The industry's perspective:
Lessons from previous technology changes

Future of blood grouping

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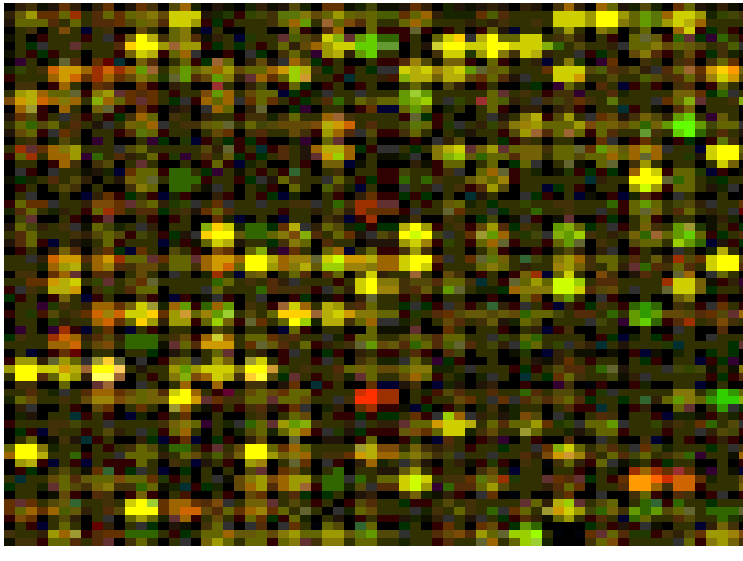

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Factors promoting technology changes

- Limited performance of existing diagnostic procedures
- Standardization
- Cost pressure
- Lack of qualified personnel
- Automation
- Regulations

Technology changes in routine blood grouping

Change	Objective
Monoclonal reagents	Standardization
Automation in donor screening	Cost reduction, throughput
New test formats	Performance, simple procedures
Automation in non-donor segment	Reduction of personnel, data safety
 ?	
Molecular Typing	?

Utilisation of molecular biology in different diagnostic segments

Bacteriology

Actual diagnosis is dominated by classical culture methods

Virology

Successful use in special applications

HLA-Typing

Continuous replacement of serology (serology < 50%)

Molecular biology in bacteriology

Use of molecular biology is limited to special applications (e.g. detection of mycobacteria) where cultural methods reveal poor results.

At present a general replacement of classical procedures is not realistic due to:

- Technical limitations of molecular biology e.g.
  identification of multiple infections
  sample preparation
  identification of unknown or modified bacteria

- Guidelines favor established procedures

- Lower costs of cultural methods

Molecular biology in virology

- A wide range of different diagnostic techniques is used in routine viral diagnosis (culture, antigen detection, DNA/RNA detection, serology, histochemistry)

- Molecular assays have been established very quickly in segments where conventional procedures are not able to reveal comparable results (e.g. viral load, donor screening, strain identification)

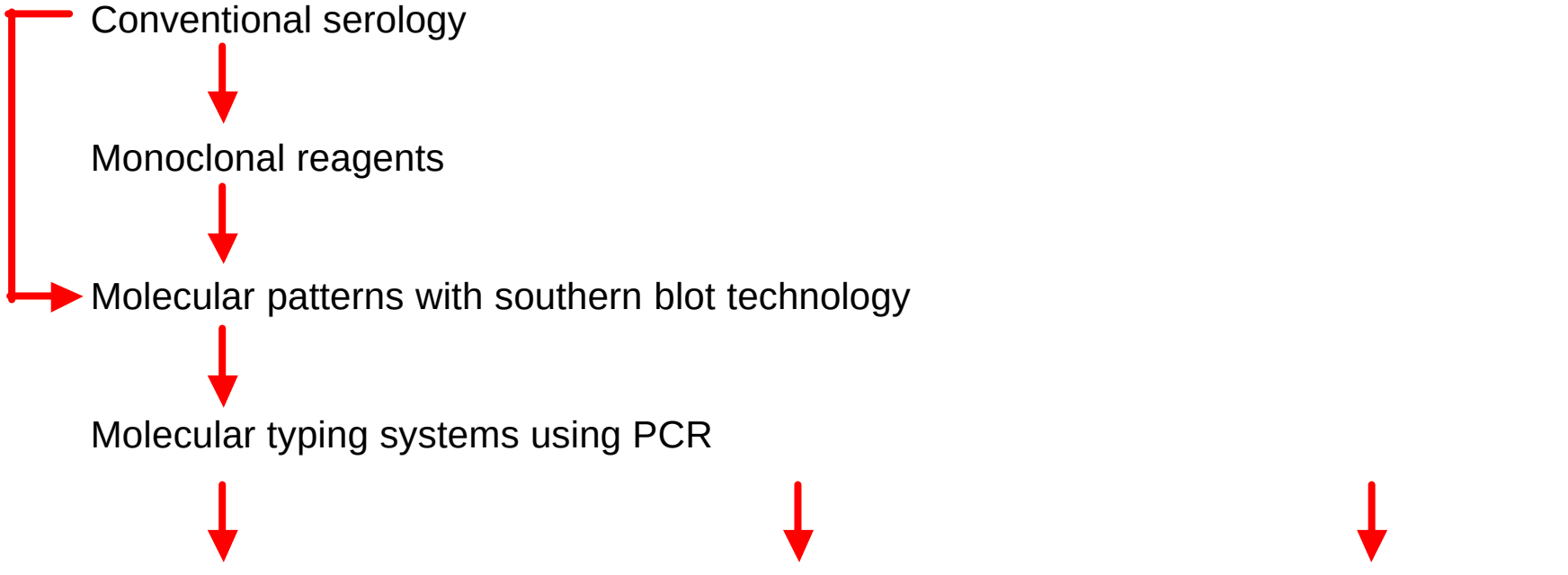
- In segments with relevant test volumes commercial systems are available and high prices are established (patent situation)

- Minor applications are dominated by homebrewed tests

Factors promoting shift from serology to molecular typing in HLA-diagnosis

- Limited resolution in serotyping (espec. class 2)
- Lack of reproducibility due to polyclonal reagents
- Some loci are not covered by serology
- No automation available
- Demand for high throughput in registry segment
- HLA community is extremely open for innovative technical solutions

Technology changes in HLA-typing

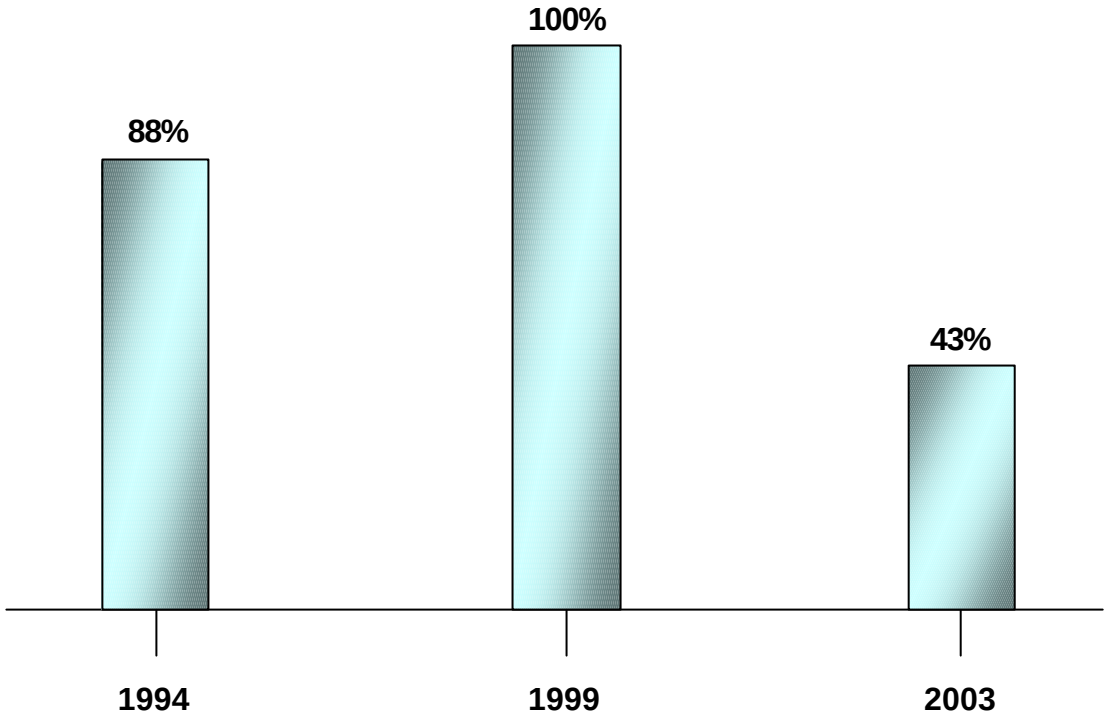


DATA MANAGEMENT BY SOFTWARE TOOLS

15 years of experience in molecular HLA-typing (1)

Transition to molecular biology is much slower than expected
➔ almost stagnant situation in selected countries and segments

Biotest's sales in HLA-serology



15 years of experience in molecular HLA-typing (2)

- Registry segment is dominated by SSO-systems (strips, MT-plates, beads) with different automation levels

- Despite better performance and higher production costs SSO-systems are sold below price level of serology

- SSP-systems are predominantly used in small laboratories mainly in connection with sold organ transplantation

- Biochip projects initiated in molecular HLA-typing failed

General conclusions = Lessons to be learned

- Acceptance of innovative technologies may vary in different diagnostic segments
- Even with proven superior performance replacement of established procedures may be a long lasting process
- End users are in general not willing to accept higher prices for better diagnostic tests
- Fast transition to new technology is possible in segments with corresponding requirements
- Usually regulations or specific guidelines slow down technology changes
- The special demands of diagnostic segments have to be considered

Special aspects of blood grouping

- Erythrocyte as major diagnostic target
- Combination with antibody detection
- Conservative user group
- Highly regulated (IVD-D, FDA) / Guidelines
- Assay time compared to conventional procedures
- Price level of serology
- Sample preparation
- Level of automation expected by different user groups

(LISTING ISN'T COMPLETE)

Conclusions II

- Focus on special applications where classical procedures fail or show poor results

- Generate practical experience and routine data to convince the user community

- Develop a technical platform which considers specific requirements