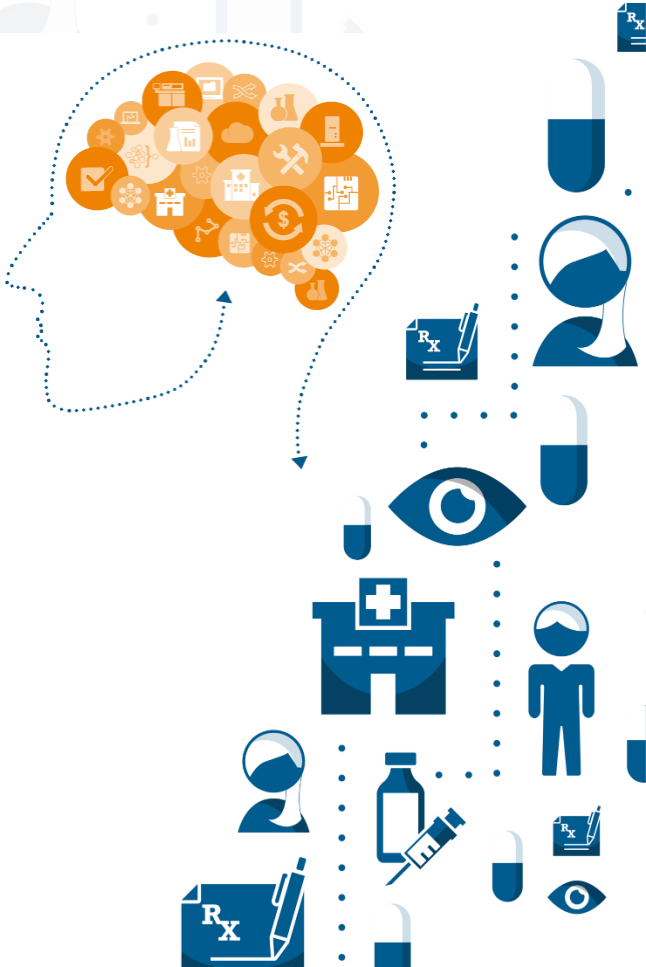
How Supporting Full Autoverification with Lean and DMAIC Generates Big Cost Savings in Lab Labor, Faster TAT, and Fewer Errors



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Objectives

- Realize why measuring autoverification by laboratory workload produces a logarithmic return on investment (financially, clinically, and operationally) and proves that <60% AV produces little return.
- Understand how to create a lab-wide AV design plan, and how to determine best options for implementation.
- Comprehend the risk associated with manual verification, poor autoverification design and maintenance, and vendor-provided rules packages.
- Appreciate why an AV project is never truly completed and how Lean concepts show us how to continuously improve.

Bill Marquardt

- Clinical Chemistry Technologist (ASCP)
- Bench tech at 500+ bed hospital
- Field Tech Support then SME for Roche chemistry / instruments
- Reagent and Automation product manager
- Lab IT consultant
- Co-authors on AUTO10-A (CLSI Autoverification of Clinical Laboratory Tests Results; Approved Guideline)
- Certified Six Sigma / LEAN Black Belt
- Direct of Lab IT Services for 4th largest US based lab (8 yrs)
    - Lead the Laboratory LEAN Workflow Optimization Team
    - Interfaced hundreds of instruments over large geographical areas
    - Built autoverification algorithms and implemented in every lab area
    - Architected and led a design time to build a complete homegrown LIS
- Author “A step-by-step process to 95% Autoverification” – CAP Today Dec 2015
- **Chairman – CLSI AUTO15 - Department Spec Autoverification – September 11, 2019**

Labor and Cost Containment are Lab's Biggest Issues

MT/MLT 50-80% Vacancy Rate[1,2,3]

335,700 open positions in 2016, will grow >40K by 2026[17]

20% turnover rate[3]
Labs actively recruiting globally

$7,500 / position

$14K if >3 months[10]

Medical Error

Now the 3rd leading cause of death in the US[14]

2.9 – 26.9%
Human error rate[12]

Test Requests Increasing

Growing at 7% globally[15]

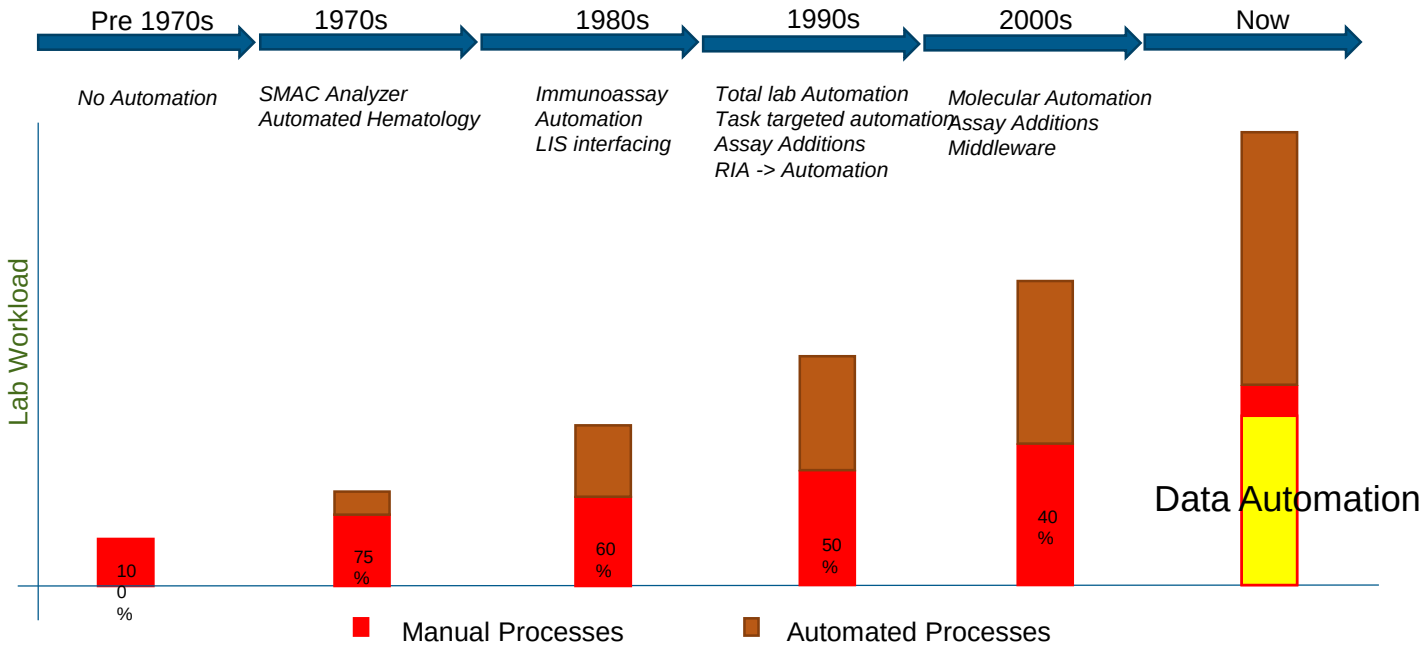
TAT / DOT

Lab testing ordered on 41% of all visits AND at least 10% of diagnoses delayed until testing is complete[16]

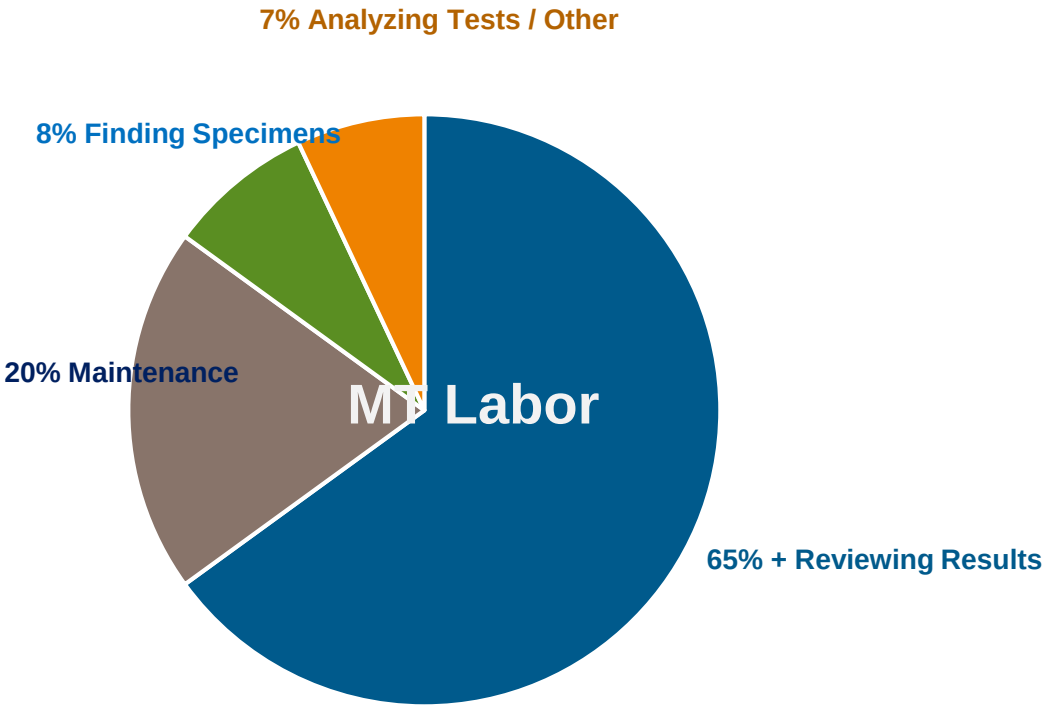
Physicians ordering the WRONG tests

66% Vitamin D orders are ordered incorrectly[18]

Diminishing Returns of Hardware Automation in the clinical laboratory



Where do labs spend their skilled labor



Data Automation Eliminates Non-Value Add Activities

Autoverification - The use of algorithms that enable the automatic commenting and releasing of results immediately to the LIS / EMR.

Is NOT – Releasing normal results (common misconception)

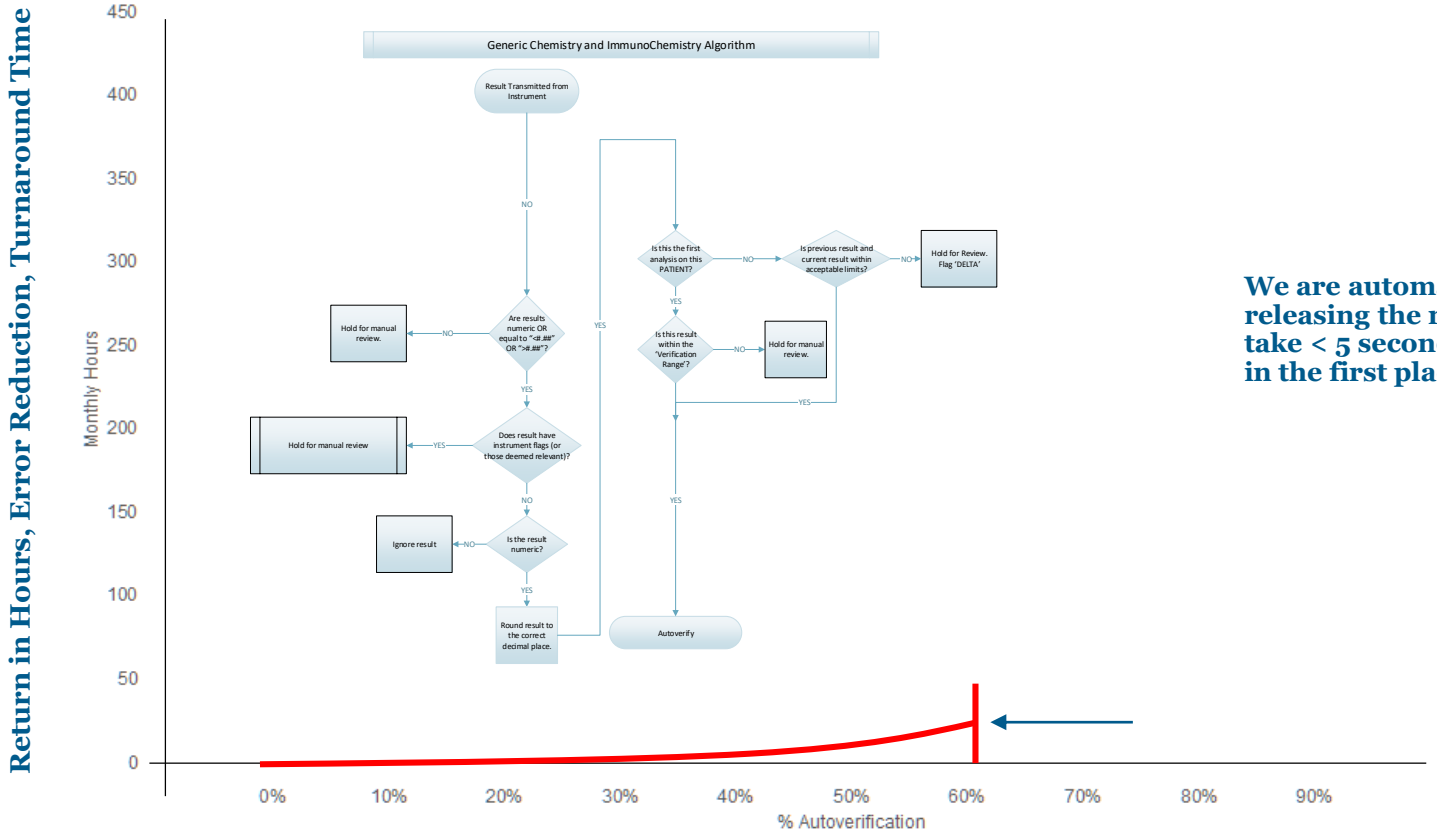
Assisted Review- Using instructions, colors, icons to help identify the reason for an exception and the suggested actions for resolution.

Analytics- Continuous improvement using machine learning

Examples

- **AST is normal – do you release?**
  - Oh, btw… ALT, ALP, GGT – all critically high…
  - Wouldn't it be nice if the 'system' looked at this and held all of them?
- **Glucose critically high do you rerun / release?**
  - Oh, btw… It's lower than last glucose done 2 hours ago…
  - Wouldn't it be nice if the 'system' knew this, and didn't hold this up?
- **Albumin is normal – do you release?**
  - Oh, btw... it's higher than the total protein…
  - Now, do you rerun Albumin (3+ times) or wouldn't it be nice if the 'system' told us that there is a rare potential interferant that could cause this (outlined in the package insert.)
- **BUN and Creatinine are critically high, do you rerun and call to floor?**
  - Oh, btw… this is a dialysis patient…
  - Wouldn't it be nice if the 'system' knew this and didn't put it on the call list?

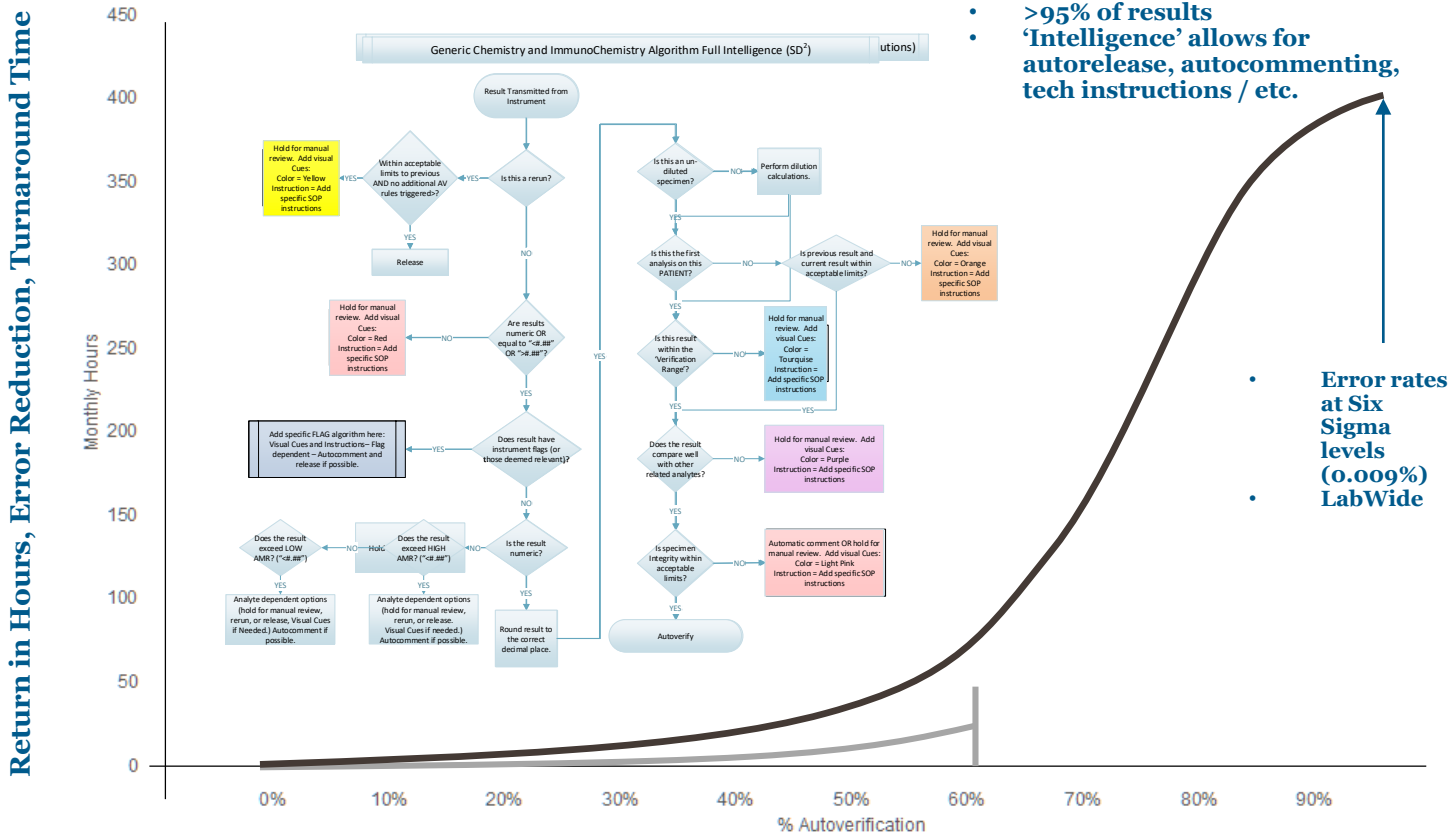
Autoverification rates <60% - Great Start – Provides Little Return



We are automatically releasing the results that take < 5 seconds to review in the first place.

* Average results based on 1000 analyte per day laboratory

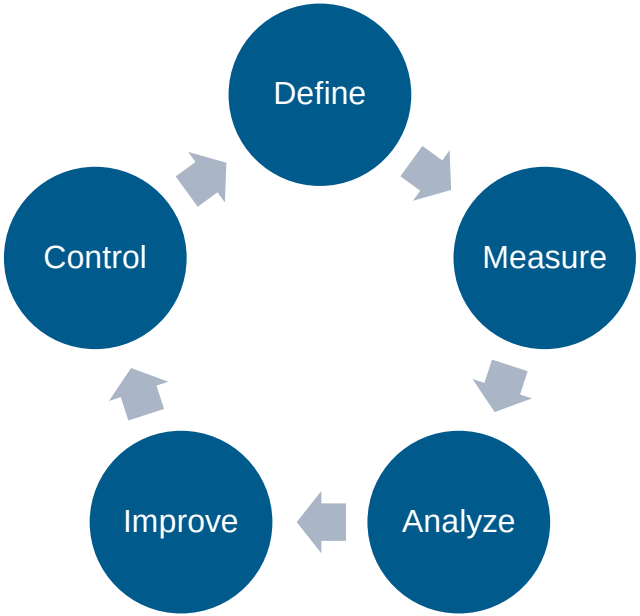
Fully intelligent autoverification is critical to lab survival



- >95% of results
- 'Intelligence' allows for autorelease, autocommenting, tech instructions / etc.
- Error rates at Six Sigma levels (0.009%)
- LabWide

* Average results based on 1000 analyte per day laboratory

LEAN / Six Sigma in Autoverification

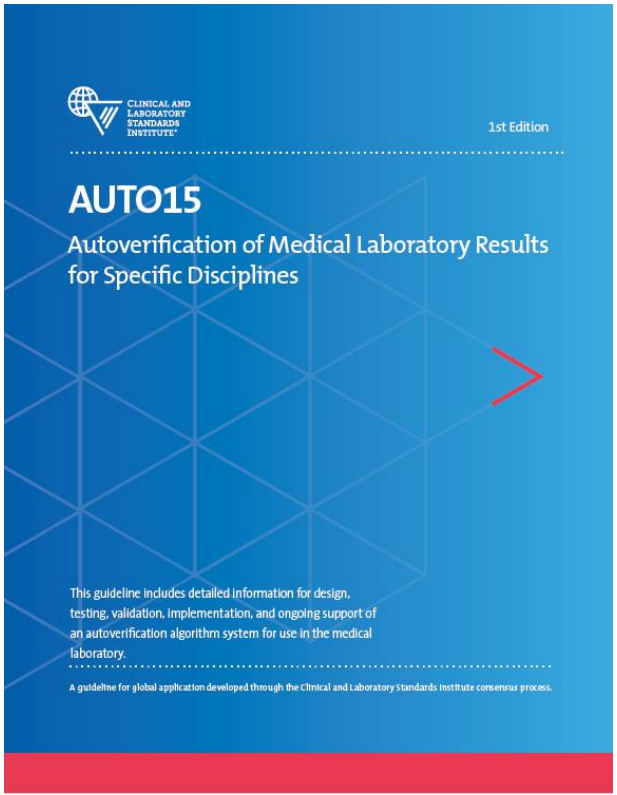


- Data Automation is CONTINUOUS process improvement
  - The project should NEVER be considered ‘COMPLETE’
- Advanced analytics must be a key part
- Pareto principle (80/20 rule)
  - Address the ‘low hanging fruit’ first

>95% of labs are inefficient

- AV rates (lab-wide) of <80% provide little value
  - Automation of the ‘easy’ to release specimens leads to no significant improvement
  - Logarithmic return on efficiency / TAT / error rate
- LIS systems have limited capability to construct algorithms and to measure outcomes combined with limited clinical expertise
- Industry guidance has been limited
- Be weary of LEAN ‘Consultants’
  - Non- clinical consultants may deem you as ‘LEAN’ because they do not necessarily know which processes maybe actually unnecessary
  - Consultants employed by hardware vendors will always show you the data in a way that makes their system look better

CLSI Auto15 – Available as of 9/11/2019



HOT OFF THE PRESS!

AUTO15, 1st ed.
September 2019

Autoverification of Medical Laboratory Results for Specific Disciplines

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Abstract

Clinical and Laboratory Standards Institute guideline AUTO15—*Autoverification of Medical Laboratory Results for Specific Disciplines* provides general guidance, as well as discipline-specific direction, on design and validation of an autoverification system. Autoverification is the process by which laboratory analyte results are accepted or rejected for automatic delivery to a patient data repository. This process uses a predetermined set of criteria applied at one or more points during the electronic flow of information. This guideline is provided for use by laboratorians, personnel responsible for information systems, and vendors for medical informatics and *in vitro* diagnostics.

Clinical and Laboratory Standards Institute (CLSI). *Autoverification of Medical Laboratory Results for Specific Disciplines*. 1st ed. CLSI guideline AUTO15 (ISBN 978-1-68440-056-0 [Print]; ISBN 978-1-68440-057-7 [Electronic]). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2019.

Keith LeBlanc

- Medical Technologist (ASCP) >24 years
- Held various leadership positions in critical access laboratory associations
- Laboratory Director Rutland Regional Medical Center
  - Second largest hospital in Vermont
  - 144 Bed Hospital
  - >2 MM Orderables / year
  - Full service laboratory
    - LIS – Cerner
    - Chem / IA – Siemens
      - CentraLink Middleware
    - Hematology – Sysmex
      - WAM Middleware
    - Microbiology – BMX
      - Myla Middleware

RRMC Lab – LEAN Journey

- LEAN Training
- Modification of lab design to eliminate Waste
  - Instrument Flow
  - Eliminate non-value add steps
  - Limited autoverification due to LIS capabilities

- LIS Upgrade Increased AV capability
- Worked with vendor able to get some systems to high level of AV (or so we thought) but no on all systems
- Difficult to get real time analytics
- Decisions made on potentially flawed data
- Sometimes having to gut instincts

- RFP to vendors for chemistry analyzers
- Demonstrations from vendors on promised high levels of AV
  - Vendor specific
  - No holistic approach

- Partnered with McKesson using Mckesson SD2 for multiple departments
  - Robust AV rules
  - Analytics to direct decisions

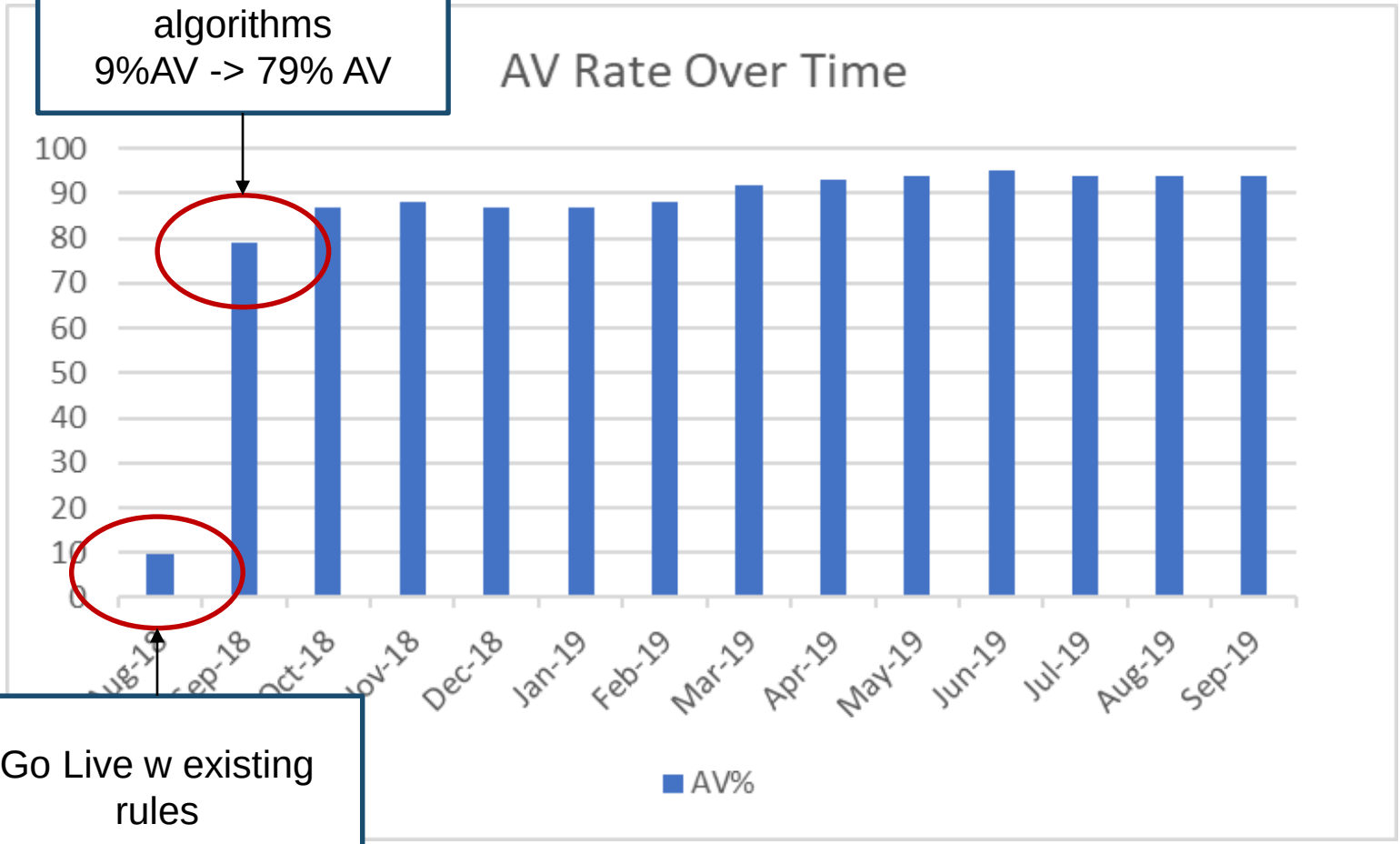
- Will continue to improve process by implementing
  - All instruments
  - Additional Dashboards

Challenges

- LIS functionality
- Lack of data analytics
  - –AV rates were much lower than we actually *assumed*
- People / change management
  - –Different way of thinking
  - –Things are done in the lab because we THINK we should do them
  - –A whole lotta paper

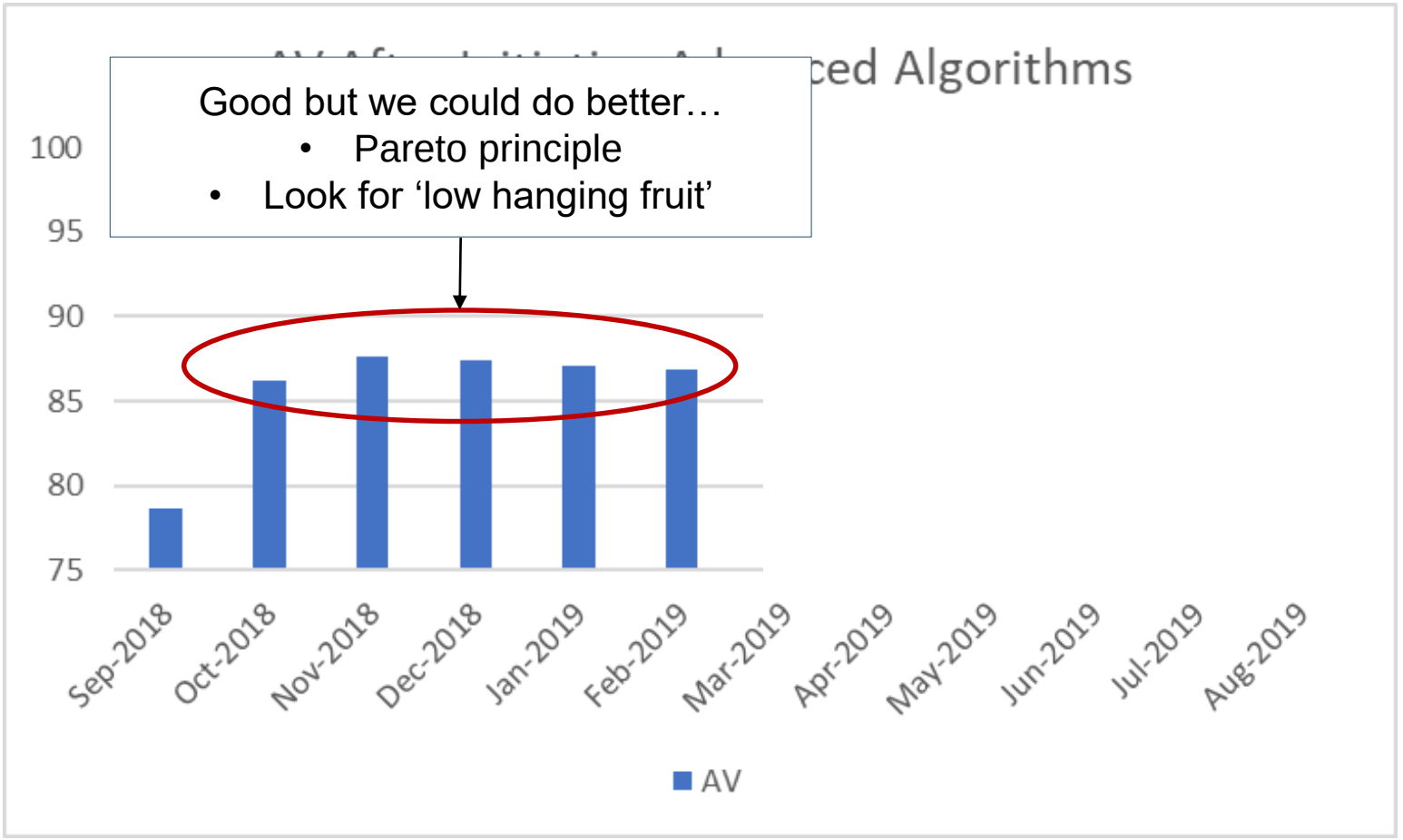
2018 – Implementation of McKesson SD² w/ New Clinical Chemistry Analyzers

Addition of advanced algorithms
9%AV -> 79% AV



Go Live w existing rules

Note: Magnification of x-axis



LEAN / Six Sigma Approach To Algorithm Enhancement

Delta Check Efficacy

- Determine clinical efficacy and operational efficiency delta check

- Rule reasoning
- Technical Resolution
- Clinical Outcomes

With SD² Lab Intelligence Software

- What did we do?
- Why did we do it?
- Should we keep doing it?

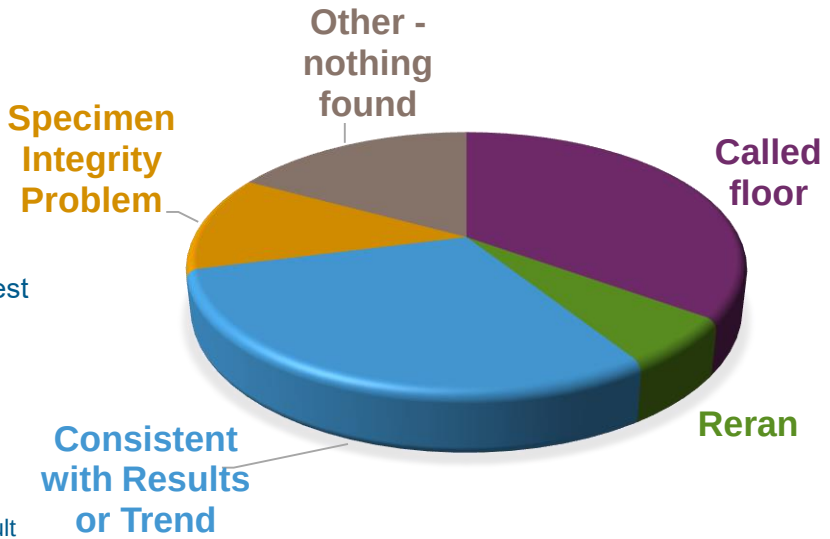
- Can should we change / eliminate non-value add rules / steps
- Will this have a clinical affect

- Continuous

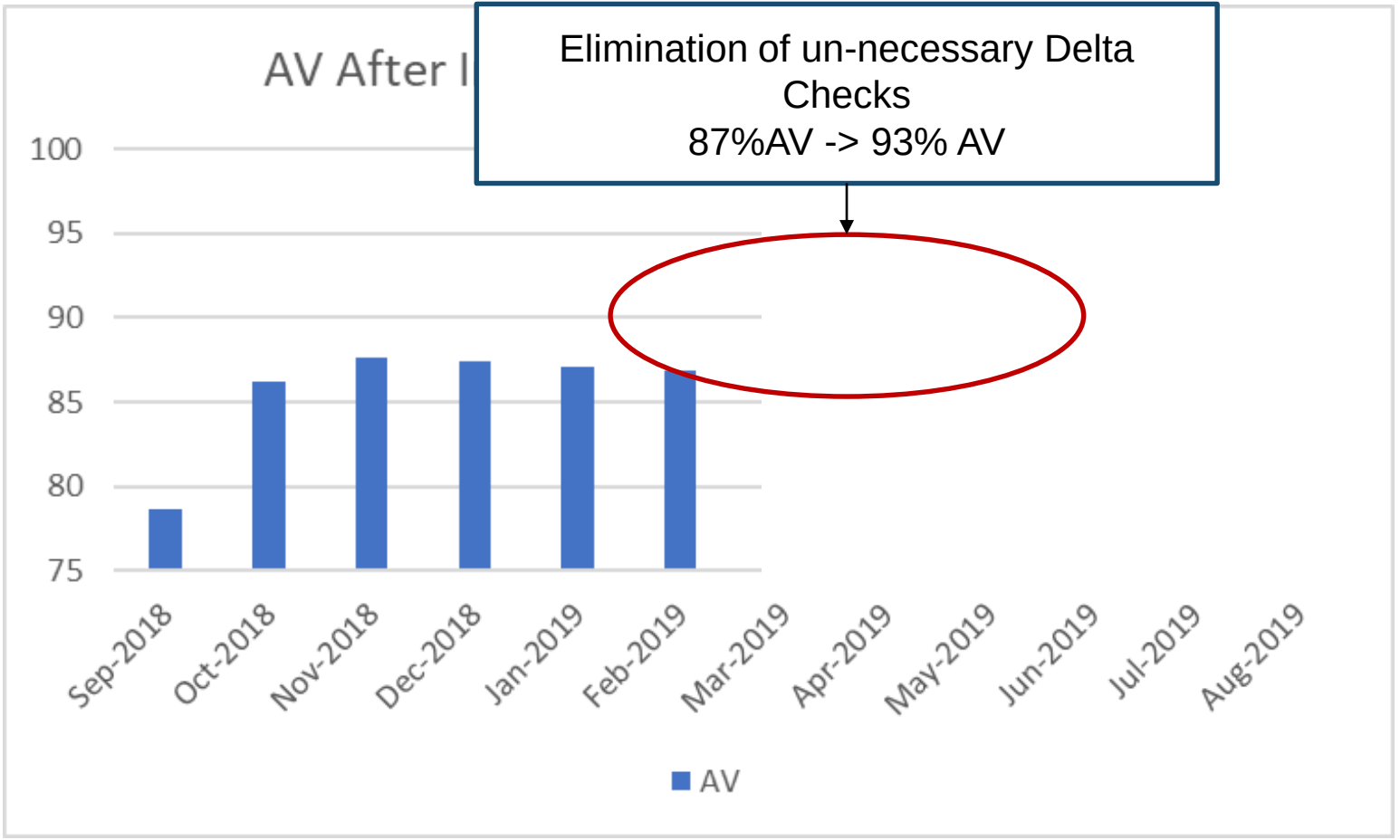
Delta Checks
(Data from SD² Lab Intelligence)

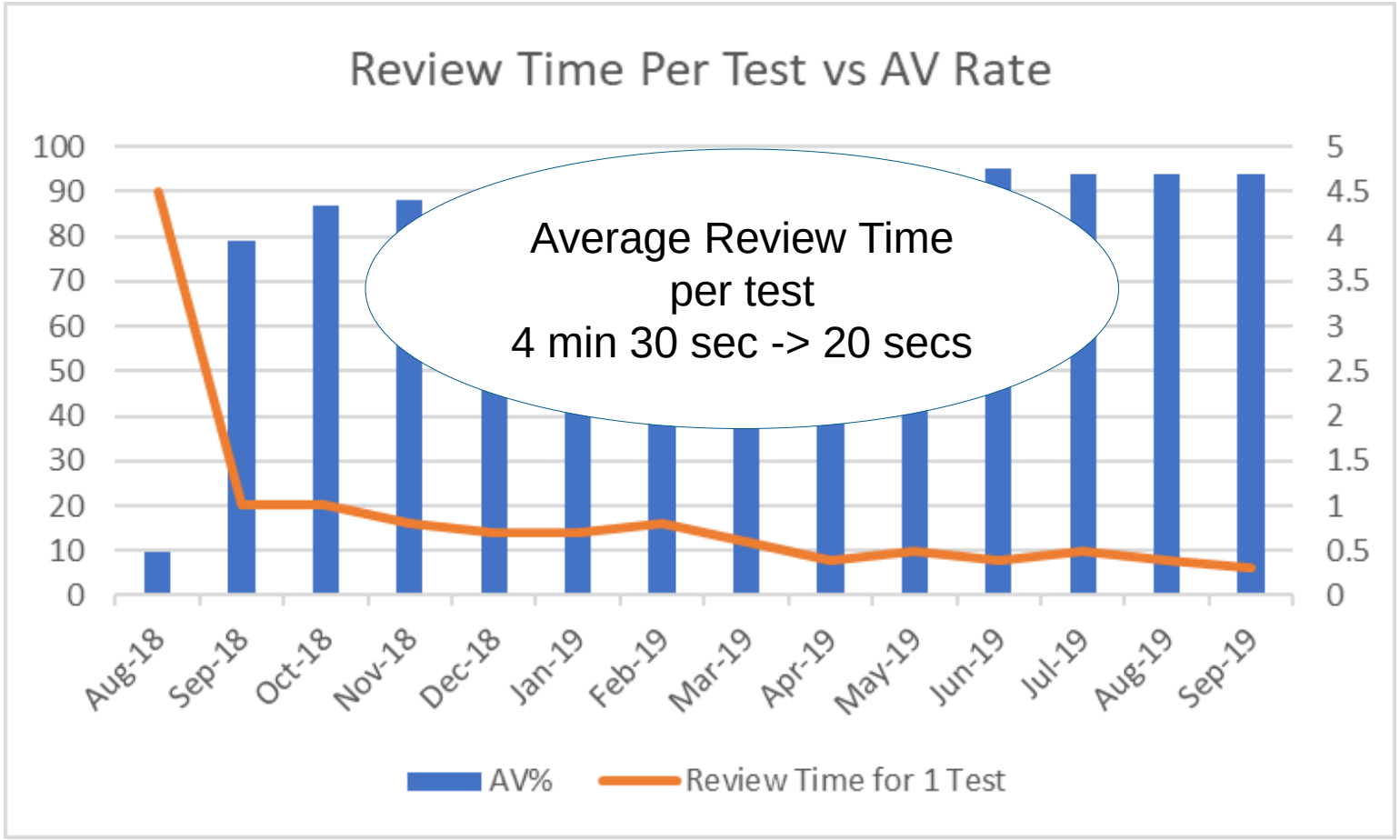
- 1393 Delta Checks total

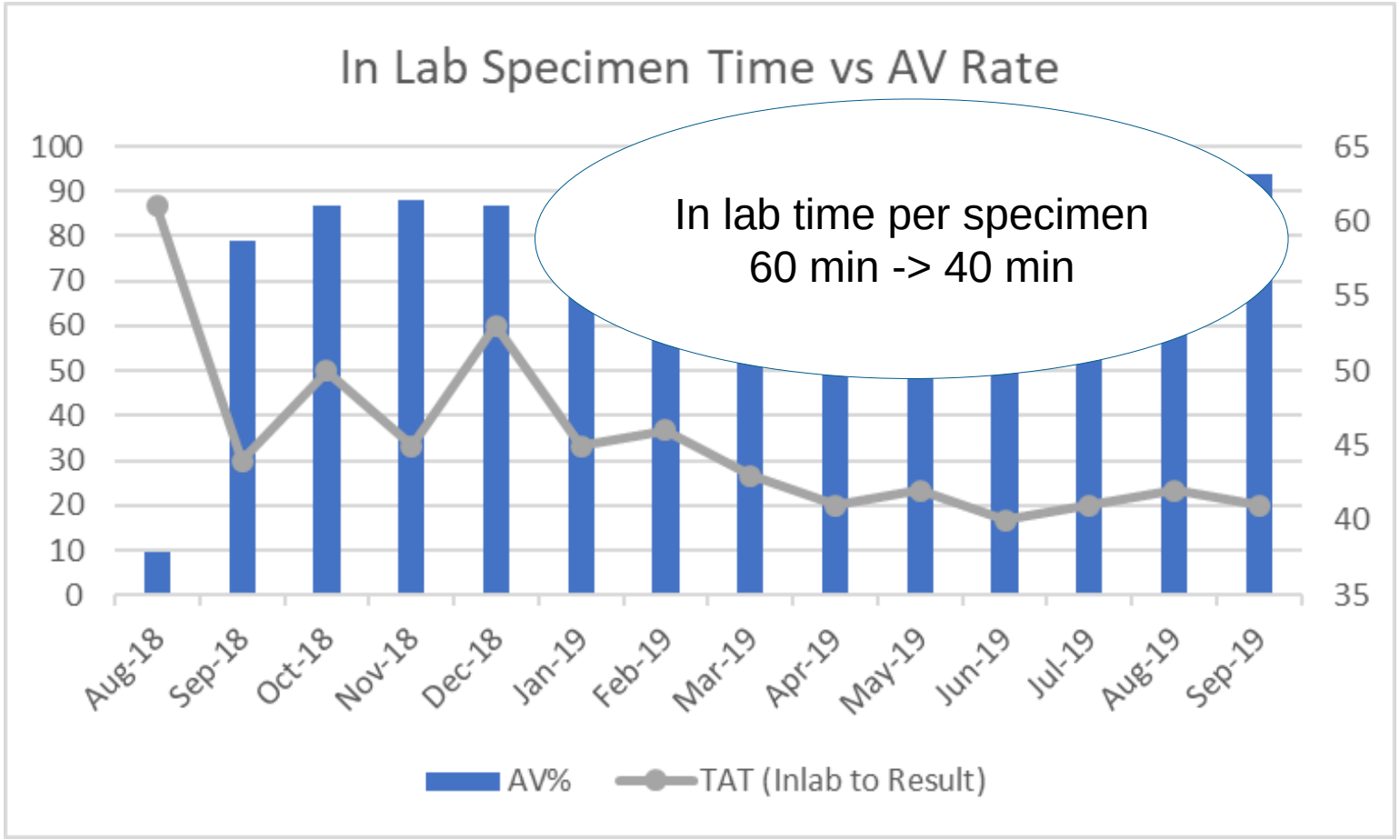
- Results Modified?
  - 0
- Comments Added / Modified?
  - 0
- Results rejected?
  - 1 (result was in inaccurate, nurse: “We really don’t need the test anyway so we will cancel the order”)
- Added FTE time?
  - ~500 hours / year
- TAT Impact?
  - Any rerun added 30 min to TAT and ALL reruns confirmed previous result
  - >5 min per TEST
  - >7 min per Specimen



- Conclusion: Delta checking is not only non-value add, but potentially harmful to patients (due to increased TAT) and definitely harmful to efficiency in and OUT of the laboratory


AV After I
Elimination of un-necessary Delta Checks
87%AV -> 93% AV
100
95
90
85
80
75
Sep-2018
Oct-2018
Nov-2018
Dec-2018
Jan-2019
Feb-2019
Mar-2019
Apr-2019
May-2019
Jun-2019
Jul-2019
Aug-2019
AV

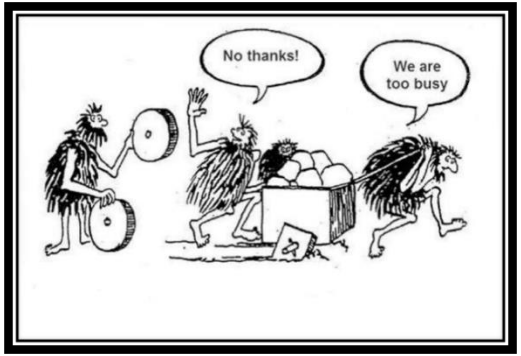

Review Time Per Test vs AV Rate
100
90
80
70
60
50
40
30
20
10
0
5
4.5
4
3.5
3
2.5
2
1.5
1
0.5
0
Aug-18
Sep-18
Oct-18
Nov-18
Dec-18
Jan-19
Feb-19
Mar-19
Apr-19
May-19
Jun-19
Jul-19
Aug-19
Sep-19
Average Review Time
per test
4 min 30 sec -> 20 secs
AV%
Review Time for 1 Test


In Lab Specimen Time vs AV Rate
In lab time per specimen
60 min -> 40 min
100
90
80
70
60
50
40
30
20
10
0
65
60
55
50
45
40
35
Aug-18
Sep-18
Oct-18
Nov-18
Dec-18
Jan-19
Feb-19
Mar-19
Apr-19
May-19
Jun-19
Jul-19
Aug-19
Sep-19
AV%
TAT (Inlab to Result)

Lessons Learned

- Chemistry may not be the best place to start
- Personnel / change management
- Unforeseen Challenges
- Unforeseen Gains
- Next steps for the laboratory

Summary



- Autoverification (AV) should be the number one thing on the mind of an efficient laboratory director
- Autoverification should be considered a continuous process improvement project and should never be deemed ‘completed’
- <90% rates should be considered unacceptable
- DMAIC can (and should) be used to ensure labs are maintaining optimization, efficiency, and best quality

Questions?

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