Technology driven Process Excellence in Clinical Laboratories

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Introduction

- What is the perception of laboratory medicine/test result to a clinician?

- Does laboratory medicine practice that clinical side?

Evidence based practice

A multicenter randomized clinical cross over placebo controlled cross over trial of **plasma glucose measurement** in **platform A versus platform B** for **diabetic neuropathy grade I** in the **urban slum population from city A** using **hexokinase and oxidase-peroxidase methods** by splitting the collected specimen

The (?ideal) proposed culture of EBM in labs

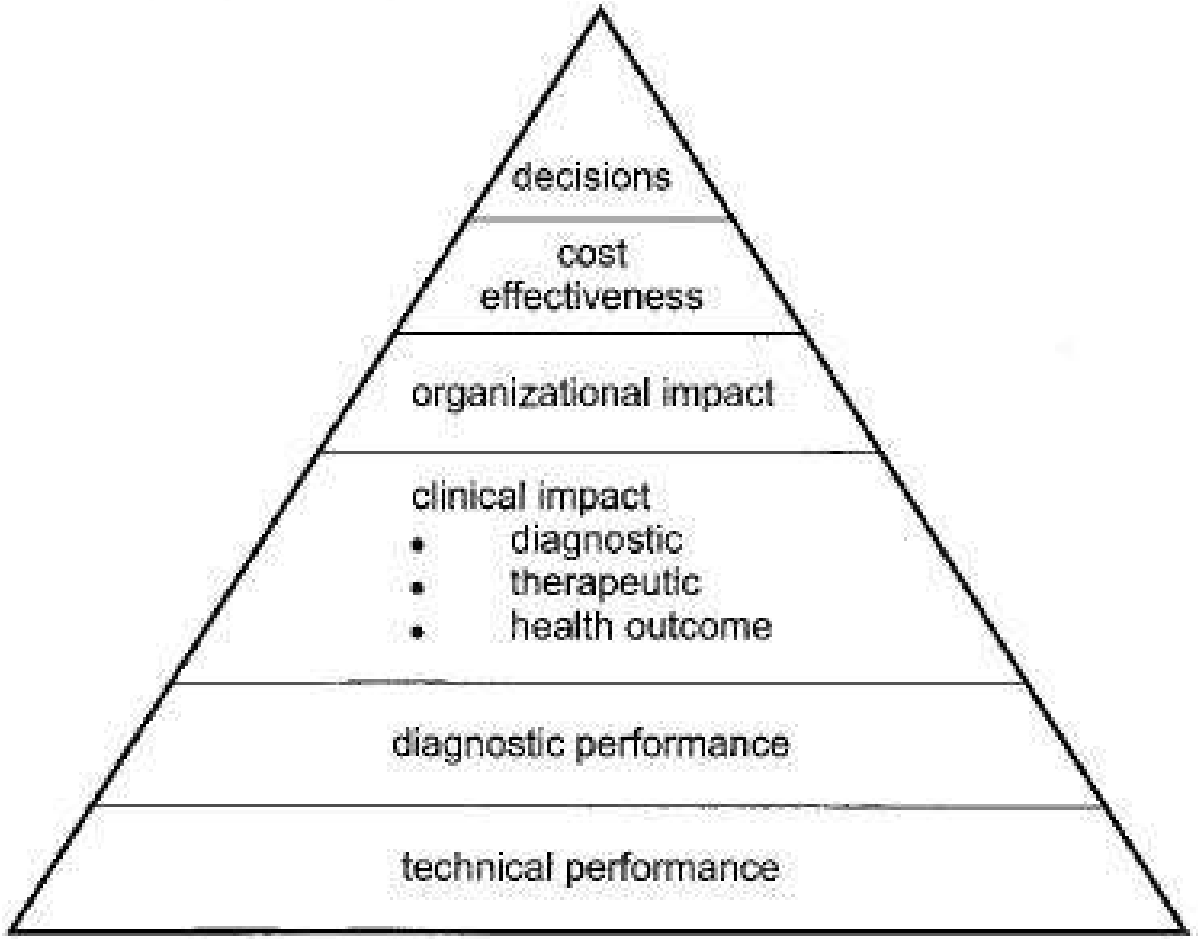
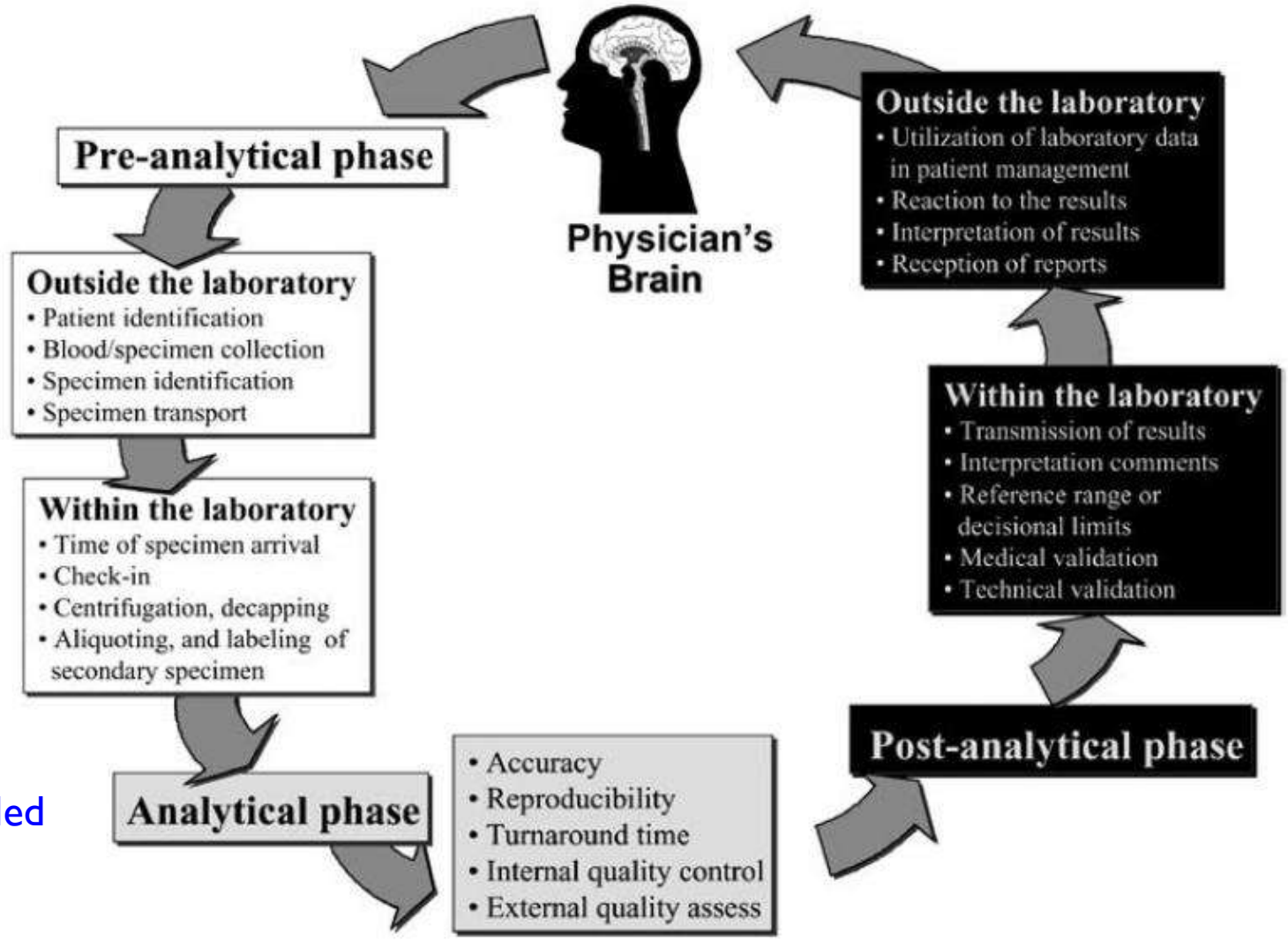


Fig. 2. Evidence of performance designed to facilitate decision-making.

Christopher P. Price: Clinical Chemistry 46:8;1041–1050 (2000)

Not all processes can be automated or should be automated.



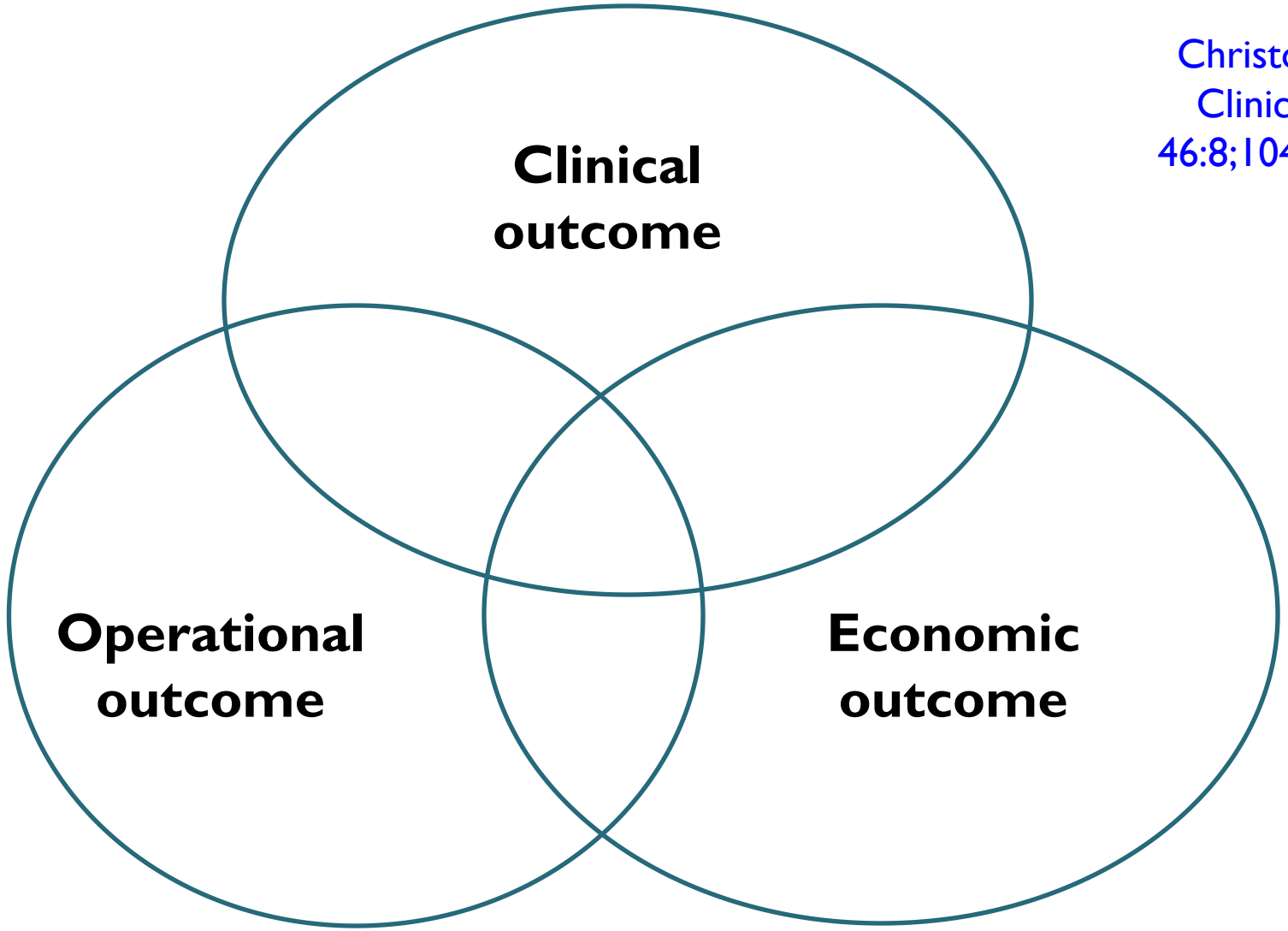
Plebani M et al., Clin Chem Lab Med 2006;44(2):150–160

Not all processes should be automated

"Automating a poor process still leaves one with a poor process…."

Hawker D. C. Clinical Chemistry 63:6 1074-1082(2017)

Newer paradigm shift in expected for value delivery by labs



Christopher P. Price: Clinical Chemistry 46:8;1041–1050 (2000)

So what can we automate in non-analytical automation?

- **Machine vision technology** is a further addition to high volume testing laboratories and are currently used to check the fill of evacuated tubes or reagent containers (manufactureing plants)
- **Telepathology** for remote sites and communication networks
- Automated **Call-Centre IVRS support**

Hawker C. D. Clinical Chemistry 63:6; 1074–1082 (2017):

Table 1. Possible steps for work flow mapping.

Removal from transport carriers (pneumatic tubes, racks, shipping containers)
Presorting
Temperature preservation
Accessioning
Document management (requisitions, transfer lists, etc.)
Labeling
High level sorting
Centrifugation
Labeling aliquot tubes
Decapping
Aliquoting
Sorting
Transport to laboratory sections
Subsorting
Work list preparation
Labeling analyzer-specific tubes for samples
Pouring or pipetting analyzer-specific samples
Loading analyzers
Test analyses (steps such as extraction, centrifugation, precipitation, dilution, etc., are not listed here)
Unloading analyzers
Recapping
Data manipulations (calculations)
Results review and verification
Results reporting
Transport samples to postanalytic storage system
Postanalysis storage of samples
Reflexive testing
Repeat testing, with sample dilution, if needed
Additional physician-ordered testing
Sample retrieval for additional or repeat testing
Disposal of expired samples

Automation is not easy! Set up Quality Indicators

Table 1 Quality indicators and specifications of the pre-analytical phase [modified from ref. (11)].

Quality indicator	Specification target, %
Requests	
• Error in patient identification	0.08
• Physician identification missing	0.50
• Erroneous specification of hospital unit	0.60
• Request unintelligible	0.10
• Correction of errors or test ordered	0.30
• Total error in outpatient requests	1.25
Sampling	
• Uncollected phlebotomy request, inpatients	7.00
• Uncollected phlebotomy request, outpatients	0.30
• Tourniquets and holders contaminated with blood	2.50
• Needle stick injuries per 100,000 venipunctures	0.01
• Samples redraw	2.00
• Specimen collected from infusion route	20.6
• Inappropriate container used	0.015
• Errors found in identification wristbands	3.00
Transport and receiving samples	
• Inadequate sample collection and transport	0.004
• Sample rejection, whole blood count	0.45
• Sample rejection, chemistry	0.35
• Sample lost/not received	0.12
• Improperly labeled container	0.002
• Sample damaged in transit	0.002
• Sample clotted, hematology	0.20
• Sample clotted, chemistry	0.006
• Sample hemolyzed, hematology	0.009
• Sample hemolyzed, chemistry	0.20
• Laboratory accident	0.004
• Insufficient sample volume	0.05
Inadequate sample/anticoagulant volume ratio	0.02

Plebani M et al., Clin Chem Lab Med 2006;44(2):150–160

The development of the total laboratory automation concept

Dr. Masahide Sasaki

Vlazasis V. Siemens Trade publication (2006)

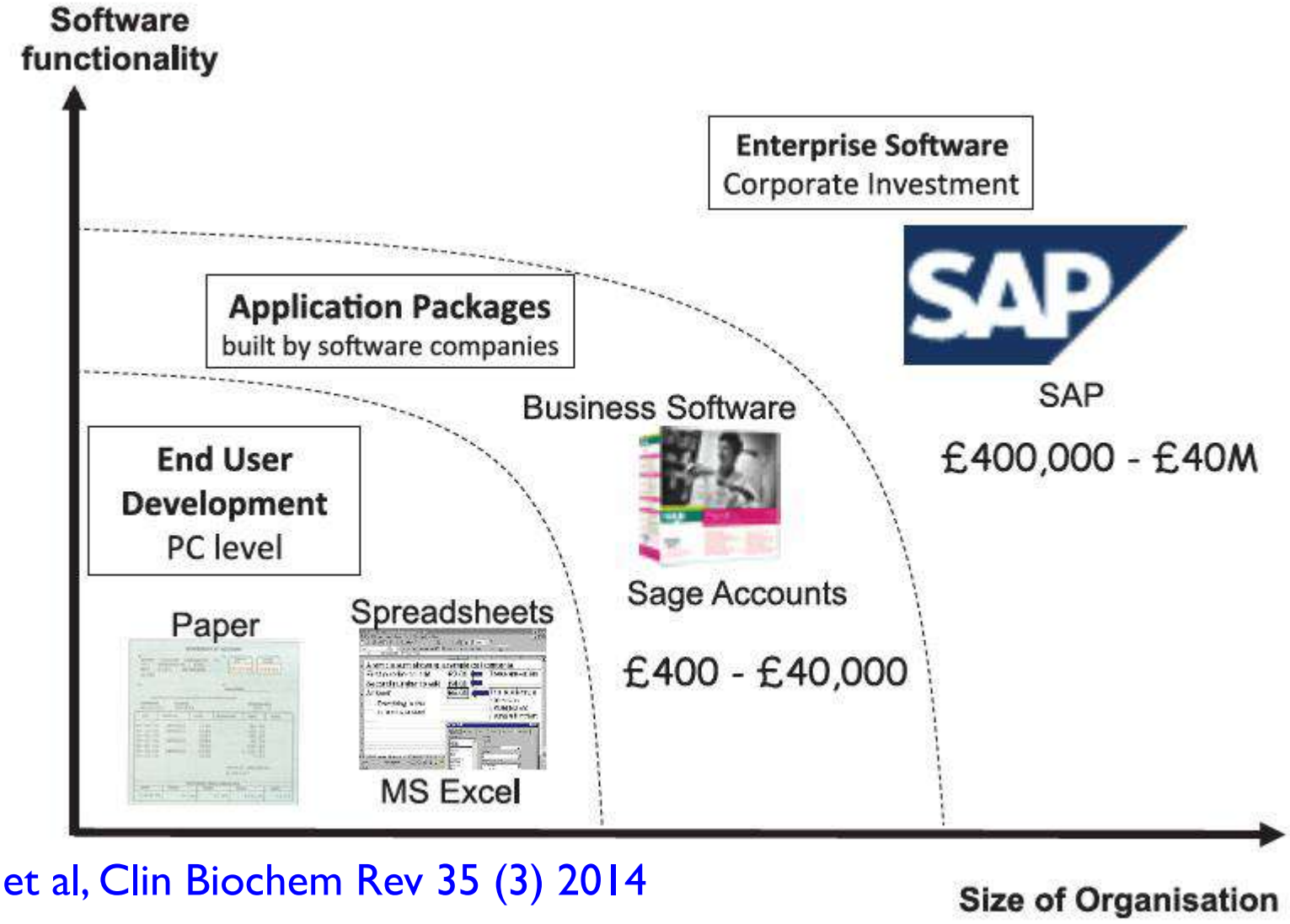
Total laboratory automation and test loads

CAP Today(2016): 3:30; 28-48. *Data for 2020 is from our hospital

Efficiency: Set your goals!!

- Which areas will see improvements in patient outcomes
- What is required to do so? Can that be automated
- Risks associated (assessment)
- Human Support
- Space and Finances
- Vendor support (including back up)
- Redundancy

To understand goals focus on the business model



Jones R. G. et al, Clin Biochem Rev 35 (3) 2014

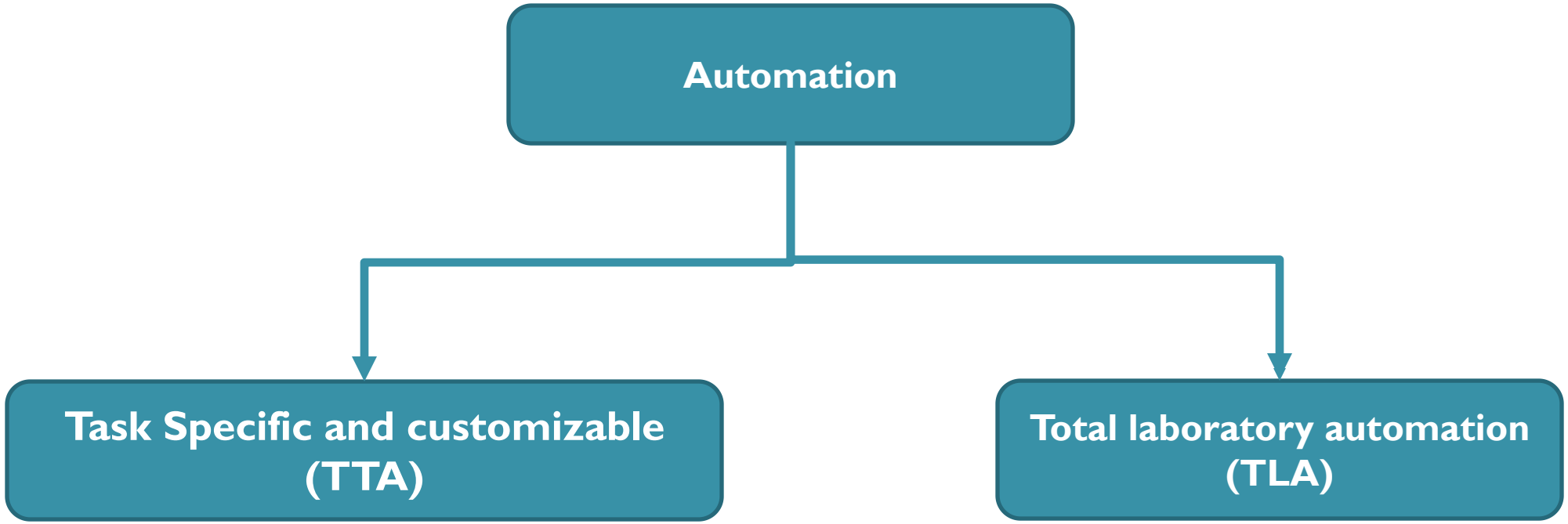
Technophobia ?

Table 3. Future Informatics skill profiles for pathology staff.

Skill Level	Required competencies	Staff to which these apply
Basic	PC literacy including data access and entry, web browsing	Administrative & clerical Technical
Intermediate	General applications, including word processing, spreadsheets, databases	Administrative & clerical Supervisory technical Scientific
Advanced	More advanced applications, including statistical analysis, modelling, bioinformatics, web site design	Scientific Research & development Management
Specialist	Information system strategy, development and other specialist applications, including design of customised management or decision support systems	System managers IT support

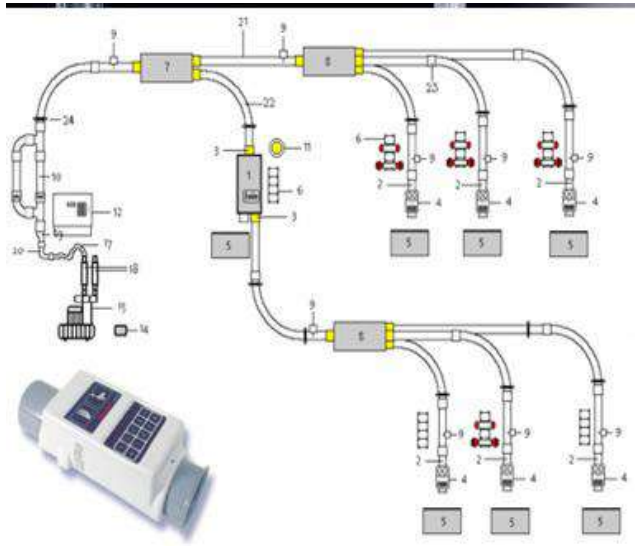
Jones R. G. et al, Clin Biochem Rev 35 (3) 2014

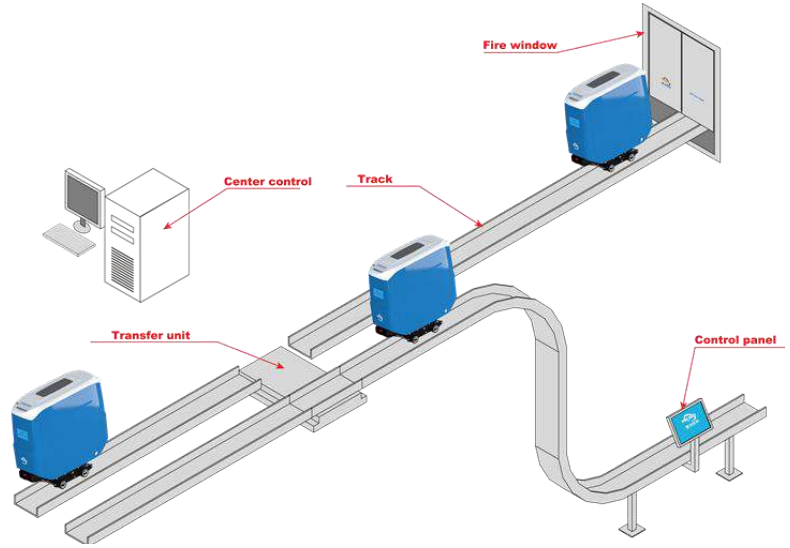
Two major types of automation are available



Specimen identification

Sample transport





What are the new automation concepts and what does it influence in the laboratory?

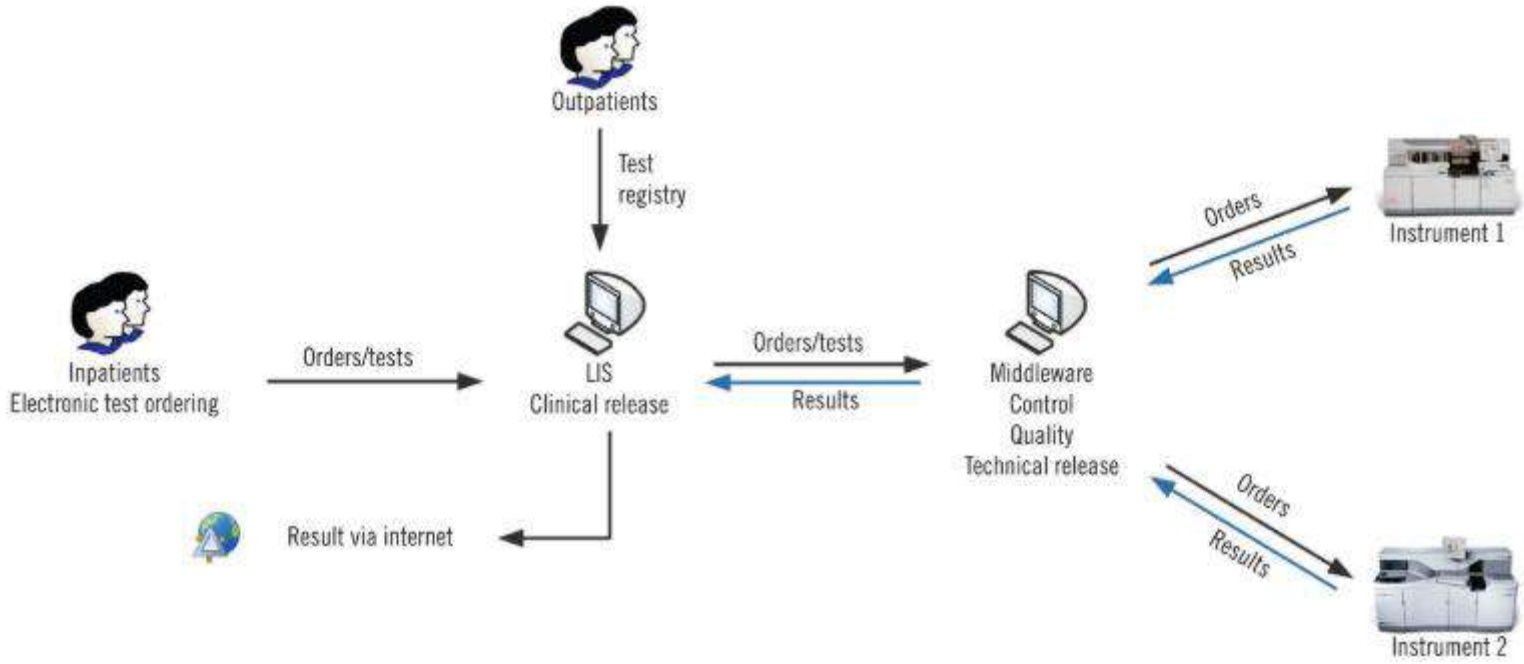
The LIS and the HMS

SLAM

Modern laboratories are way too complex

LIS Cost	IT Staffing	Legacy LIS Integration	Adapting workflows
Downtimes	Different Specialties	Database interfaces	Instrument APIs
Imaging	Non clinical interfaces	Host interfaces	Test routing (remote)

Enter the laboratory middleware



Feitosa S.M. et al., J. Bras. Patol. Med Lab. vol.52 no.3 June 2016 Epub June 27, 2016

Capabilities of a middleware

Connections and instrument support

Autoverification and total laboratory automation

Quality control and moving averages

Security and segmentation

Capabilities of a middleware

- Log in
- Autovalidation
- Connections
- Quality control
- Security
- Backup
- Workflow management
- Downtimes and support

Tata Medical Center's Journey

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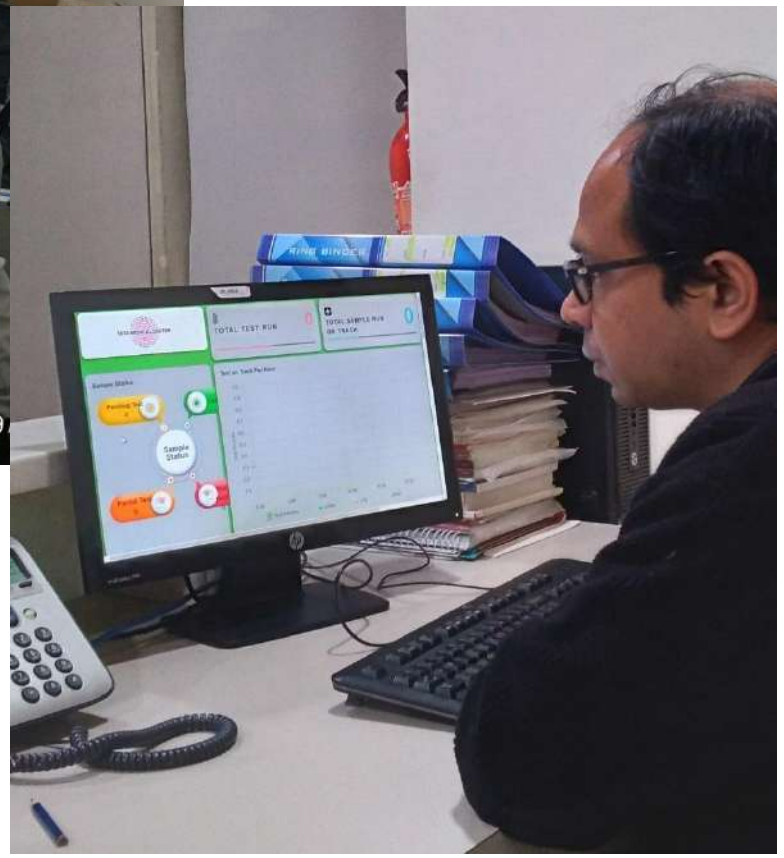
Tata Medical Center's Journey

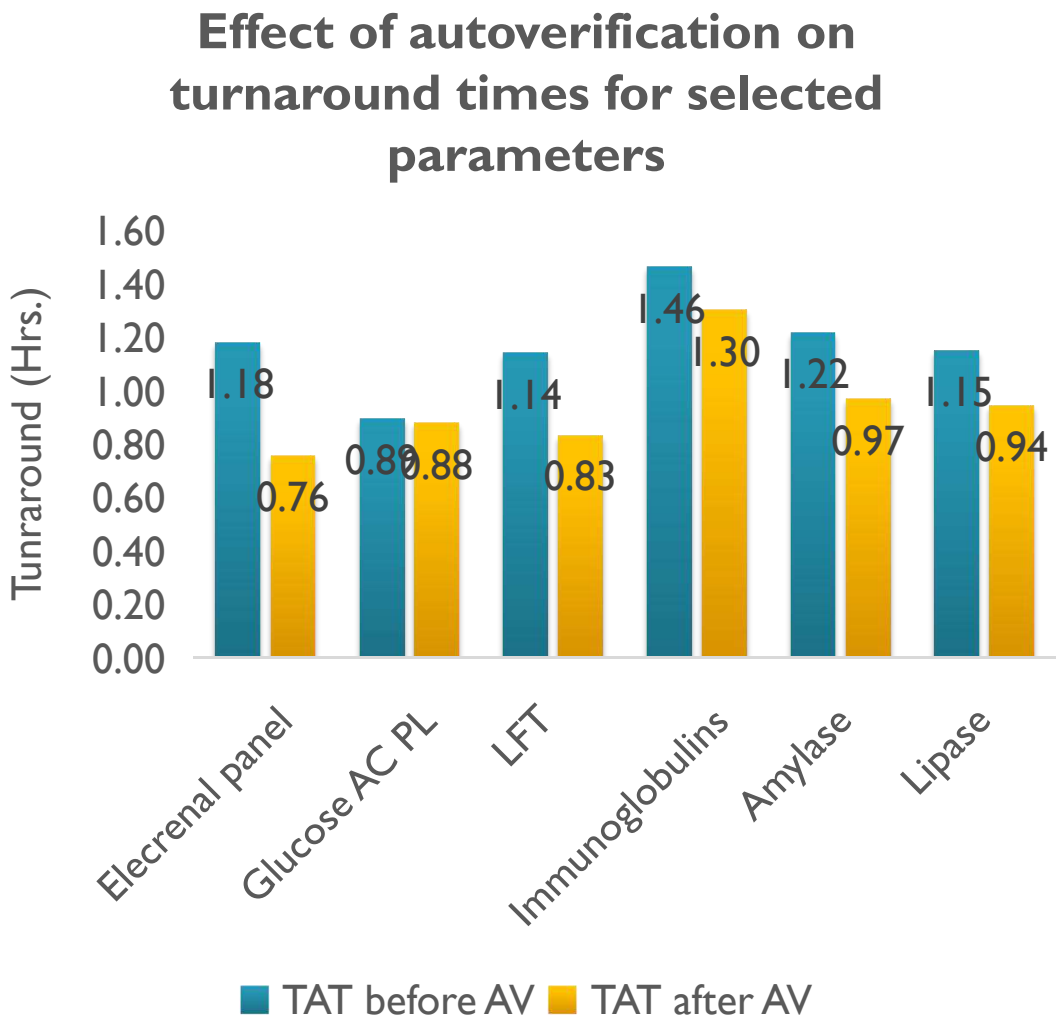


What patient goals did we meet

- ***Quick*** patient identification
- ***Rapid*** sample transport
- ***Direct loading*** onto the pre-analytical module and sorting
- ***Automated*** analysis
- ***Autoverification***
- ***Faster*** turnaround
- ***Rapid*** error detection in the preanalytical phase
- ***Redundancy***
- ***Remote*** monitoring

Does it mean we have gone error free?

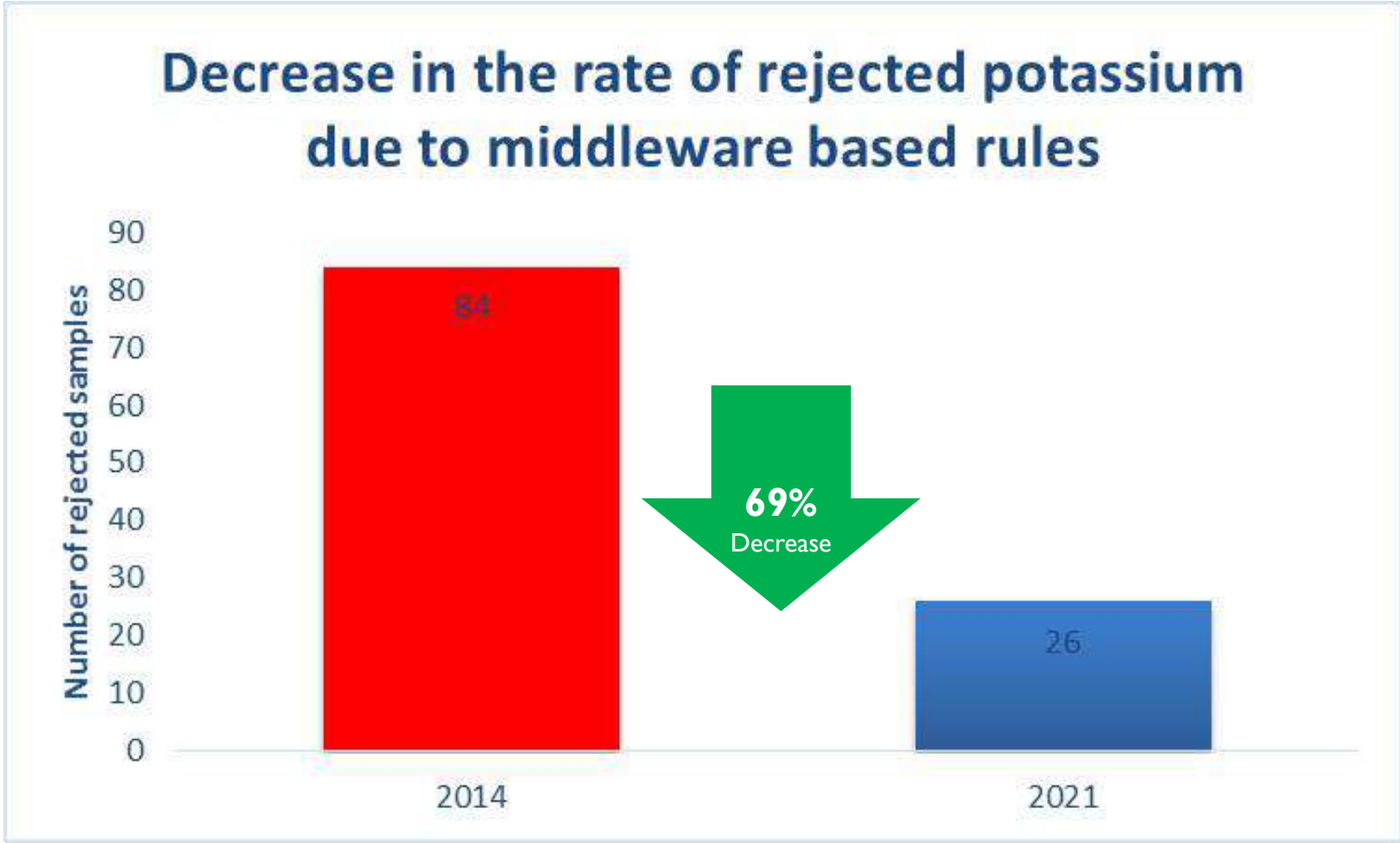
How has IM helped TMC?



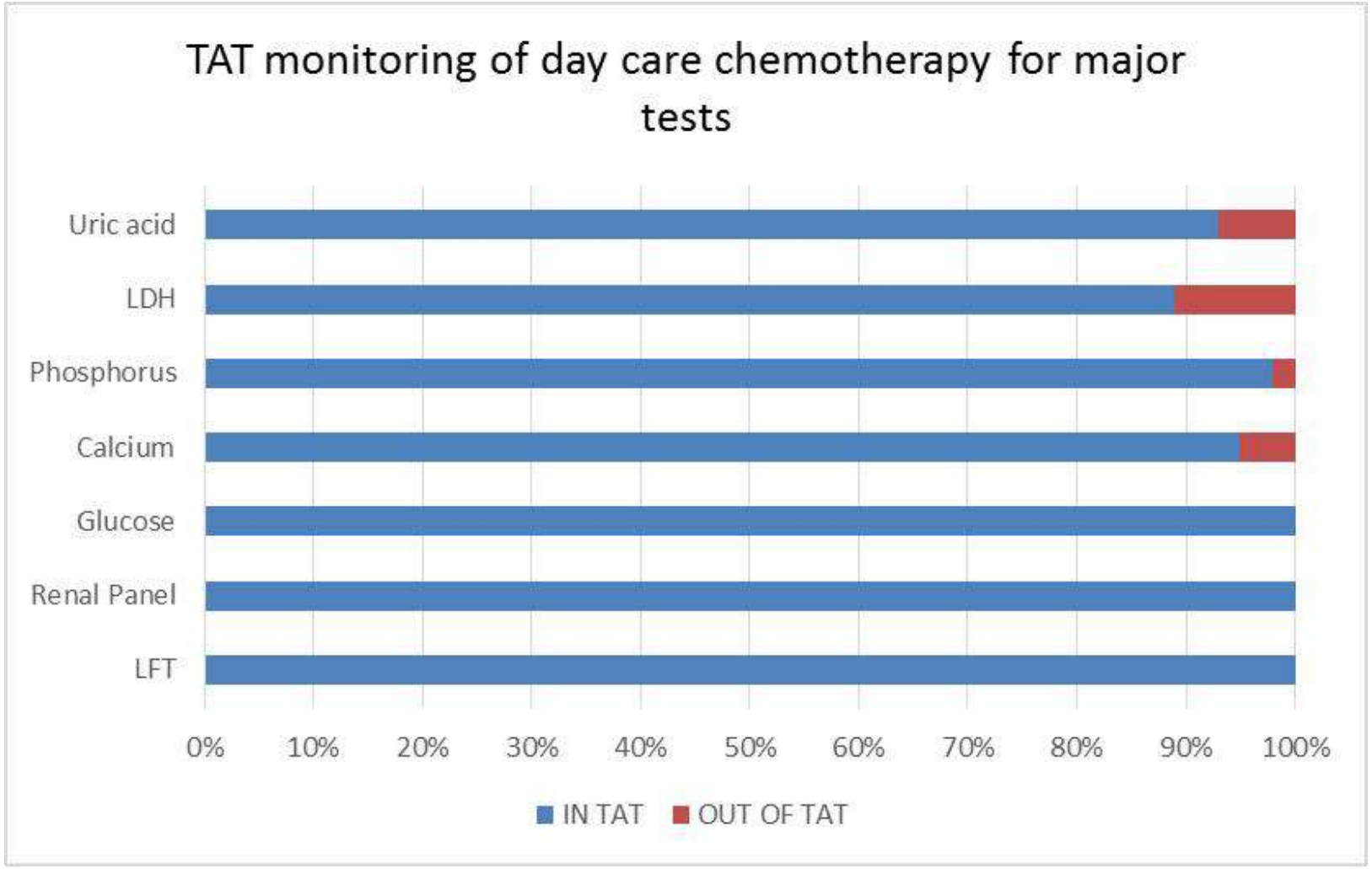
Parameter	TAT before AV	TAT after AV	Reduction in TAT
Elecrenal panel	1.18	0.76	**35.8%**
Glucose AC PL	0.89	0.88	**1.9%**
LFT	1.14	0.83	**26.8%**
Immunoglobulins	1.46	1.30	**11.0%**
Amylase	1.22	0.97	**20.5%**
Lipase	1.15	0.94	**17.9%**

90-92% of the metabolic parameters are being validated online

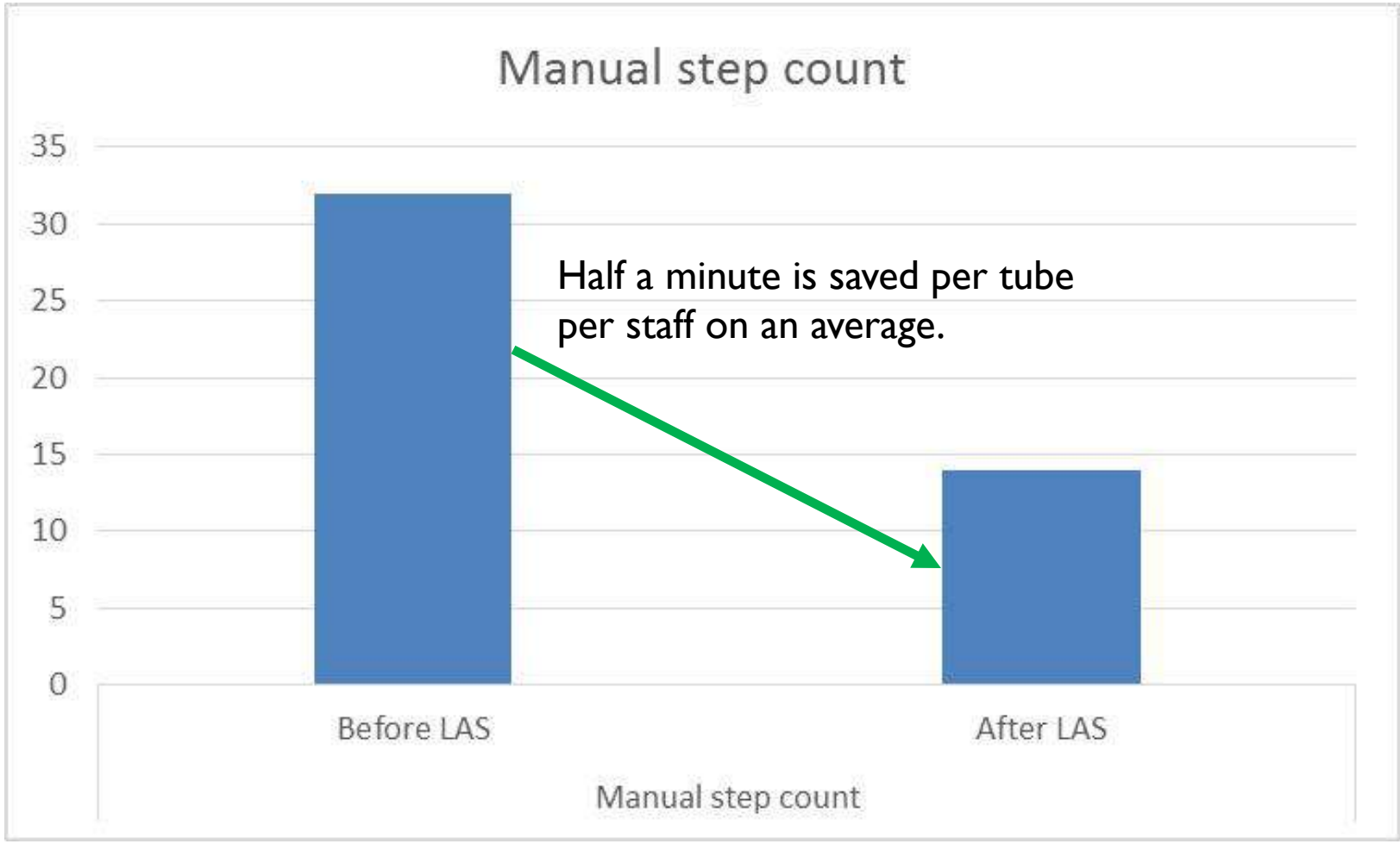
Decrease in sample rejection rate (s. K)



OPD sample collection for day care chemotherapy and TAT status (monthly median)



Manual step count



What the patients don't realize

- Correct identification
- Faster collection
- Faster turnaround time for results
- Less hold up times to consultation entry
- Rapid start of chemotherapy and day-care procedures
- Greater satisfaction with the process

Choosing my middleware

- What are my needs?
- Do I have a team? [Techs/SOs/Consultant/IT/Management]
- Budget and financial considerations.
- What are you going to do with your existing LIS?
- Department, Instruments, personnel, test volumes, test menu
- EMR integration
- Implementation schedule
- Goals for the laboratory

Route to Middleware implementation

- Retrospective data analysis (archival transmission of data)
- Define applicable rules
- Networking and hardware testing
- Verification
- Merging with a legacy system

Third party accreditation

- Define authorities and responsibilities
- Validated and verified by the vendor
- Documentation of daily functionalities
- Security
- National guidelines to be followed. Clause 5.10/ISO 15189:2012

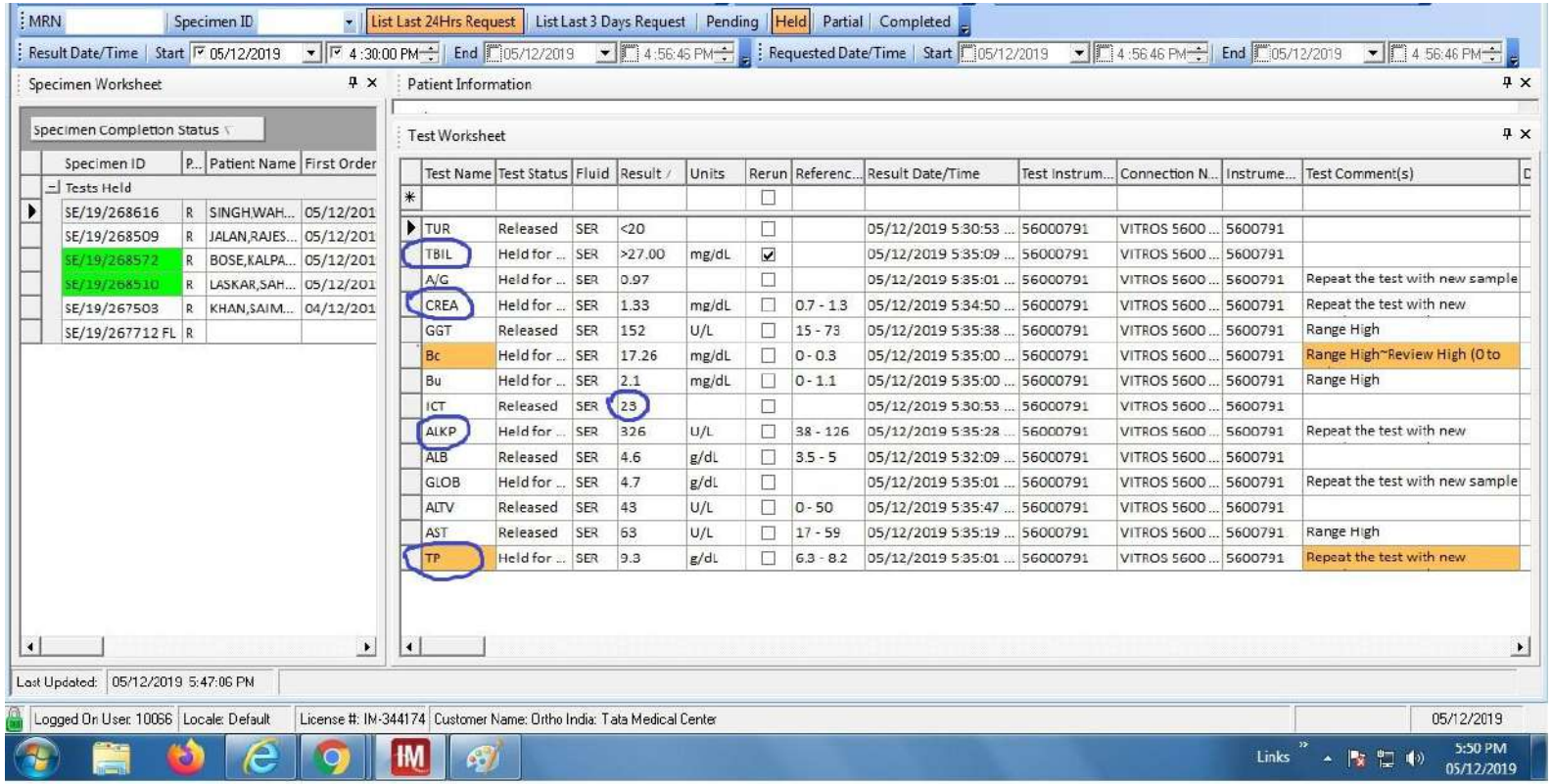
Hurdles in automation

- Patented hardware and software
- Integration of machines from different vendors
- Laboratory layout and geometry
- Process mapping in the laboratory before implementation of automation

Practical demonstration & Case Studies

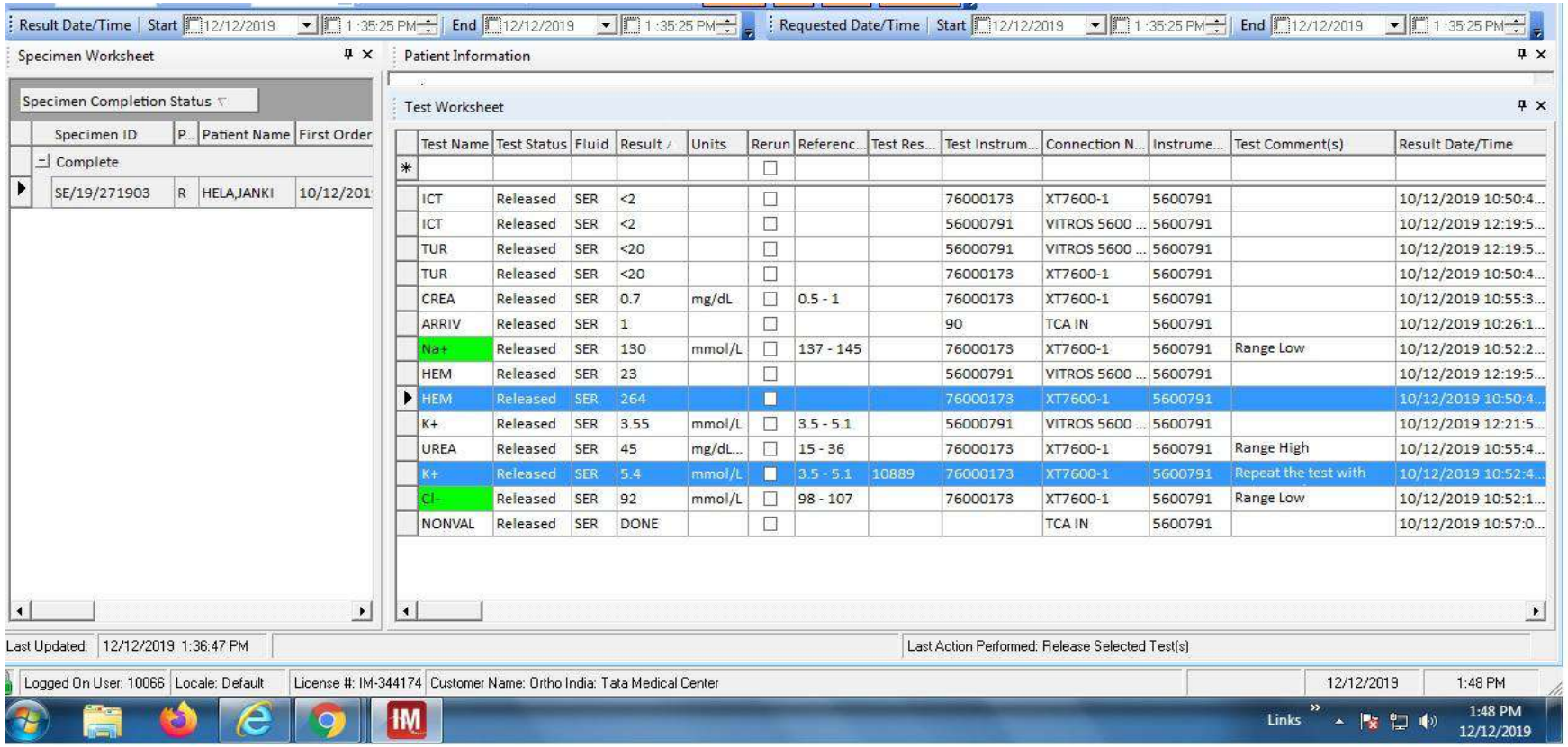
Mr. S.Sugumar, MSc., MPhil (Scientific Officer)
Mr. Ranjan Bhattacharjee, BSc., DLT (Technologist)
Department of Biochemistry
Tata Medical Center

Case study on IM (1)



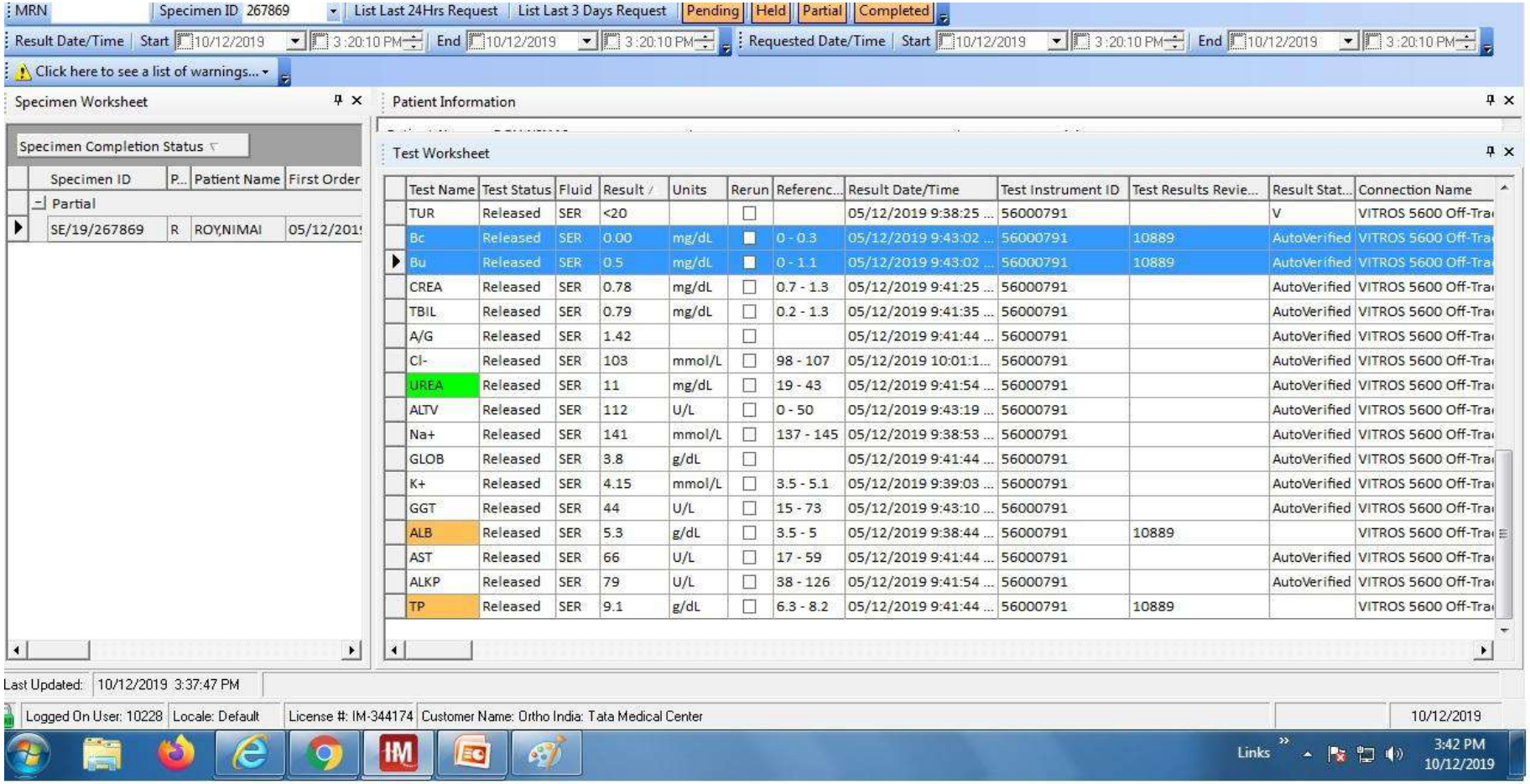
Capabilities of sample quality indicator: icterus

Case study on IM (2)



Capabilities of sample quality indicators: hemolysis

Case study on IM (3)

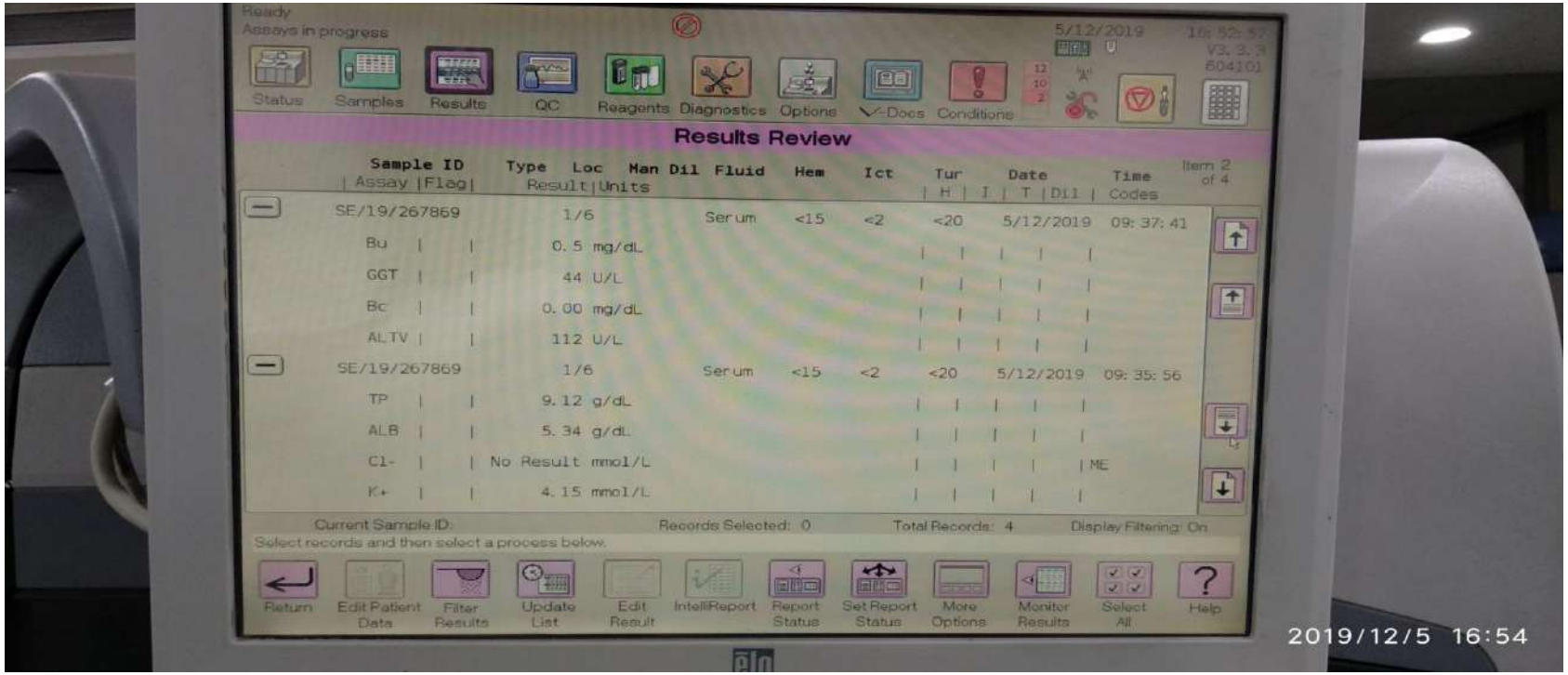


A combination of aspiration failures and recheck prevents release of results.

Case study on IM (3)

- Hold Bu, Bc test for verification if

$$(Bu+Bc) \geq TBil$$


Ready
Assays in progress
Status
Samples
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QC
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Item 2 of 4
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Bu 0.5 mg/dL
GGT 44 U/L
Bc 0.00 mg/dL
ALTV 112 U/L
SE/19/267869 1/6 Serum <15 <2 <20 5/12/2019 09:35:56
TP 9.12 g/dL
ALB 5.34 g/dL
Cl- No Result mmol/L ME
K+ 4.15 mmol/L
Current Sample ID:
Records Selected: 0
Total Records: 4
Display Filtering: On
Select records and then select a process below.
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More Options
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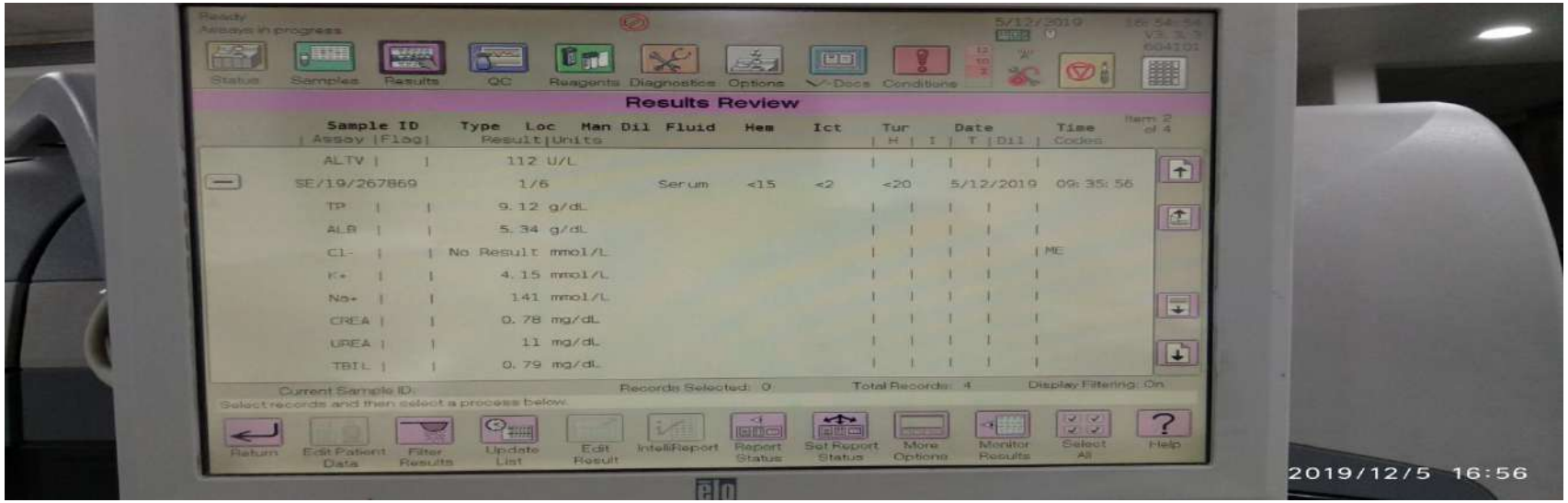
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Cl- No Result mmol/L ME
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Na+ 141 mmol/L
CREA 0.78 mg/dL
UREA 11 mg/dL
TBIL 0.79 mg/dL
Current Sample ID:
Records Selected: 0
Total Records: 4
Display Filtering: On
Select records and then select a process below.
Return
Edit Patient Data
Filter Results
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Report Status
Set Report Status
More Options
Monitor Results
Select All
Help
2019/12/5 16:56

Case study on IM (4)

- IM is a part of Total Laboratory Automation at our center.
- We can now check elements of haemolysis, icterus and lipaemia, dilutions, and elements of track at a glance from the screen.
- It has reduced repeatative and manual steps
- We have additionaly got the convenience of checking error flags and take necessary action.
- For all of them they key steps of **PHYSICAL CHECK** has been reduced.

Case study on IM (4)

- Auto validation effectively frees up time from repetitive strenuous manual tasks. We can now divert our attention to--
  - Quality assurance
  - Accreditation work
  - Learning new technologies (LC-MS2)

Image courtesy: thebalancecareers.com