Automation and Process Re-Engineering are Required to Achieve Six-Sigma Quality:

Our 27-Year History of Continuous Improvement

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Prior Publication

Some of the content of this presentation has been published:

Messinger BL, Rogers DN, Hawker CD. Use of automation and process improvement to achieve a Six Sigma level of nonanalytic quality. *J Appl Lab Med*, 2017, *2*(1):86-91.

Messinger BL, Rogers DN, Hawker CD, Automation and process re-engineering work together to achieve Six-Sigma quality: a 27-year history of continuous improvement. Lab Med. 2019; doi/10.1093/labmed/lmy081/5307617.

This presentation was also previously given at Lab Quality Confab, Atlanta, GA, Oct. 9, 2018.

Objectives

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

- Define various process improvement actions and describe 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.

Outline

1. Introduction
2. Eight automation stages
3. Nineteen process improvement steps
4. Results over 27 years
5. Conclusions

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	Mislabeled specimens Requisition order errors Sub-optimal specimens
1/100,000	The above plus standardization, error-proofing, elimination of fatigue & distractions	Lost specimens Corrected reports
1/1,000,000	The above plus automation, robotics, software enhancements, advanced process design	Bar code reading Interfaced result entry

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

Introduction, continued

- Six-Sigma quality is extremely difficult to achieve in pre- and post-analytic processes in clinical laboratories because there is so much manual handling and variation in inputs.

- Since our founding in 1983, our laboratory has monitored numerous quality indicators, both analytic and non-analytic (pre- and post-analytic).

Introduction, continued

- One indicator, lost samples, has shown continuous improvement over the past 27 years as a result of extensive automation and process re-engineering and in a number of months has exceeded Six-Sigma levels.

- In summary, in order to achieve Six-Sigma quality, we believe both automation and process re-engineering are required.

Automation Stages

A. 1998 The first track (MDS AutoLab)

B. 2003 Two story freezer automated storage and retrieval system (AS/RS)

C. 2004 Major expansion of track system

D. 2004 Two Motoman storage sorting robots

Automation Stages

E. 2006 — Addition of four sorters to track

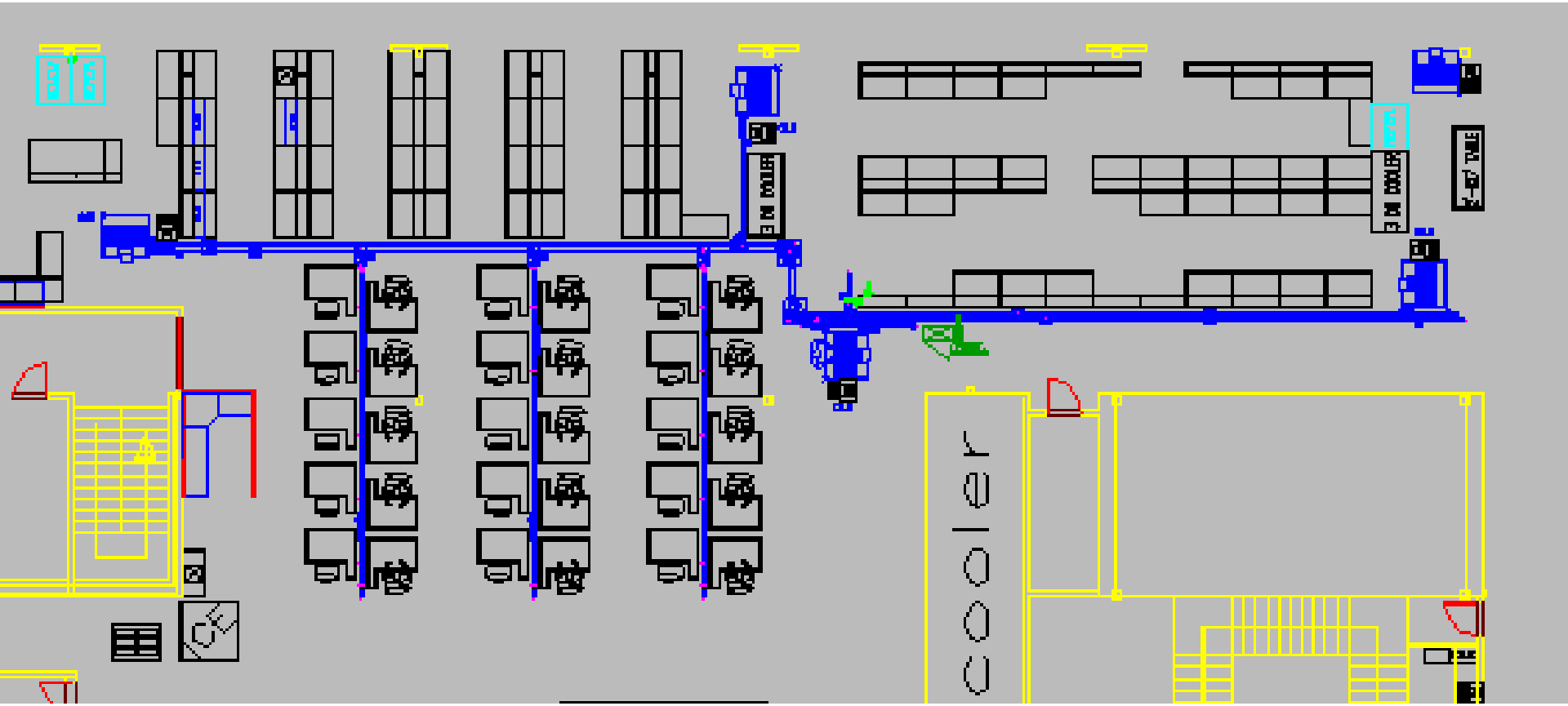
F. 2009-10 — *Sort-to-Light* automated system for sorting manual specimens

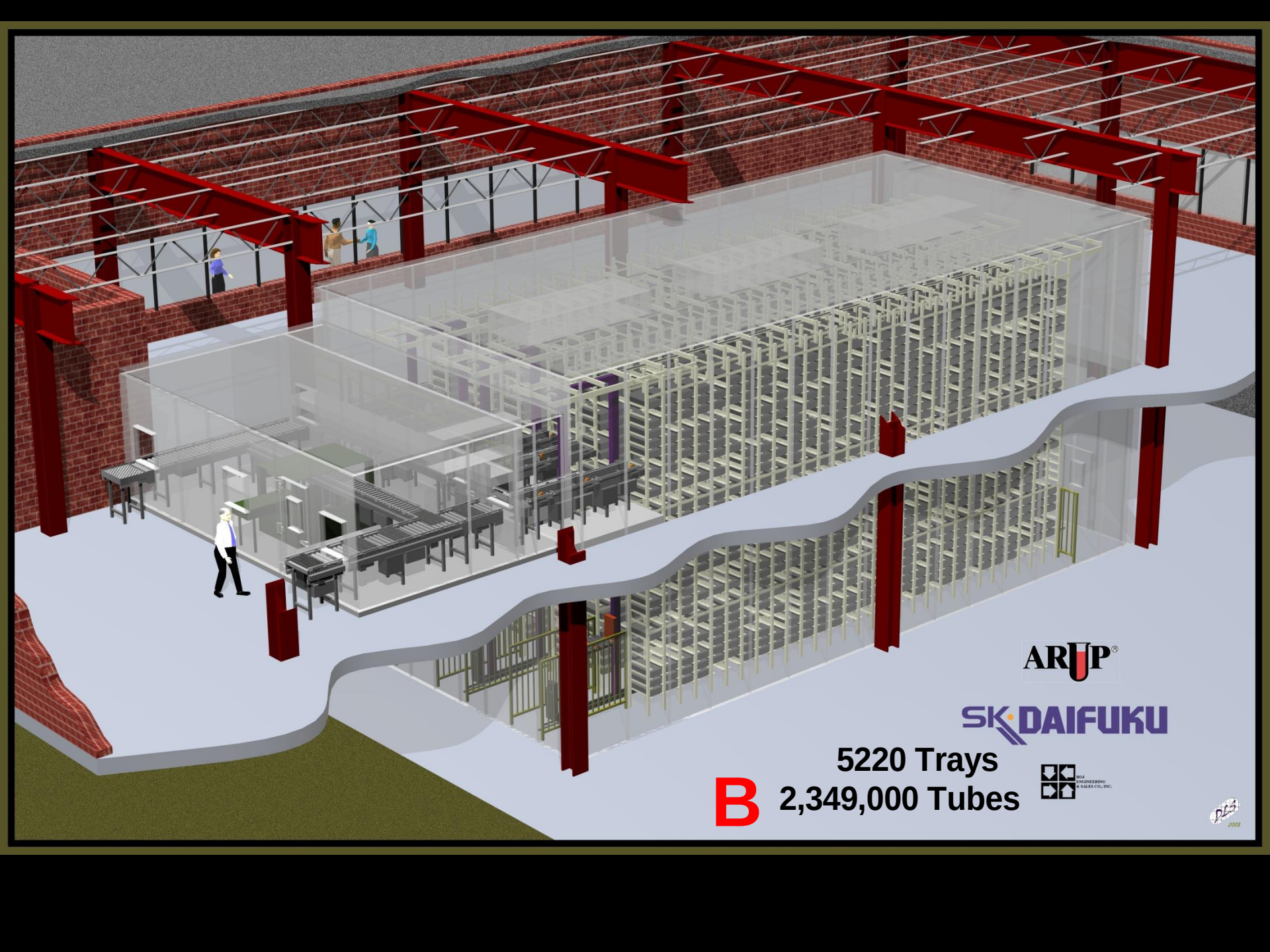
G. 2010 — ATS 4000 per hour automated storage sorter

H. 2014 — New track system: MagneMotion MagneMover LITE® with 20 robots

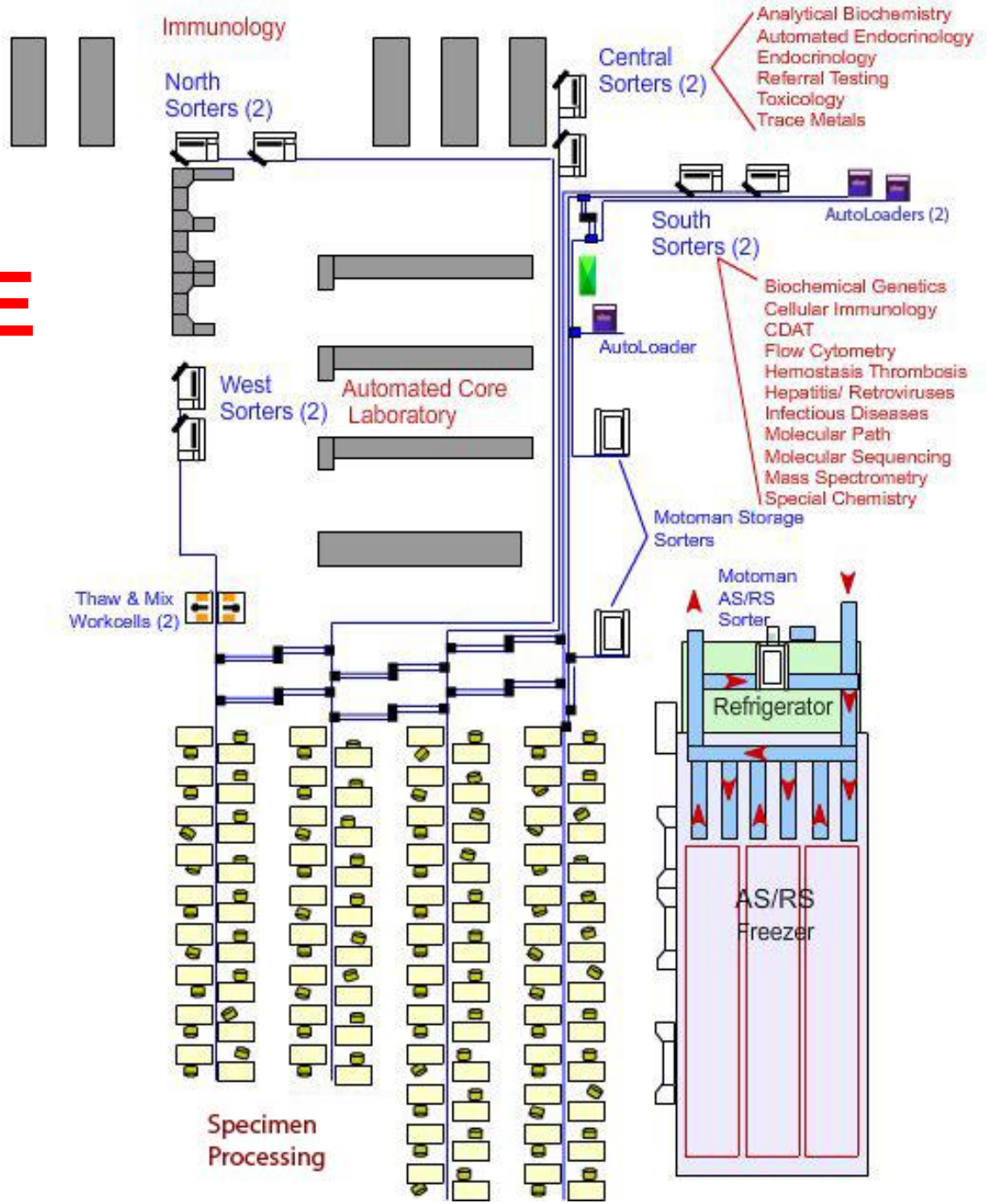
A ARUP Automation, November 17, 1998

2000 specimens/hour, 30 workstations, 4 sorters




ARUP
SK DAIFUKU
5220 Trays
B
2,349,000 Tubes

C, D, E


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

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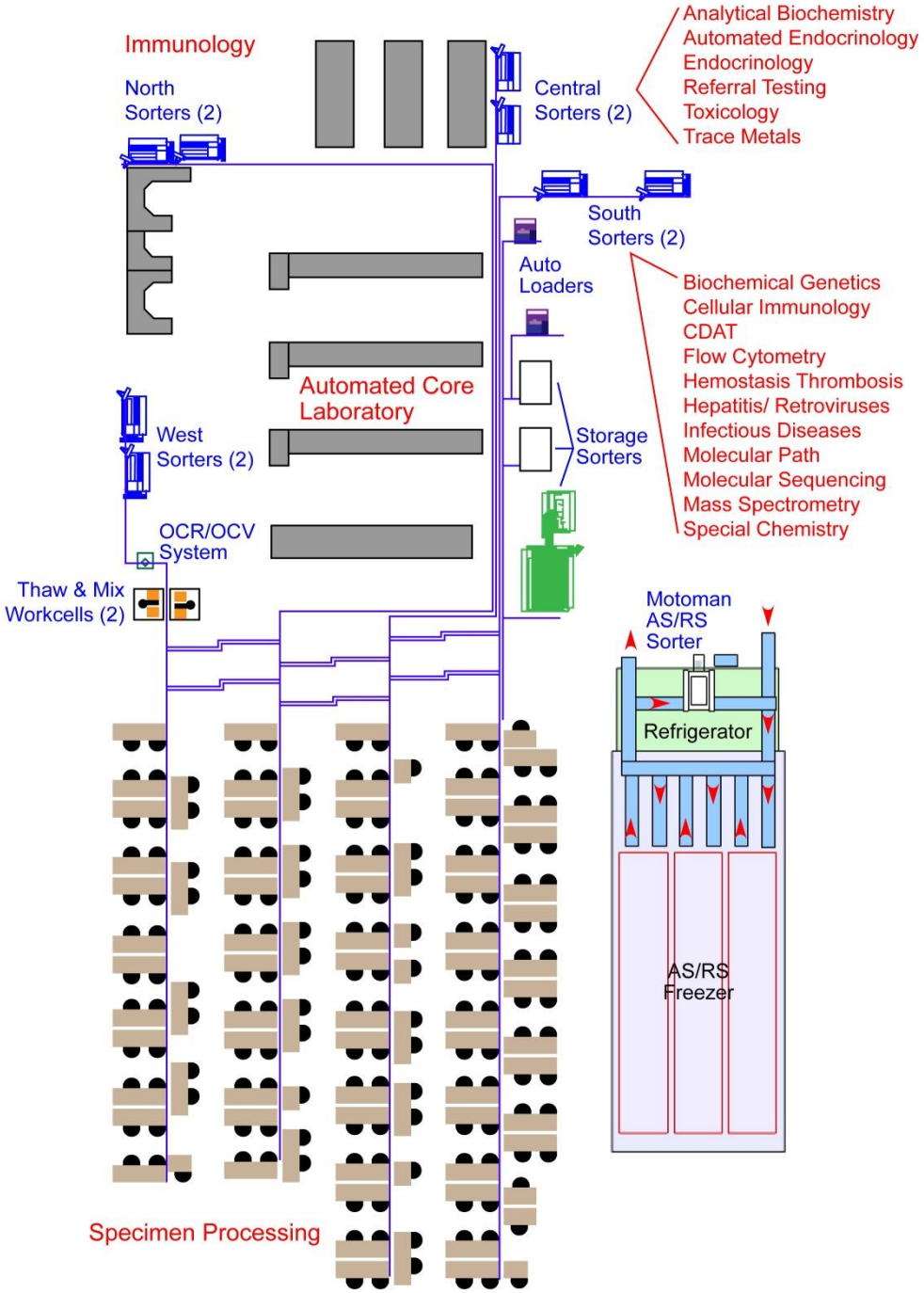
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Toxicology
Trace Metals
South
Sorters (2)
Auto
Loaders
Biochemical Genetics
Cellular Immunology
CDAT
Flow Cytometry
Hemostasis Thrombosis
Hepatitis/ Retroviruses
Infectious Diseases
Molecular Path
Molecular Sequencing
Mass Spectrometry
Special Chemistry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

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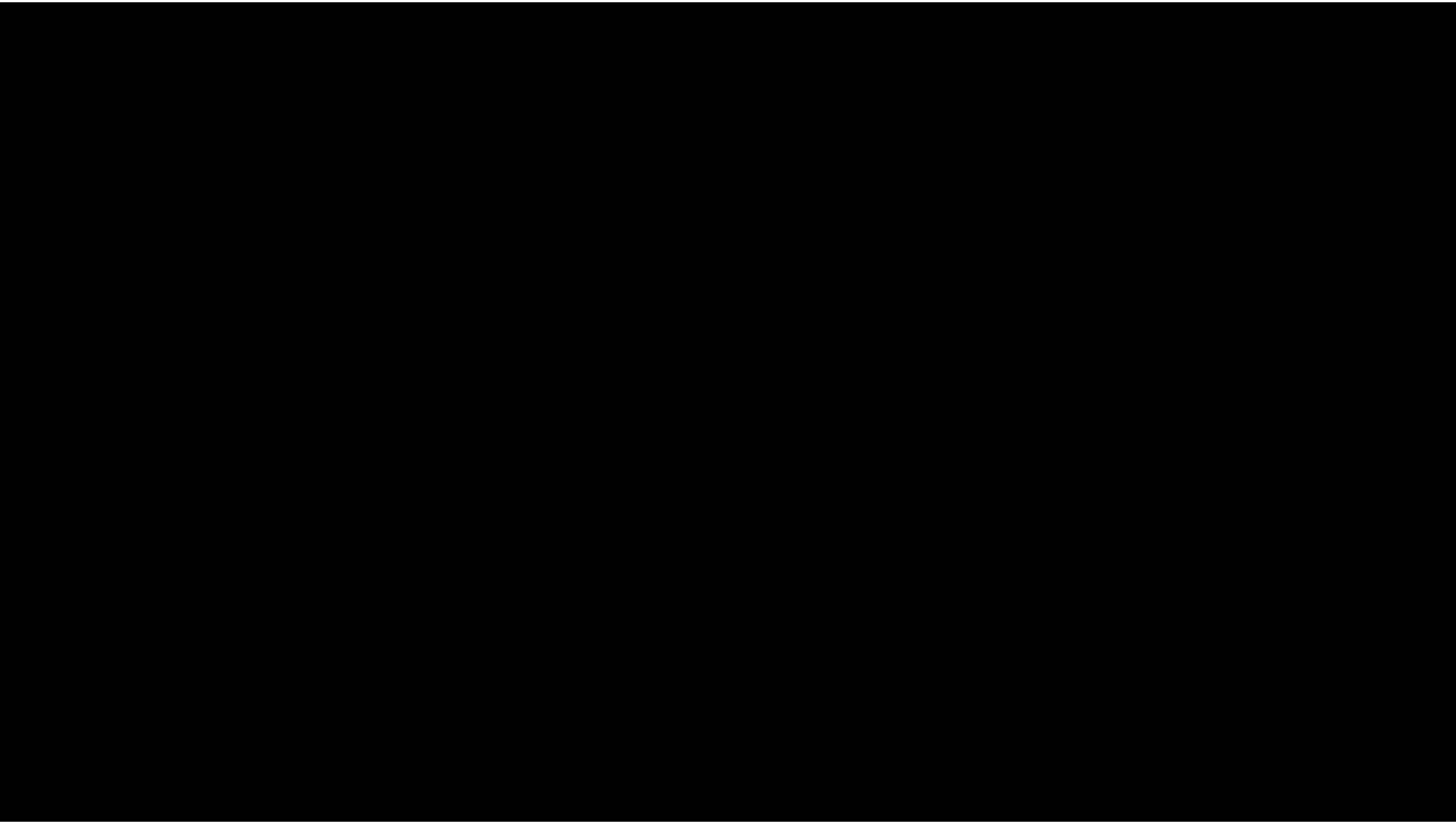


Process Improvements & Engineering Controls

1. 1992 Lost specimen checklists
2. 1997 Standard tubes
3. 1997 Single-piece flow
4. 1998 Raised edge workstations
5. 1999 Programming change to prevent storage of in-process samples

Process Improvements & Engineering Controls (2)

6. 1999 Redesign and move of waste receptacles
7. 2000 Skirting material installed around equipment
8. 2003 Realigned light fixtures
9. 2005 Checklist revision protocol
10. 2009 Daily visual sweeps

Process Improvements & Engineering Controls (3)

11. 2010 Lost specimen pattern analysis

12. 2010 Specimen Processing “pods” (teams)

13. 2011 Paraffin tissue and extracted nucleic acid transport submission kit

14. 2011 Barcode scans for batch receipt of shipments

Process Improvements & Engineering Controls (4)

15. 2012 Big data reports

16. 2013 Installed multiple video cameras

17. 2014 Clean line of sight

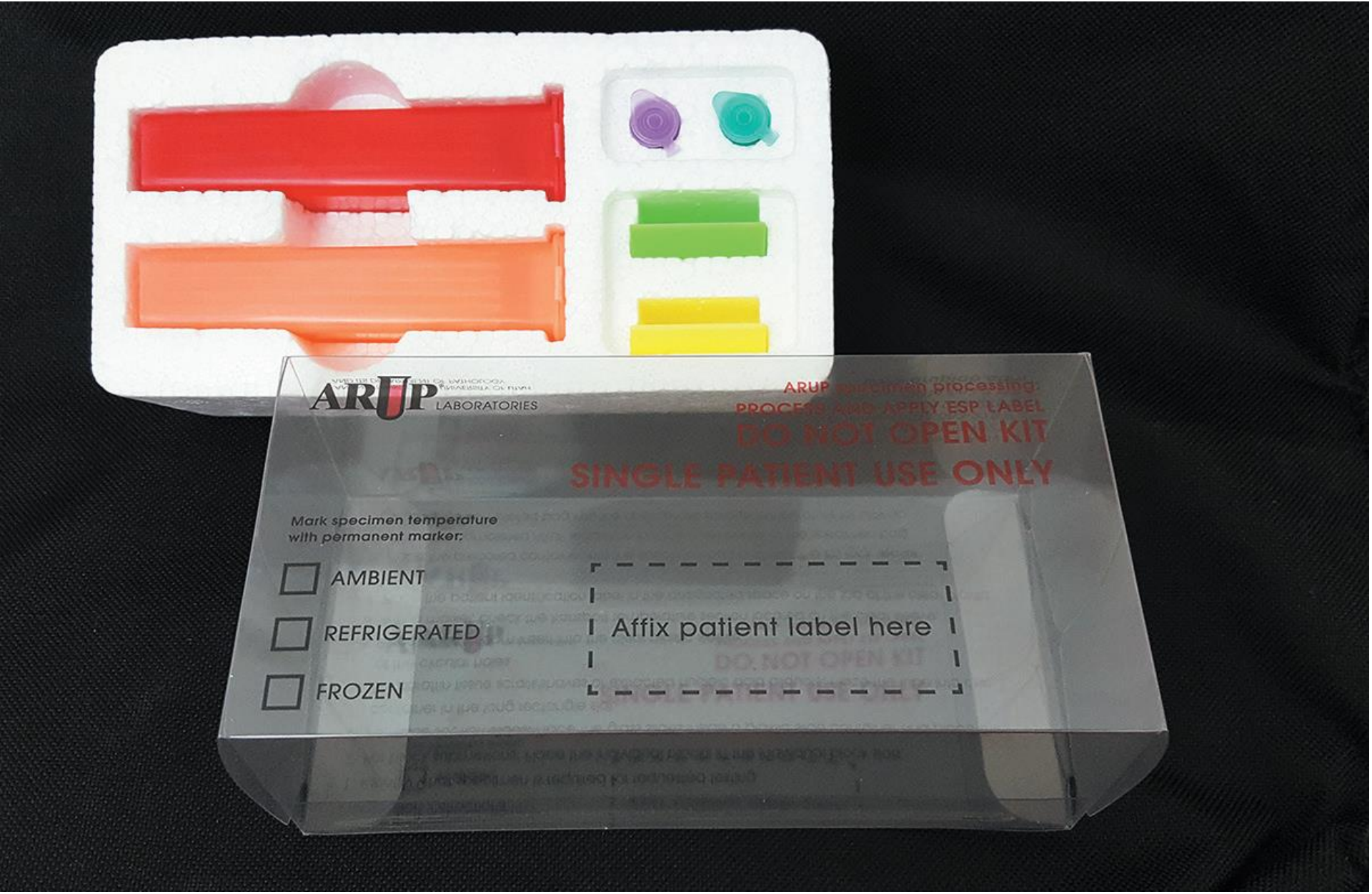
18. 2017 Extended “big data” with a “No Track Event” report

19. 2018 Green, tagged bags for S.P. waste

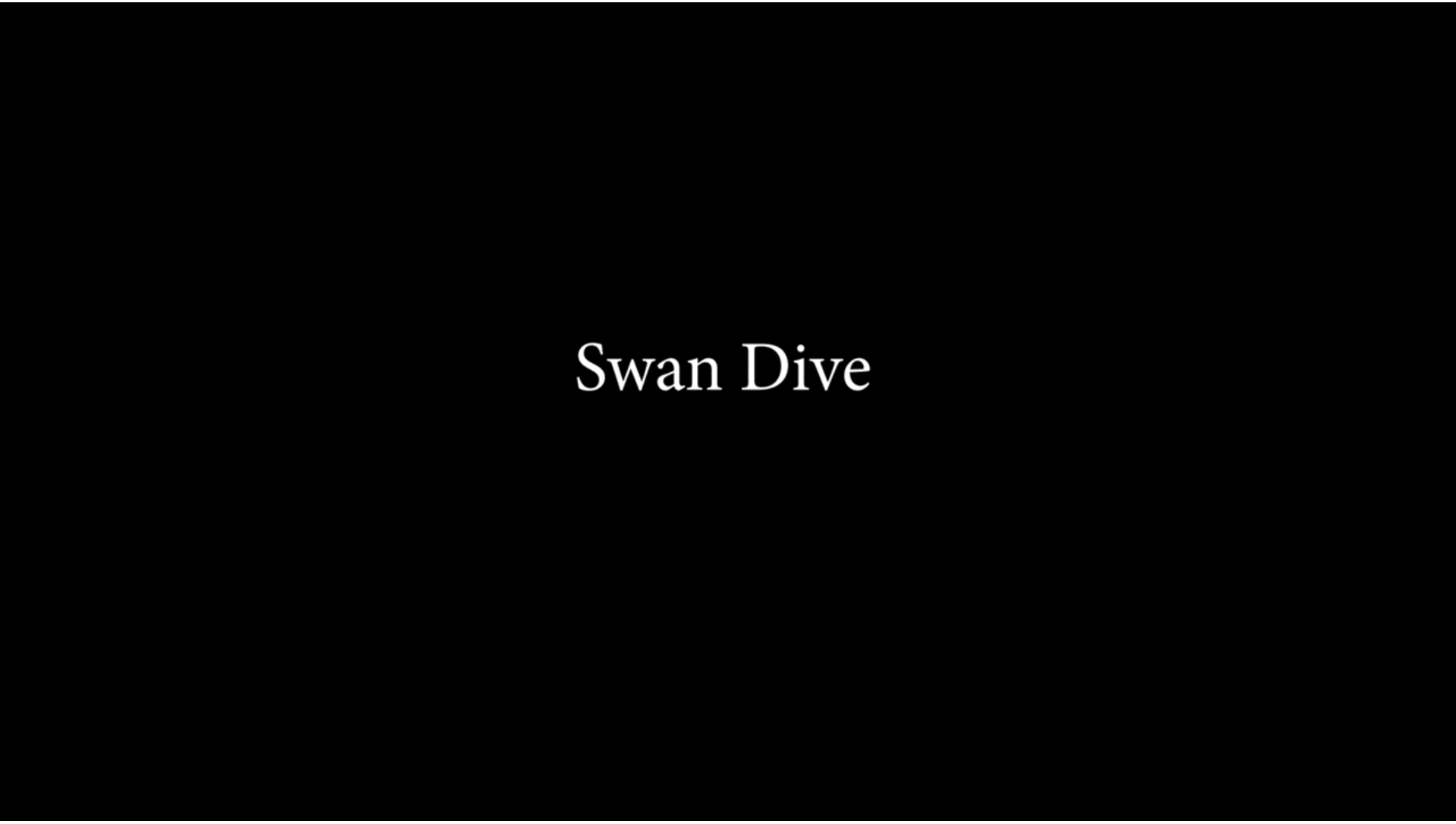
6 WASTE RECEPTACLE FITTED WITH ROUNDED COVER AND NARROW SLIT

7 SKIRTING MATERIAL INSTALLED AT EQUIPMENT BASE (OUTLINED IN RED)

12 SPECIMEN PROCESSING WORKSTATIONS ARRANGED IN A “POD” OF FOUR



13 PARAFFIN TISSUE AND EXTRACTED NUCLEIC ACID TRANSPORT SUBMISSION KIT



16 USE OF VIDEO CAMERAS

19 WASTE RECEPTACLE FITTED WITH GREEN BAG

Six-Sigma

- 3.4 defects per million opportunities (DPMO)
- Estimated average hand-offs/specimen = 6
- Each hand-off = Lost Sample “Opportunity”

Six-Sigma

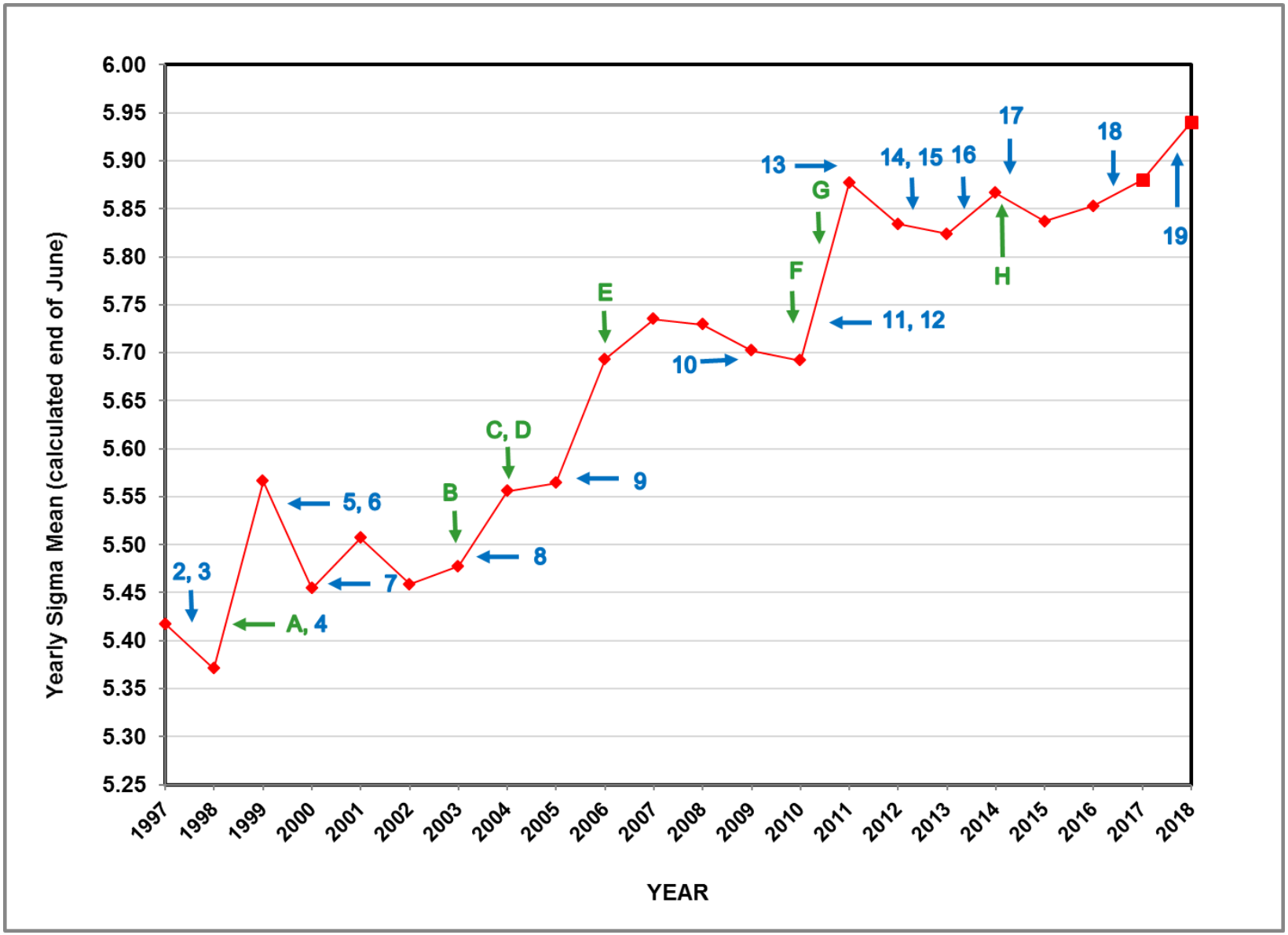
For consistency and comparison over time, we used units in place of opportunities.

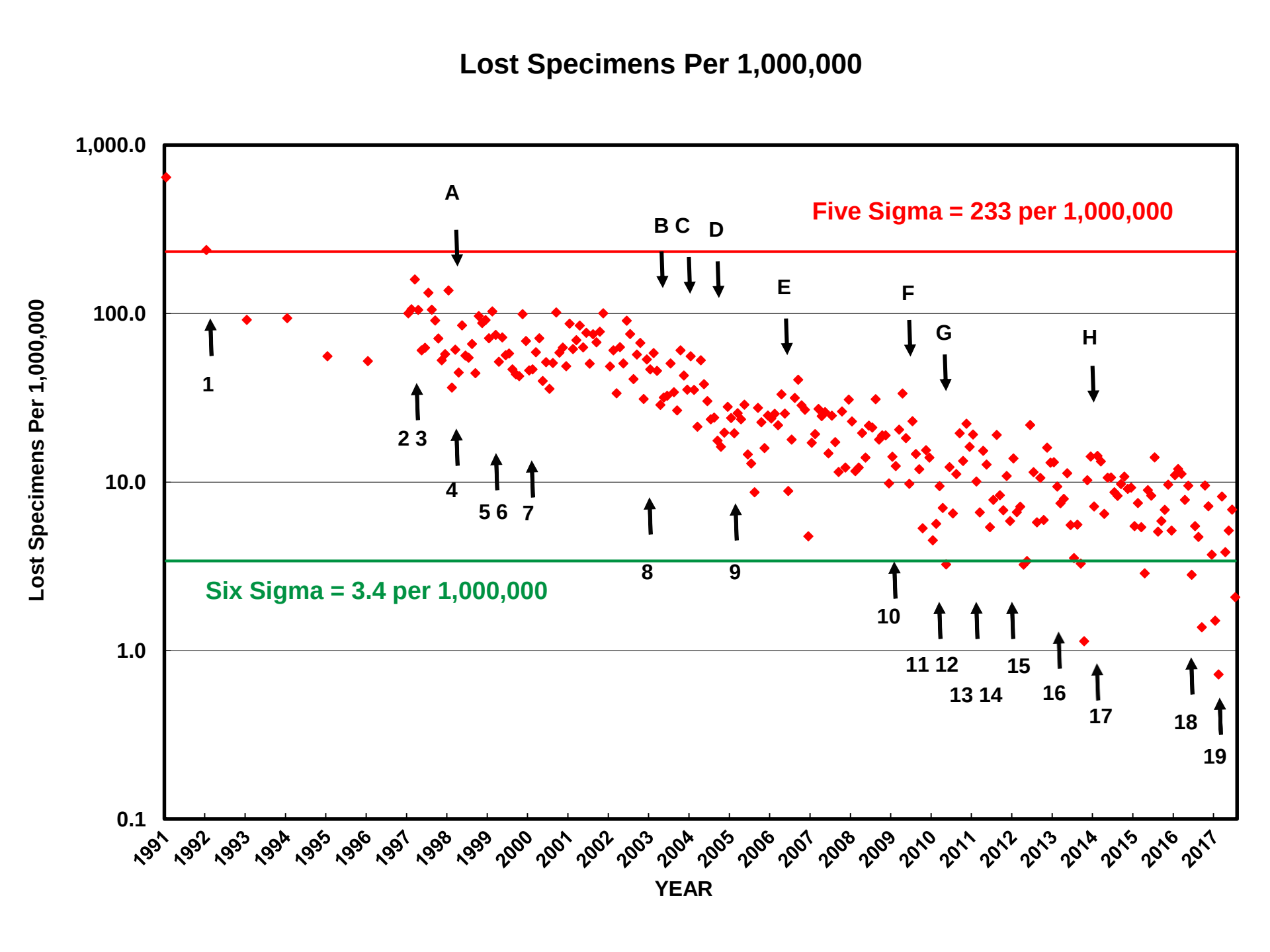
1) Billed units (1.6 per specimen)
2) Specimens

“Opportunity”

- Chances per unit for a defect
- Independent of other opportunities
- Measurable and observable
- Relates directly to “Critical to Quality” (CTQ)

LOST SAMPLES PER 1,000,000 BILLED UNITS




Lost Specimens Per 1,000,000
1,000.0
100.0
10.0
1.0
0.1
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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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.

What You Can Do In Your Lab

- Require employees to “check out” specimens from a centralized storage system for archived specimens before giving them the location (box/rack #, row #, column #).
- Design specimen processing areas to minimize opportunities for errors (misplaced specimens).
- Implementing small improvements in an iterative fashion leads to continuous improvement.

Summary

Steady improvement for 27 years

- Re-engineering and behavioral controls
  - Foundation for iterative improvement
  - “Don’t automate a broken process”
- Automation
  - Boosts improvement potential to 6 Sigma levels