

Technology driven Process Excellence in Clinical Laboratories



Dr. Subhosmito Chakraborty, MD|DNB
Consultant and Head
Department of Biochemistry
Tata Medical Center
Kolkata

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

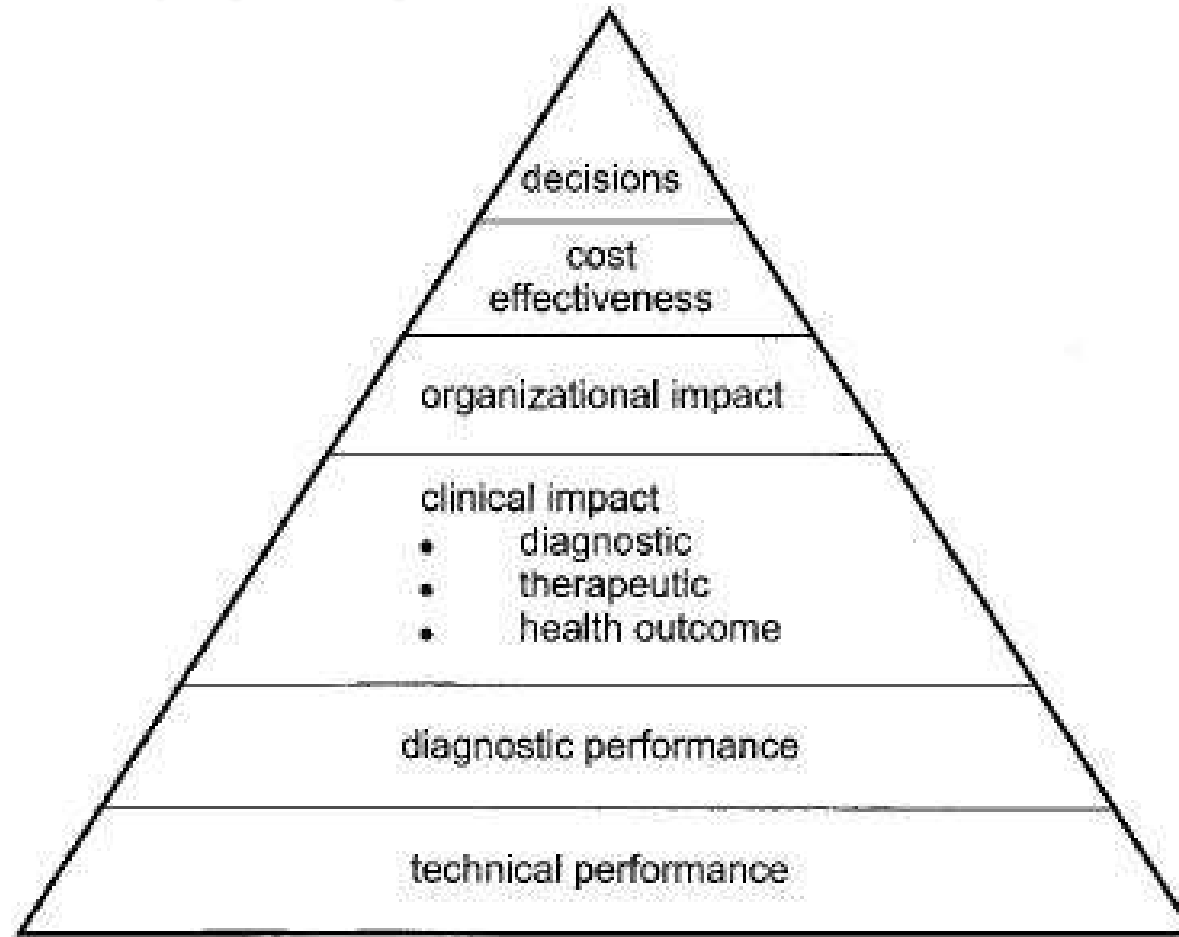
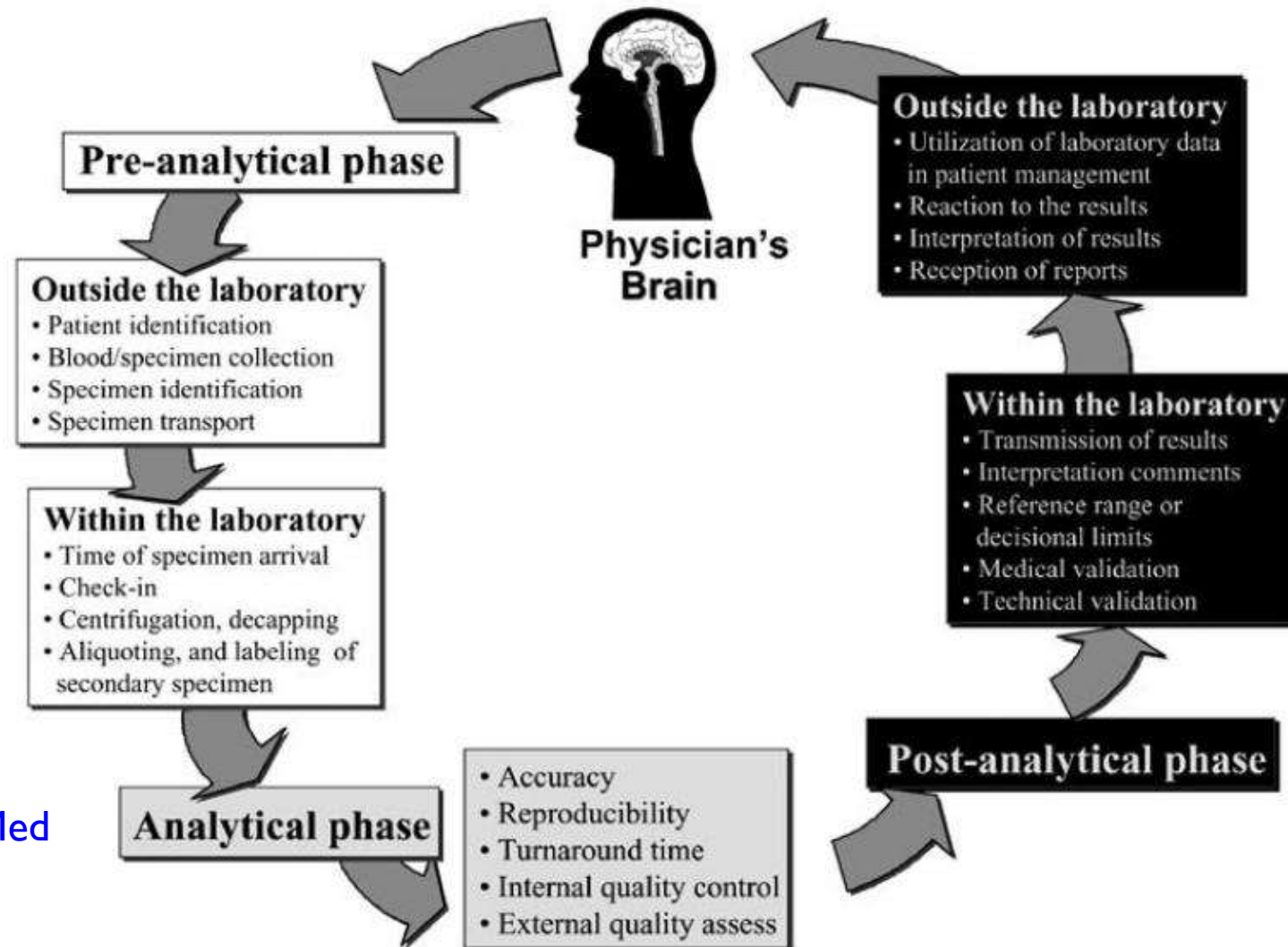


Fig. 2. Evidence of performance designed to facilitate decision-making.

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

Not all processes can be automated or should be automated.



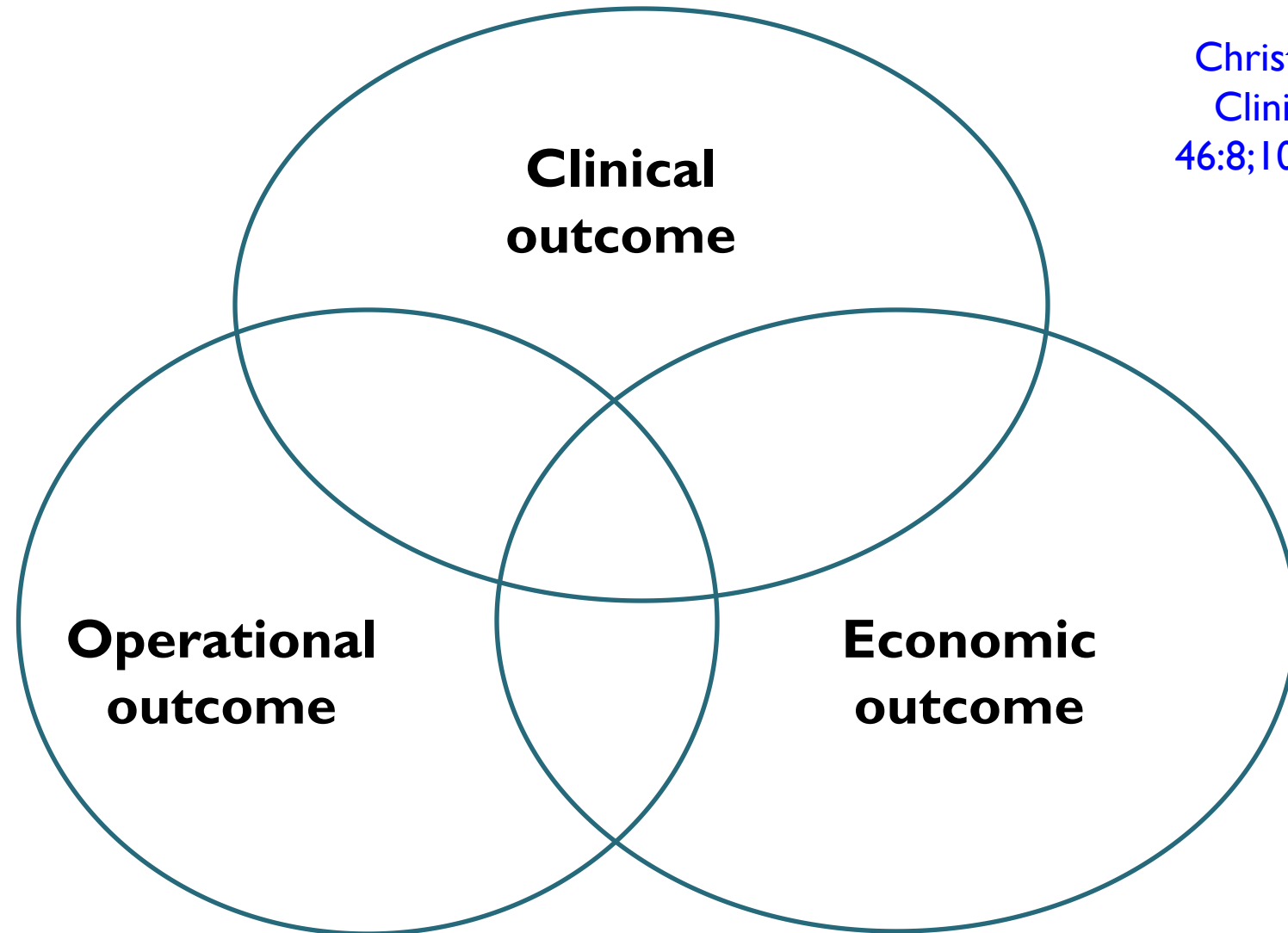
Not all processes should be automated

“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

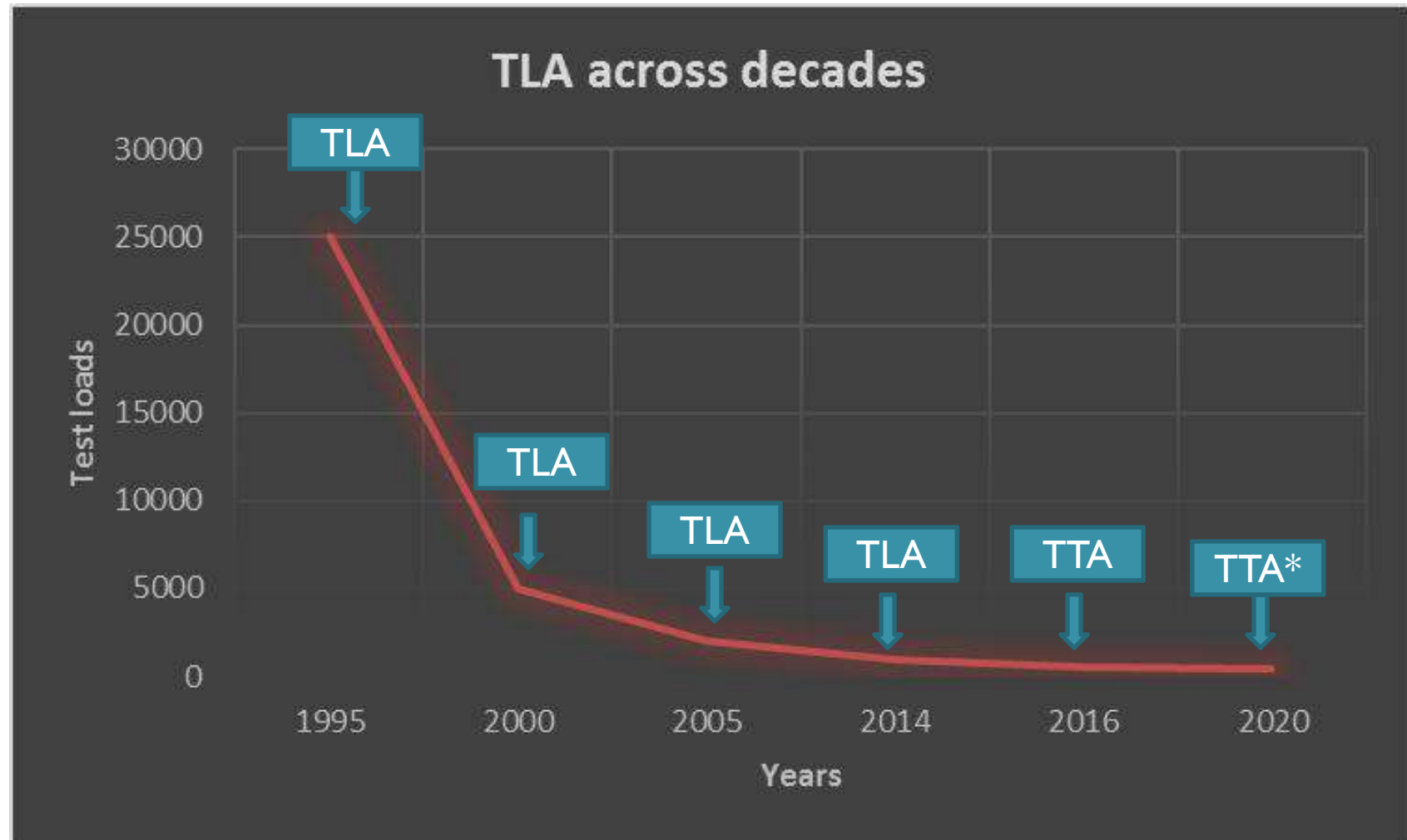
The development of the total laboratory automation concept



Vlazasis V. Siemens Trade
publication (2006)

Dr. Masahide Sasaki

Total laboratory automation and test loads

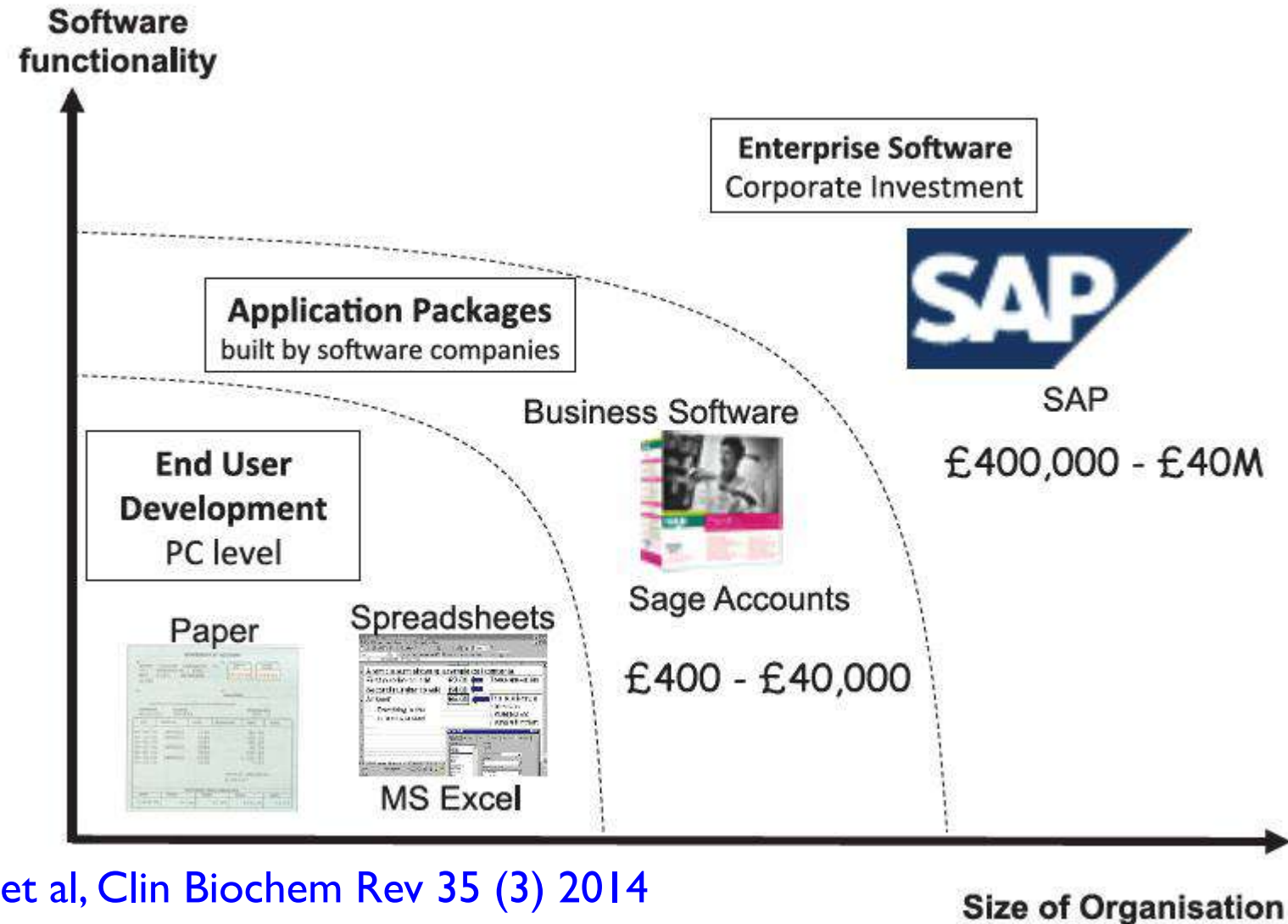


CAP Today(2016): 3:30; 28-48. *Data for 2020 is from our hospital

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

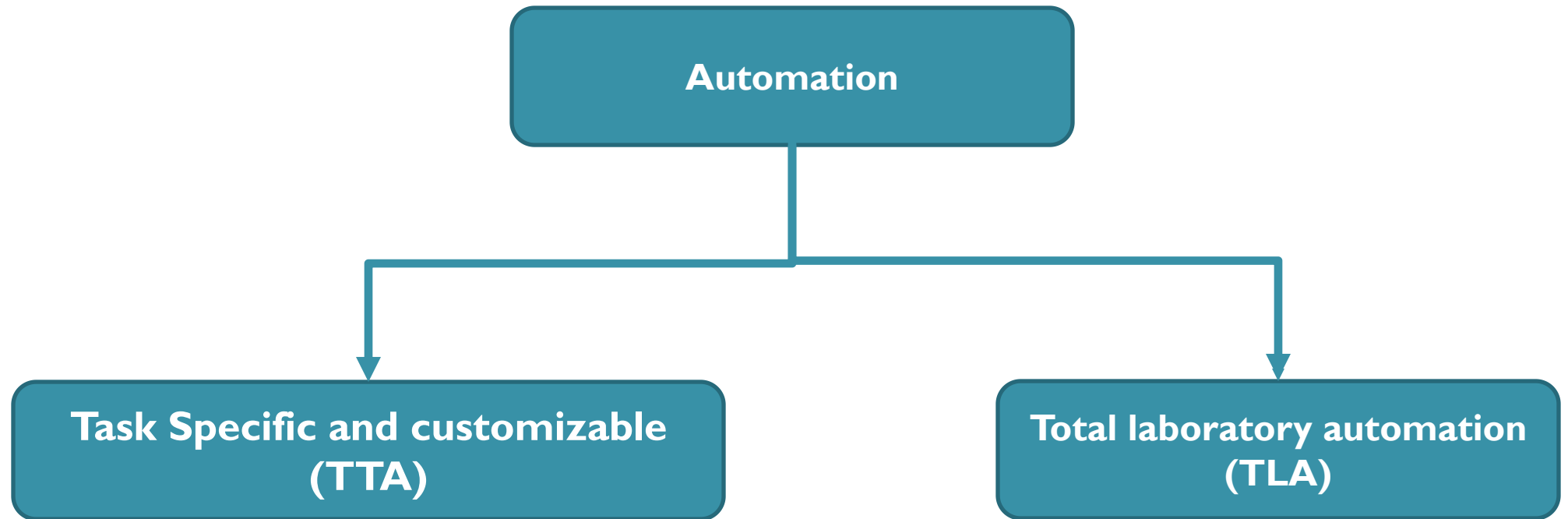


Technophobia ?

Table 3. Future Informatics skill profiles for pathology staff.

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

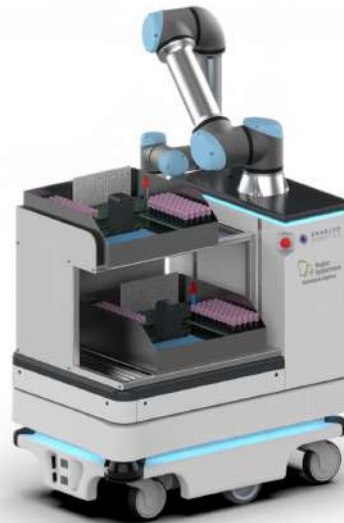
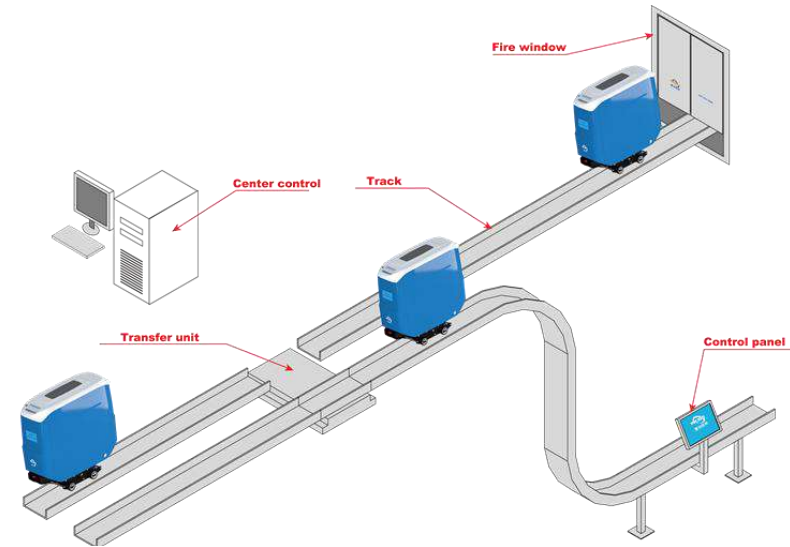
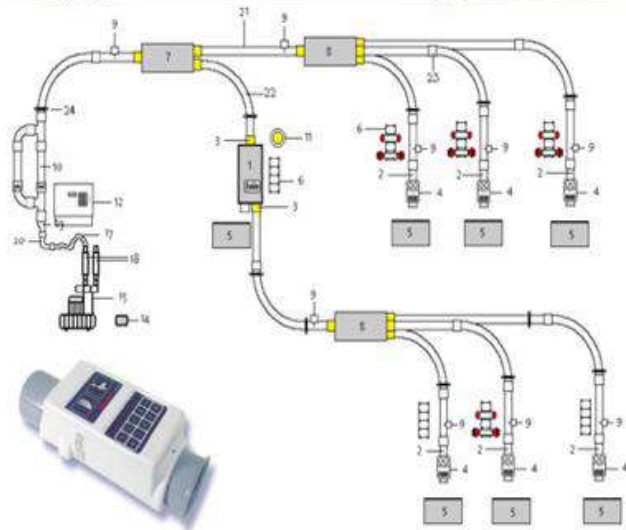
Two major types of automation are available



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**

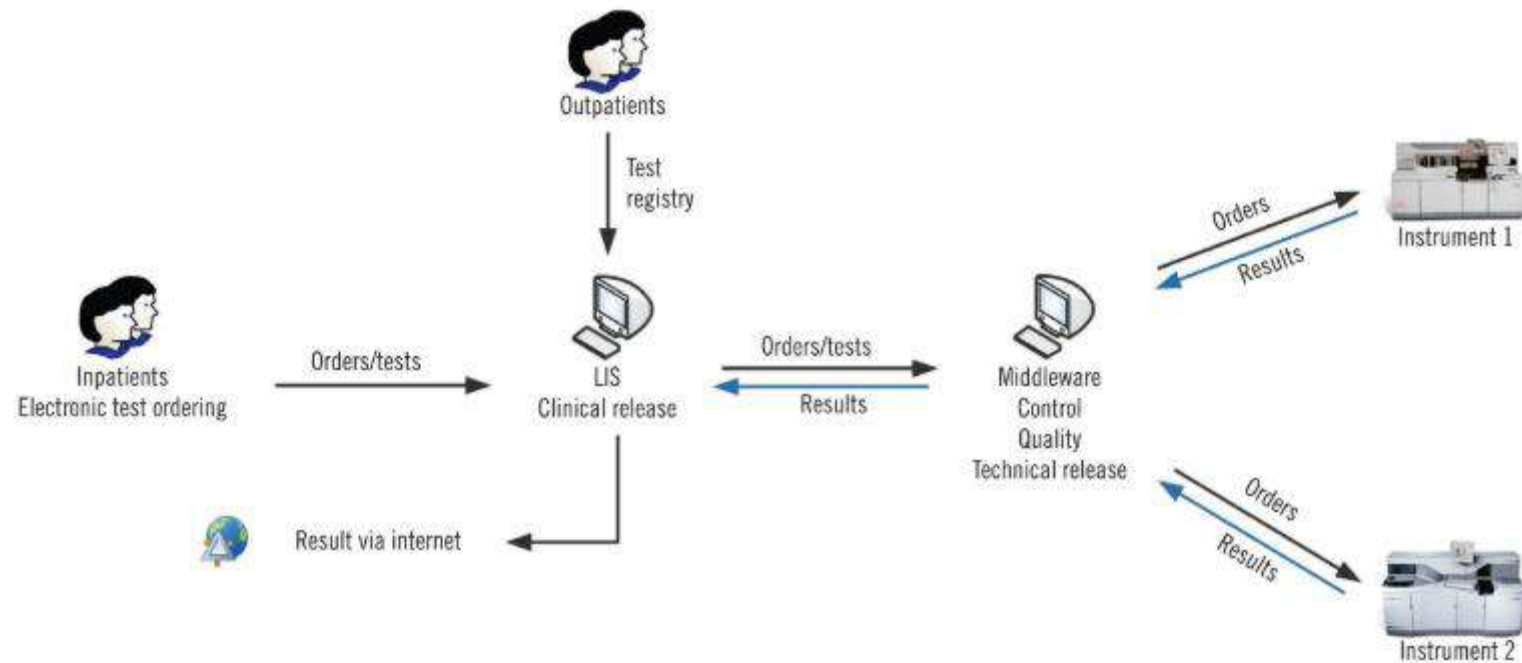
Imaging

**Non clinical
interfaces**

Host interfaces

**Test routing
(remote)**

Enter the laboratory middleware



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



Tata Medical Center's Journey



Tata Medical Center's Journey

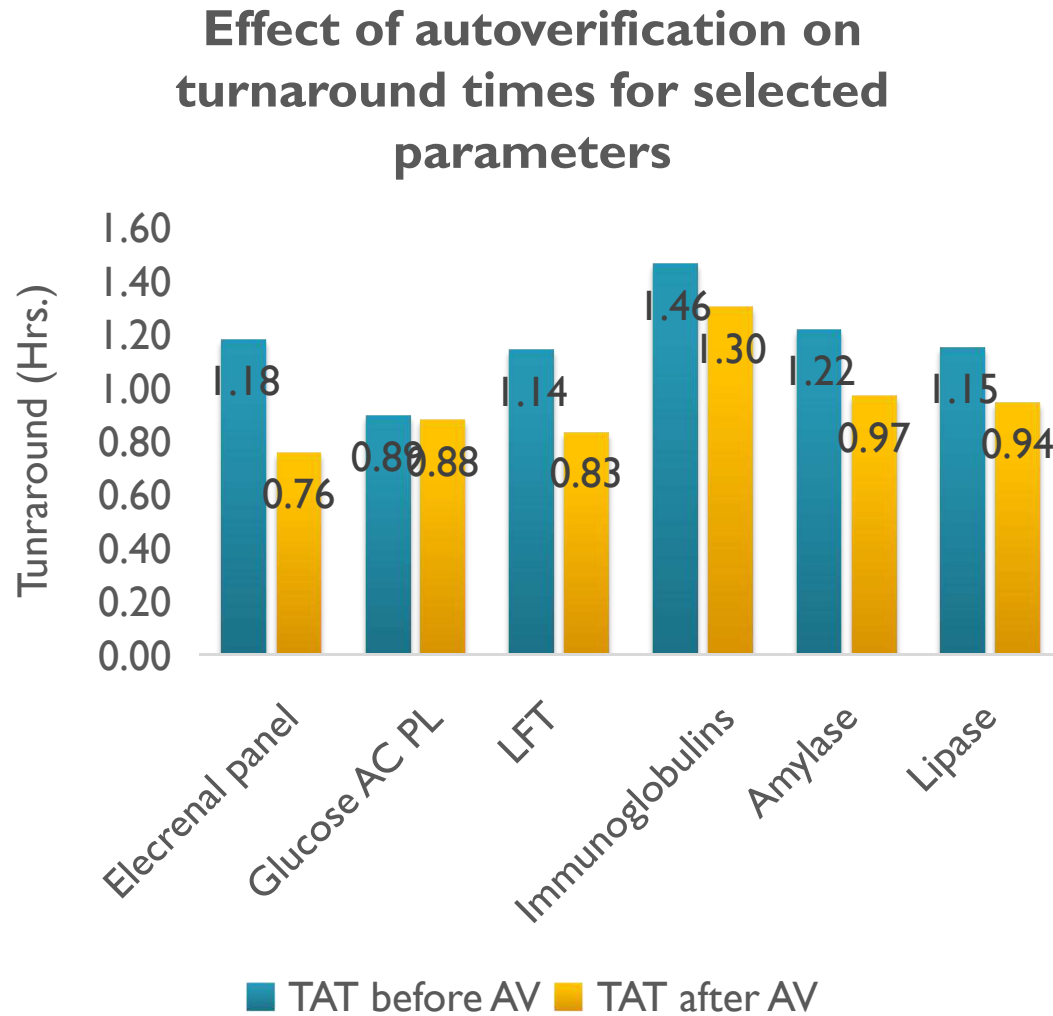


What patient goals did we meet

- **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?

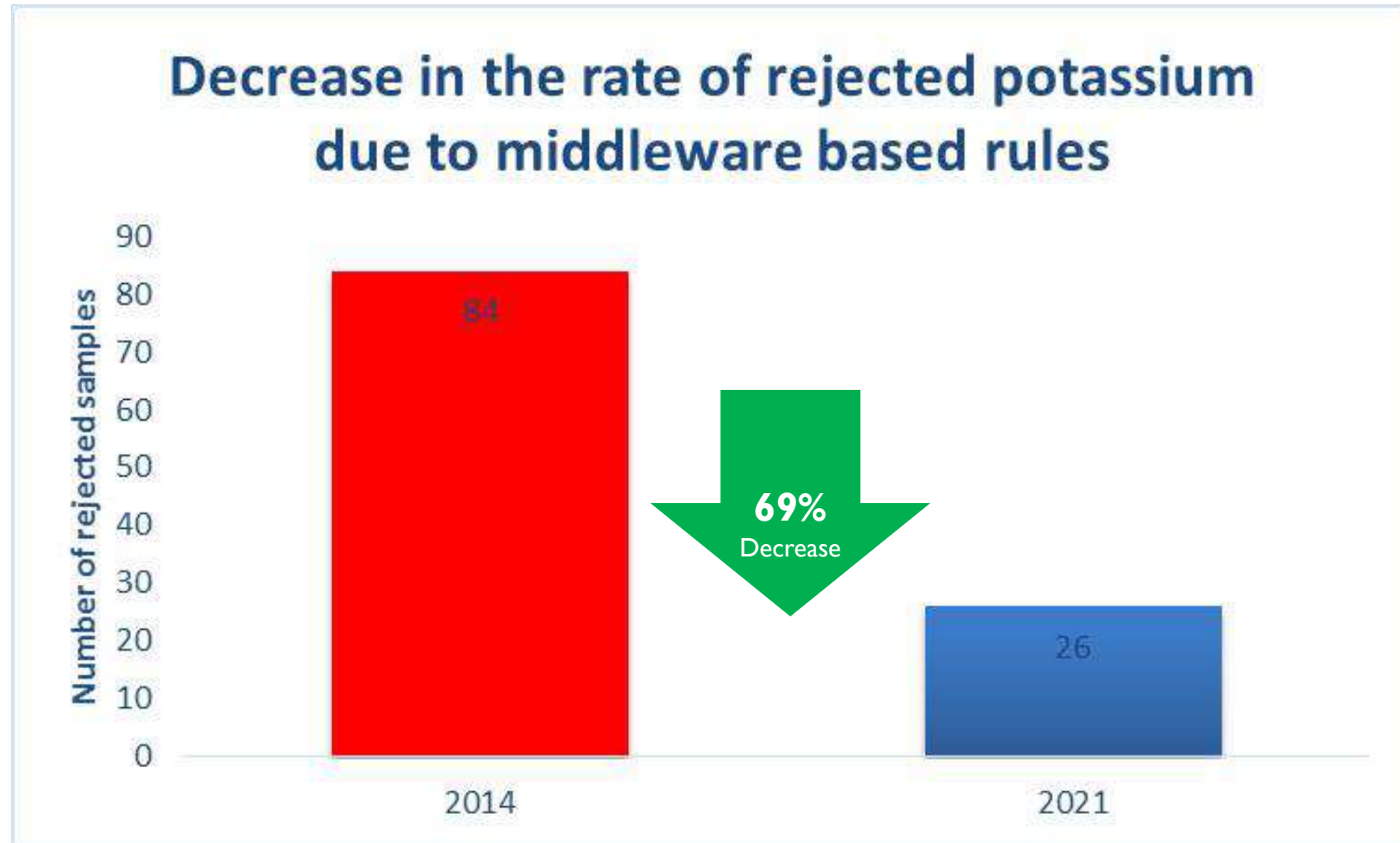
How has IM helped TMC?



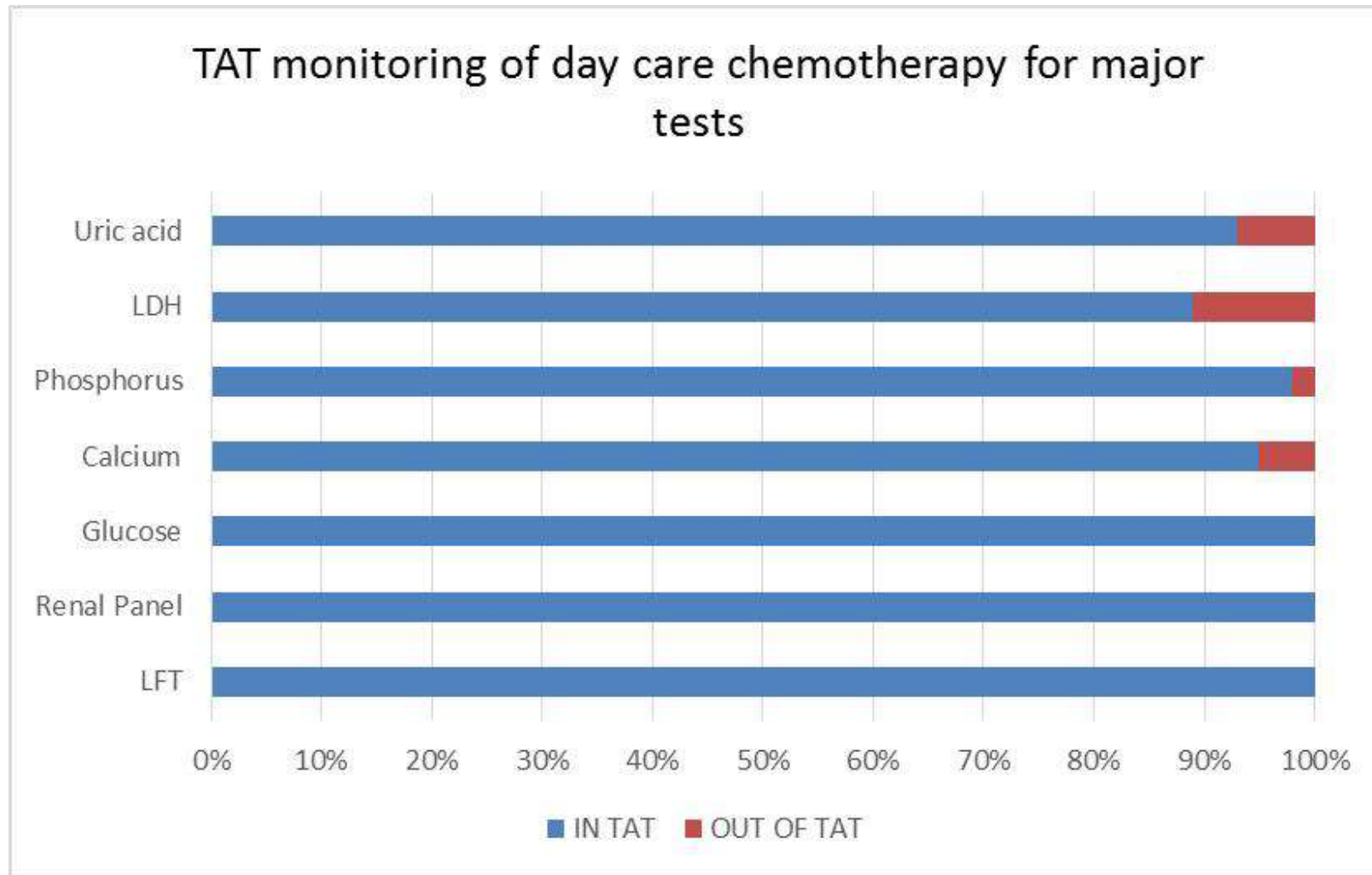
Parameter	TAT before AV	TAT after AV	Reduction in TAT
Elecrenal panel	1.18	0.76	35.8%
Glucose AC PL	0.89	0.88	1.9%
LFT	1.14	0.83	26.8%
Immunoglobulins	1.46	1.30	11.0%
Amylase	1.22	0.97	20.5%
Lipase	1.15	0.94	17.9%

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

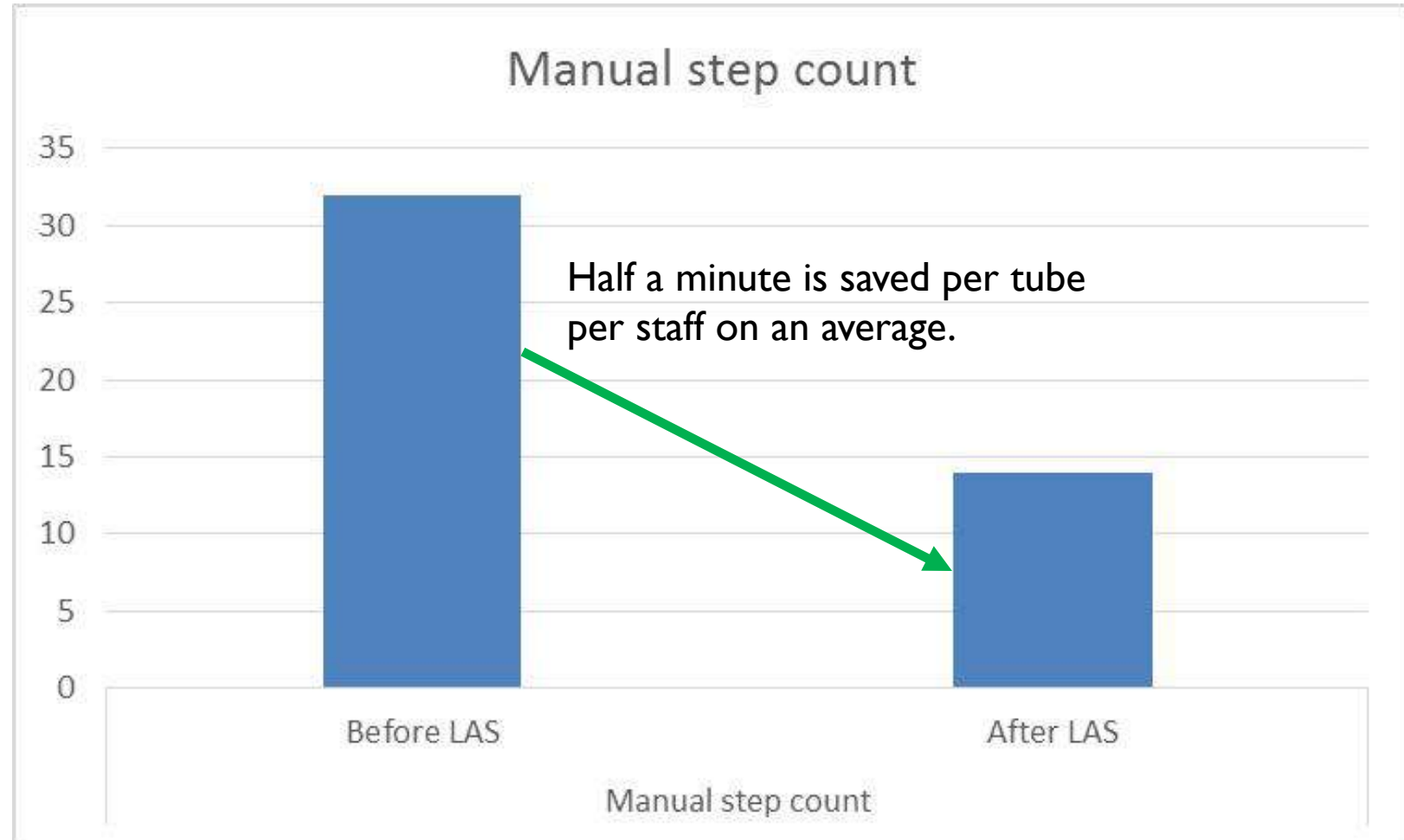
Decrease in sample rejection rate (s. K)



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 (I)

MRN: Specimen ID: List Last 24Hrs Request | List Last 3 Days Request | Pending | Held | Partial | Completed

Result Date/Time: Start 05/12/2019 4:30:00 PM End 05/12/2019 4:56:46 PM Requested Date/Time: Start 05/12/2019 4:56:46 PM End 05/12/2019 4:56:46 PM

Specimen Worksheet

Specimen ID	P...	Patient Name	First Order
SE/19/268616	R	SINGHWAH...	05/12/201
SE/19/268509	R	JALAN,RAJES...	05/12/201
SE/19/268572	R	BOSE,KALPA...	05/12/201
SE/19/268510	R	LASKAR,SAH...	05/12/201
SE/19/267503	R	KHAN,SAIM...	04/12/201
SE/19/267712 FL	R		

Test Worksheet

Test Name	Test Status	Fluid	Result /	Units	Rerun	Referenc...	Result Date/Time	Test Instrum...	Connection N...	Instrume...	Test Comment(s)
TUR	Released	SER	<20		☐		05/12/2019 5:30:53 ...	56000791	VITROS 5600 ...	5600791	
TBIL	Held for ...	SER	>27.00	mg/dL	☒		05/12/2019 5:35:09 ...	56000791	VITROS 5600 ...	5600791	
A/G	Held for ...	SER	0.97		☐		05/12/2019 5:35:01 ...	56000791	VITROS 5600 ...	5600791	Repeat the test with new sample
CREA	Held for ...	SER	1.33	mg/dL	☐	0.7 - 1.3	05/12/2019 5:34:50 ...	56000791	VITROS 5600 ...	5600791	Repeat the test with new
GGT	Released	SER	152	U/L	☐	15 - 73	05/12/2019 5:35:38 ...	56000791	VITROS 5600 ...	5600791	Range High
Bc	Held for ...	SER	17.26	mg/dL	☐	0 - 0.3	05/12/2019 5:35:00 ...	56000791	VITROS 5600 ...	5600791	Range High~Review High (0 to
Bu	Held for ...	SER	2.1	mg/dL	☐	0 - 1.1	05/12/2019 5:35:00 ...	56000791	VITROS 5600 ...	5600791	Range High
ICT	Released	SER	123		☐		05/12/2019 5:30:53 ...	56000791	VITROS 5600 ...	5600791	
ALKP	Held for ...	SER	326	U/L	☐	38 - 126	05/12/2019 5:35:28 ...	56000791	VITROS 5600 ...	5600791	Repeat the test with new
ALB	Released	SER	4.6	g/dL	☐	3.5 - 5	05/12/2019 5:32:09 ...	56000791	VITROS 5600 ...	5600791	
GLOB	Held for ...	SER	4.7	g/dL	☐		05/12/2019 5:35:01 ...	56000791	VITROS 5600 ...	5600791	Repeat the test with new sample
ALT	Released	SER	43	U/L	☐	0 - 50	05/12/2019 5:35:47 ...	56000791	VITROS 5600 ...	5600791	
AST	Released	SER	63	U/L	☐	17 - 59	05/12/2019 5:35:19 ...	56000791	VITROS 5600 ...	5600791	Range High
TP	Held for ...	SER	9.3	g/dL	☐	6.3 - 8.2	05/12/2019 5:35:01 ...	56000791	VITROS 5600 ...	5600791	Repeat the test with new

Last Updated: 05/12/2019 5:47:06 PM

Logged On User: 10066 Locale: Default License #: IM-344174 Customer Name: Ortho India: Tata Medical Center

05/12/2019 5:50 PM

Capabilities of sample quality indicator:
icterus

Case study on IM (2)

Result Date/Time Start 12/12/2019 1:35:25 PM End 12/12/2019 1:35:25 PM Requested Date/Time Start 12/12/2019 1:35:25 PM End 12/12/2019 1:35:25 PM

Specimen Worksheet Patient Information

Specimen Completion Status

Specimen ID	P...	Patient Name	First Order
SE/19/271903	R	HELAJANKI	10/12/2019

Test Worksheet

Test Name	Test Status	Fluid	Result /	Units	Rerun	Referenc...	Test Res...	Test Instrum...	Connection N...	Instrume...	Test Comment(s)	Result Date/Time
ICT	Released	SER	<2		☐			76000173	XT7600-1	5600791		10/12/2019 10:50:4...
ICT	Released	SER	<2		☐			56000791	VITROS 5600 ...	5600791		10/12/2019 12:19:5...
TUR	Released	SER	<20		☐			56000791	VITROS 5600 ...	5600791		10/12/2019 12:19:5...
TUR	Released	SER	<20		☐			76000173	XT7600-1	5600791		10/12/2019 10:50:4...
CREA	Released	SER	0.7	mg/dL	☐	0.5 - 1		76000173	XT7600-1	5600791		10/12/2019 10:55:3...
ARRIV	Released	SER	1		☐			90	TCA IN	5600791		10/12/2019 10:26:1...
Na+	Released	SER	130	mmol/L	☐	137 - 145		76000173	XT7600-1	5600791	Range Low	10/12/2019 10:52:2...
HEM	Released	SER	23		☐			56000791	VITROS 5600 ...	5600791		10/12/2019 12:19:5...
HEM	Released	SER	264		☐			76000173	XT7600-1	5600791		10/12/2019 10:50:4...
K+	Released	SER	3.55	mmol/L	☐	3.5 - 5.1		56000791	VITROS 5600 ...	5600791		10/12/2019 12:21:5...
UREA	Released	SER	45	mg/dL...	☐	15 - 36		76000173	XT7600-1	5600791	Range High	10/12/2019 10:55:4...
K+	Released	SER	5.4	mmol/L	☐	3.5 - 5.1	10889	76000173	XT7600-1	5600791	Repeat the test with	10/12/2019 10:52:4...
Cl-	Released	SER	92	mmol/L	☐	98 - 107		76000173	XT7600-1	5600791	Range Low	10/12/2019 10:52:1...
NONVAL	Released	SER	DONE		☐				TCA IN	5600791		10/12/2019 10:57:0...

Last Updated: 12/12/2019 1:36:47 PM Last Action Performed: Release Selected Test(s)

Logged On User: 10066 Locale: Default License #: IM-344174 Customer Name: Ortho India: Tata Medical Center

12/12/2019 1:48 PM

**Capabilities of sample quality indicators:
hemolysis**

Case study on IM (3)

MRN Specimen ID 267869 List Last 24Hrs Request List Last 3 Days Request Pending Held Partial Completed

Result Date/Time Start 10/12/2019 3:20:10 PM End 10/12/2019 3:20:10 PM Requested Date/Time Start 10/12/2019 3:20:10 PM End 10/12/2019 3:20:10 PM

Click here to see a list of warnings...

Specimen Worksheet Patient Information

Specimen Completion Status

Partial

SE/19/267869 R ROY,NIMAI 05/12/2019

Test Worksheet

Test Name	Test Status	Fluid	Result /	Units	Rerun	Referenc...	Result Date/Time	Test Instrument ID	Test Results Revie...	Result Stat...	Connection Name
TUR	Released	SER	<20				05/12/2019 9:38:25 ...	56000791		V	VITROS 5600 Off-Trai
Bc	Released	SER	0.00	mg/dL		0 - 0.3	05/12/2019 9:43:02 ...	56000791	10889	AutoVerified	VITROS 5600 Off-Trai
Bu	Released	SER	0.5	mg/dL		0 - 1.1	05/12/2019 9:43:02 ...	56000791	10889	AutoVerified	VITROS 5600 Off-Trai
CREA	Released	SER	0.78	mg/dL		0.7 - 1.3	05/12/2019 9:41:25 ...	56000791		AutoVerified	VITROS 5600 Off-Trai
TBIL	Released	SER	0.79	mg/dL		0.2 - 1.3	05/12/2019 9:41:35 ...	56000791		AutoVerified	VITROS 5600 Off-Trai
A/G	Released	SER	1.42				05/12/2019 9:41:44 ...	56000791		AutoVerified	VITROS 5600 Off-Trai
Cl-	Released	SER	103	mmol/L		98 - 107	05/12/2019 10:01:1...	56000791		AutoVerified	VITROS 5600 Off-Trai
UREA	Released	SER	11	mg/dL		19 - 43	05/12/2019 9:41:54 ...	56000791		AutoVerified	VITROS 5600 Off-Trai
ALT	Released	SER	112	U/L		0 - 50	05/12/2019 9:43:19 ...	56000791		AutoVerified	VITROS 5600 Off-Trai
Na+	Released	SER	141	mmol/L		137 - 145	05/12/2019 9:38:53 ...	56000791		AutoVerified	VITROS 5600 Off-Trai
GLOB	Released	SER	3.8	g/dL			05/12/2019 9:41:44 ...	56000791		AutoVerified	VITROS 5600 Off-Trai
K+	Released	SER	4.15	mmol/L		3.5 - 5.1	05/12/2019 9:39:03 ...	56000791		AutoVerified	VITROS 5600 Off-Trai
GGT	Released	SER	44	U/L		15 - 73	05/12/2019 9:43:10 ...	56000791		AutoVerified	VITROS 5600 Off-Trai
ALB	Released	SER	5.3	g/dL		3.5 - 5	05/12/2019 9:38:44 ...	56000791	10889		VITROS 5600 Off-Trai
AST	Released	SER	66	U/L		17 - 59	05/12/2019 9:41:44 ...	56000791		AutoVerified	VITROS 5600 Off-Trai
ALKP	Released	SER	79	U/L		38 - 126	05/12/2019 9:41:54 ...	56000791		AutoVerified	VITROS 5600 Off-Trai
TP	Released	SER	9.1	g/dL		6.3 - 8.2	05/12/2019 9:41:44 ...	56000791	10889		VITROS 5600 Off-Trai

Last Updated: 10/12/2019 3:37:47 PM

Logged On User: 10228 Locale: Default License #: IM-344174 Customer Name: Ortho India: Tata Medical Center

10/12/2019 3:42 PM 10/12/2019

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

5/12/2019 16:52:57
V3.3.3
604101

Status Samples Results QC Reagents Diagnostics Options Docs Conditions

Results Review

Sample ID	Type	Loc	Man	Dil	Fluid	Hem	Ict	Tur	Date	Time	Item 2 of 4
Assay Flag	Result	Units						H I T Dil		Codes	
SE/19/267869		1/6			Serum	<15	<2	<20	5/12/2019	09:37:41	
Bu		0.5			mg/dL						
GGT		44			U/L						
Bc		0.00			mg/dL						
ALT		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.

Return Edit Patient Data Filter Results Update List Edit Result IntelliReport Report Status Set Report Status More Options Monitor Results Select All Help

2019/12/5 16:54

Ready
Assays in progress

5/12/2019 16:54:54
V3.3.3
604101

Status Samples Results QC Reagents Diagnostics Options Docs Conditions

Results Review

Sample ID	Type	Loc	Man	Dil	Fluid	Hem	Ict	Tur	Date	Time	Item 2 of 4
Assay Flag	Result	Units						H I T Dil		Codes	
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						
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 Update List Edit Result IntelliReport 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 additionally got the convenience of checking error flags and take necessary action.
- For all of them the 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)

*Thank
you*

