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# L'automazione della fase analitica: consolidamento ed integrazione

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*Giuliano Soffiati*

Bari, 18 gennaio 2008

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# Strumentazione analitica

- Chimica-clinica
  - Immunochimica
  - Elettroforesi
  - Analisi delle urine
  - Cromatografia
  - Biologia molecolare
  - Microbiologia
  - Ematologia
  - Citofluorimetria
  - Coagulazione Immunoematologia
  - POCT
-

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# Consolidamento e Integrazione

## ■ Consolidamento

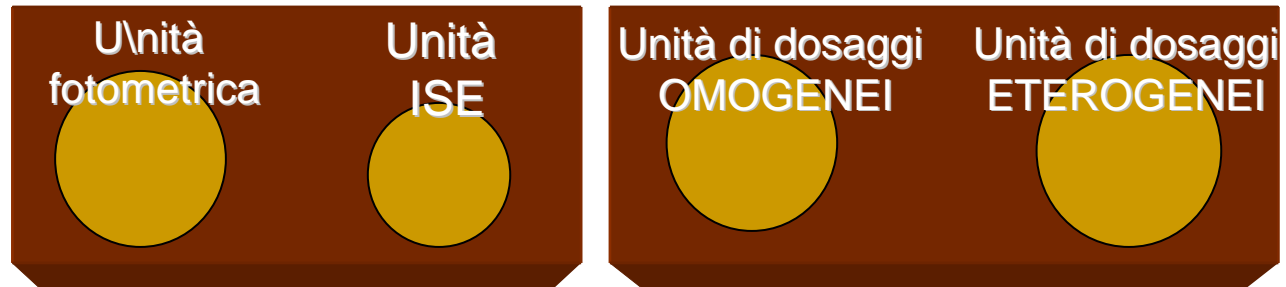
- concentrazione di differenti aree analitiche sulla stessa piattaforma strumentale

## ■ Integrazione

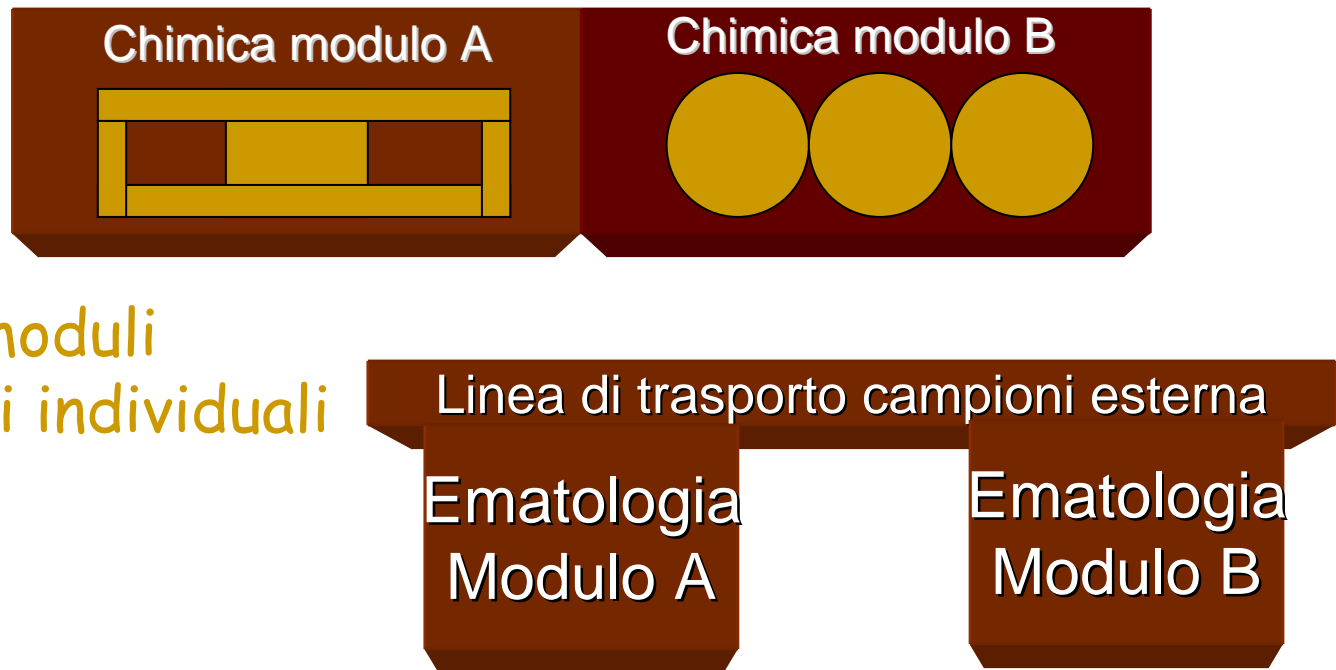
- ottimizzazione su di un unico sistema (stazione di lavoro) di tutte le fasi del processo analitico, incluse quelle pre- e post-analitiche
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# Consolidamento di tecnologie analitiche

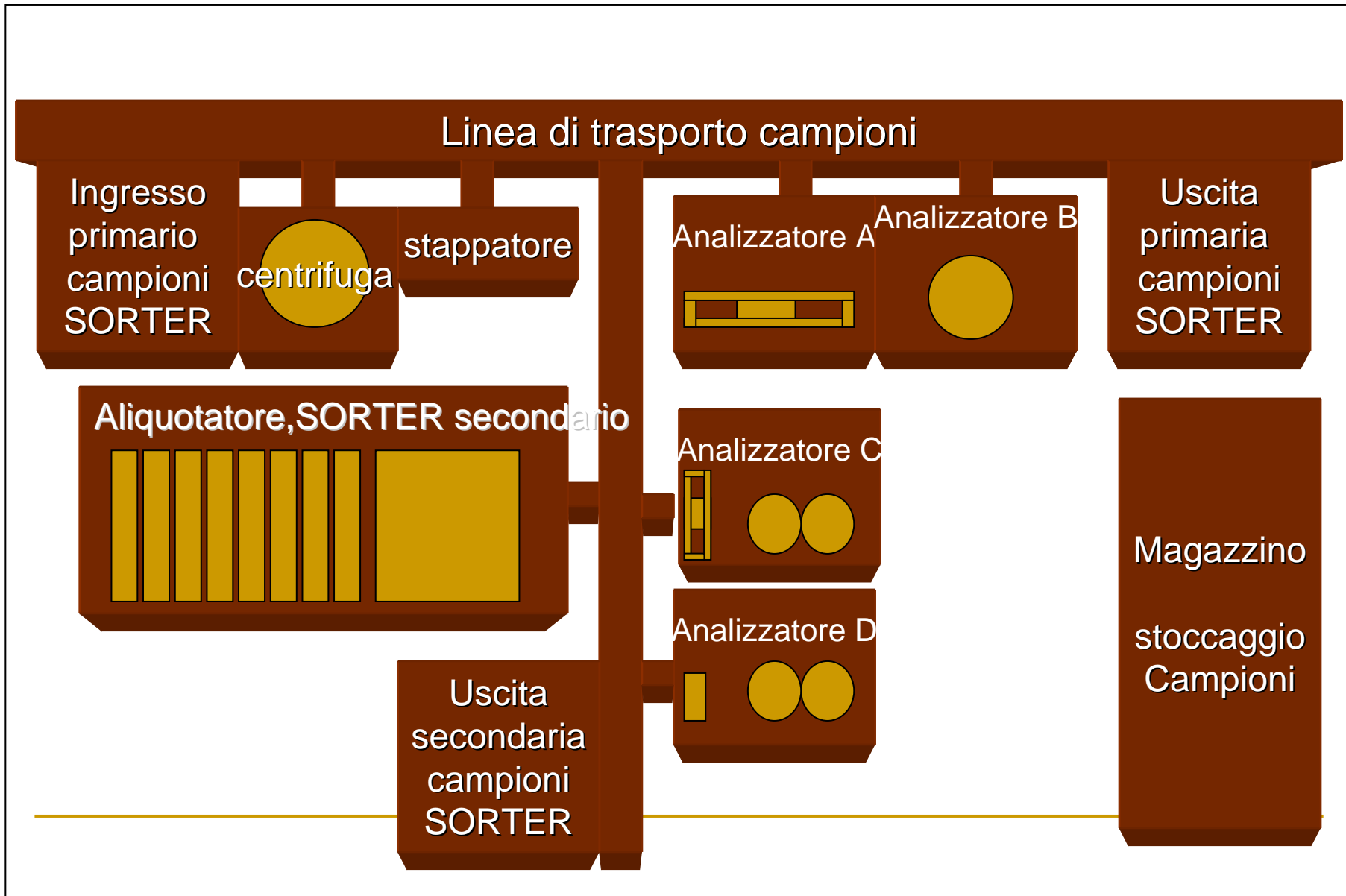
Su uno strumento



Su un gruppo di moduli strumentali individuali



# Integrazione di tecnologie analitiche



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# Automazione Fase Analitica

## Consolidamento ed integrazione

- Check-in (loading station)
  - Sorting
  - Trasporto
  - Stappaggio
  - Centrifugazione
  - Aliquotatore
  - Collegamento hardware autoanalizzatori
  - Analizzatori
  - Recapper
  - Magazzino/stoccaggio
  - Workflow Management
    - Controllo di processo
    - LIS-LAS interfaccia
    - LAS-Analizzatori interfaccia
    - Motore di regole
    - Motore per il referto
-

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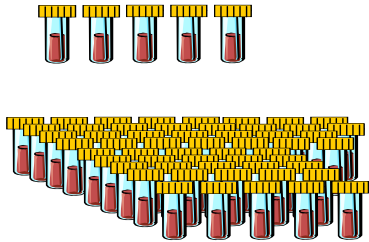
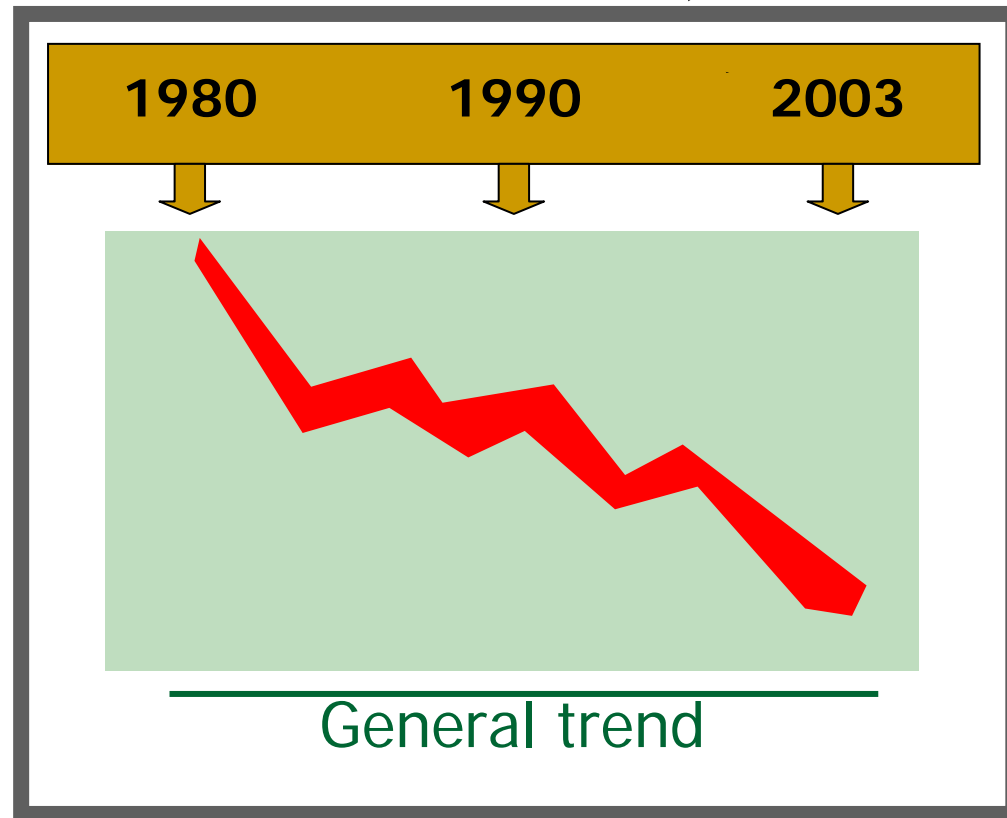
# Automazione Fase Analitica

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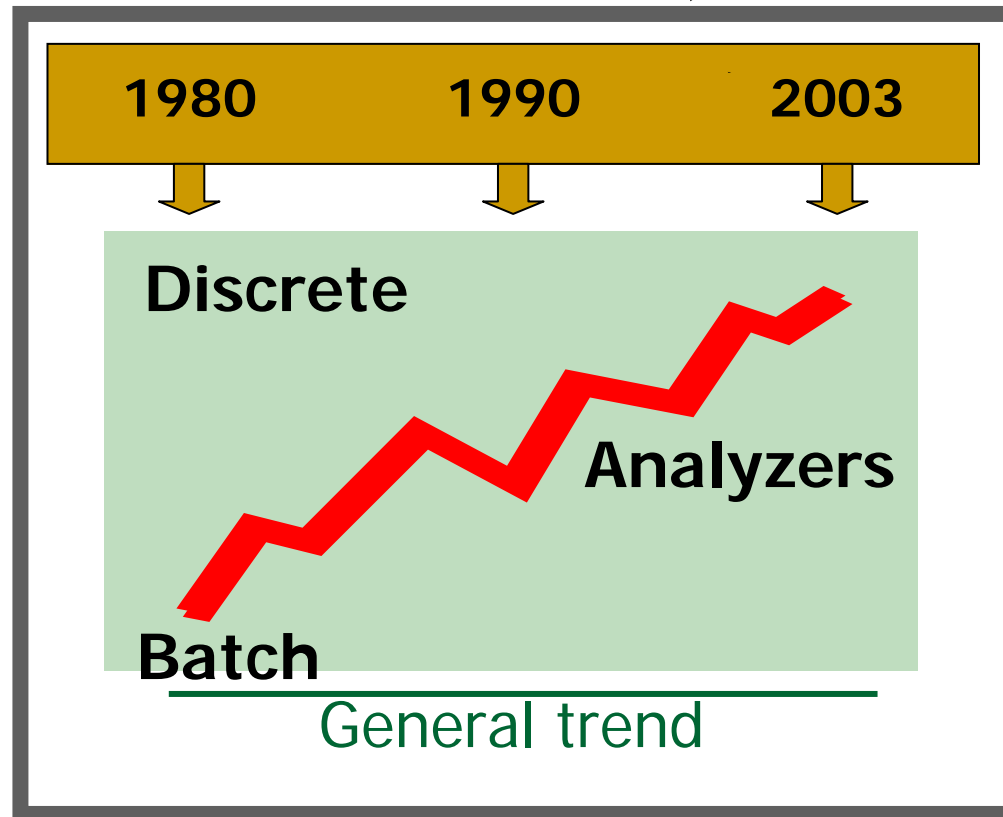
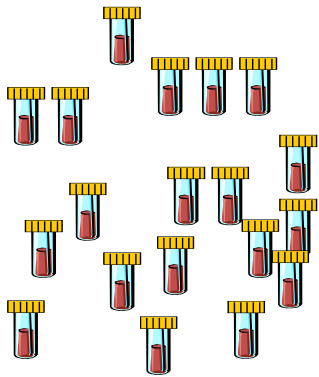
# Laboratory evolution

## Batch Testing



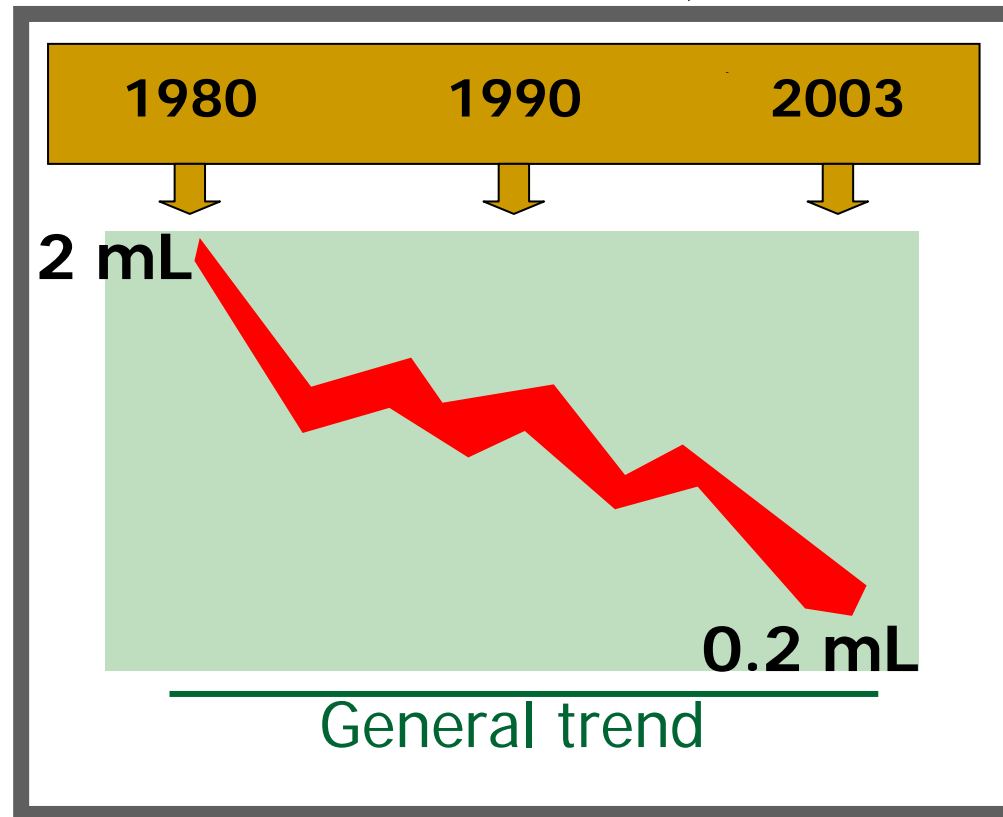
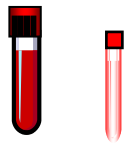
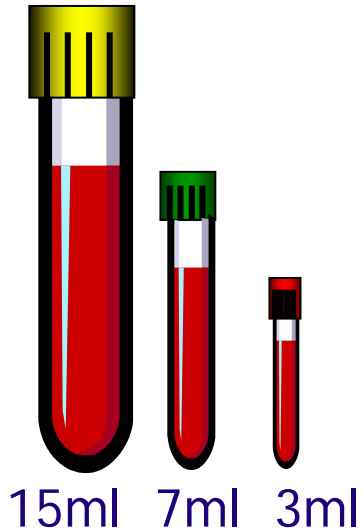
# Laboratory evolution

## Random Testing



# Laboratory evolution

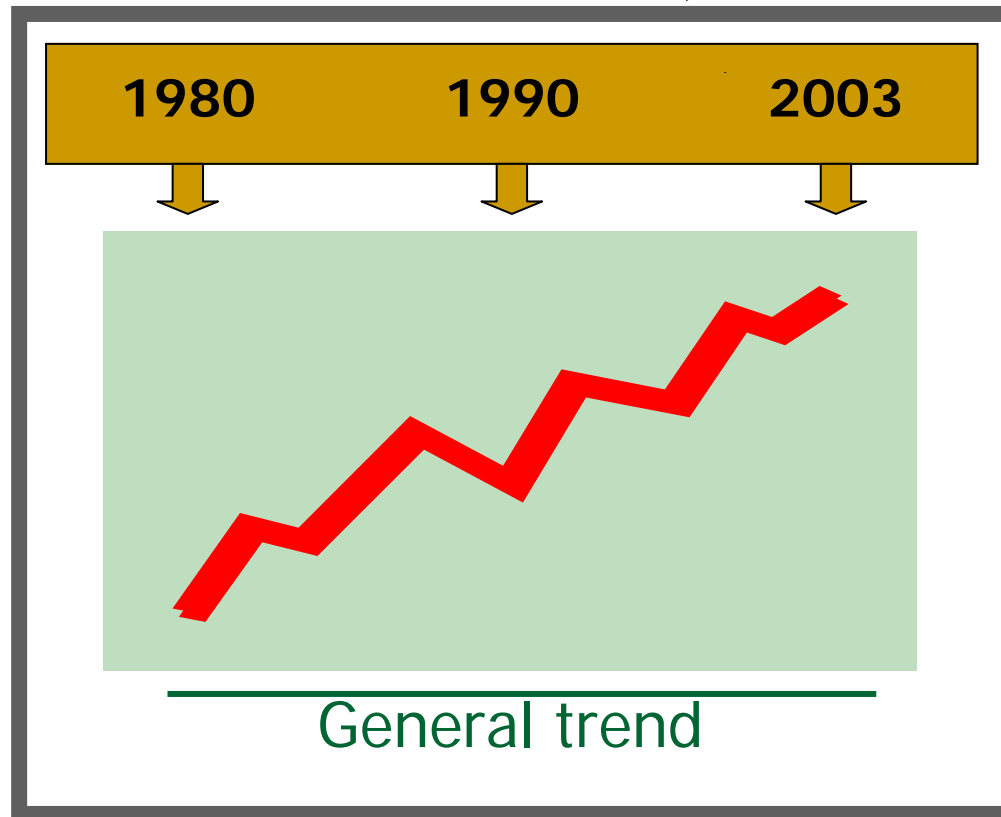
## Sample volume



# Laboratory evolution

## Available methods

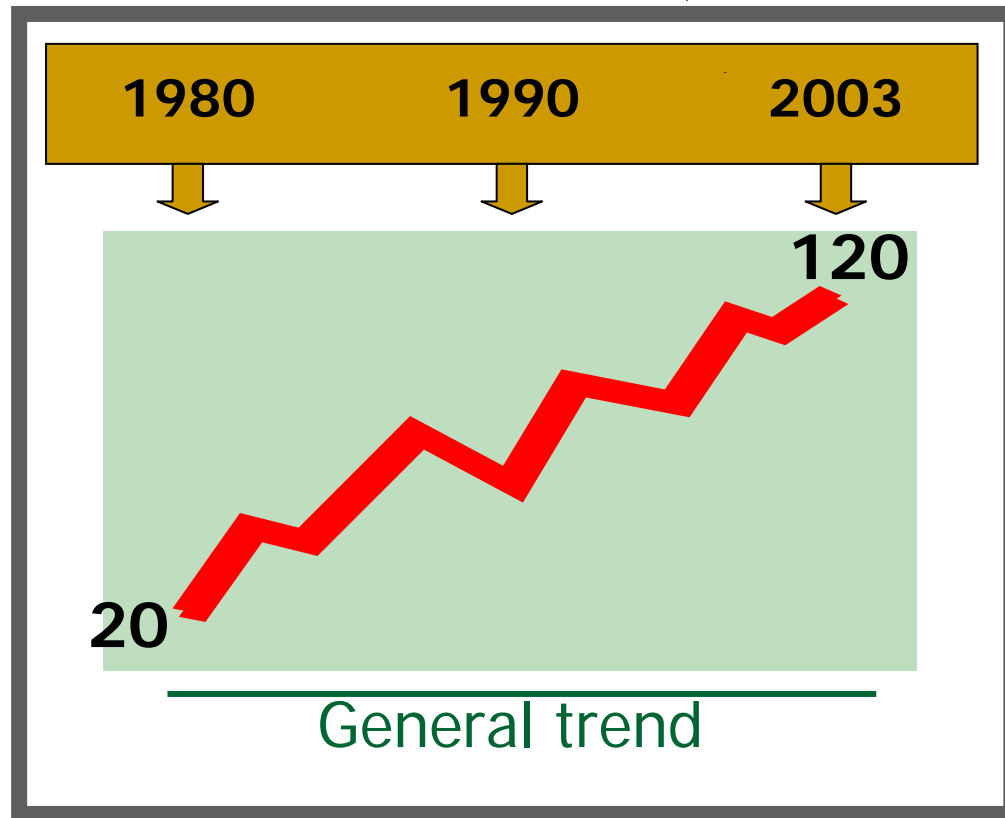
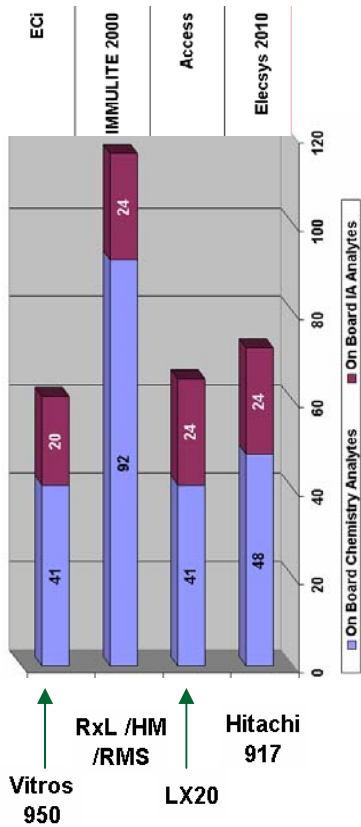
TEST NAME
COCAINE METABOLITES
COMPLEMENT COMPONENT C3
CREATINE KINASE, TOTAL
CREATININE
CREATININE (RANDOM URINE)
DIGOXIN
ETHYL ALCOHOL
FASTING GLUCOSE
FASTING URINE GLUCOSE
FERRITIN
FOLIC ACID
GAMMA GLUTAMYL TRANSFERASE
GENTAMICIN, RANDOM
GLUCOSE TOLERANCE TEST 3 HOUR
GLUCOSE, 50 GM SCRIN
GLUCOSE; FASTING
GLUCOSE, RANDOM
HCG QUAL. SERUM
HCG QUAL. URINE
HDL CHOLESTEROL
HEMOGLOBIN GLYCATED A1C
HEPATIC FUNCTION PANEL
IMMUNOGLOBULIN M
IONIZED CALCIUM
IRON/IRON BINDING PROFILE
LDH
LIPASE
LIPIDS PANEL
MAGNESIUM
MICROALBUMIN RANDOM
MICROALBUMIN (U) 24 HR
OPIATES
PARATHYROID HORMONE, INTACT



TEST NAME
PHENCYCLIDINE
PHENYTOIN
PHOSPHOROUS
POTASSIUM
PREALBUMIN
PROSTATE SPECIFIC ANTIGEN
PROTEIN, TOTAL
RHEUMATOID FACTOR SCREEN
SERUM IRON
SODIUM
T3 UPTAKE
T-4 (THYROXINE) FREE
THEOPHYLLINE
THYROID STIMULATING HORMONE
THYROXINE (T4)
TOBRAMYCIN; PEAK
TOBRAMYCIN, TROUGH
TOTAL IRON BINDING CAPACITY
TRIAGE II DRUG SCREEN
TRICYCLIC ANTIDEPRESSANTS
TRIGLYCERIDES
TROPONIN-I
UNSATURATED IRON BINDING CAP
URIC ACID
URINE CREATININE
URINE CREATININE CLEARANCE
URINE POTASSIUM, RANDOM
URINE SODIUM, RANDOM
URINE TOTAL PROTEIN MEAS.
VANCOMYCIN, PEAK
VANCOMYCIN, RANDOM
VANCOMYCIN, TROUGH
VITAMIN B12

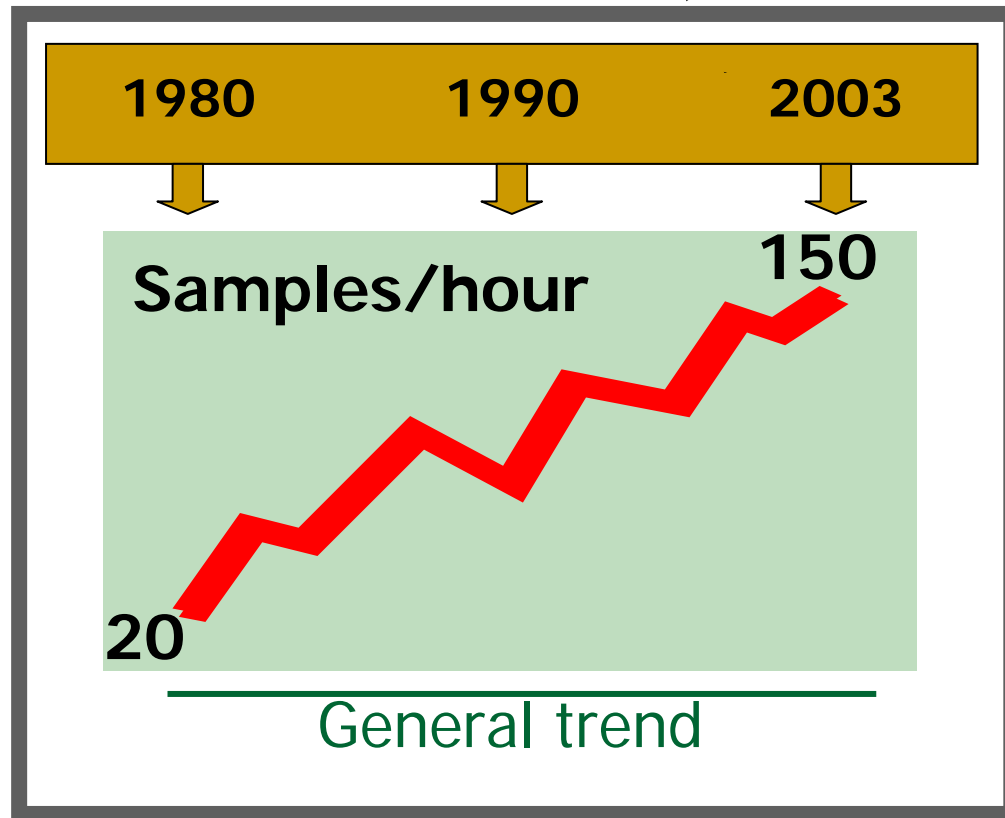
# Laboratory evolution

## On-board Analytes



# Laboratory evolution

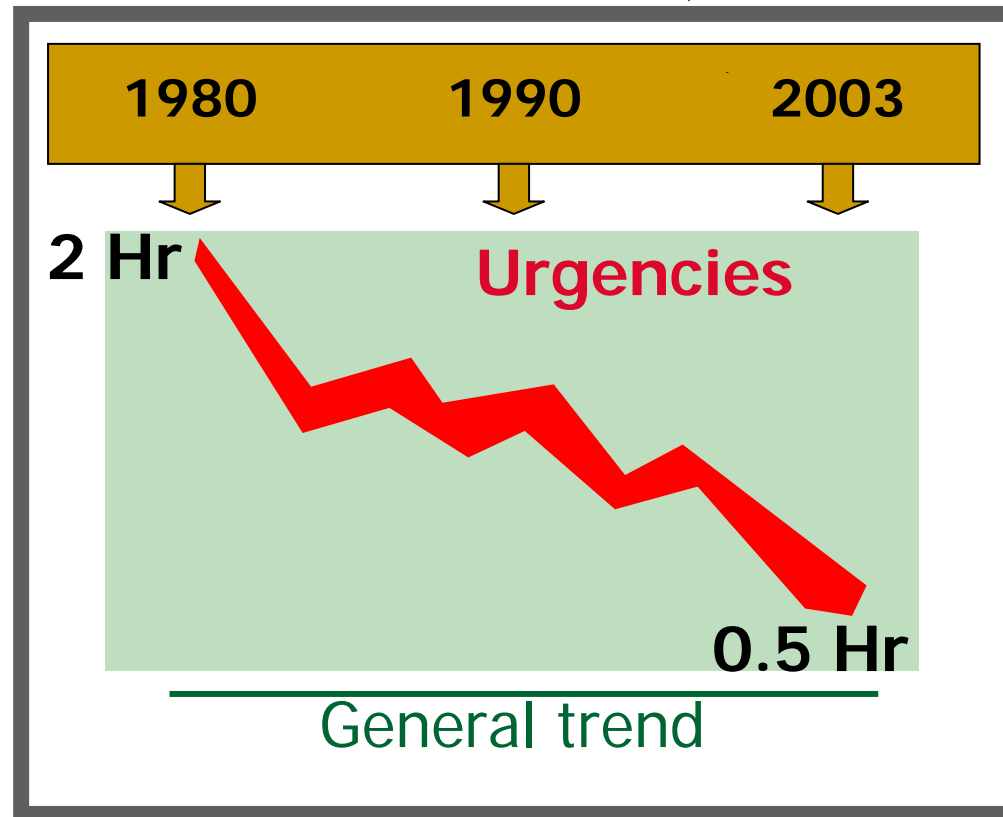
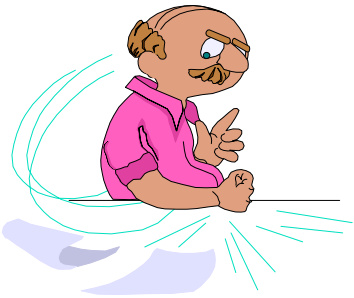
## Instrument performance



# Laboratory evolution

## Turn Around Time

*Where  
are my  
Lab  
Results?*



New  
needs

# What did not change ?

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1980

1990

2003

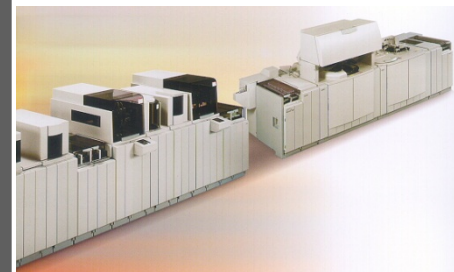
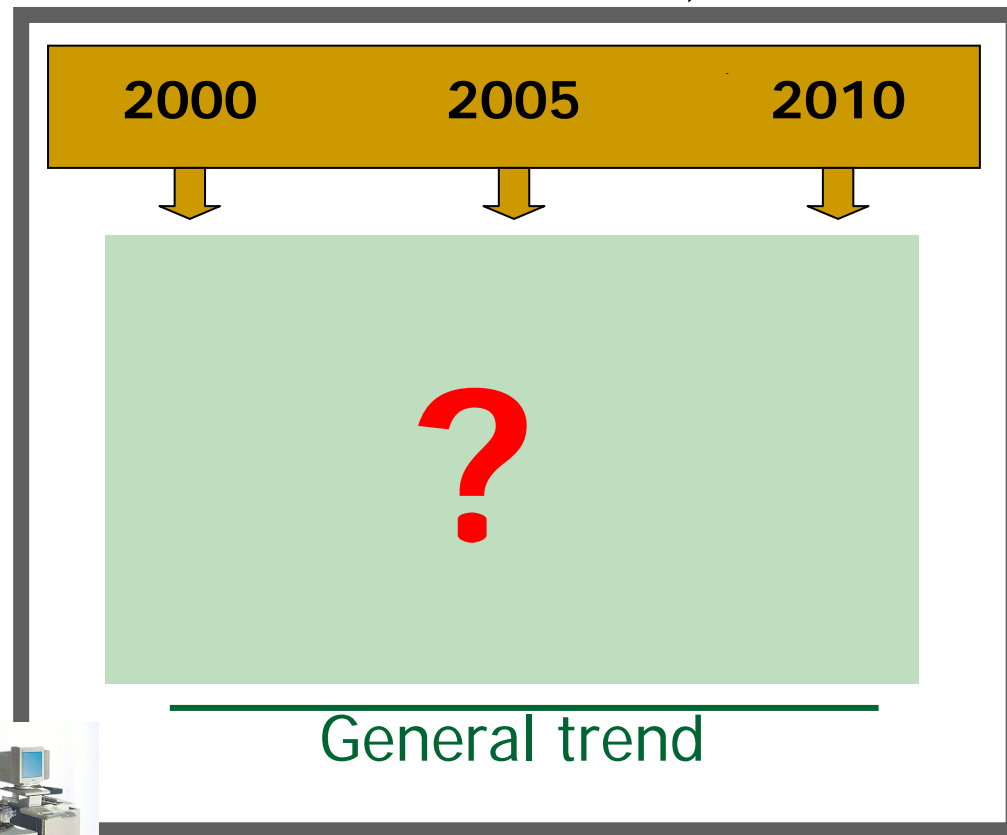


The need to

- provide efficacious and accurate information
- reduce errors
- improve safety
- improve TAT
- provide more with less

# Laboratory evolution

## Total Lab Automation



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# Strumentazione: consolidamento

- Chimica - Immunochimica
- Chimica - Immunochimica - Immunometria
- Chimica – Immunochimica - Immunometria - Farmacologia
- Chimica- Immunochimica- Immunometria - Farmacologia - Infettivologia

**CONSOLIDAMENTO** cosiddetta “**AREA SIERO**”

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# Strumentazione: integrazione

- Ematologia-preparatore vetrini
- Ematologia-preparatore vetrini-microscopia
- Ematologia-preparatore vetrini-microscopia-citofluorimetria
- Ematologia-preparatore vetrini-microscopia-citofluorimetria-coagulazione

**INTEGRAZIONE “AREA EMATOLOGIA”**

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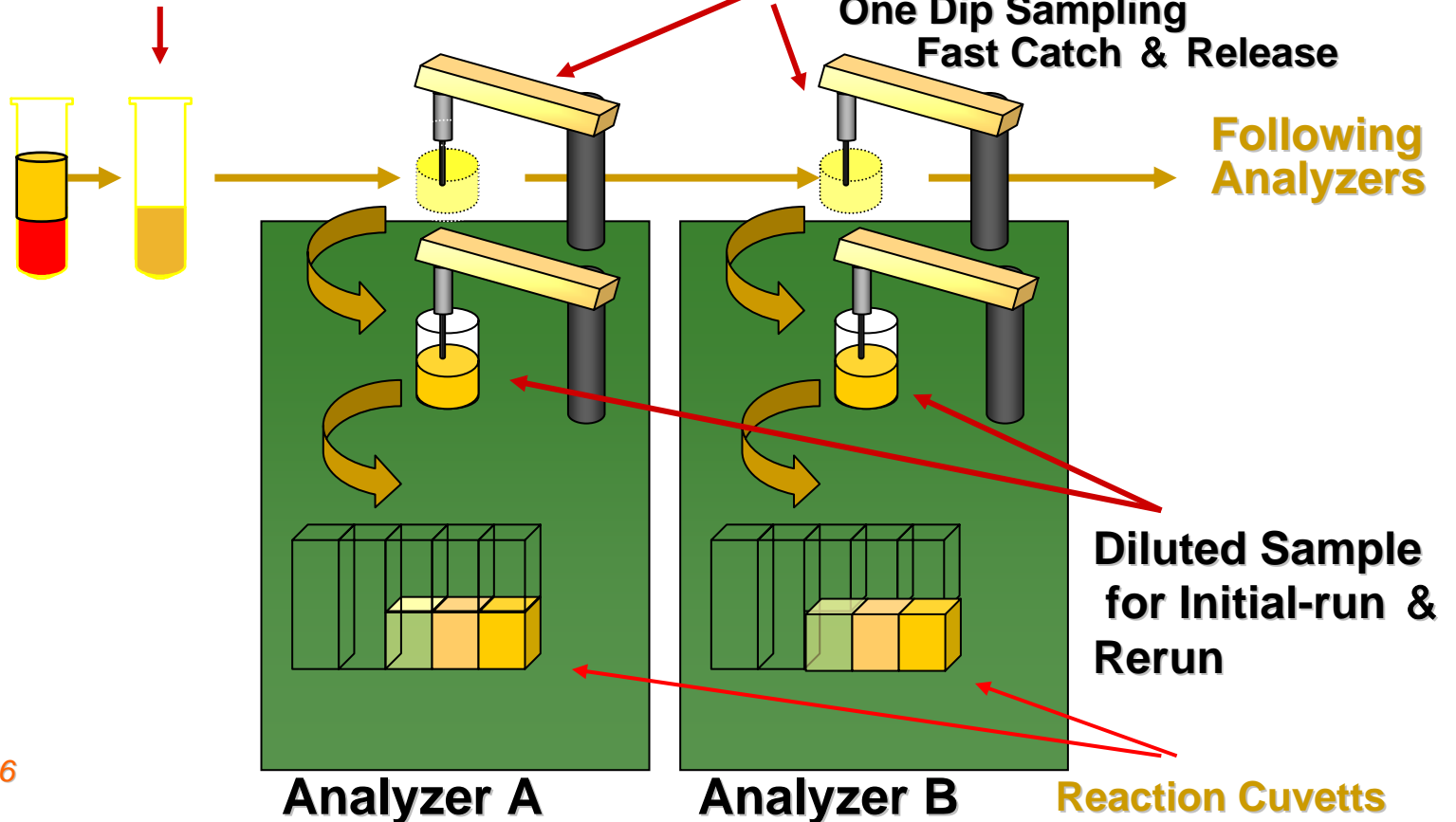
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# Criteria generali per la scelta dei strumenti

- Stabilità dei metodi
- Stabilità della calibrazione
- Stabilità degli elettroliti
- Possibilità di campionamento fuori dello strumento
- Menu dei test adeguato

# Modular Point-in-space Sampling

Only One Sample Required  
for Multiple Analysis



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# Criteri generali per la scelta dei strumenti

- La stabilità dei strumenti dovrebbe richiedere l'esecuzione dei controlli una volta ogni 24 ore
- Poca manutenzione
- Possibile utilizzo di provette di differenti dimensioni
- Determinazione degli indici di siero
- Ampio range di linearità
- Possibilità di autoverifica
- Utilizzo di puntali monouso
- Detection del coagulo

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# Automazione: integrazione

- Check-in (loading station)
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    - Motore per il referto
-

# Automazione Fase Analitica

## Consolidamento ed integrazione

- **Check-in (loading station)**
- **Sorting**
- **Trasporto**
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  - **LAS-Analizzatori interfaccia**
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# Tipologia dei sistemi di automazione

- Aperti
  - Chiusi
  - Integrati
  - Modulari
  - Di isola analitica, di settore, di area...
  - Di laboratorio, di dipartimento...
-

# Criteri generali per la scelta della automazione

- Qualitativi
  - TAT
  - Sicurezza
- Quantitativi
  - Numero di test/die
- Organizzativi
  - Routine/Urgenze
  - Struttura

 **Software di simulazione**

## Integrated Laboratory

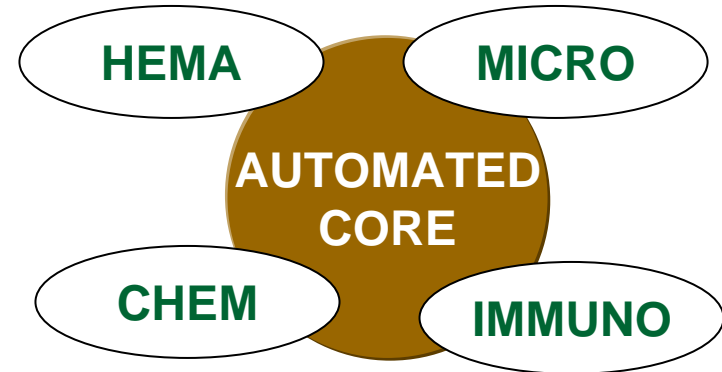
1950s

### CLINICAL LABORATORY

CHEMISTRY  
HEMATOLOGY  
MICROBIOLOGY  
SEROLOGY

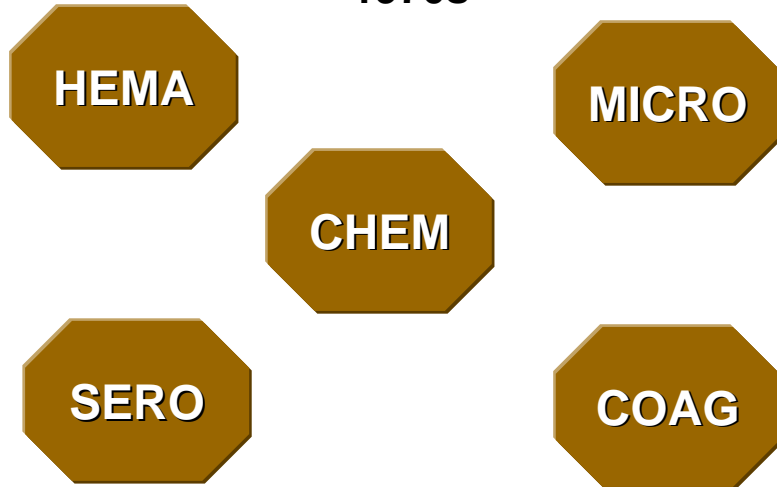
## TAT Driven Laboratory

1990s



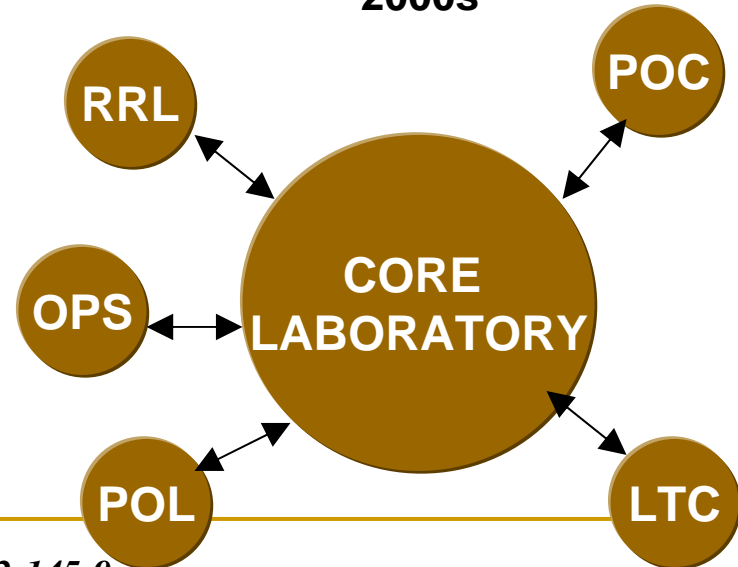
## Compartmentalized Laboratory

1970s

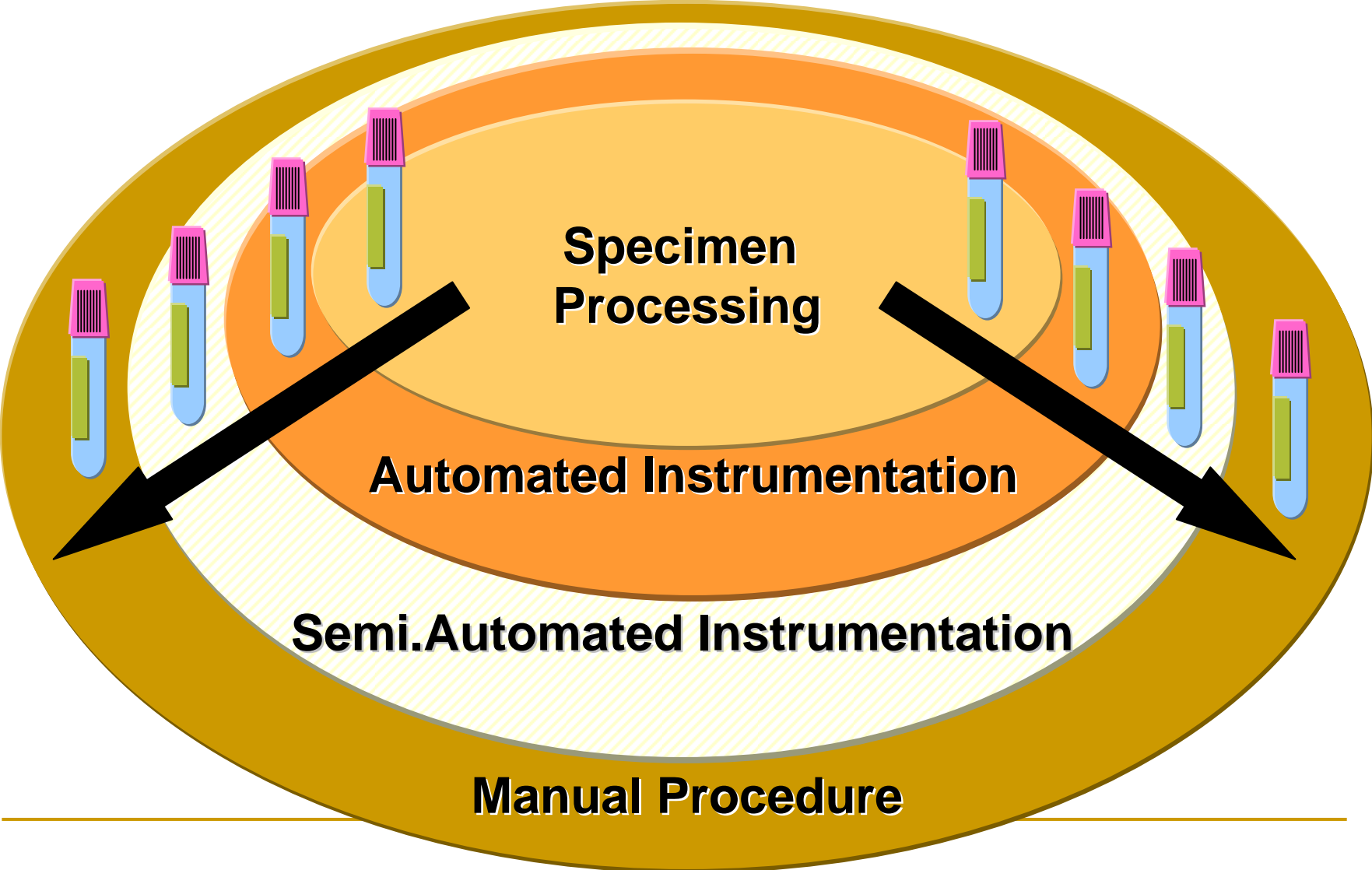


## Consolidated Diagnostics

2000s



**SCHEMATIC REPRESENTATION OF OPTIMAL SPECIMEN FLOW-SPECIMEN PROCESSING SCHEME FOR LABORATORY AUTOMATION PLATFORM**



# Total Laboratory Automation

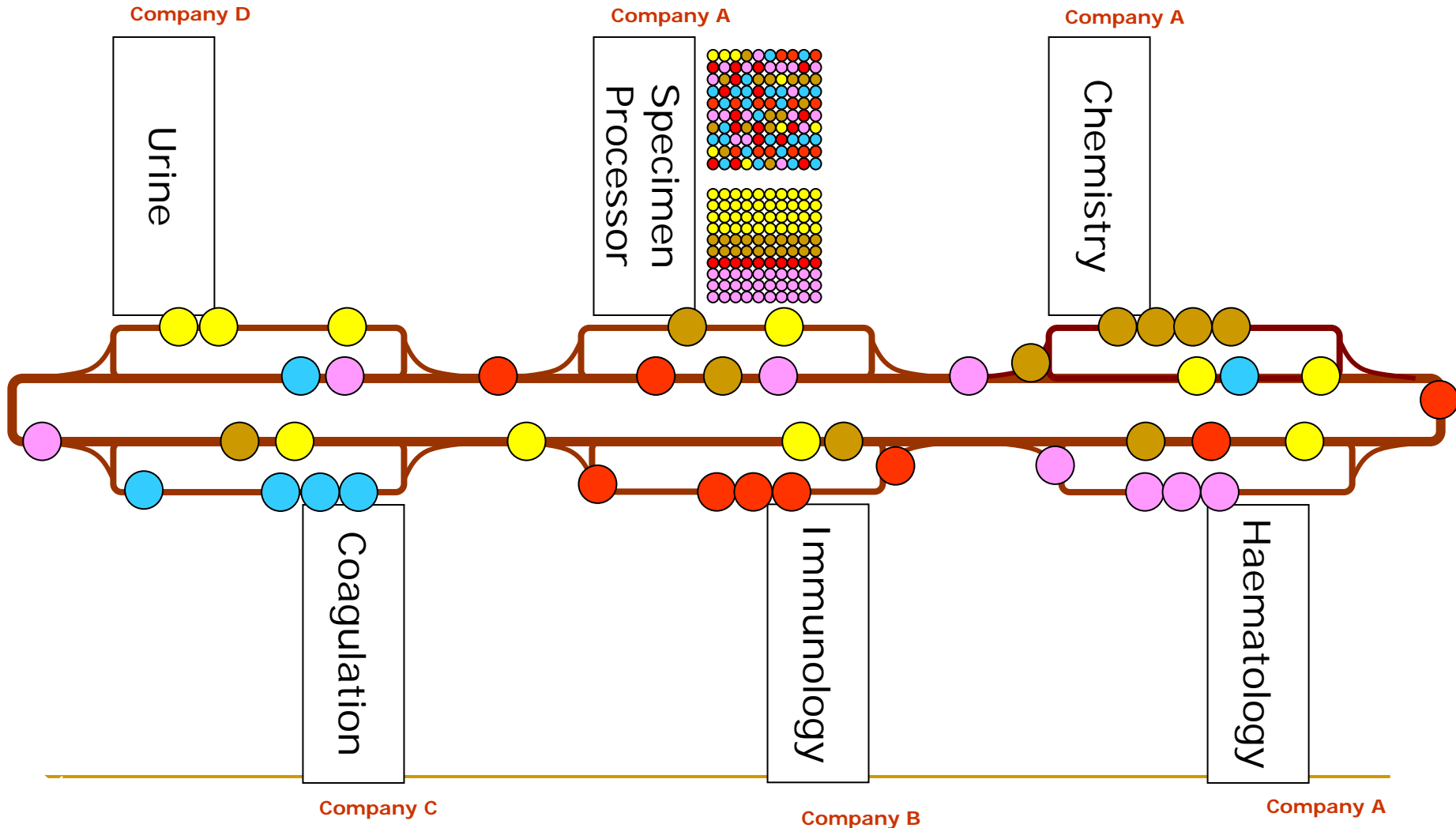
- This term has a historic background dating from the 1980s, when developers were enthusiastic about the idea of “**human-less**” **robotic laboratories**. In the meantime, it has become clear, that this paradigm was quite utopic.
- The third generation, just like the two preceding ones, will require skilled human operators, albeit with a different spectrum of tasks. “Total automation” in a sense of **100% replacement of humans is neither desirable nor feasible**.

# Systematization or TLA

We would like to suggest that the term is used with caution and is restricted to systems that

- **automate most of the manual tasks** of a clinical routine laboratory
- require **hands-on work only for sample loading and unloading**
- **enable technicians to focus on work of higher value** such as result validation, interpretation, microscopic examination, test development etc.

# Automatic sorting and processing of specimens by the conveyor line



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# Integration and consolidation designs

**yesterday**

Chemistry  
analyzers

Infectious  
disease  
analyzers

Urine  
analyzers

Coagulation  
analyzers

Haematology  
analyzers

**today**

One integrated platform

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# Laboratory Automation



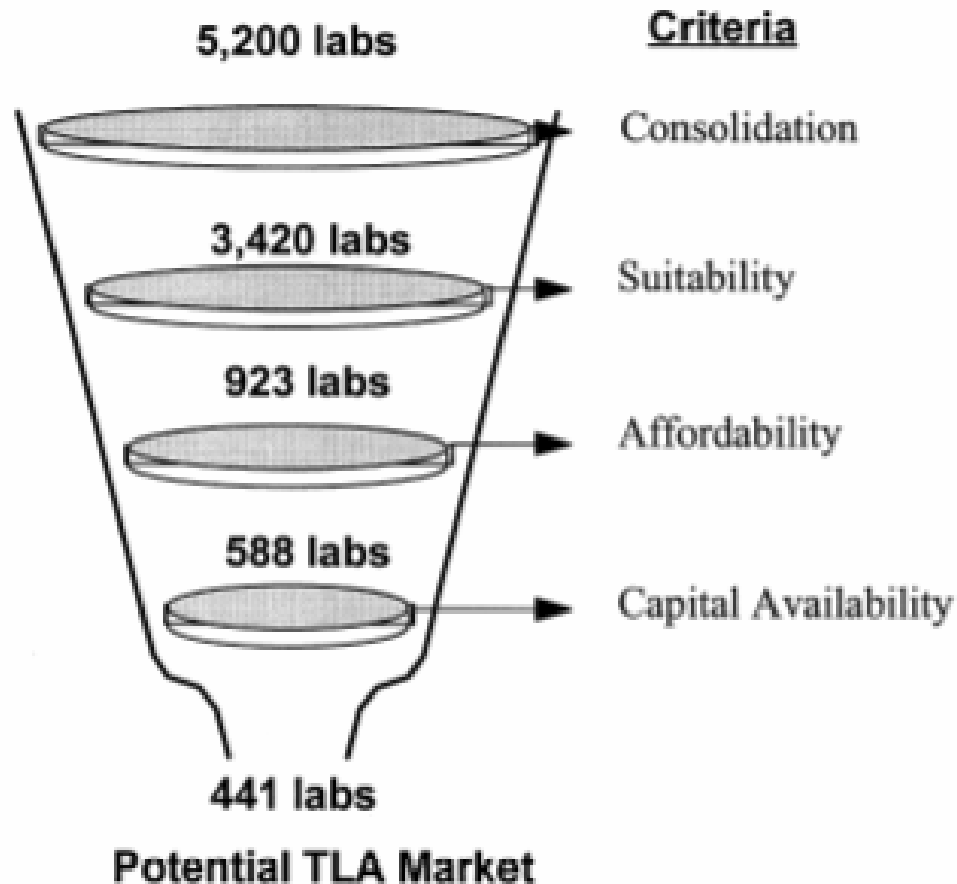
Sonic Healthcare  
Sydney, Australia



The University of Virginia  
Clinical Laboratory  
Charlottesville, VA

# From TLA to *Modular Automation*

Total U.S. Hospital Lab Market



R Felder 1998

# From TLA to *Modular Automation*

Two items are of major *practical* importance:

- consists of **physically separated modules or comes in one box**
- is installed **all at a time or in stages.**

It has been predicted that ***modular systems, built in stages*** will represent about 90% of all ***third generation systems***, at least in the Western hemisphere

# Modular Workcell

- **Workcell** – A workcell is a combination of a specimen manager with instrument(s), or consolidated instrument(s).
- **Specimen manager** – A specimen manager is a mechanical device that allows the storage and buffering of specimens prior to and after analysis.
- **Modular workcell** – A modular workcell consists of instruments that are configured to interface directly with a specimen manager.

# Modular Workcell

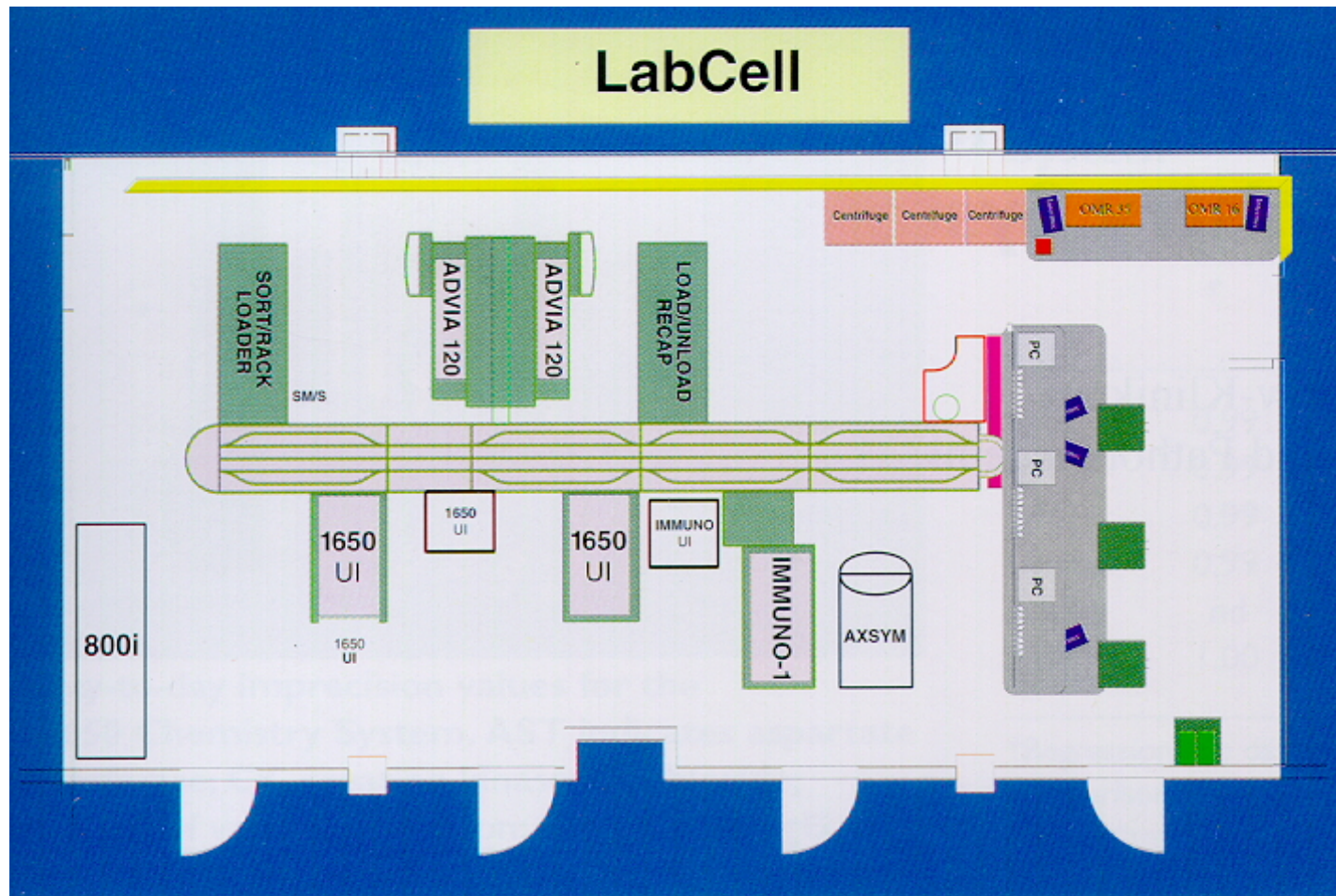


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# Island of automation

- A form of modular automation technology, based upon **consolidating instruments**
- Preanalytic modules for analytic islands include at minimum a loading station, decapper, and triage/sorting unit
- **Process control software is essential** to optimize analytic automation (repeating, diluting, reflex, errors)

# Island of automation



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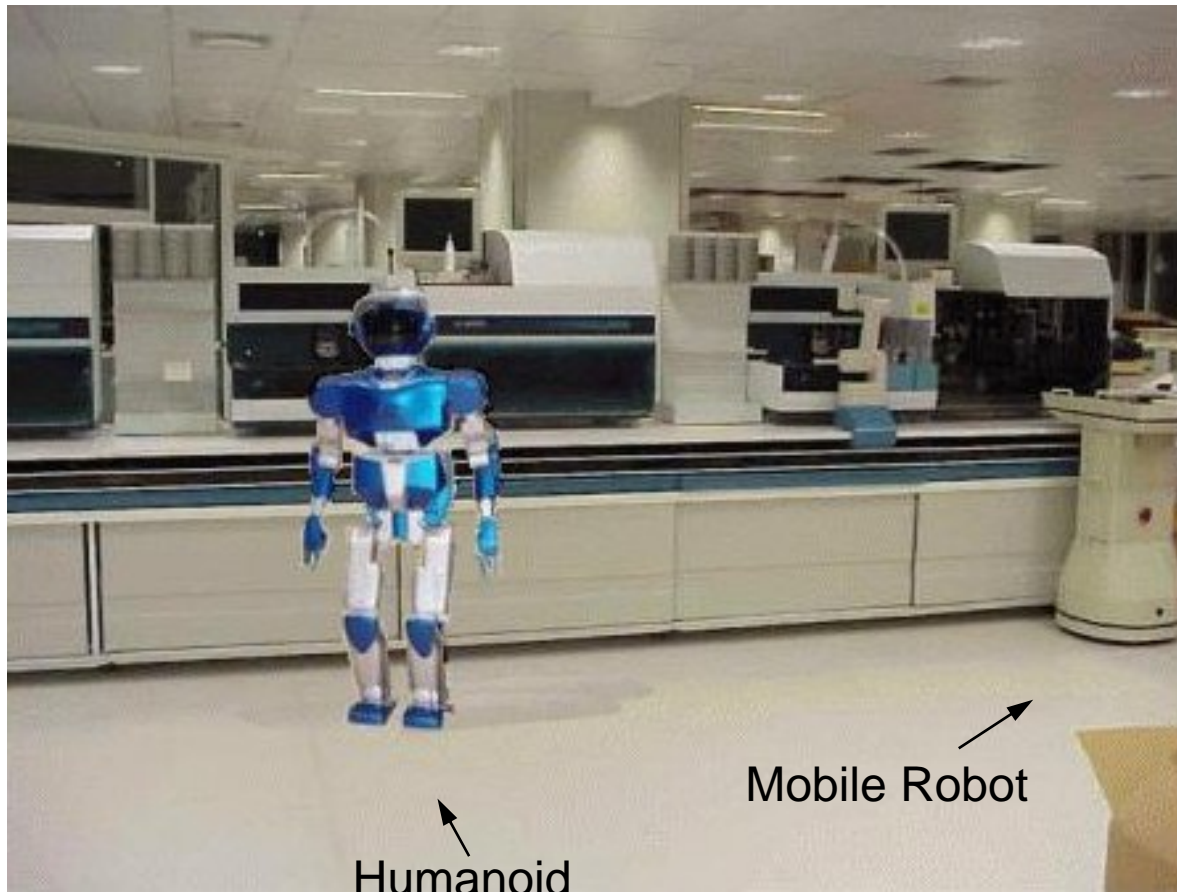
# 4<sup>th</sup> Generation Laboratory Automation

- Full Bi-directional Automation
  - Handles all tube sizes with individual tube transport
  - Throughput is less than 15 minutes per specimen
  - Modular total laboratory automation
    - Point in space sampling with dilution on the analyzer
    - Bidirectional interface with LIS
    - Lean linear design
  - Post analytical storage and retrieval
-

# Advancements in Laboratory Automation



# The Automated Laboratory of the Future ?



Humanoid

Mobile Robot

The Humanoid Technologist Program at the  
Medical Automation Research Center

*R Felder 2006*

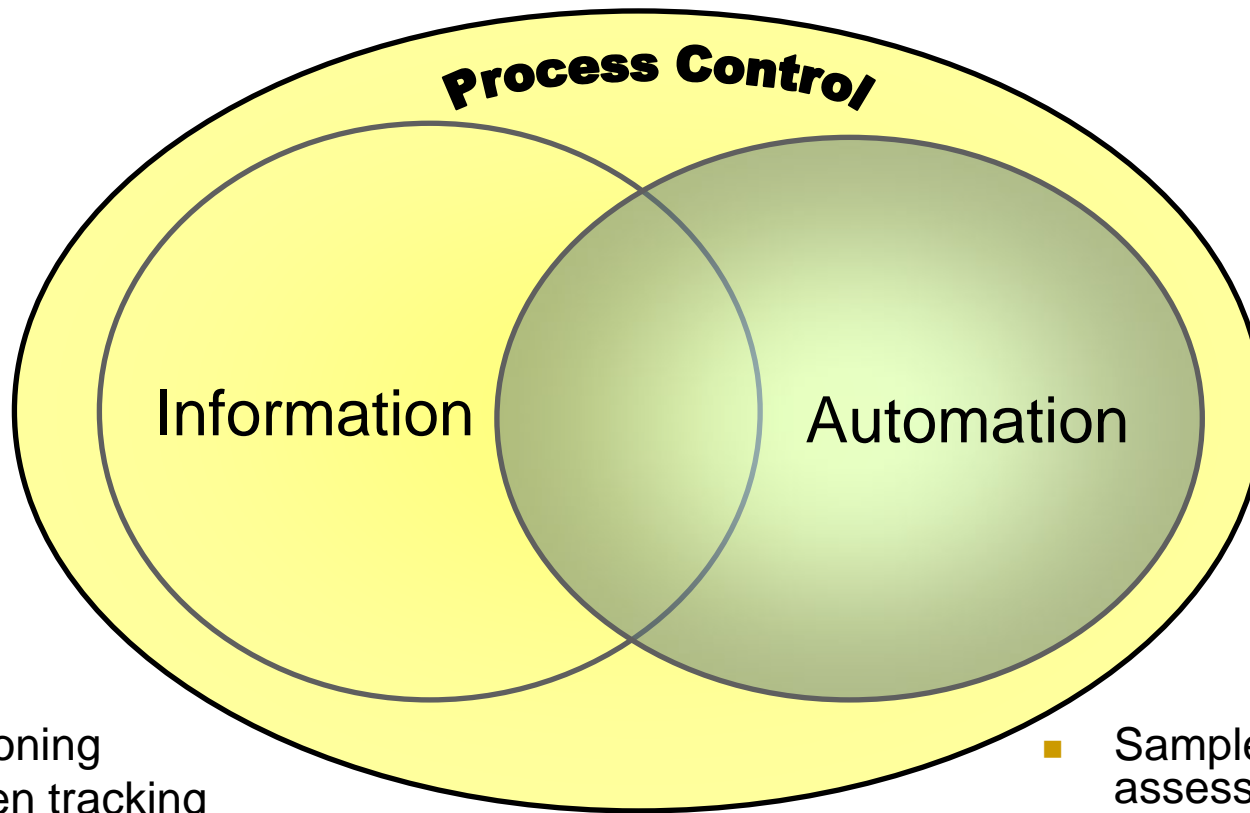
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# Automazione Fase Analitica

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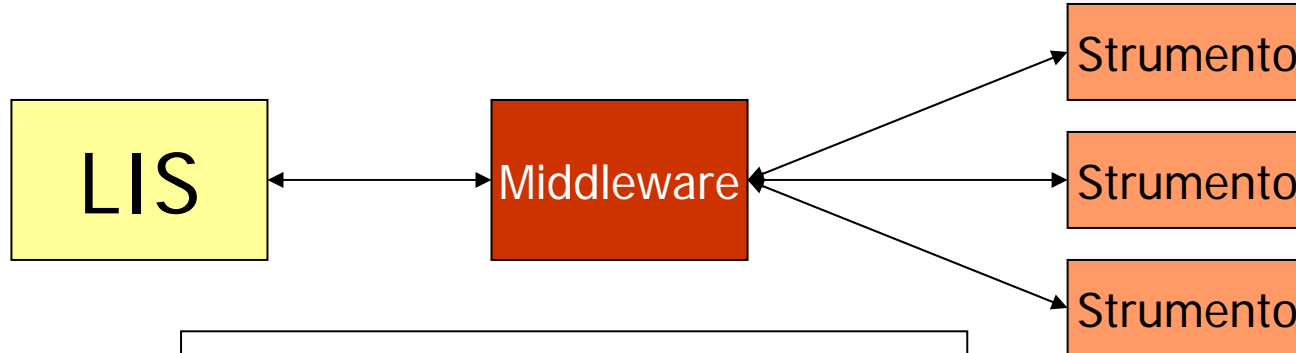
# Workflow Management



- Accessioning
- Specimen tracking
- Data logging and reporting
- Quality control documentation

- Sample quality assessment
- Optimal routing and scheduling
- Intelligent reporting

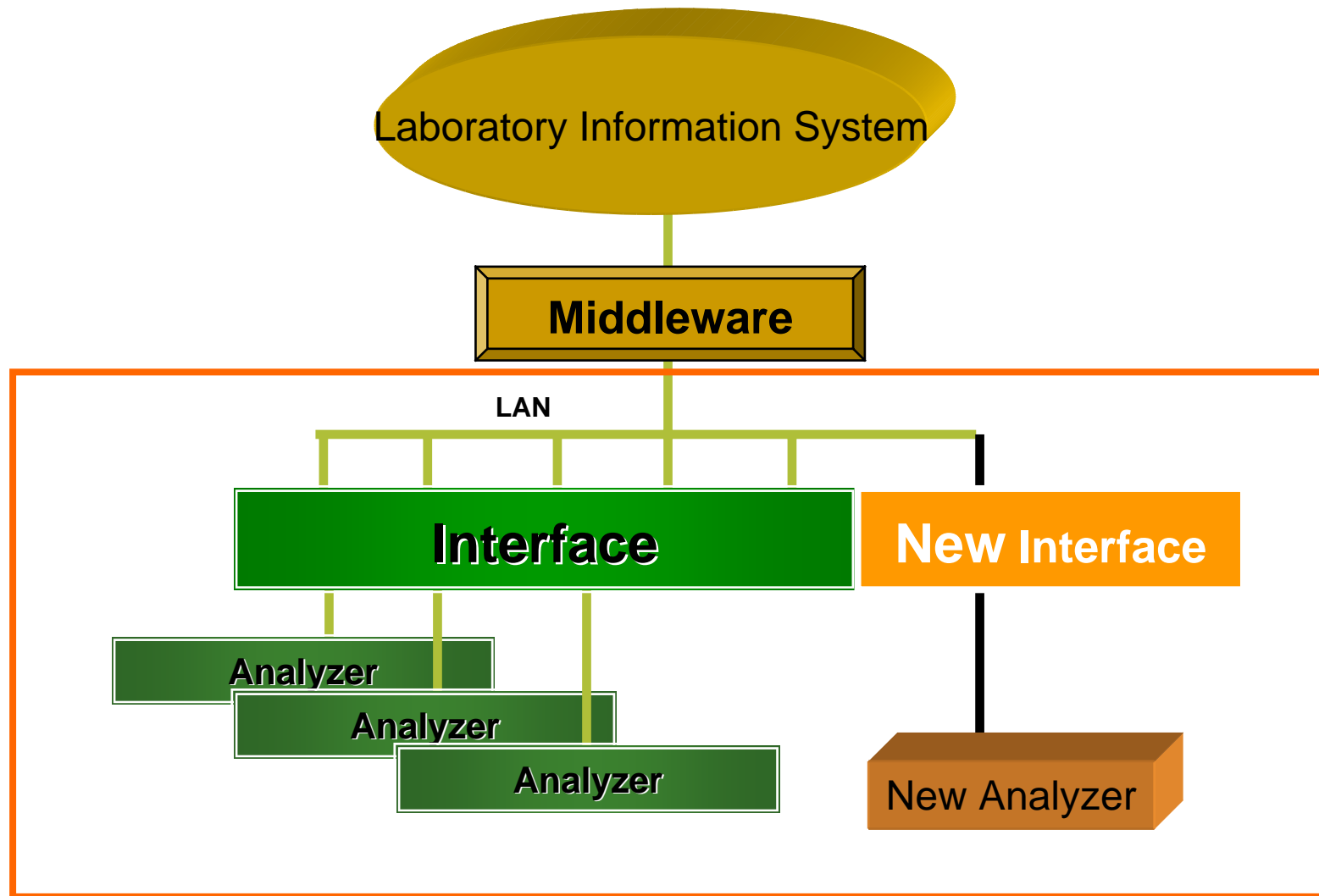
# Controllo del processo



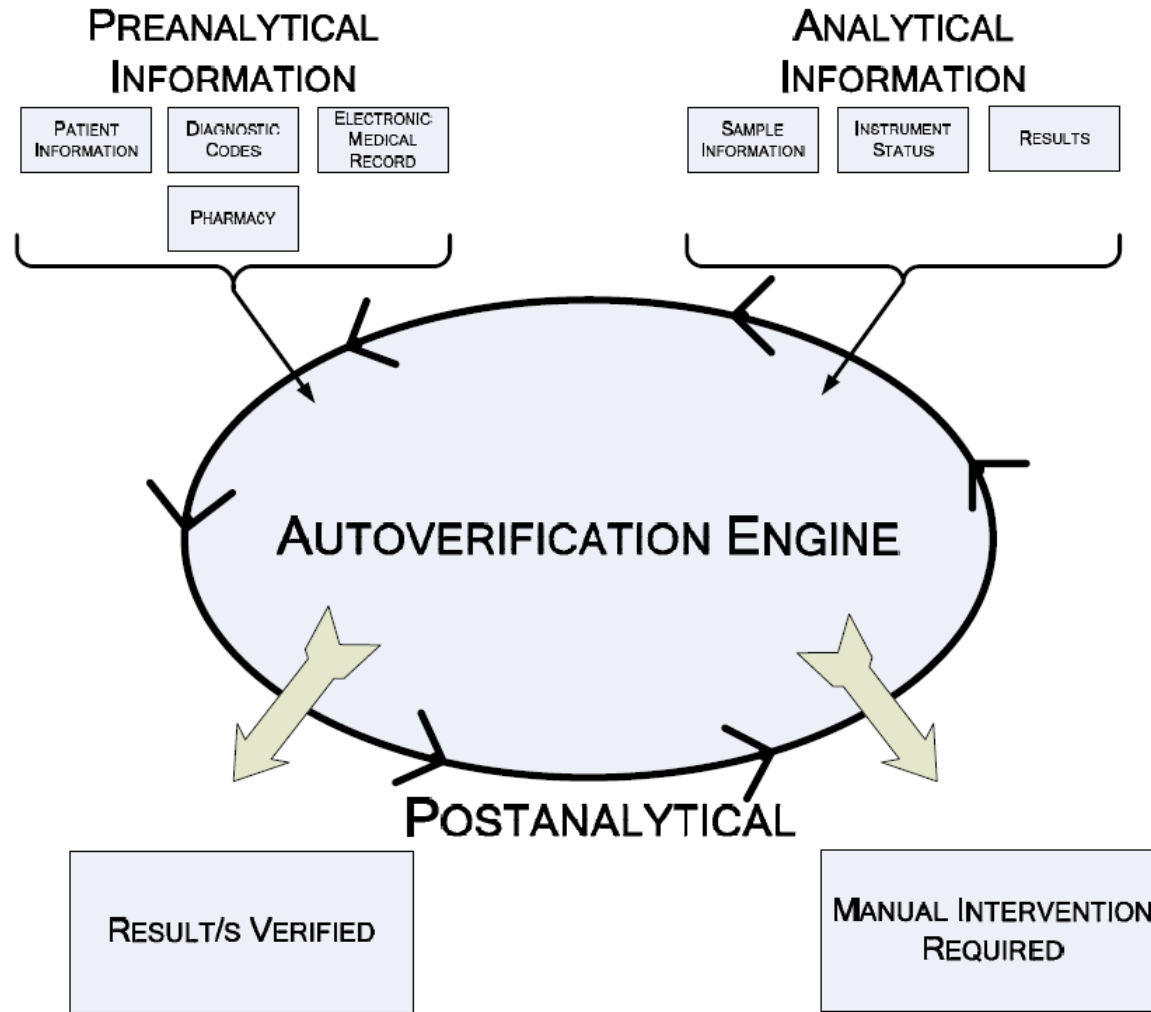
## Middleware

- Software interposto tra client e server, in LAB, tra LIS e strumenti
- Gestione dei risultati
- Autoverifica
- Ottimizzazione dei processi analitici

# Proper Laboratory Information System Process Control Architecture



# Autoverification Process



# CHOICE OF INSTRUMENTS & AUTOMATION

- PRODUCTIVITY
- COMPLEXITY
- TURN AROUND TIME
- SPECIALIZATION
- SECURITY
- AUTOMATION

"Relative Weight"

**COST/  
BENEFIT**

## Appropriateness and technology assessment in cardiology: a case study of computed tomography

Redberg RF. Evidence Health Affairs 2007; 26(1):86-95.

L'autrice dell'articolo, Rita Redberg, direttrice del Women's Cardiovascular Services presso il Medical Center della University of California San Francisco, afferma che

una **nuova tecnologia** è valutabile solo in termini del **miglioramento che apporta allo stato di salute dei pazienti**.

“Il modello attuale *'paga subito, i benefici forse verranno poi'* è in parte colpevole dell'enorme spesa pro capite statunitense per le cure mediche, maggiore di ogni altra nazione, alla quale però corrisponde un sistema sanitario che raggiunge solo il trentasettesimo posto in quanto a performance”.

## Appropriateness and technology assessment in cardiology: a case study of computed tomography

Redberg RF. Evidence Health Affairs 2007; 26(1):86-95.

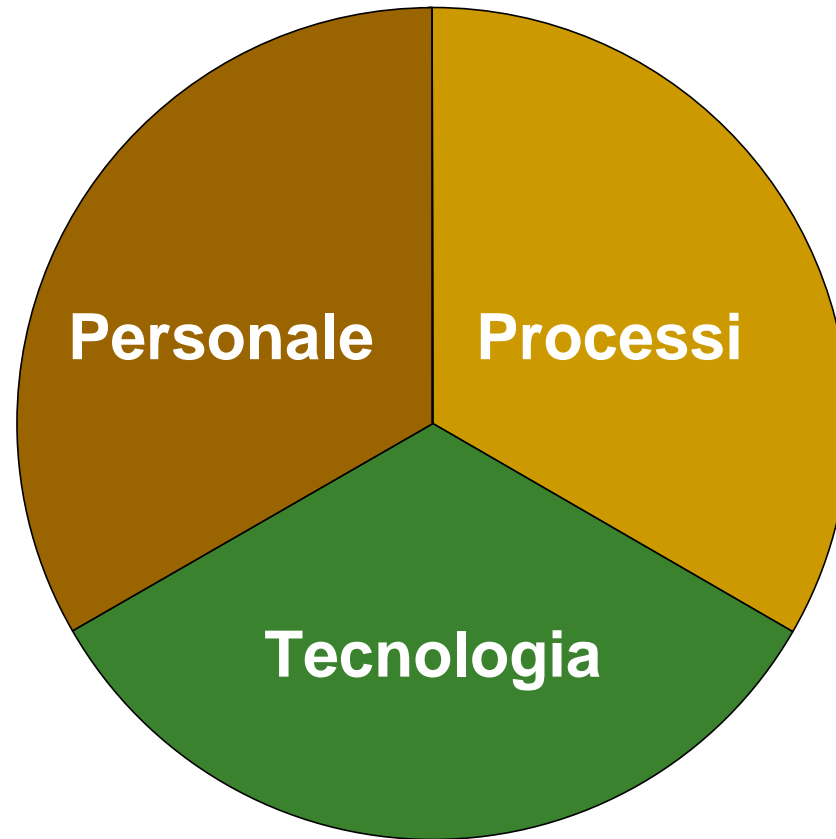
La Redberg propone un processo di valutazione evidence-based che risulterebbe in una politica medica meglio equipaggiata per affrontare le tensioni dovute al **contrasto tra qualità, innovazione e valore economico** rispetto al sistema attuale. Secondo l'autrice una valutazione della tecnologia evidence-based sta assumendo un'importanza sempre maggiore:

**“Con il crescere del volume, della complessità e dei costi delle nuove tecnologie mediche diviene sempre più pressante il bisogno di una corretta valutazione costi/benefici. Sfortunatamente attualmente vengono applicati pochissimi criteri sistematici che verificano i benefici riportati dai pazienti”.**

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*Automazione in laboratorio:  
impatto organizzativo e gestionale*



# LABORATORY AUTOMATION QUESTIONS

- Is this laboratory large enough to justify an automation investment?
- What target benefits are used to help justify an investment in automation?
- What qualitative, nonfinancial benefits can be expected?
- Is front-end preanalytic automation right for this laboratory?
- What routine laboratory task can be automated?
- Does it make sense to consider an LAS that does not include front-end automation
- The laboratory runs a high number of stat orders. Does automation help or hinder turn-around time (TAT)?
- What is process control as applied to laboratory automation? What distinguish open versus closed systems?
- What other features should be evaluated?
- We deal with a mix of laboratory errors that negatively impact our productivity or the quality of our service. How can automation help?

# AUTOMAZIONE: mezzo e non fine

L'automazione è un mezzo, non il fine del nostro lavoro. Alcuni obiettivi, oggi necessari non sono raggiungibili senza i mezzi adeguati.

**Automazione = NECESSITA'**

Con i soli "mezzi" si può andare anche nella direzione sbagliata.

