



2ª EDIZIONE | 6-8 NOVEMBRE 2024 | VICENZA

LA FIERA DEDICATA A SOLUZIONI TECNOLOGICHE,
INNOVAZIONE, AFFIDABILITÀ E COMPETENZE 4.0 - 5.0

VERSO L'AUTOMAZIONE:
la sfida della Transizione Tecnologica
nell'accreditamento delle prove e tarature

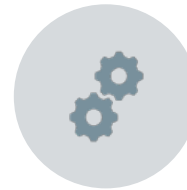
L'automazione al servizio della Medicina di Laboratorio

Dott.ssa Michela Pellosso
UOC Medicina di Laboratorio, DIDAS Servizi di diagnostica integrata
Azienda Ospedale – Università di Padova

ROAD MAP



**STORIA
DELL'AUTOMAZIONE NEL
LABORATORIO CLINICO**



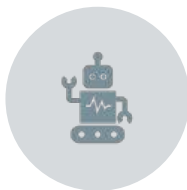
**FASI DEL TOTAL TESTING
PROCESS: DOVE E'
POSSIBILE
AUTOMATIZZARE IL
PERCORSO DEL
CAMPIONE DI SANGUE?**



**MODELLI DI
AUTOMAZIONE NEL
LABORATORIO CLINICO**



**UOC MEDICINA DI
LABORATORIO AZIENDA
OSPEDALE – UNIVERSITA'
DI PADOVA**



**ESEMPIO DI TOTAL
LABORATORY
AUTOMATION (TLA)**

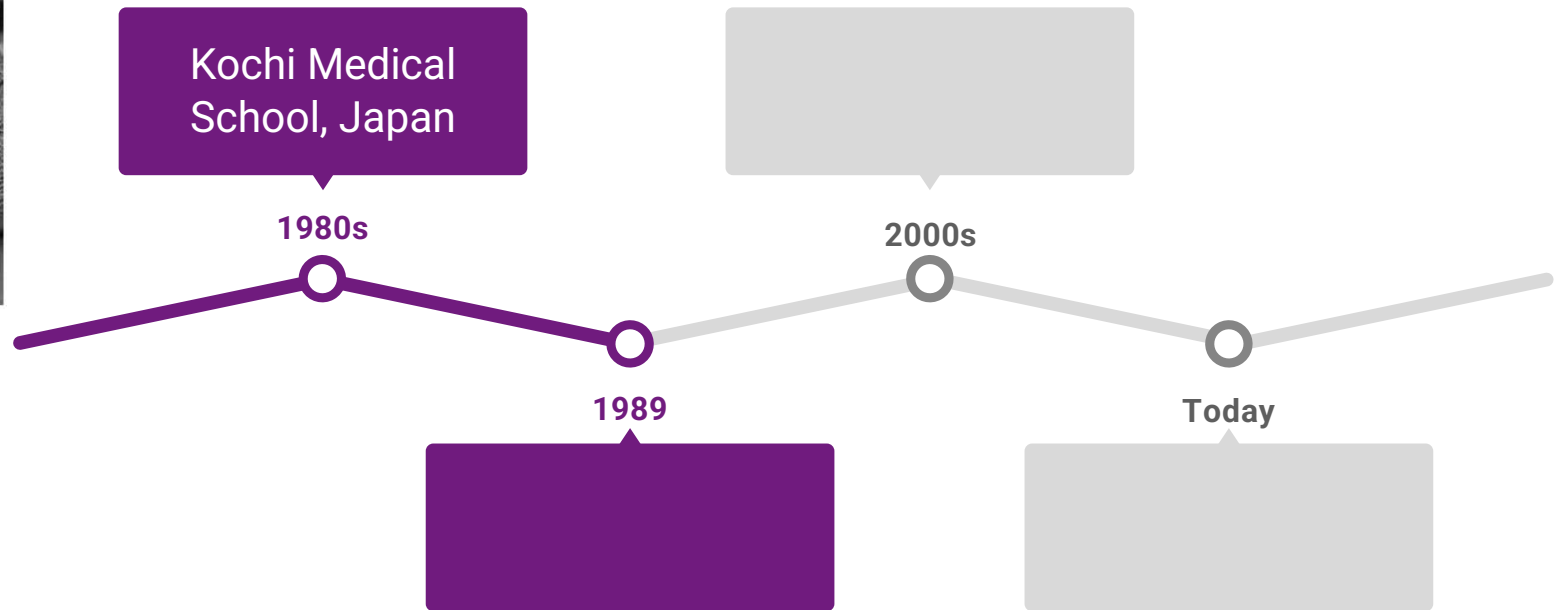


**VANTAGGI E SVANTAGGI
DELLA TLA**

Quando è nata l'automazione nel laboratorio clinico?



Dr. Masahide Sasaki
(1933 - 2005)



KOCHI MEDICAL SCHOOL, JAPAN 1980s

- Conveyor systems
- Robots that loaded and unloaded analyzers
- Supporting process control software systems



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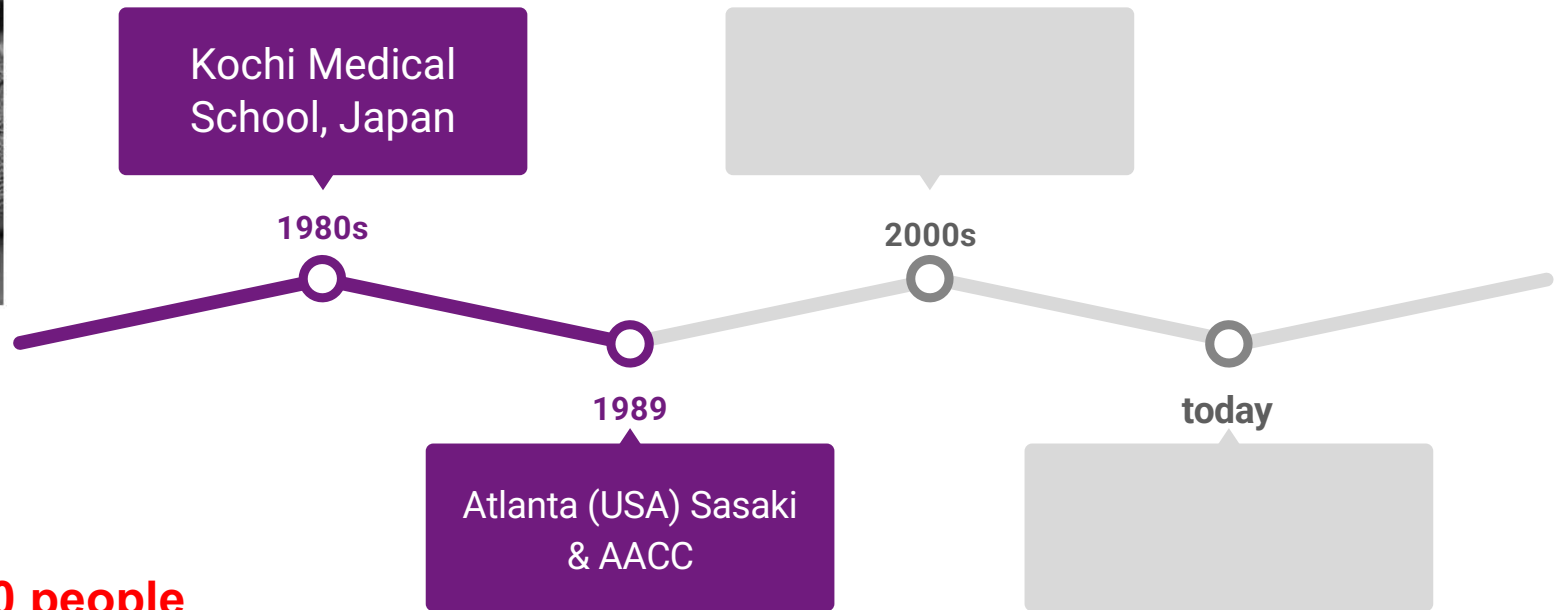


- **Error reduction**
- **Cost containment**
- **Unprecedented turnaround times**





Dr. Masahide Sasaki
(1933 - 2005)

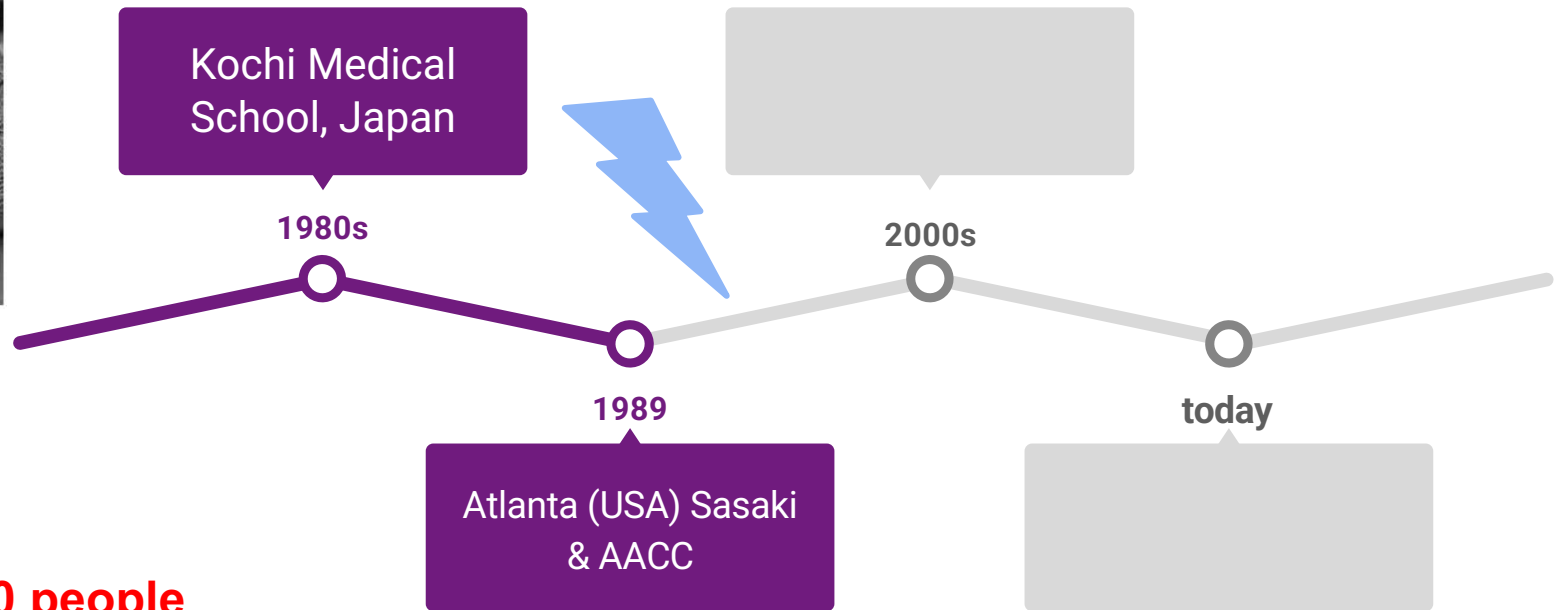


900 people
45 min movie



Dr. Masahide Sasaki
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“greatest revolution
in clinical laboratory
technology since the
autoanalyzer”

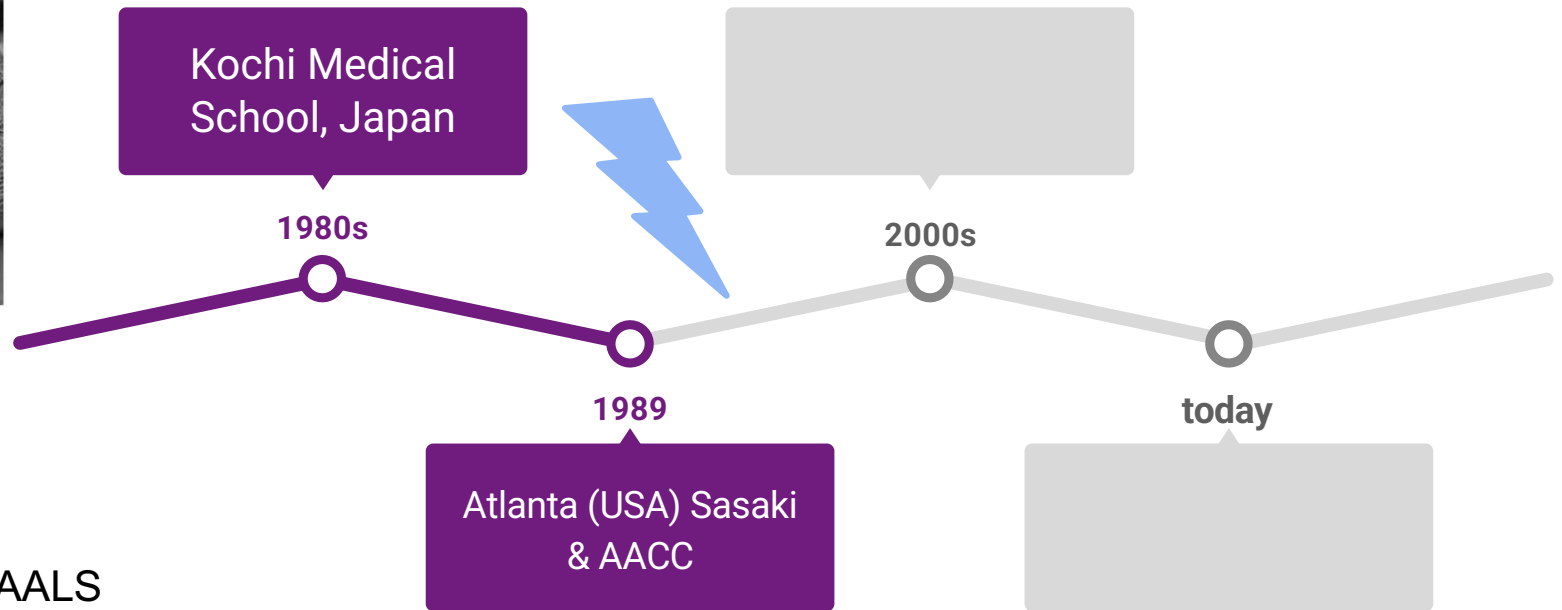


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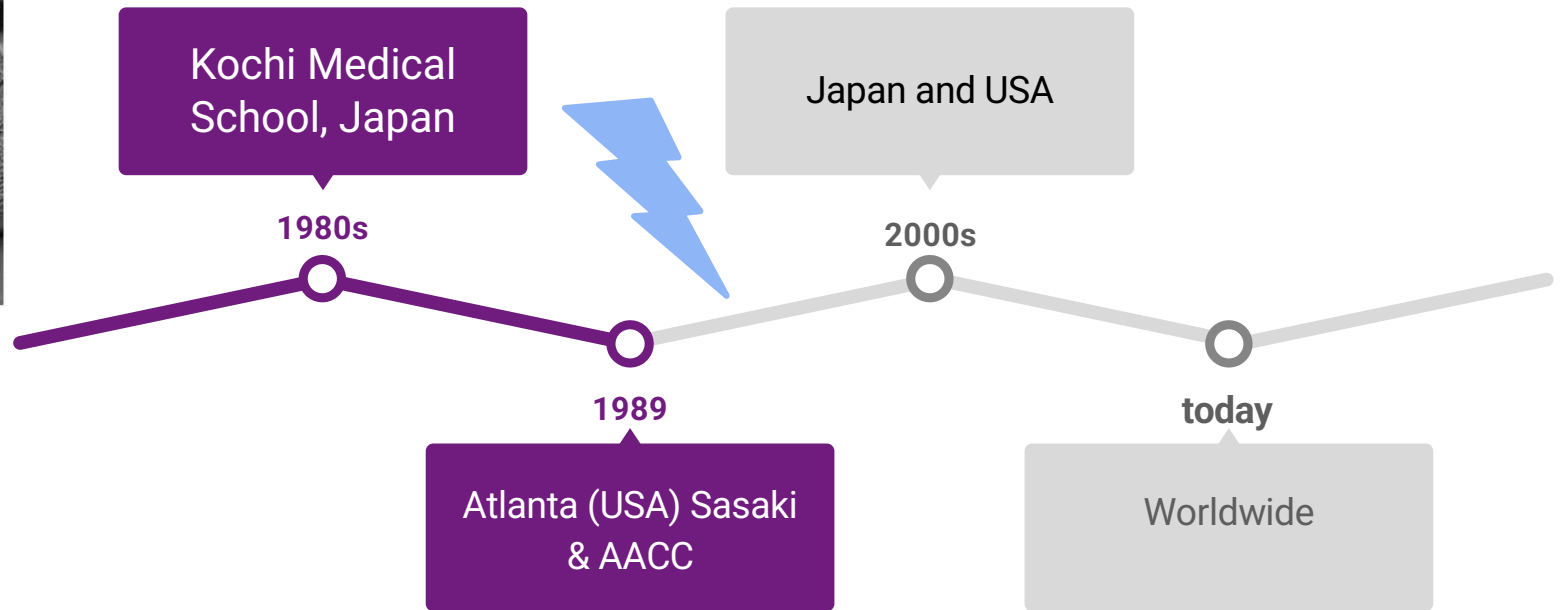


- **1989** NIST proposes CAALS
- **1997** 1st Lab Automation conference in San Diego, CA
(more than 450 attendee)
- **1999** Euro Lab Automation conference, London



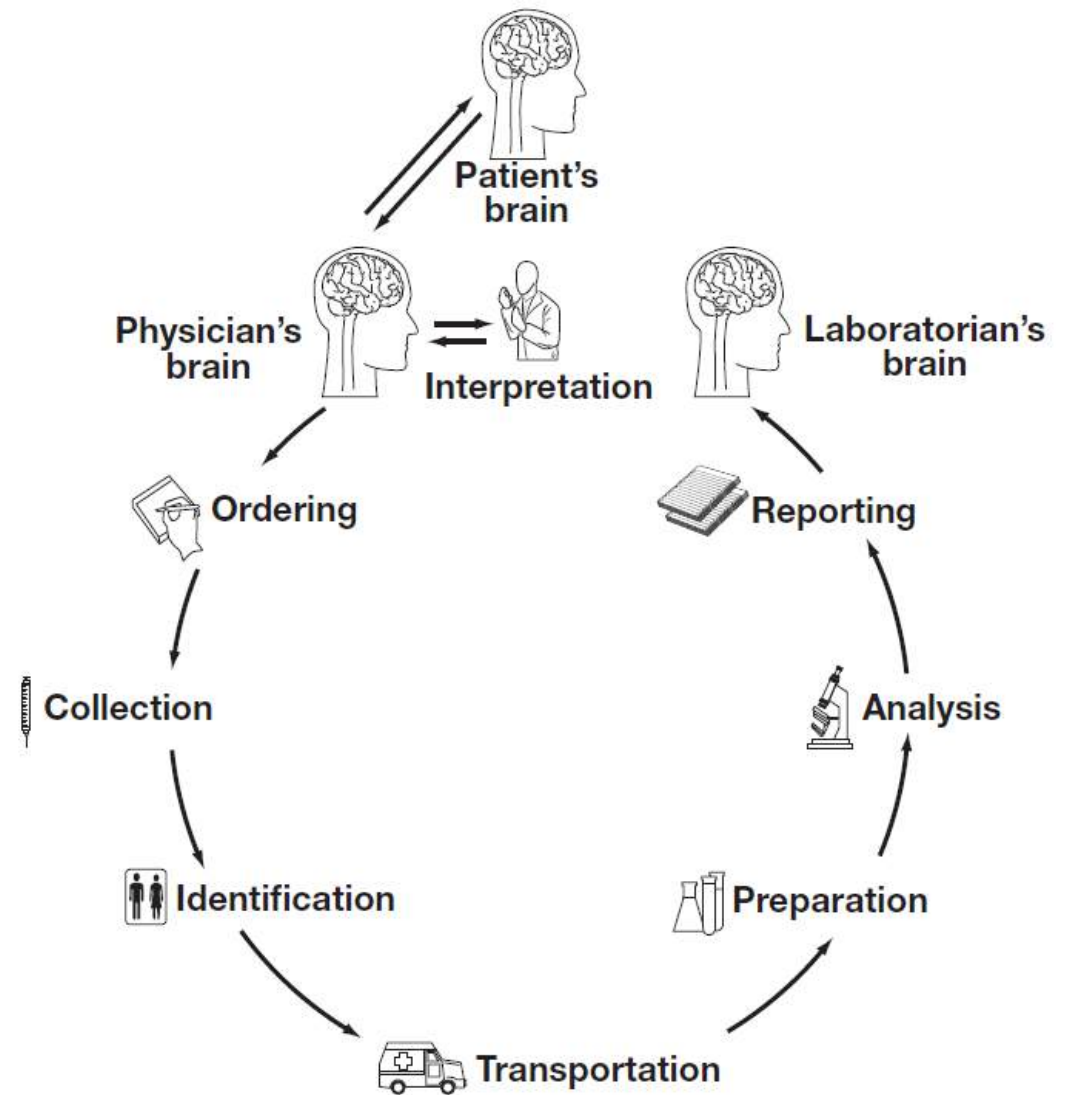
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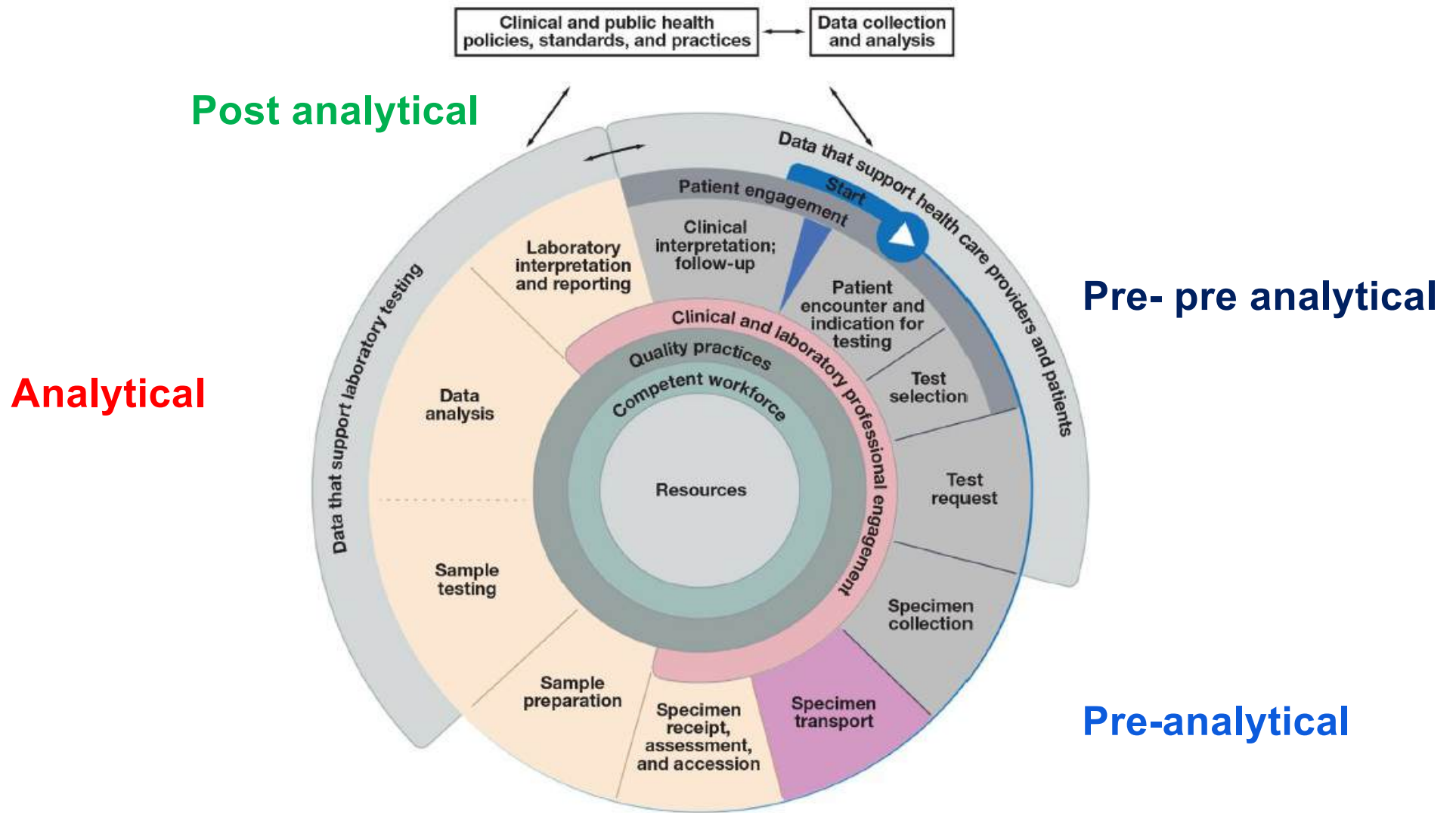
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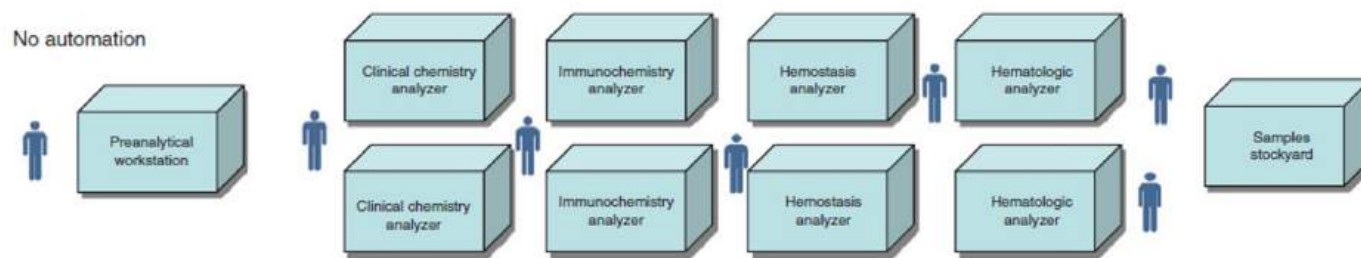


2005 Lab Automation conference attendance soars to 4805 (from 29 different countries).

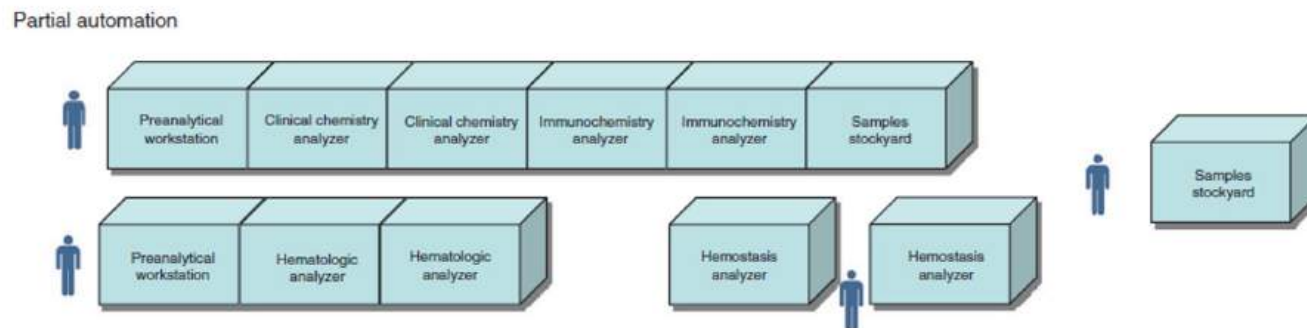
Brain - to - Brain loop and Total Testing Process (TTP)



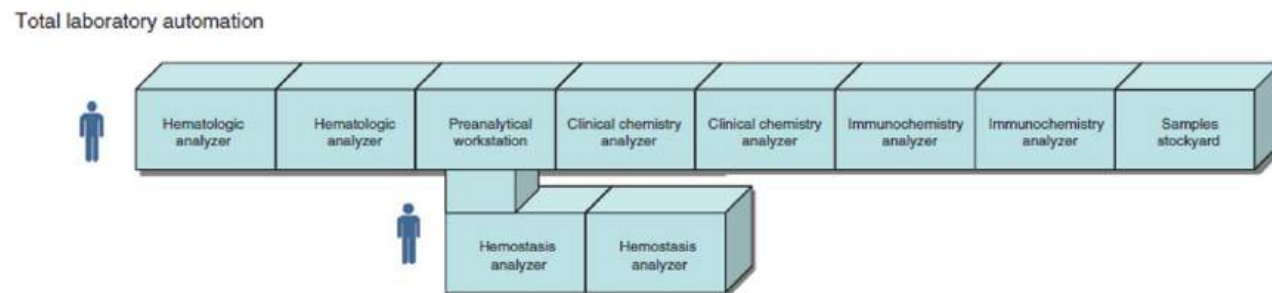




No automation
all analyzers existing as stand-alone machines



Partial automation
automation islets



Total automation (TLA)
most analyzers are physically integrated as modular systems or connected by assembly lines

Figure 1: Different potential models of laboratory automation.

UOC Medicina di Laboratorio Azienda Ospedale – Università di Padova



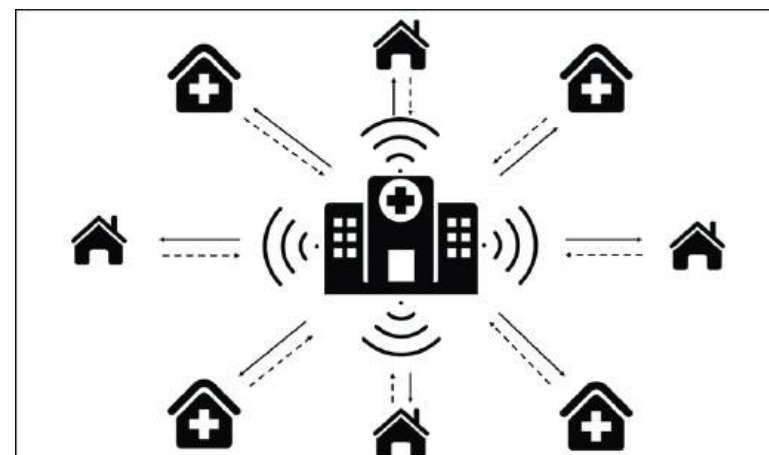
Hub di eccellenza di rilievo regionale

PS, PS Ped,

1740 posti letto, 67 specialità

65000 ricoveri/anno, 444 trapianti nel 2023

Laboratorio accreditato ISO15189



UOC Medicina di Laboratorio, Azienda Ospedale – Università di Padova

Total laboratory automation

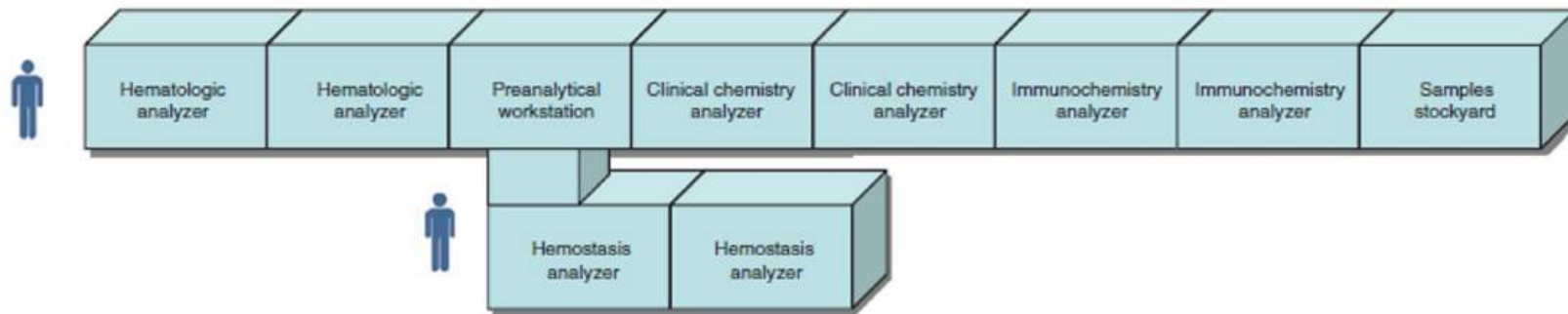


Figure 1: Different potential models of laboratory automation.

TLA
Corelab routine + urgenze, h24 7/7

UOC Medicina di Laboratorio, Azienda Ospedale – Università di Padova

Total laboratory automation

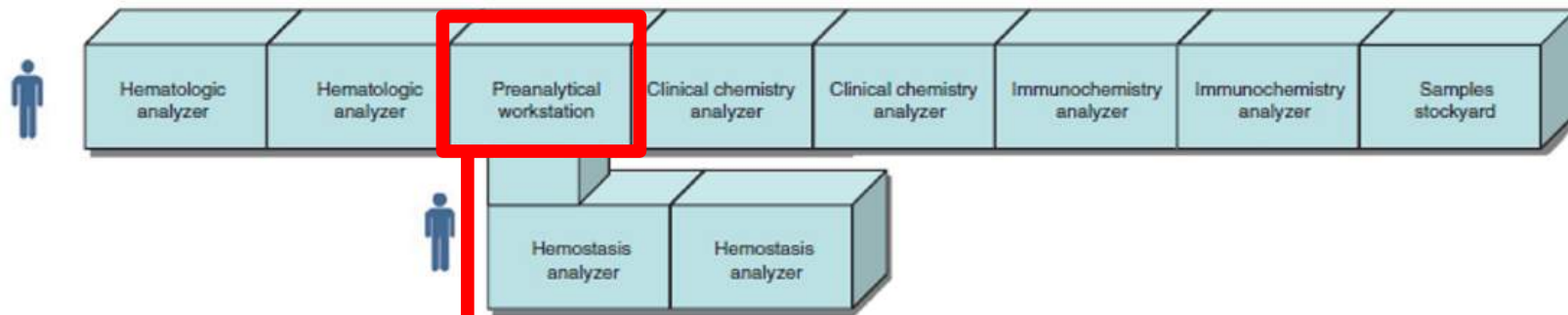
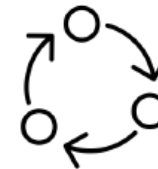
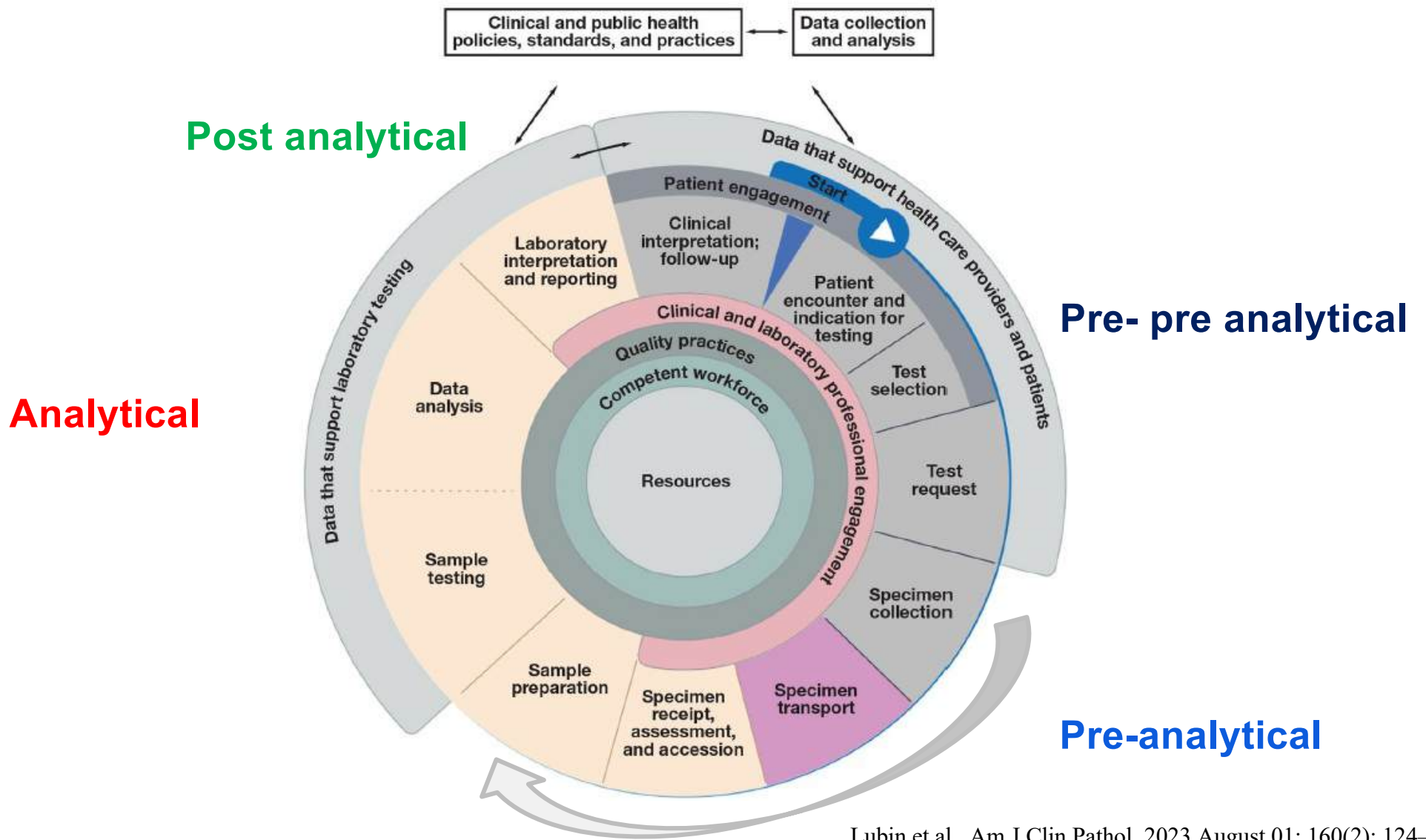


Figure 1: Different potential models of laboratory automation.

Routine, settori specialistici





Pre-analytical phase: identification and collection

The ProTube™ Suite

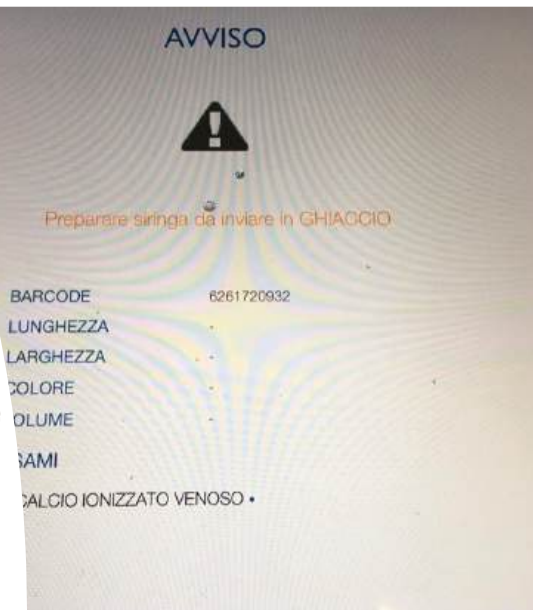
Scalable to your needs...

...and open to connect



Pre-analytical phase: identification and collection

- Right patient
- Right Tube
- Right label
- Right conservation
- Traceability



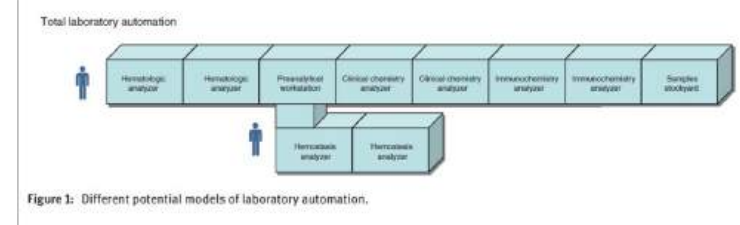
TOTAL LABORATORY AUTOMATION

SAMPLE TRANSPORTATION

Pre-analitica

storage

analizzatori



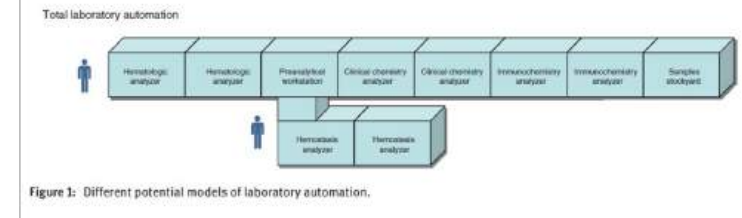
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SAMPLE TRANSPORTATION

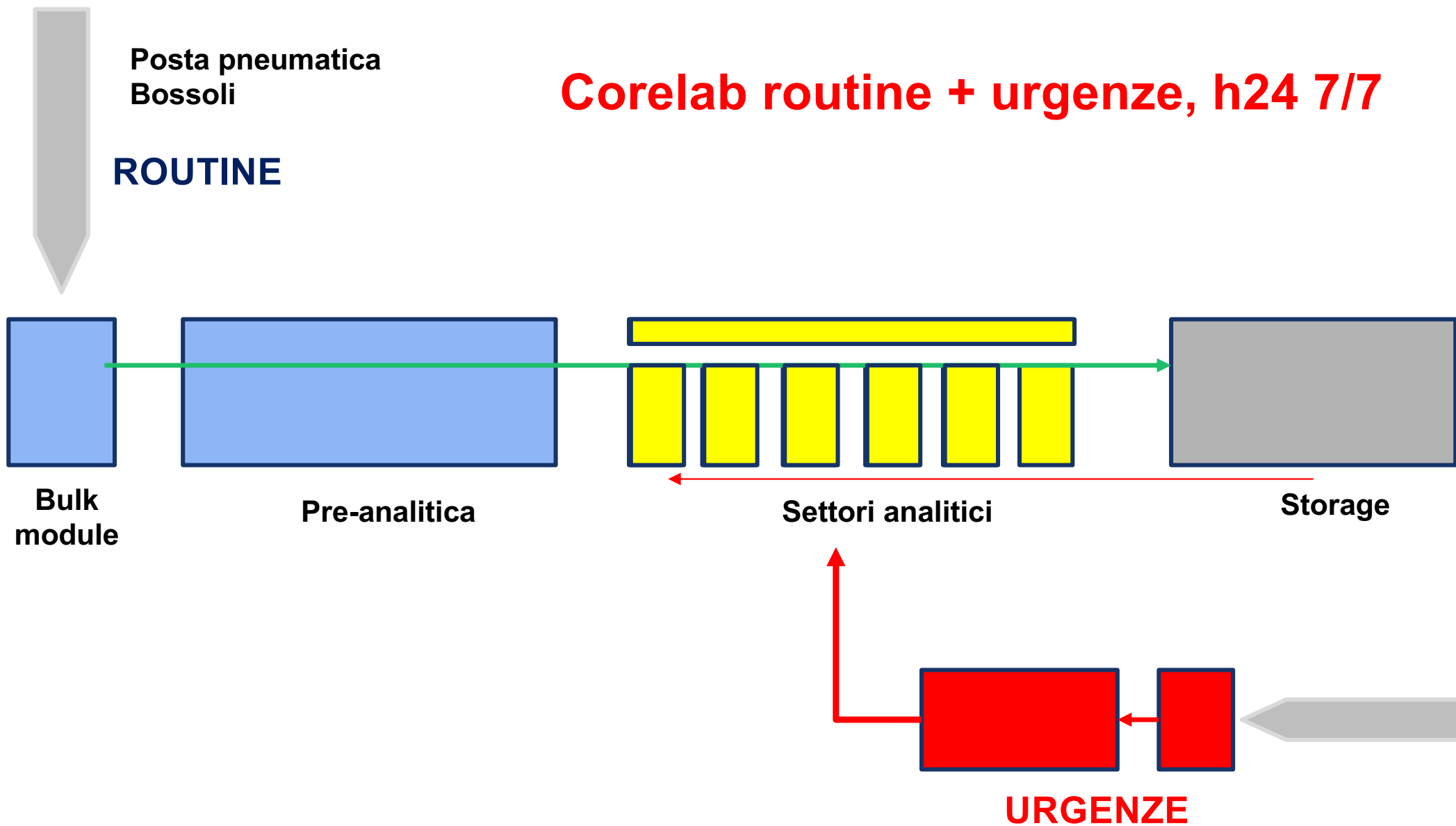
Pre-analitica

storage

analizzatori



Corelab routine + urgenze, h24 7/7



**COSA POSSIAMO
AUTOMATIZZARE
ALL'INTERNO DEL
LABORATORIO CLINICO?**

Box 2. Clinical laboratory steps for workflow mapping

Unpacking from transport containers
Presorting
Temperature preservation
Order-entry
Document management (eg, requisitions)
Labeling
Sorting
Centrifugation
Specimen inspections (labeling, clots, fibrin, hemolysis, icterus, lipemia)
Labeling of aliquot tubes
Pouring of aliquots
More sorting
Delivery to laboratory sections
More sorting
Preparing worklists
Decapping
Labeling analyzer-specific tubes for samples
Pouring or pipetting analyzer-specific samples
Loading tubes on analyzers
Performing tests (extraction, centrifugation, precipitation, dilution, and so forth are not specifically listed)
Unloading analyzers
Recapping
Data manipulations (calculations)
Result review and verification
Reporting of results
Delivery of specimens to archival storage system
Archival storage of specimens
Reflexive testing
Repeat testing, diluting, if necessary
Additional physician-ordered testing
Specimen retrieval for additional or repeat testing
Disposal of expired specimens

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AUTOMATIZZARE
ALL'INTERNO DEL
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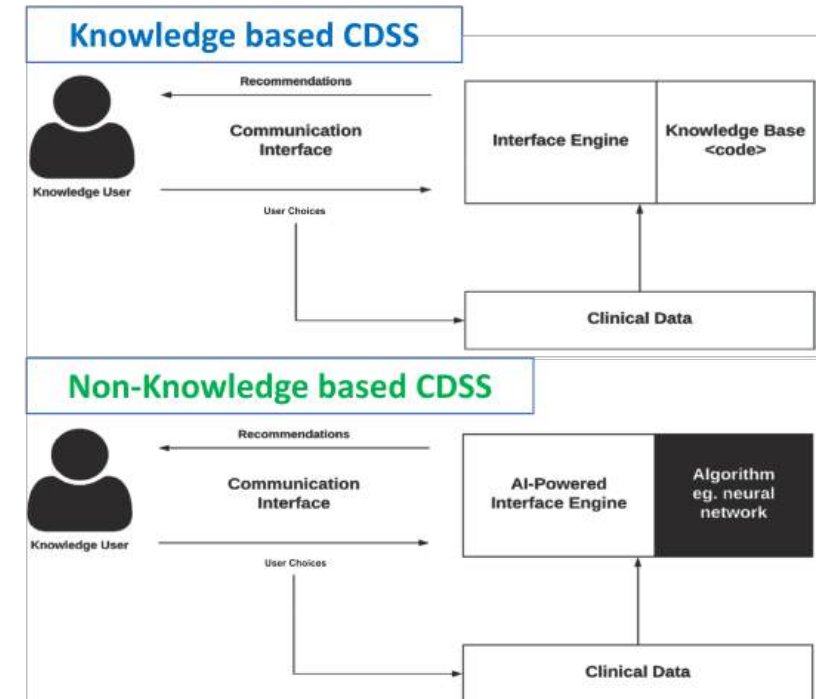
IF-THEN statements

CDS systems
classification

artificial intelligence (AI)
machine learning (ML)
statistical pattern recognition

Sutton et al., npj Digital Medicine (2020) 3:17

Clinical Decision Support System (CDSS)



Hawker CD, Clin Lab Med 27 (2007) 749–770

Box 2. Clinical laboratory steps for workflow mapping

Unpacking from transport containers

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Pre-analytical phase: transportation



**Posta pneumatica
Bossoli automatici**

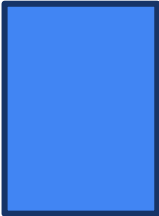


**Bulk
module**

Pre-analytical phase: transportation



Posta pneumatica
Bossoli automatici



Bulk
module



Pre-analytical phase: transportation



Posta pneumatica
Bossoli automatici



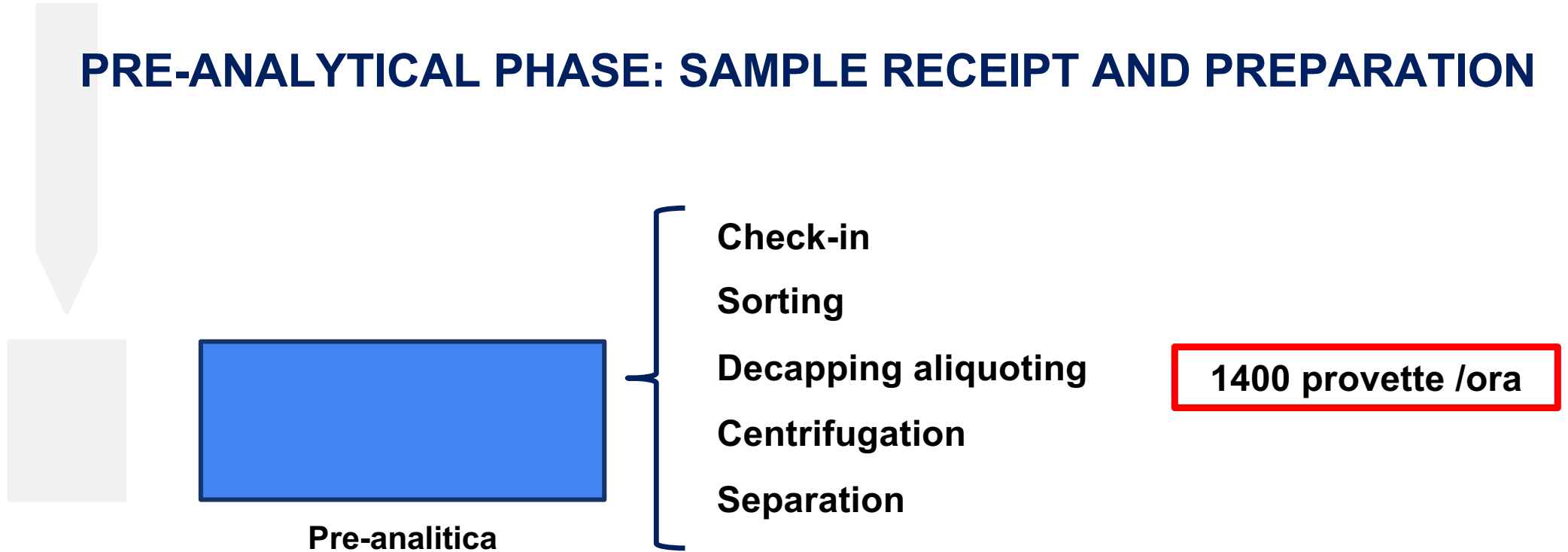
Bulk
module



Pre-analytical phase: transportation



PRE-ANALYTICAL PHASE: SAMPLE RECEIPT AND PREPARATION



Pre-analitica

Check-in

Sorting

Decapping aliquoting

Centrifugation

Separation

1400 provette /ora

Vantaggi

- Tracciabilità dall'ingresso in laboratorio
- Riduzione delle operazioni manuali a rischio biologico
- Formazione operatori e valorizzazione

**PRE-ANALYTICAL
PHASE: SAMPLE
RECEIPT AND
PREPARATION**



**PRE-ANALYTICAL
PHASE: SAMPLE
RECEIPT AND
PREPARATION**







PEGASO SYSTEMS

VIETATO APRIRE
AI NON AUTOCENTRATI
L'APERTURA DEL QUADRO E' COMPRESA
NELL'ATTIVITA' ELETTRICA

PERICOLO



Non aprire il pannello di controllo se il robot è in funzione.

Do not insert hands directly into robot.

Please check periodically for mechanical damage or wear.

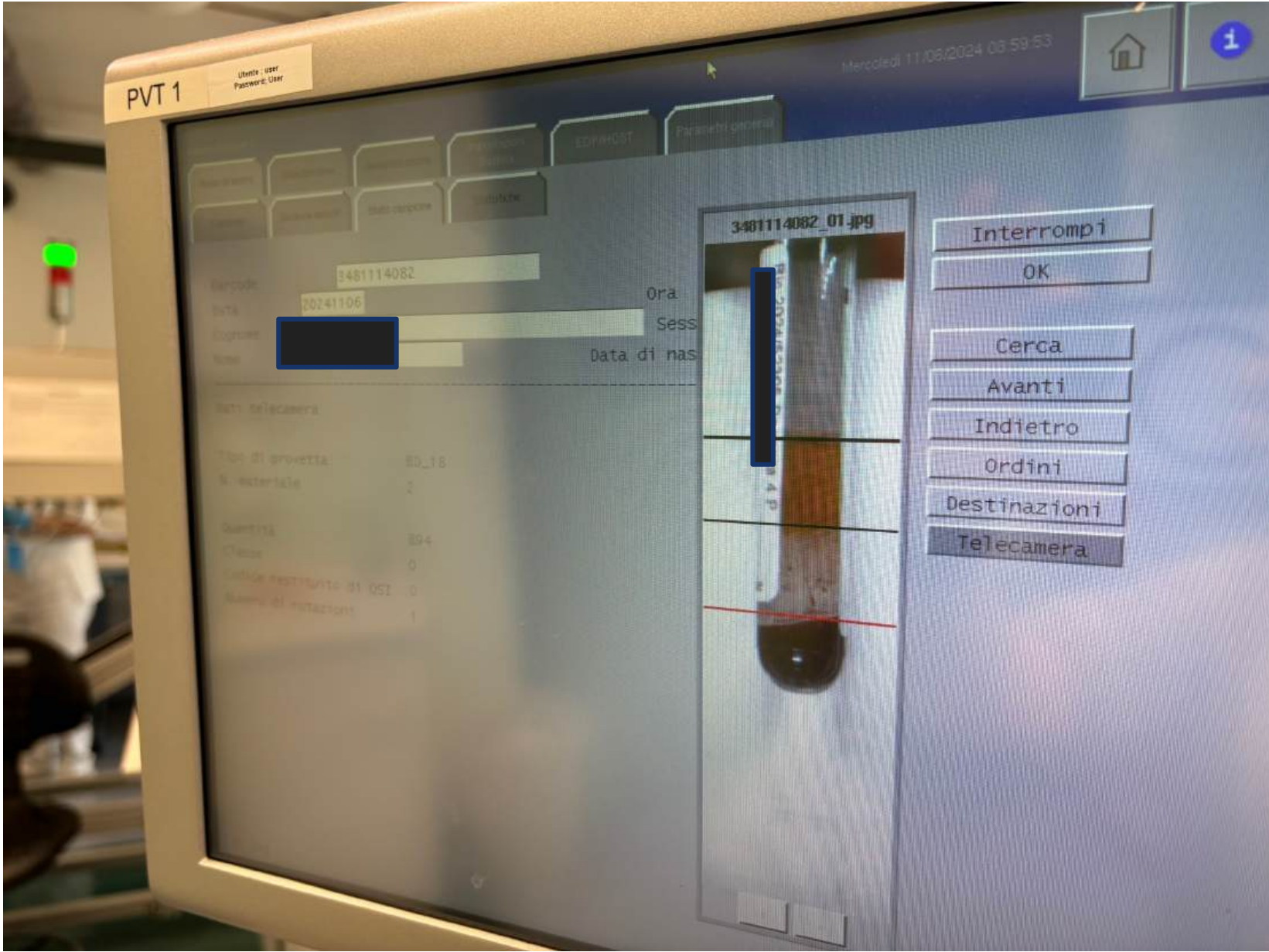


PEGASO SYSTEMS S.p.A. - Via ...

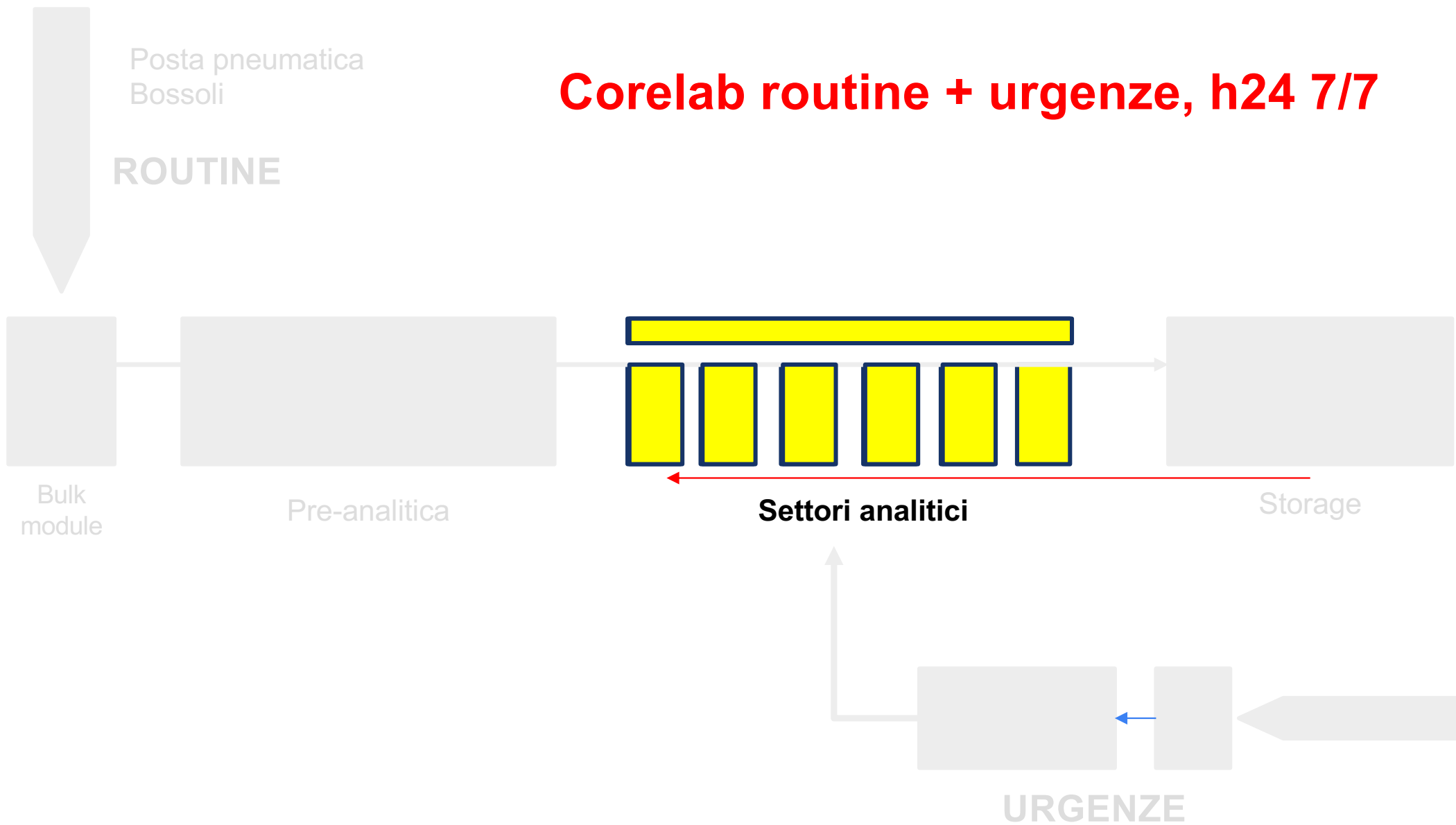


CAUTION
Preventing backflow
To prevent backflow, always aspirate and dispense with the pipette tip touching the bottom of the well.
Do not aspirate or dispense when the pipette tip is not touching the bottom of the well.

ATTENTION
Prévenir le reflux
Pour éviter le reflux, aspirez et déposez toujours avec la pointe de la pipette au fond du puits.
Ne pas aspirer ou déposer lorsque la pointe de la pipette n'est pas au fond du puits.

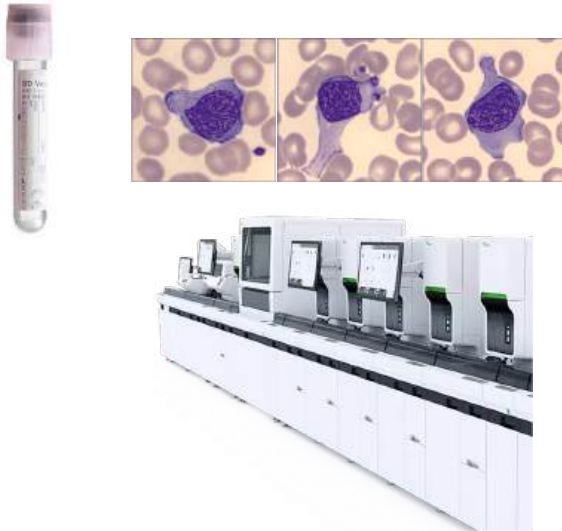


Corelab routine + urgenze, h24 7/7

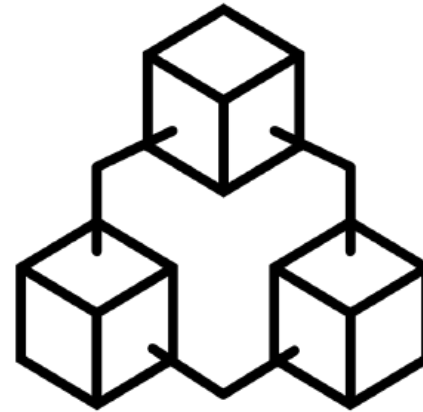
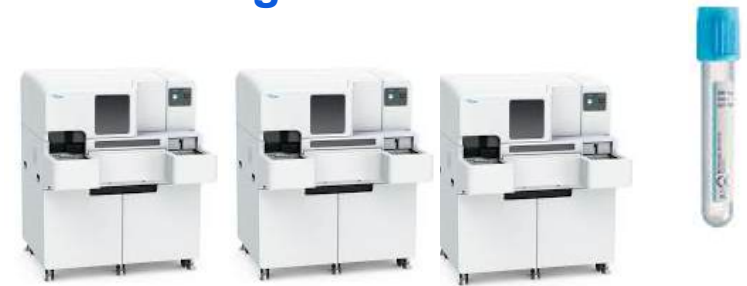


ANALYTICAL PHASE

Hematology



Coagulation



Clinical Chemistry



Troponin, sepsis marker, bhcg



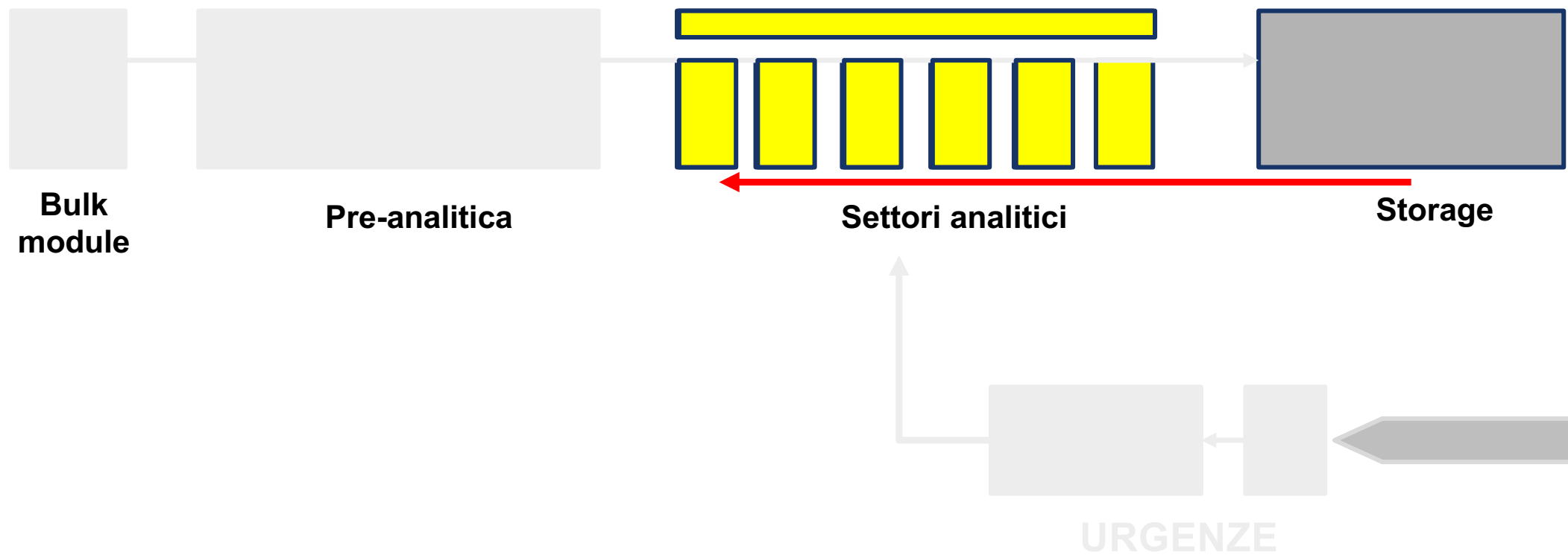
ANALYTICAL PHASE



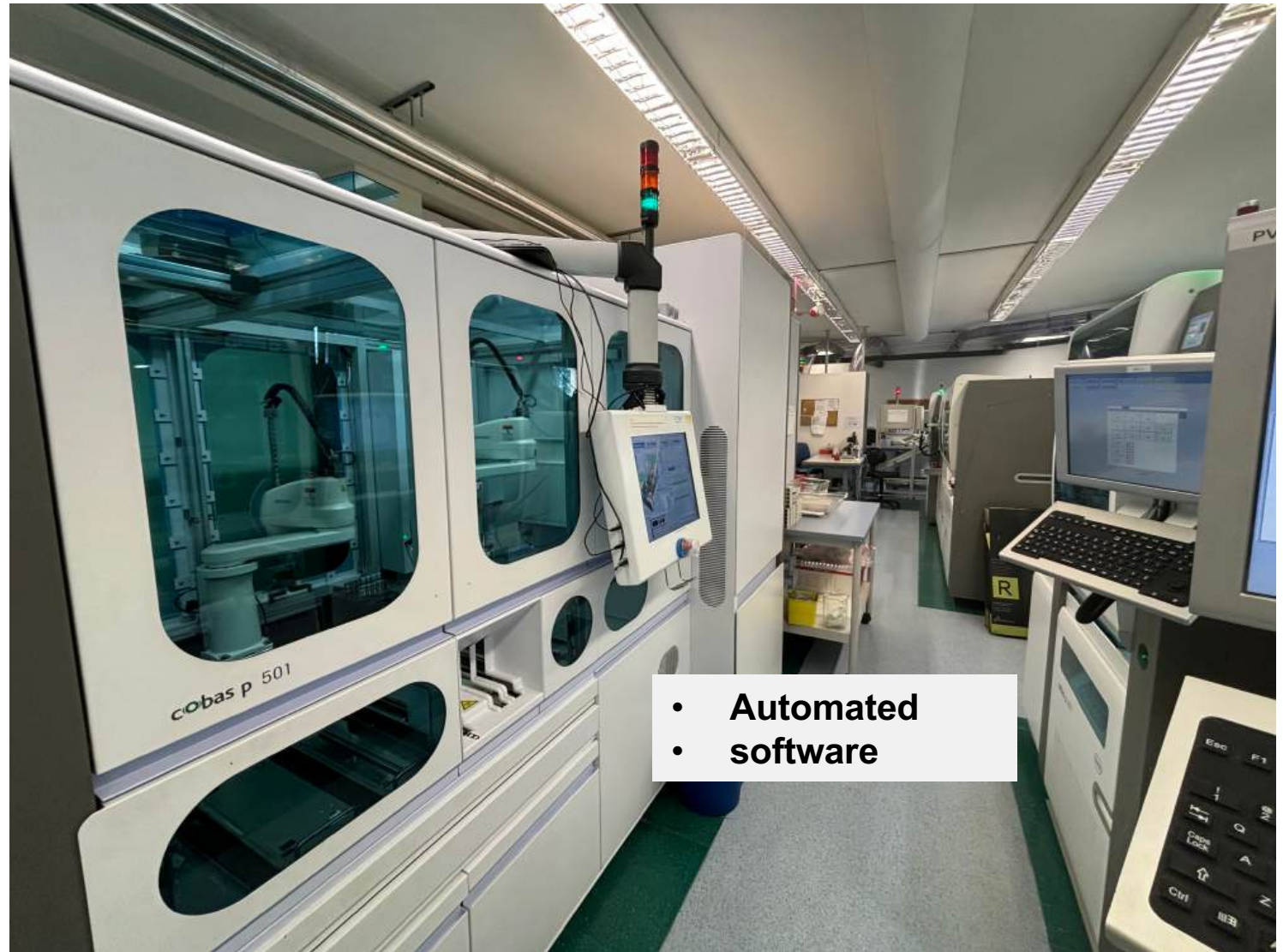
Hematology Section



STORAGE AND REFLEX / ADDED TESTS



**STORAGE
AND
REFLEX / ADDED
TESTS**



- **Automated**
- **software**

CDS, TTP and patient safety

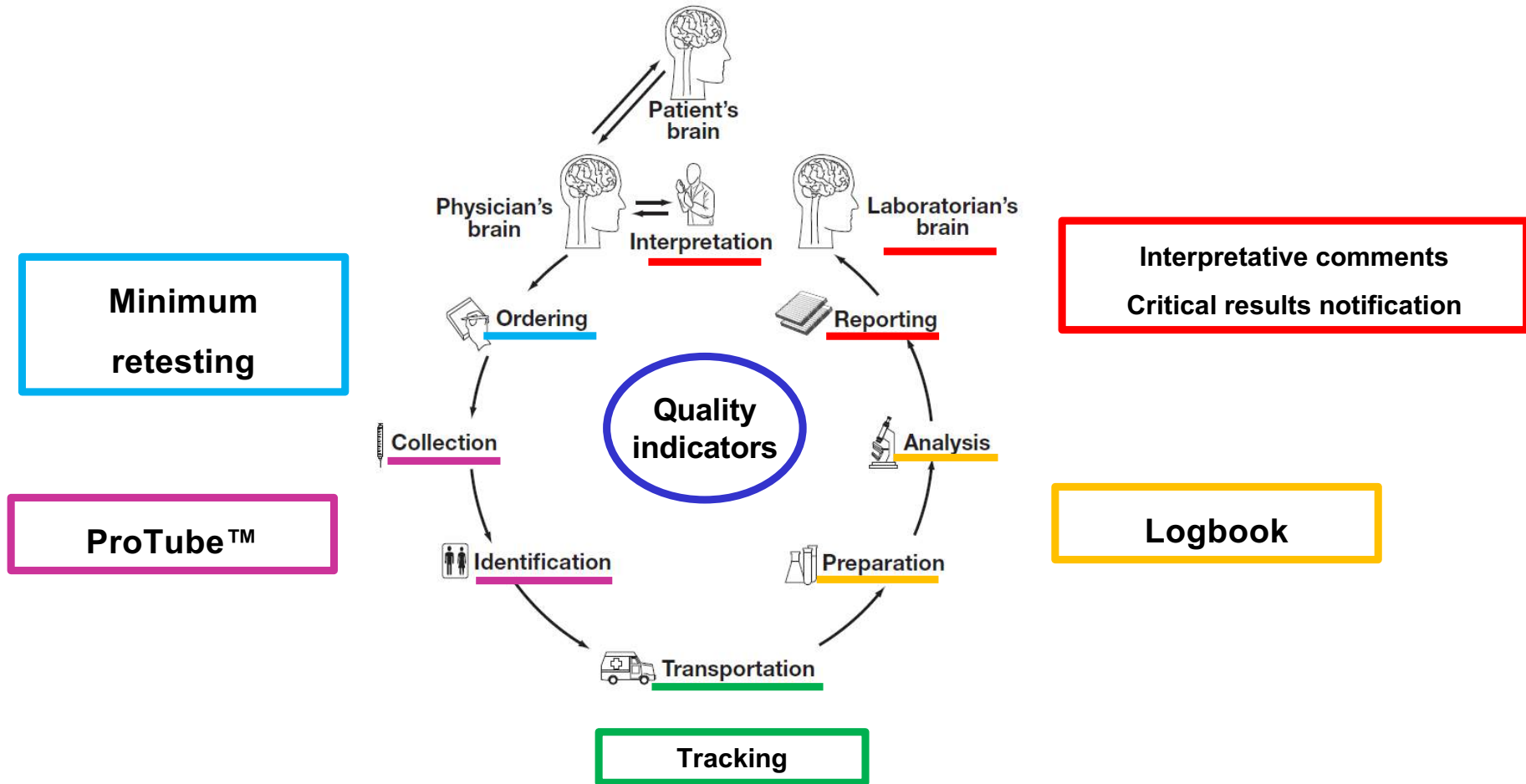


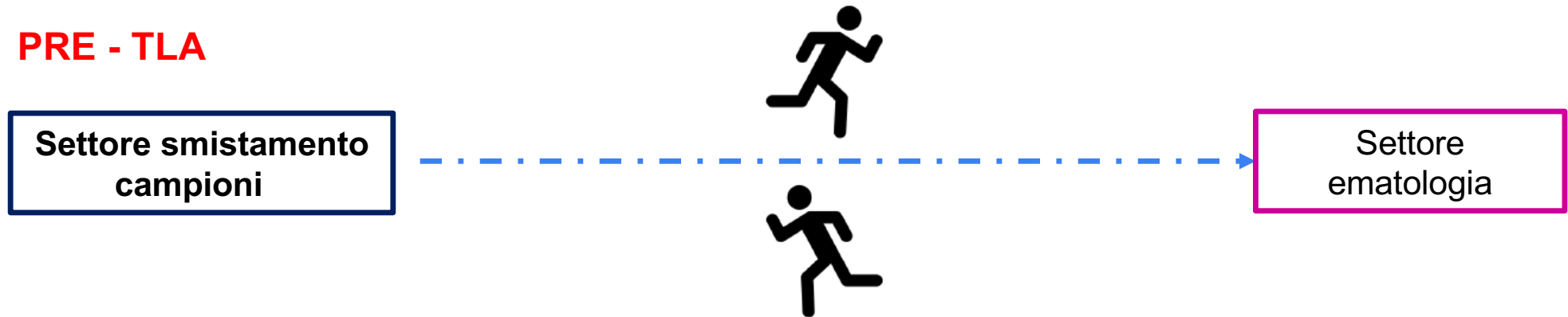
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TAT, turnaround time; TLA, total laboratory automation.

L'ESPERIENZA DEL SETTORE EMATOLOGIA PRE E POST TLA

PRE - TLA



TLA

- ✓ Primo settore dopo la preanalitica, **caricamento in continuo** di emocromi tramite catena
- ✓ Catena locale con esecuzione reflex test e vetrini ematologici
- ✓ Archivio campioni locale per test aggiuntivi
- ✓ Consolidamento emocromi, VES e assetti emoglobinici
- ✓ Emocromo automatico per test di biologia molecolare
- ✓ Formazione operatori

✓ **Primo settore dopo la preanalitica, caricamento in continuo di emocromi tramite catena**

riduzione TAT routine

TAT urgenze

eliminazione della categoria prioritari < 60'

personale non si sposta

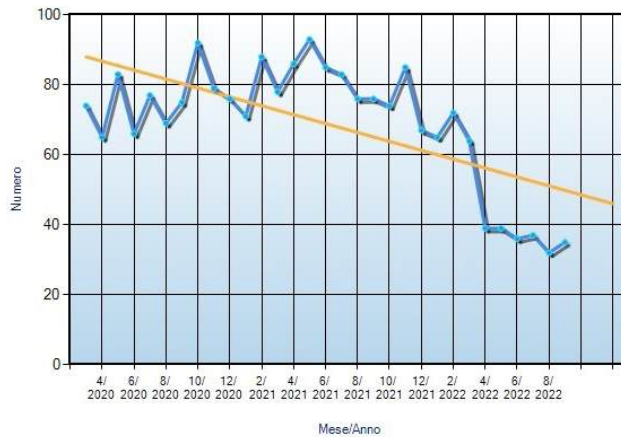
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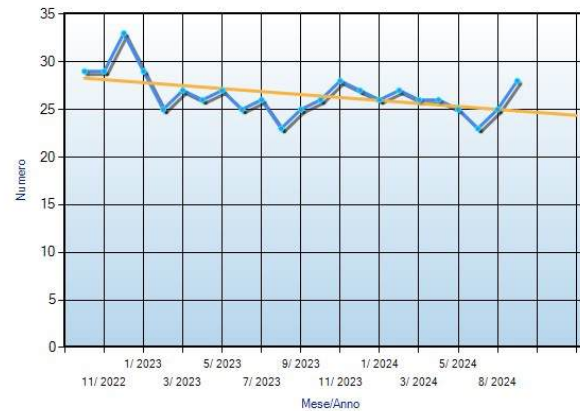
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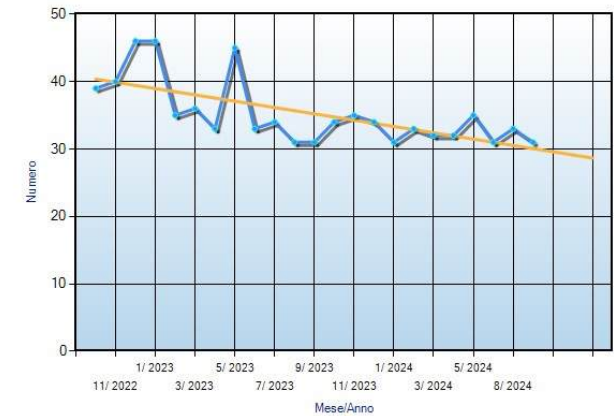
personale non si sposta



Codice Indicatore: Post-WBCTAT_urg
TAT (minuti): tempo di esecuzione del WBC (90° percentile, mensile), dal check-in alla produzione del risultato (urgenza).
N° 23 rilevazioni



Codice Indicatore: Post-WBCTAT_rout
TAT (minuti): tempo di esecuzione del WBC (90° percentile, mensile), dal check-in alla produzione del risultato (routine).
N° 23 rilevazioni



✓ **Primo settore dopo la preanalitica, caricamento in continuo di emocromi tramite catena**

riduzione TAT routine

TAT urgenze

eliminazione della categoria prioritari < 60'

personale non si sposta

✓ **Consolidamento emocromi, VES e assetti emoglobinici**

1 provetta e non 3

✓ **Emocromo automatico per test di biologia molecolare**

1 provetta e non 2

esecuzione in automatico, senza interruzione flusso lavorativo, senza personale che si sposta, risultati nel sistema informatico (eliminazione stampe strumentali uso interno)

- ✓ **Primo settore dopo la preanalitica, caricamento in continuo di emocromi tramite catena**
 - riduzione TAT routine
 - TAT urgenze
 - eliminazione della categoria prioritari < 60'
 - personale non si sposta

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- ✓ **Emocromo automatico per test di biologia molecolare**
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 - esecuzione in automatico, senza interruzione flusso lavorativo, senza personale che si sposta,
 - risultati nel sistema informatico (eliminazione stampe strumentali uso interno)

- ✓ **Formazione operatori**

LIMITAZIONI

Table 1: Potential advantages and limitations of TLA.

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TAT, turnaround time; TLA, total laboratory automation.

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VANTAGGI

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TAT, turnaround time; TLA, total laboratory automation.

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Table 1: Potential advantages and limitations of TLA.

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**GRAZIE
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