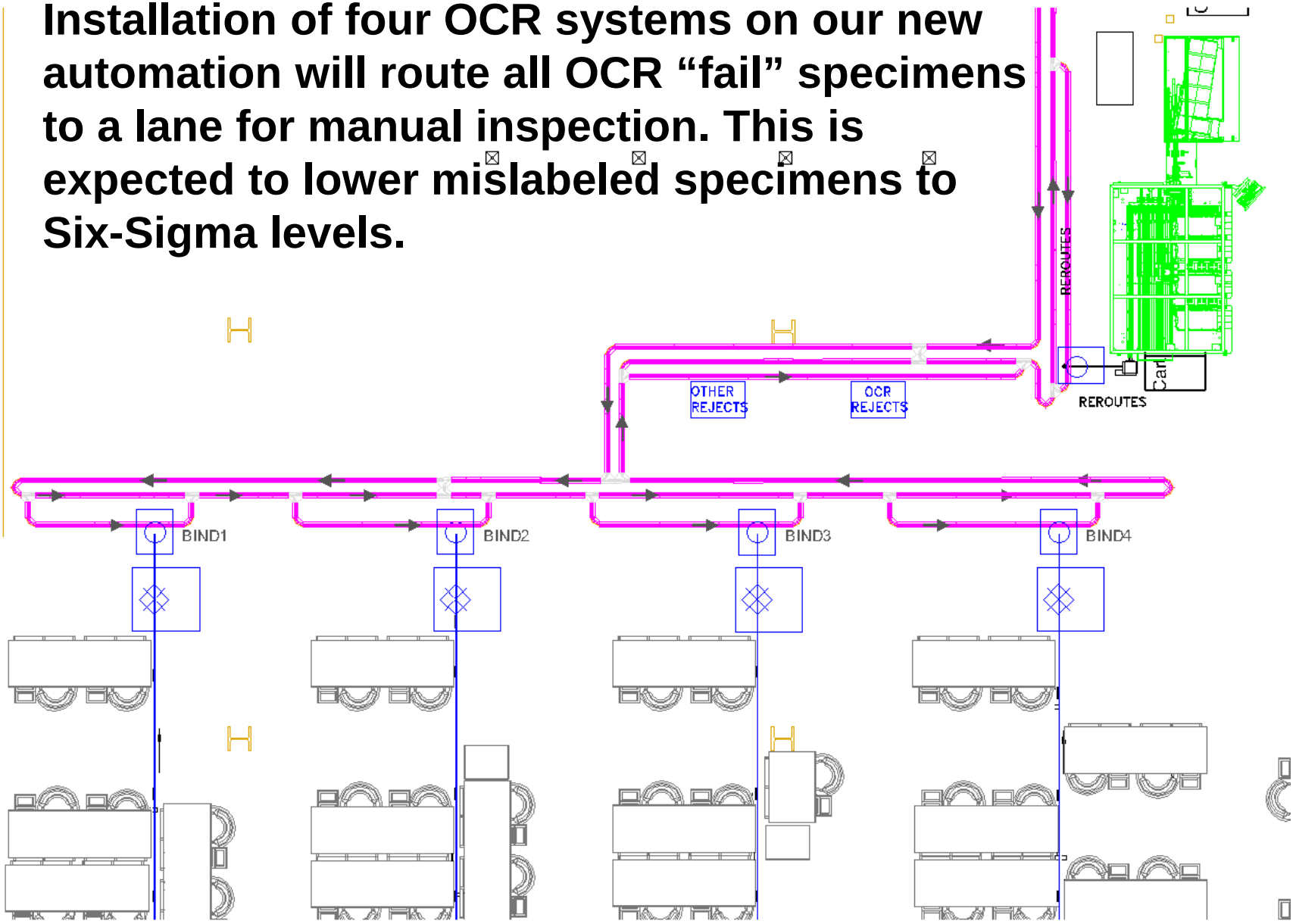
Mislabeled Specimens in the Validation Study

- Among the images “failed” by the system, 121 mislabeled specimens were found (1 per 8346), somewhat higher than the 1/10,000 expected based on historical data.
- Of these 121 mislabels, 71 were found by the testing lab or editors before testing. Investigations for possible corrected reports were initiated on 46 errors not found prior to testing. A total of 21 corrected reports were sent to clients, a rate lower than expected based on prior data.
- An additional 148 specimens were identified as “mismatched.” The patient was correct, but a spelling discrepancy in the name requires (per our policy) that the client to be called to verify that the patient and spelling are correct. Only 46 of these minor errors were found by editors prior to testing.

Current Results

- With the validation study now complete, “pass” images are no longer reviewed – only “fail” and “single” images.
- As of September 7th, 1,593,078 images have been collected.
- Of these, there have been 199 mislabels, a ratio of 1 per 8005 specimens. Only 100 were found by the testing lab or S.P. employees before testing.
- An additional 368 specimens were identified as “mismatched.” Only 107 of these minor errors were found prior to testing.
- A total of 25 corrected reports have been sent to clients. Of these, 17 were specimens sent to a high volume lab section (prior to Feb. 18); the other 8 (since Feb. 18) were sent to a lower volume lab, for which the OCR results prevented errors.
- These results suggest that prompt review of OCR images could lead to zero corrected reports for all OCR-inspected specimens.

Installation of four OCR systems on our new automation will route all OCR “fail” specimens to a lane for manual inspection. This is expected to lower mislabeled specimens to Six-Sigma levels.



CLSI Standard AUTO12-A on Label Formats

Ranganathan, Shiyali R

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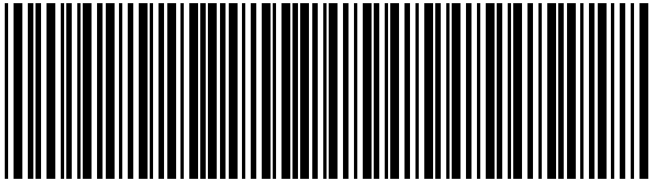

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Comp. Chem, Mg, Osm, Li

STAT CHEMISTRY

Ranganathan, Shiyali R

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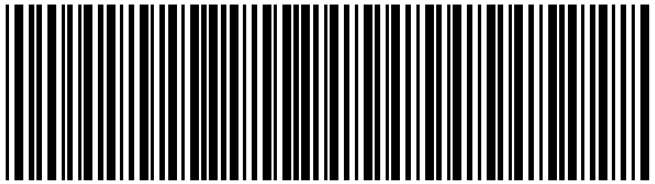

HM-09-132-00234*0000043456753

Col: 05-MAY-2009 17:43 Site:L Arm byID0047

Comp. Chem, Mg, Osm, Li

What You Can Do In Your Lab

- Reducing lost specimens is about tracking, even without automation.
- The LIS can be used to track specimens from Specimen Processing (*Central Collect* status) to lab sections (*In Lab* status). It requires an extra bar code read in the labs to verify the receipt of the specimen.
- For specimens being transported to the lab from clinics or affiliated hospitals, consider using bar codes to create transfer lists.
- Require employees to “check out” specimens from a centralized storage system for archived specimens before giving them the location (box/rack #, row #, column #).
- Mislabeled specimens can be reduced by using a wireless bed-side phlebotomy system with LIS query that prints specimen labels after the patient’s wrist band bar code has been read.
- Mislabeled specimens can also be reduced by implementing CLSI Standard AUTO12-A on Specimen Label Formats.

Summary

- Our experience over 21 years in implementing process improvements and automation has led to a steady reduction in lost specimens to a level consistently below 1 per 100,000 billed units and, in some months, in the Six-Sigma region (≤ 0.34/100,000).
- 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 offered for laboratories that can offer opportunities to achieve meaningful reductions in error rates, without the cost of expensive automation projects.

Acknowledgements

- Bonnie Messinger, ARUP's Process Improvement Manager and a Six-Sigma Black Belt, whose insights into quality systems have been invaluable.
- William McCarthy, Senior Vision Solutions Engineer, Cognex Corporation, Natick, MA, who developed the vision system.
- Dave Cleveland, President, Custom Engineering Solutions, Fraser, CO, who constructed the robotic system.
- James Fuller, Maggie Redmond, and Amanda Leech, from ARUP's Specimen Processing Department, who have each reviewed tens of thousands of images.

Acknowledgements

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