



Innovations in Sample and Assay Technologies

SystemX.ch SME Workshop

Zürich, October 19th, 2009

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Director R&D
Diagnostic Sample Preparation
QIAGEN GmbH



Technology Roadmap: Sample and Assay Technologies

Structure base on identical Workflows in all segments



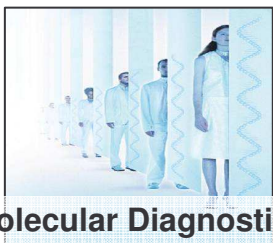
Life Science Research



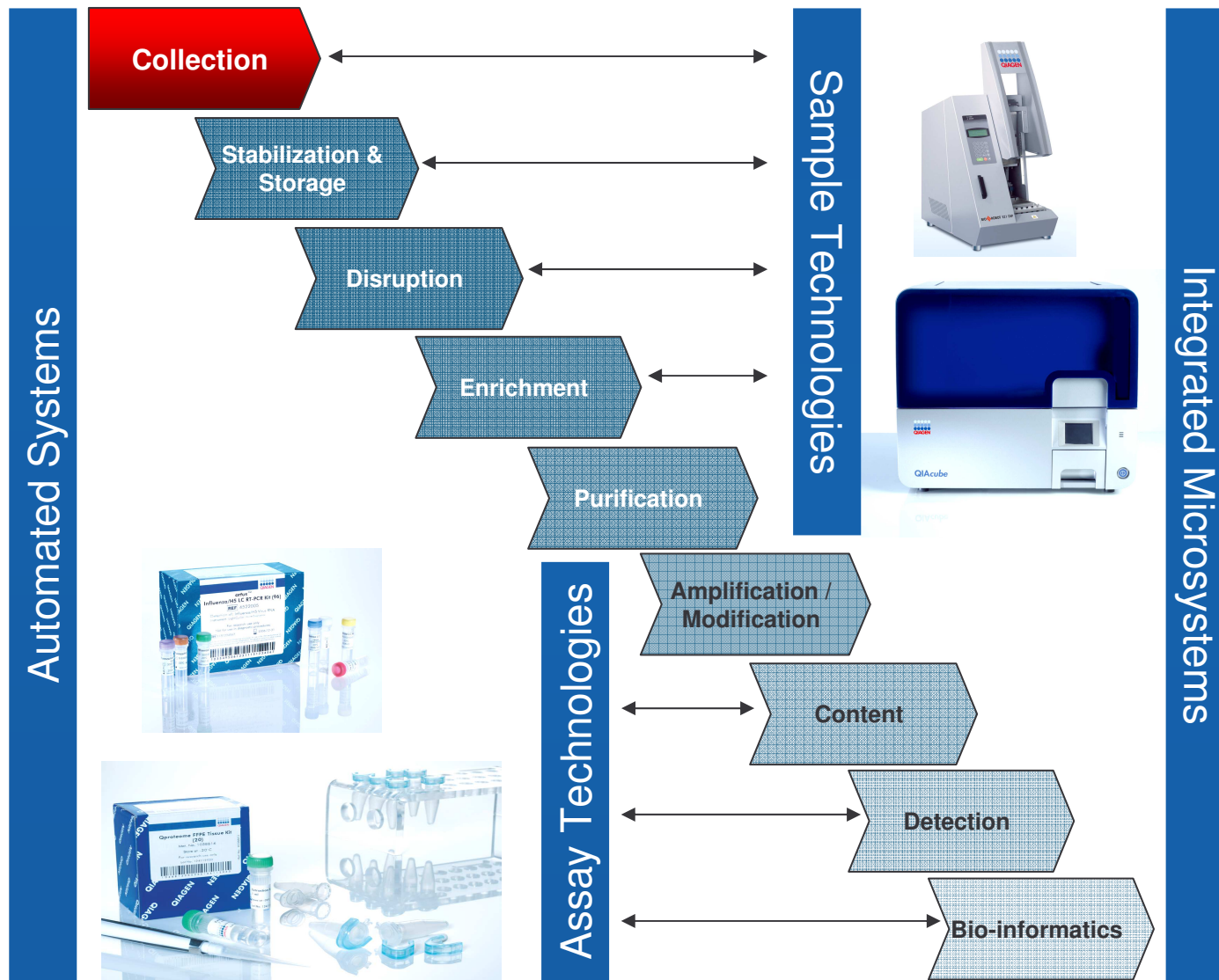
Pharma



Applied Testing

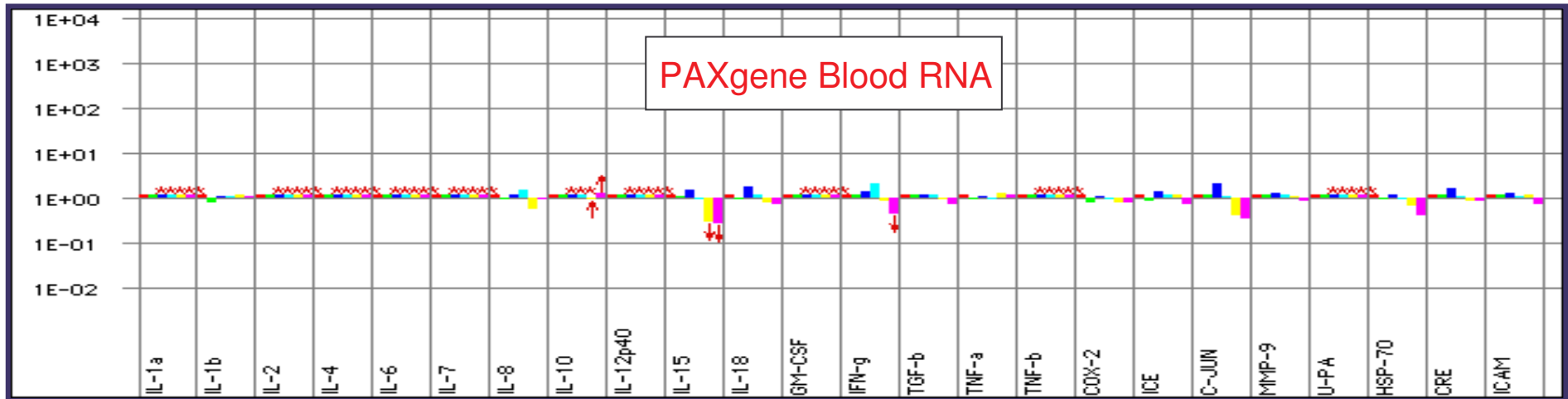
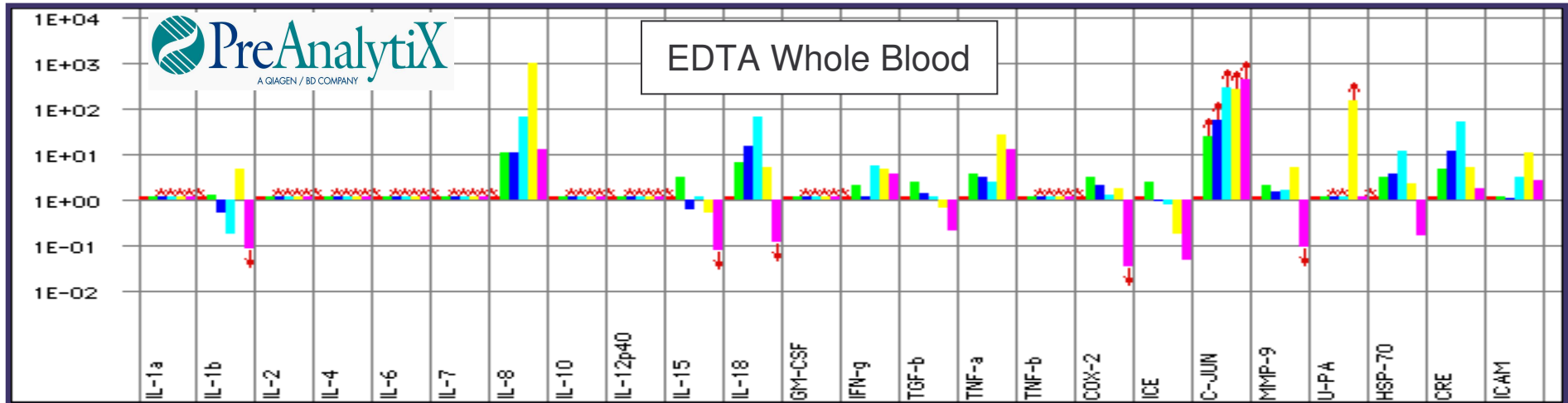


Molecular Diagnostics





PAXgene Blood RNA vs. EDTA Blood Storage at Room Temperature



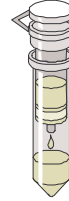


PAXgene™ Blood RNA Systems

Cellular RNA and miRNA from Human Blood



For Diagnostic Use
CE, 510(k)



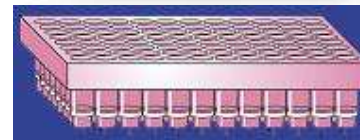
Spin Column Manual
For Diagnostic Use
CE, 510(k)



Spin Column on QIAcube
For Diagnostic Use
CE, 510(k)



QIASymphony⁽¹⁾



Manual 96⁽¹⁾



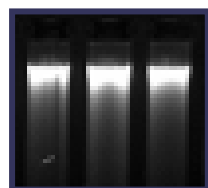
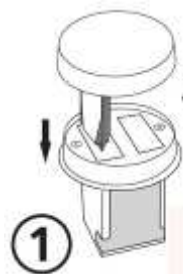
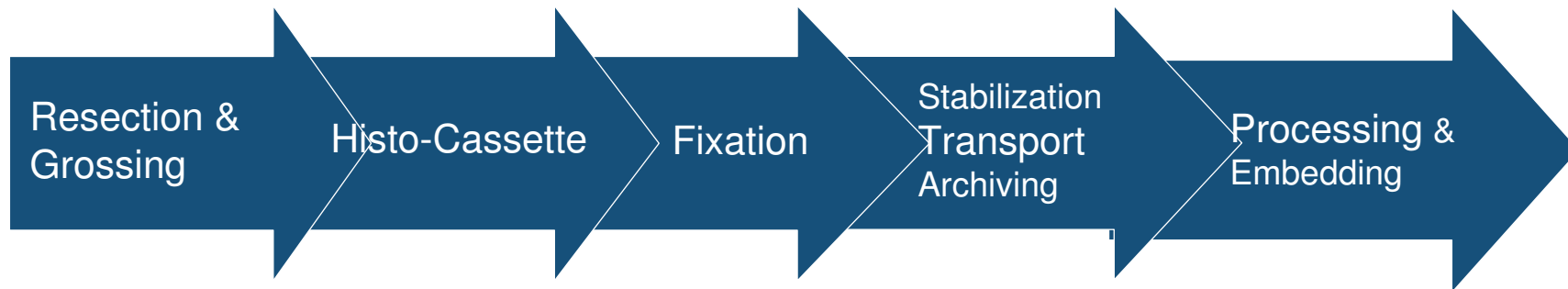
BioRobot MDx⁽¹⁾
BioRobot
Universal System⁽¹⁾

(1) FRUO or General Purpose Reagent Kits

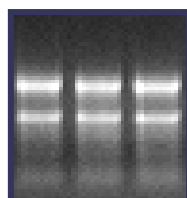


PAXgene Tissue System

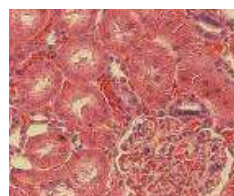
Enabling Morphology and Molecular Analysis



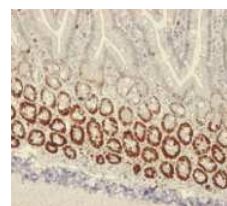
DNA



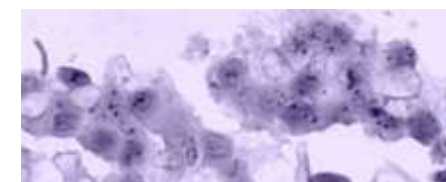
RNA and miRNA



Histomorphology



Immuno-histochemistry



in situ Hybridization



Stabilization of Biomolecules in Samples

Portfolio Overview



PAXgene™ Product Line

- PAXgene Blood RNA
- PAXgene Bone Marrow RNA
- PAXgene Blood DNA
- PAXgene Tissue



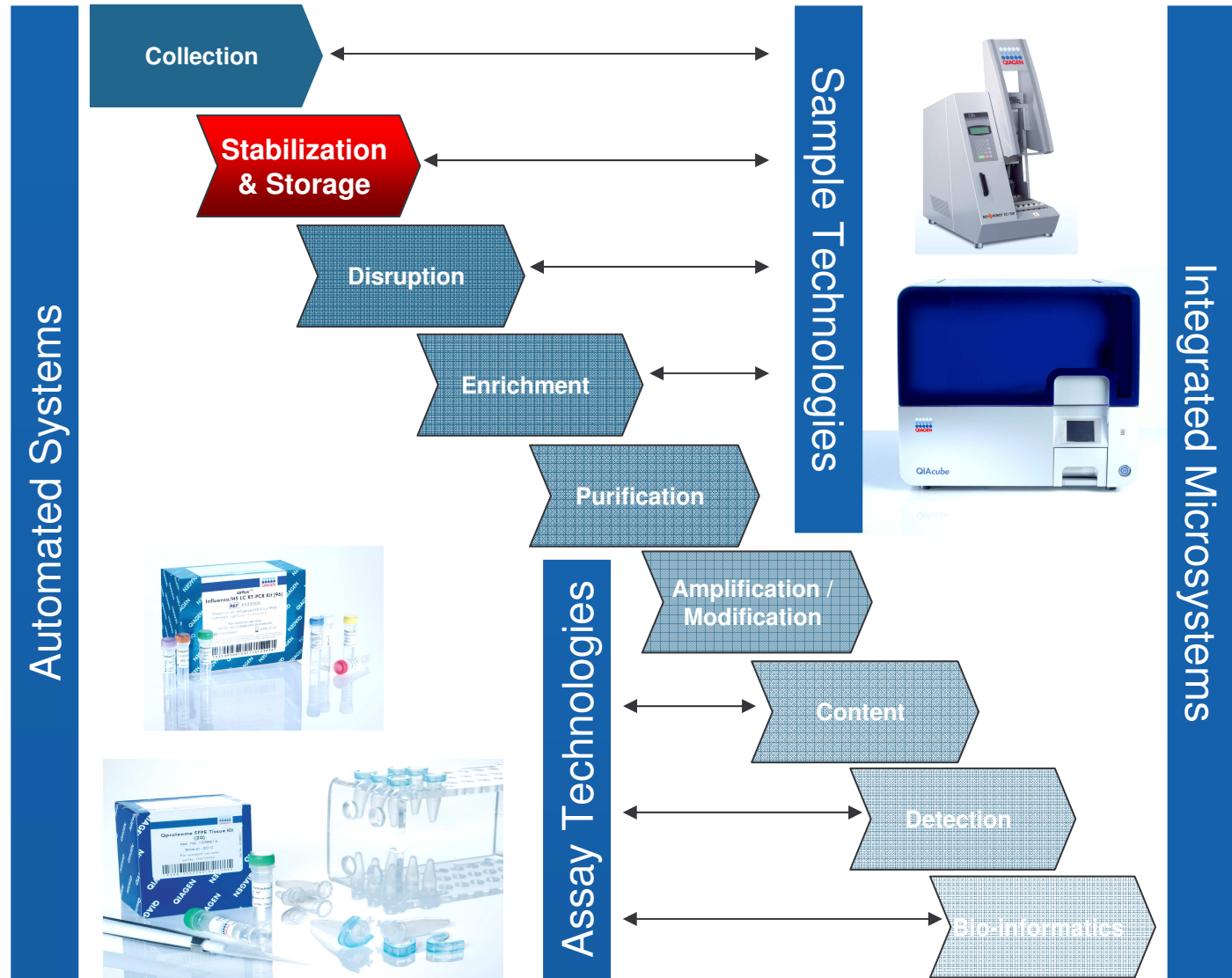
RNeasy Protect Product Line

- RNeasy Protect TissueProtect Tubes
- RNeasy Protect Saliva
- RNeasy Protect Bacteria Reagent
- RNeasy Protect Cell Reagent
- Allprotect Tissue Reagent
- RNeasyProtect Animal Blood System



Technology Roadmap: Sample and Assay Technologies

Structure base on identical Workflows in all segments

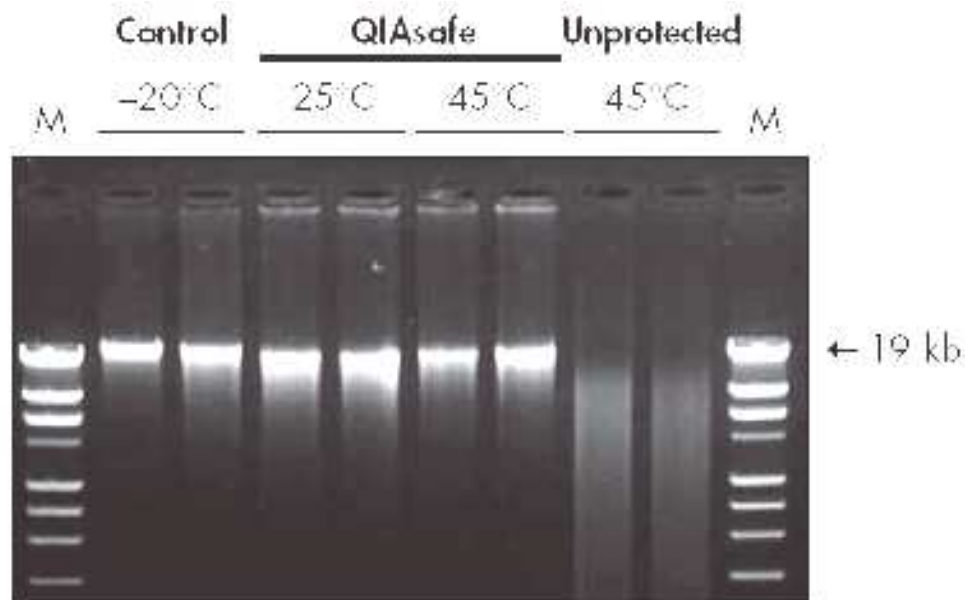




QIAsafe DNA & QIAsafe DNA Blood Archiving at Room Temperature



- Technology based on anhydrobiosis
- Stabilizes all types of DNA at room temp.
- Cost savings (no refrigeration cost)
- Significantly higher DNA yields than conventional RT-storage methods





QIAGEN coordinates the SPIDIA Consortium

Enabling Future Molecular Diagnostics



FP7-HEALTH-2007-B

Project Start Oct 1, 2008 - Funding Scheme: Collaborative Project

Standardisation and improvements of pre-analytical procedures for *in vitro* diagnostics

Provide pan-European **quality assurance schemes** and **guidelines** for pre-analytical procedures such as sample **collection, handling, transportation, processing and storing** of clinical samples. **Tissue samples, blood samples** and perhaps **other specimens** should be considered.

17 EU Partners

Duration: 4 years

Funding: 13 Mio €



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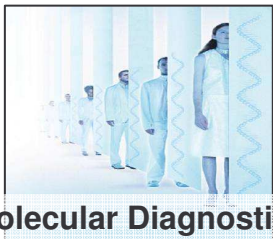
Life Science Research



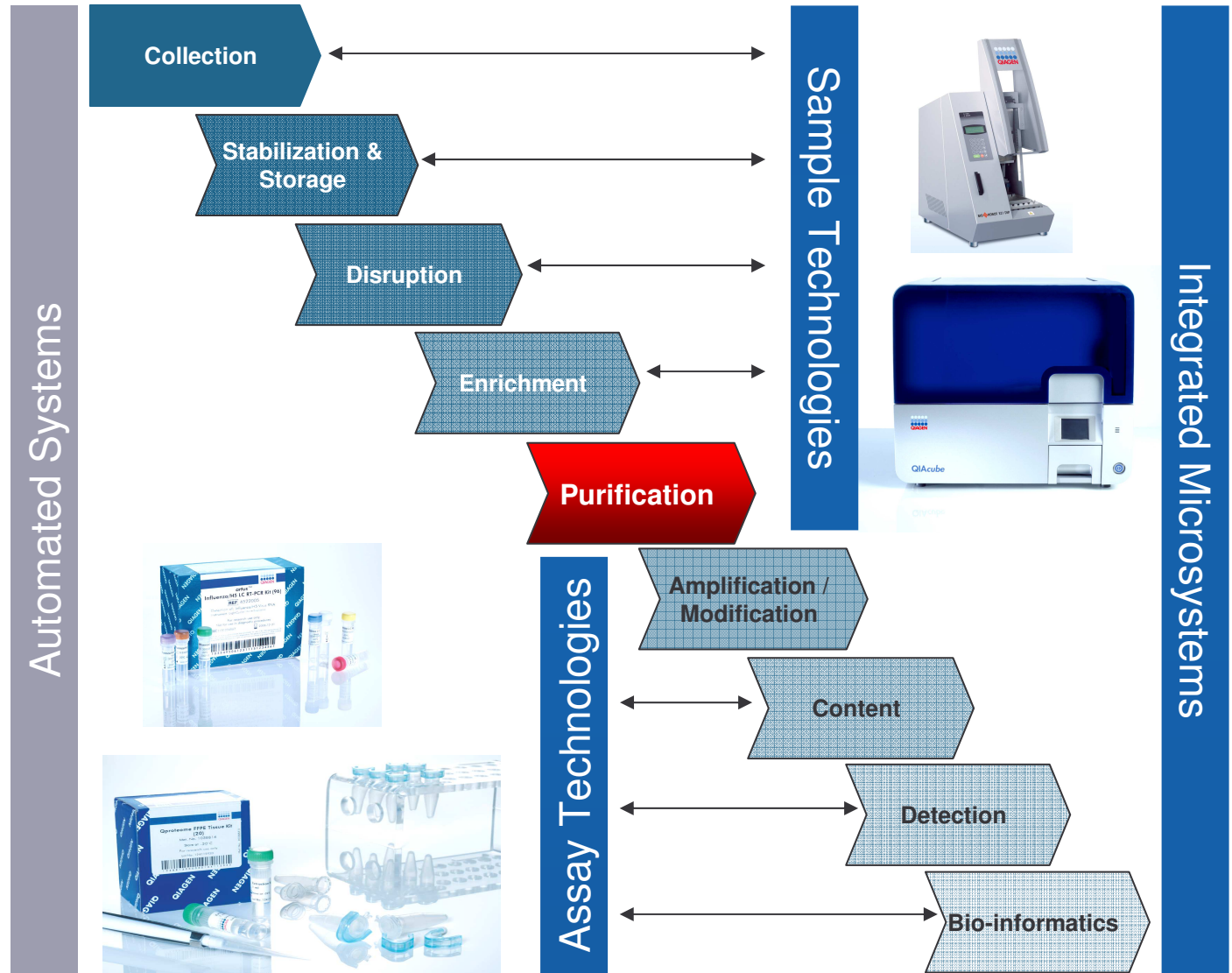
Pharma



Applied Testing



Molecular Diagnostics





Nucleic Acid and Protein Isolation



- RNeasy products
- miRNeasy
- QIAamp products
- DNeasy products
- MagAttract products
- EZ1 products
- QIAasymphony products
- AllPrep DNA/RNA/Protein
- Qproteome FFPE



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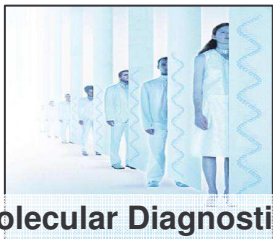
Life Science Research



Pharma



Applied Testing



Molecular Diagnostics





QIAGEN's PCR Product Portfolio

Standard PCR

Taq
HotStarTaq
HotStarTaq Plus
HotStar HiFidelity
QIAGEN Fast Cycling PCR Kit

RT-PCR

Omniscript
Sensiscript
QuantiTect Reverse Transcription Kit
QIAGEN OneStep RT-PCR Kit

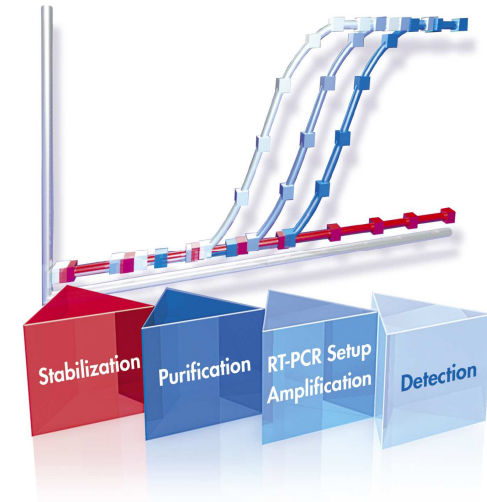
Multiplex PCR

Real-time PCR

QIAGEN Multiplex PCR Kit
QuantiTect PCR & RT-PCR System
Quantitect Virus
QuantiFast PCR & RT-PCR System
QuantiTect Multiplex PCR & RT-PCR System

Real-time PCR Assays

QuantiTect Primer Assays (>150.000)





Detection Platforms

RG6000



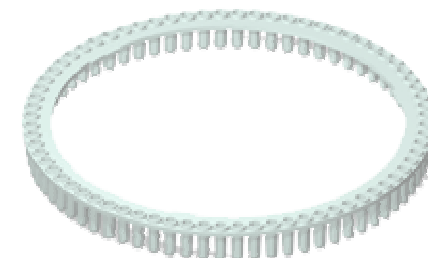
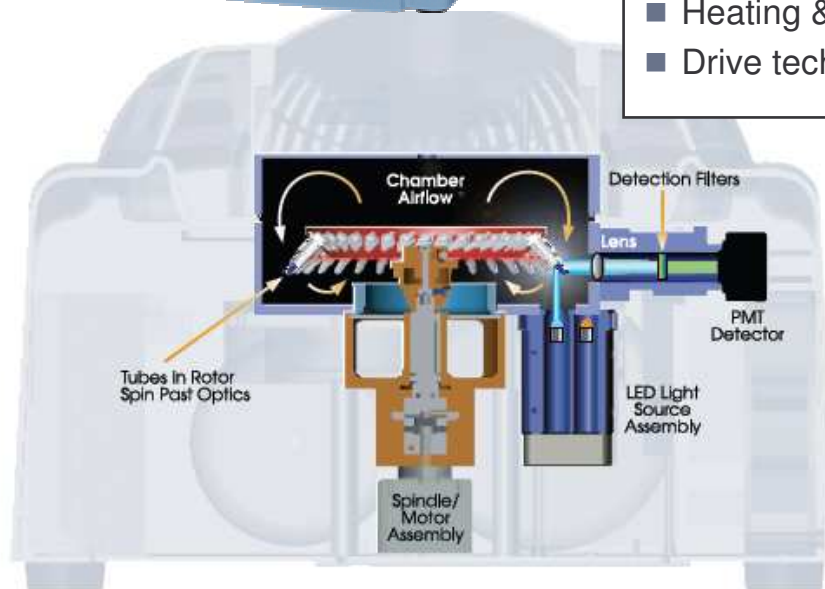
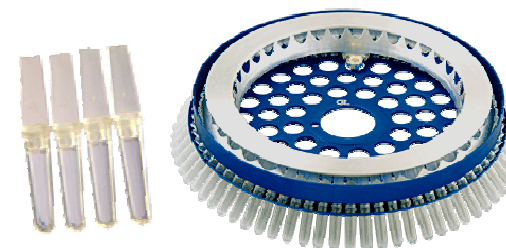
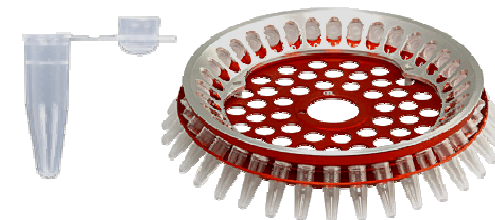
Necessary Technologies

Enabling technologies

- Cycling technologies → Corbett

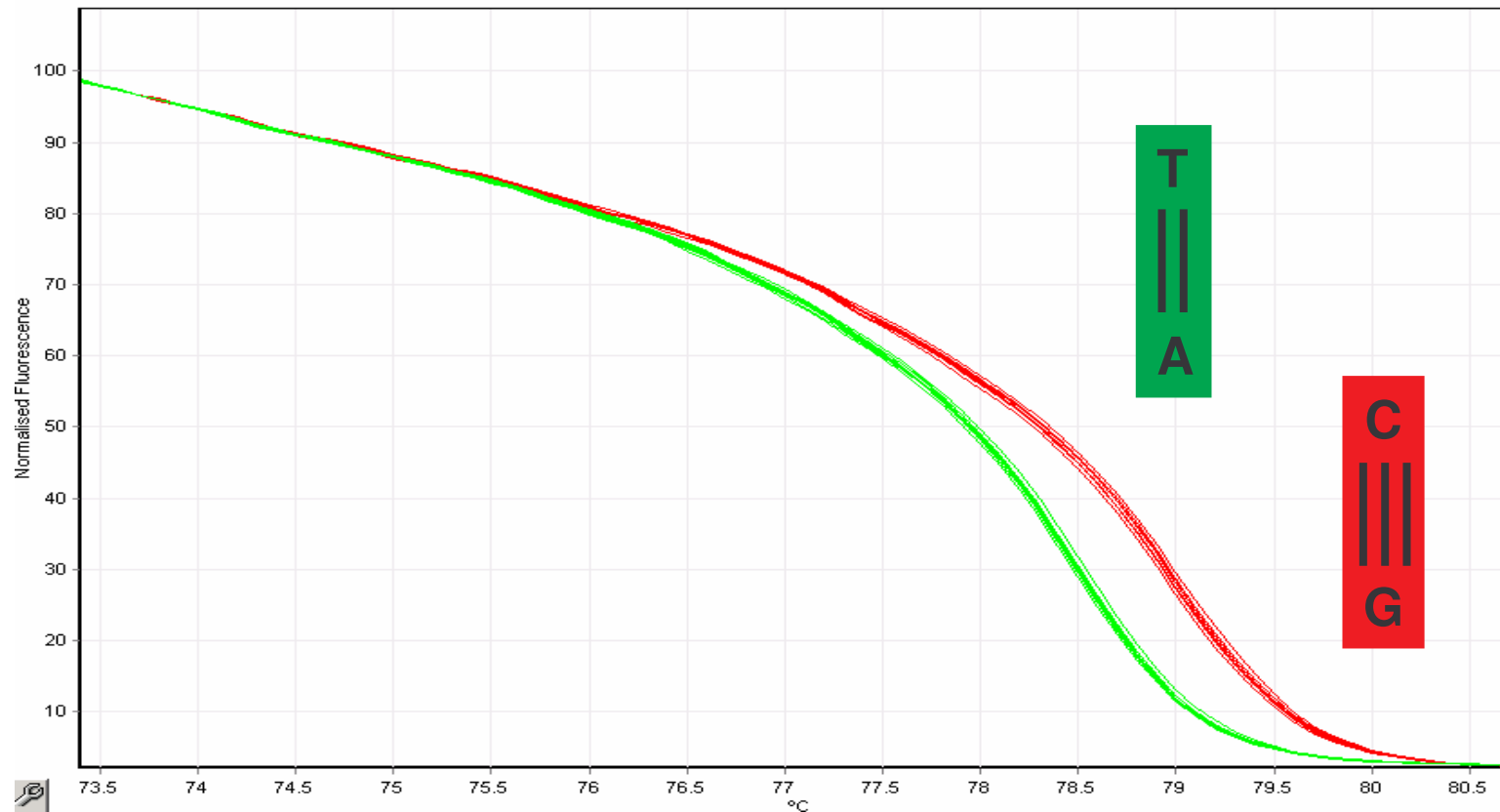
Process-independent technologies

- IT technologies (data processing)
- Light sensors
- Heating & cooling
- Drive technologies





Homoduplex C \Rightarrow T



Homozygotes are easily differentiated by different TMs.



Detection Platforms

QIAXcel

QIAXcel & Laptop & BioCalculator



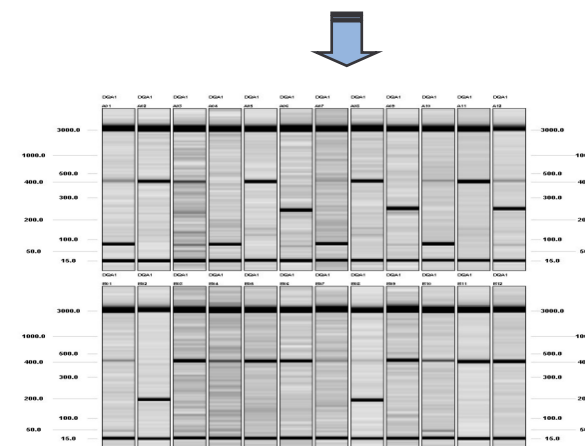
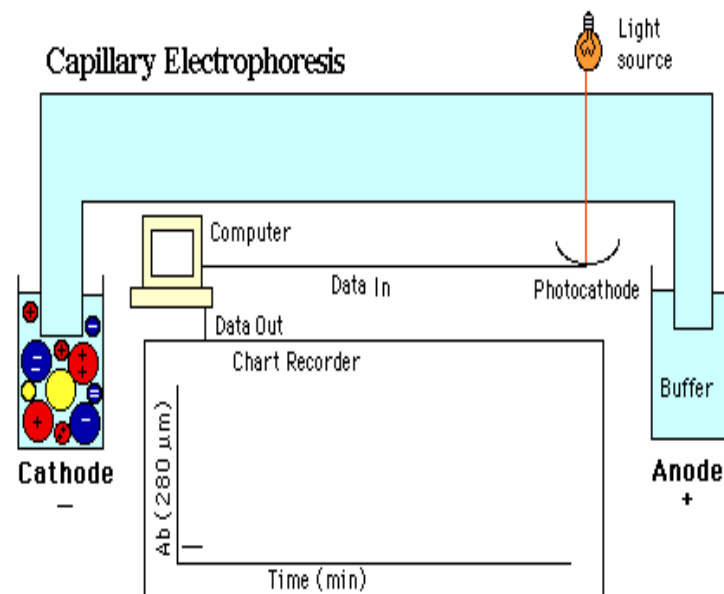
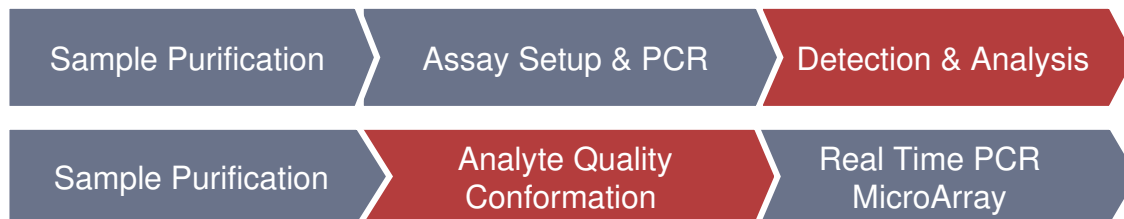
- 10 minutes/12 samples
- Sample input: ~ 10 μ l
- Detection limit: ~ 0.1 ng/ μ l
- Digital data output
- Samples in special trays
→ standard formats planned

Gel Cartridges



- ~ 200 runs possible
- Smart key
- Resolution: down to 3-5 bp
- 12 channels
- Buffer (gel) solution

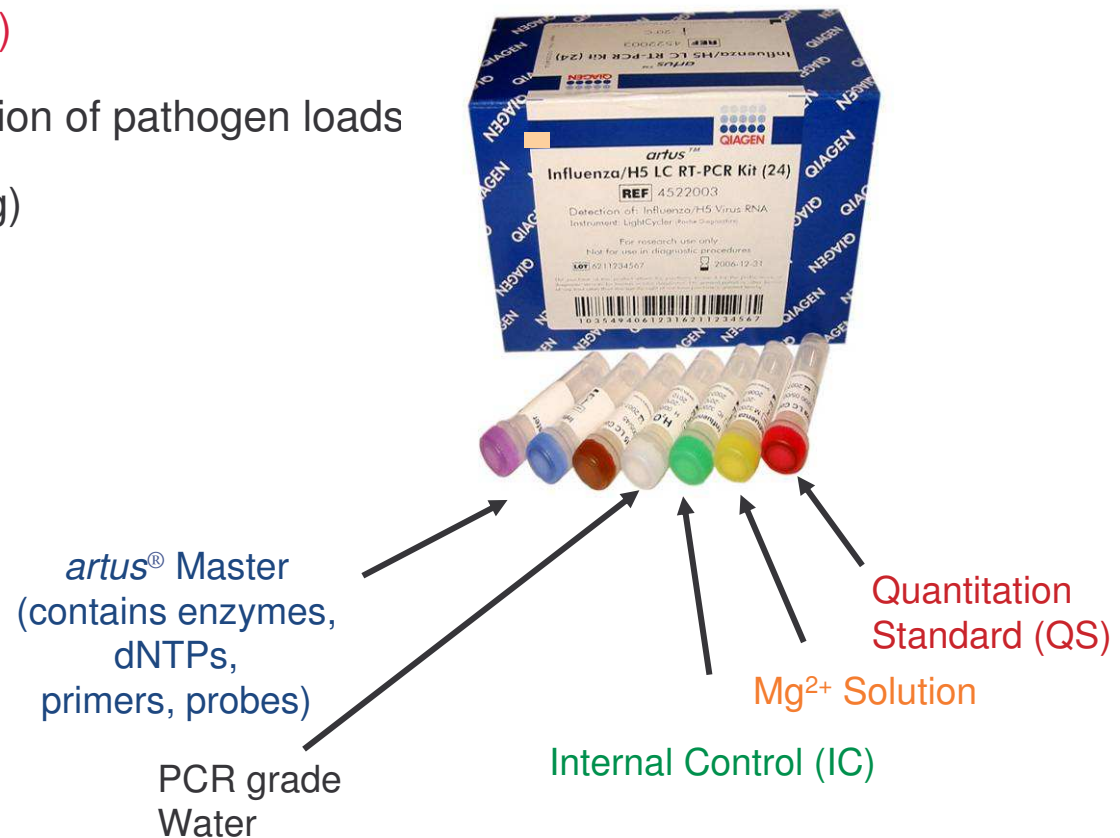
Applications of QIAXcel





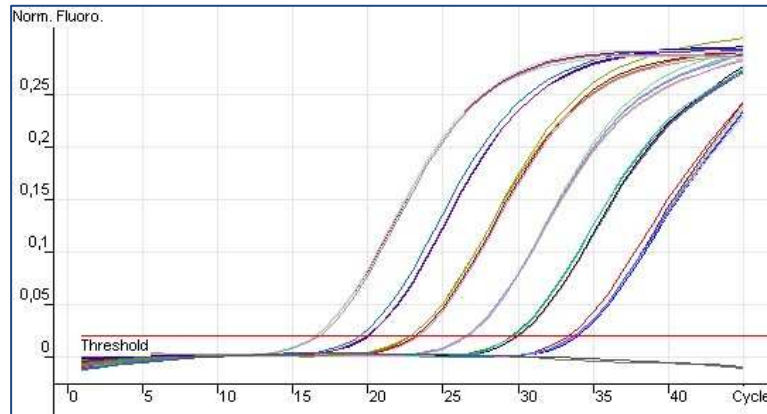
Key Features *artus*[®] PCR Kits

- High sensitivity (optimized component composition)
- High specificity (primers and probes)
- High reliability (**internal control !**)
- Quantitative results (determination of pathogen loads)
- Easy-to-use kit (simple pipetting)
- Licensed and validated
- CE marked

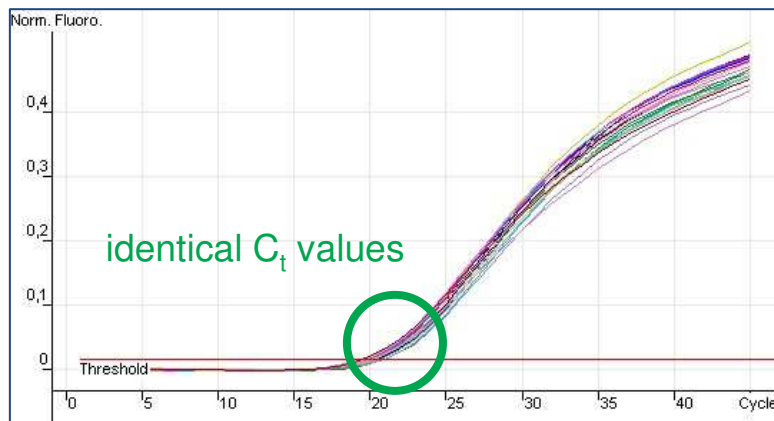


Internal Control – THE Key Feature !

"The control tells the story !"



Analytical PCR



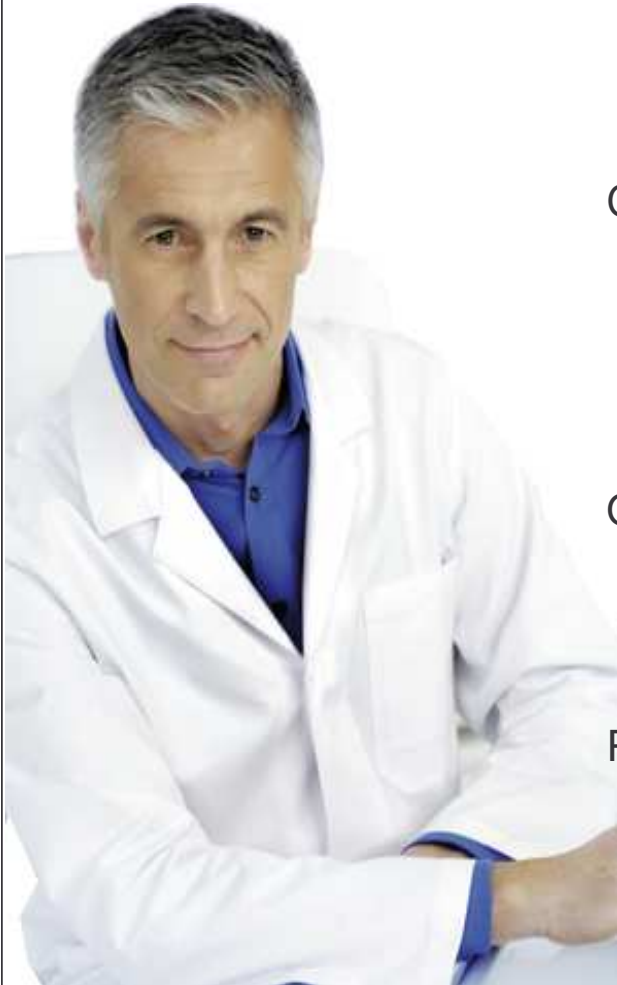
Separate fluorescence channel:

Internal Control

- Must be positive when analytical PCR is negative
- Shows that PCR was not inhibited



K-ras and its role in cancer



Oncogenic k-ras mutations found in up to 30% of all human tumors

- 15-50 % of lung cancers
- 72-90 % of pancreatic cancers
- 35-45 % of colon cancers

Colorectal cancer is major disease burden: No 2 cancer

- Global Incidence: 1.020.000 cases
- Global Mortality: 530.000 deaths
- Incidence in western world: 456.000 cases

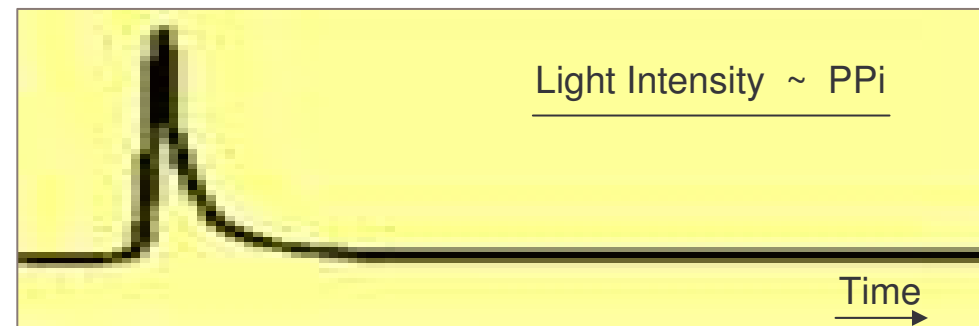
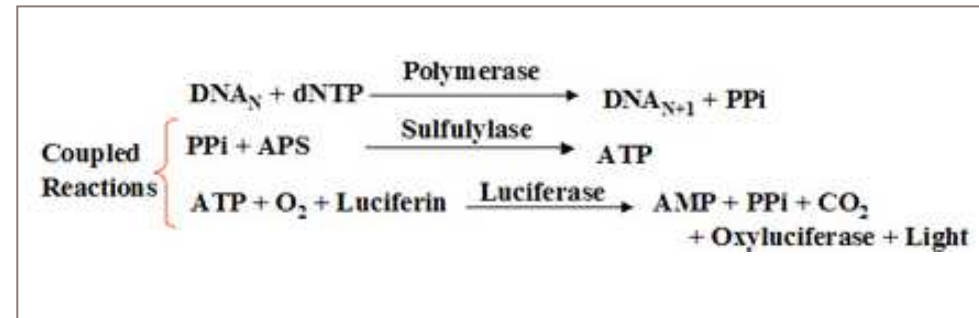
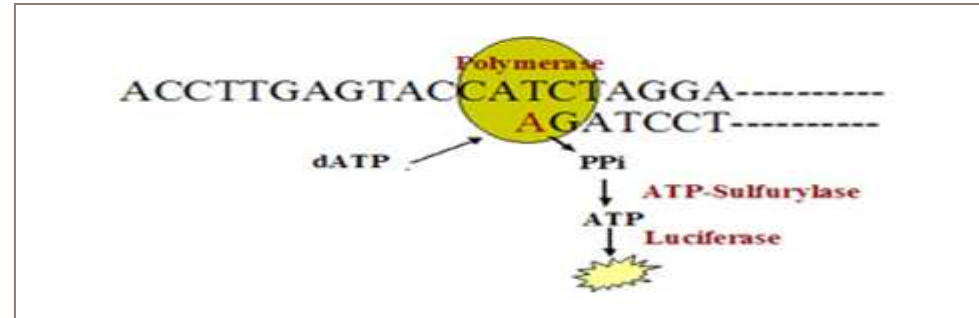
Oncogenic Ras Mutations in 4 critical positions

- PyroMark KRAS v2.0 is a pyrosequencing based assay that detects all mutations in relevant positions

Pharma with strong pipeline for colon cancer as well as Anti-EGFR

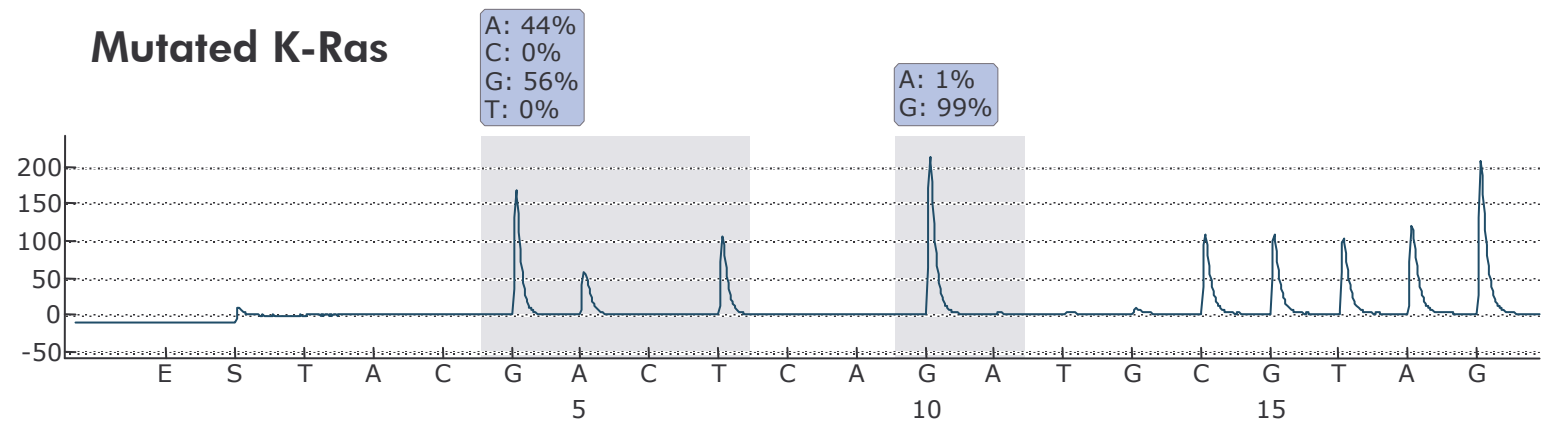
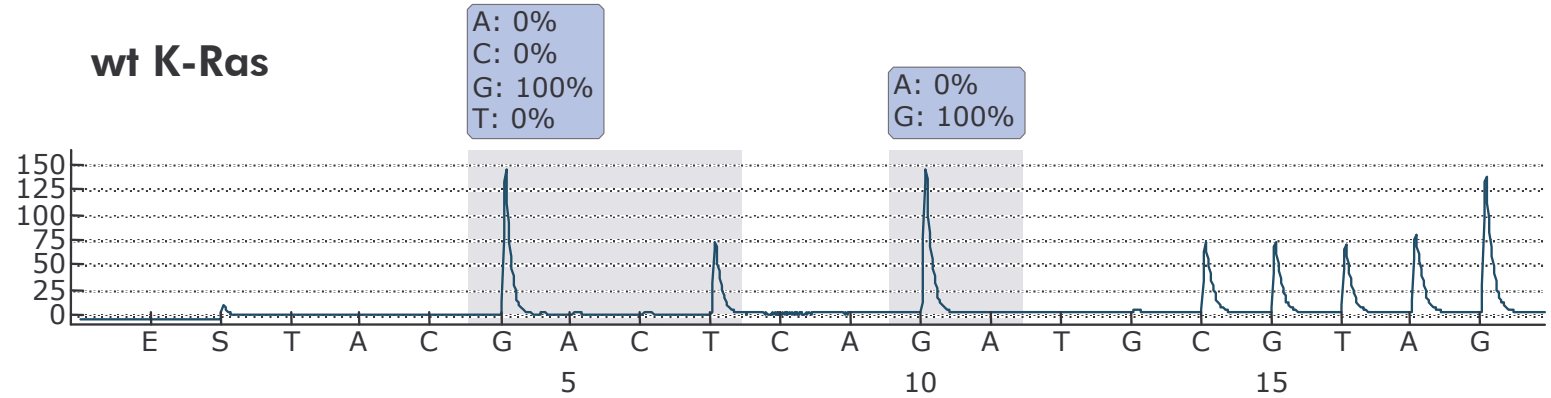
- Colon cancer: 60+ candidates in clinical phases
- EGFR inhibitors: 140+ trials citing EGFR inhibitors

How does Pyrosequencing work?





Codon 12 mutation



from Magnus Sundström, PhD Molecular Pathology at Uppsala University Hospital, Sweden



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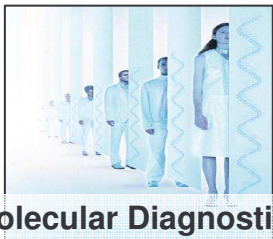
Life Science Research



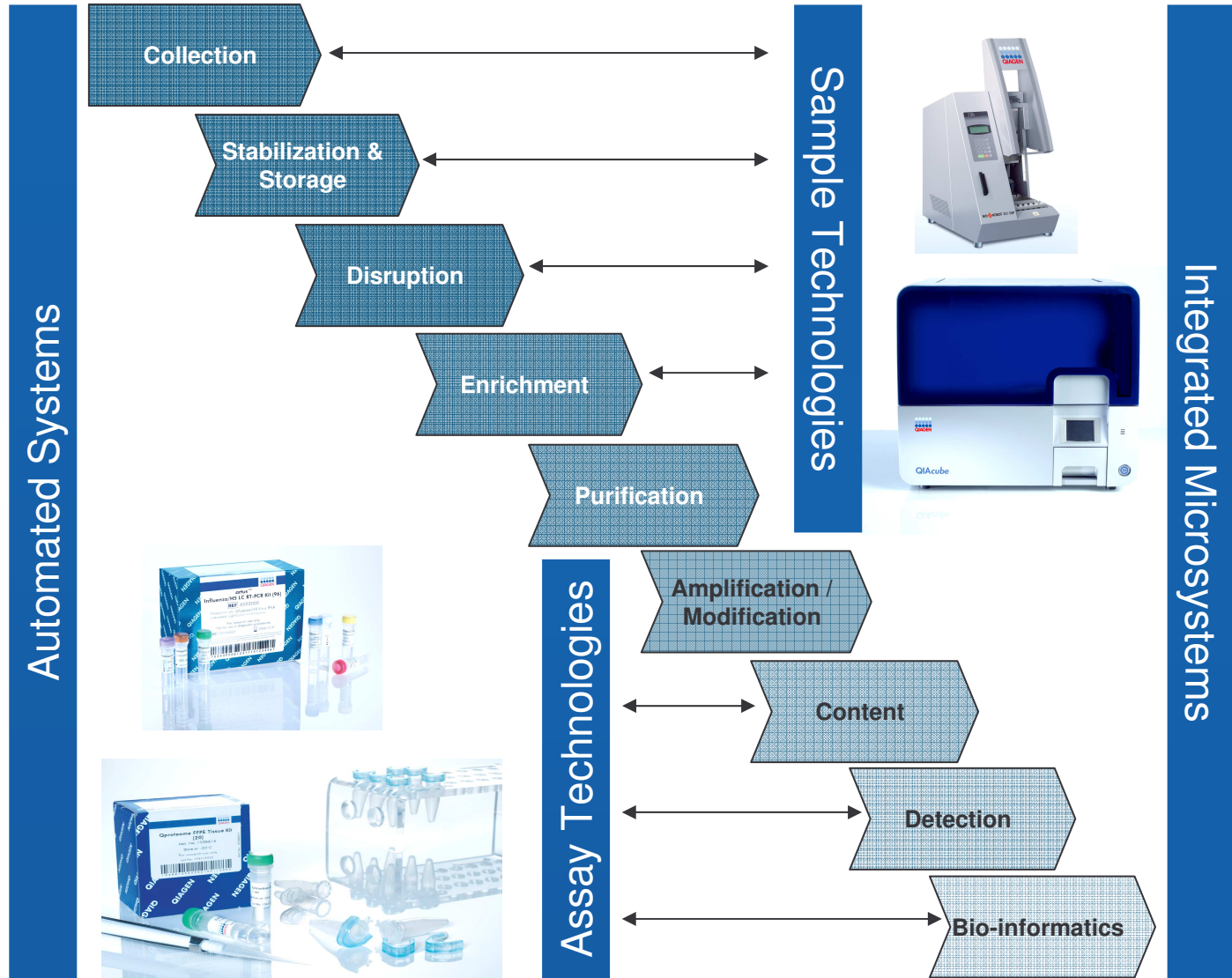
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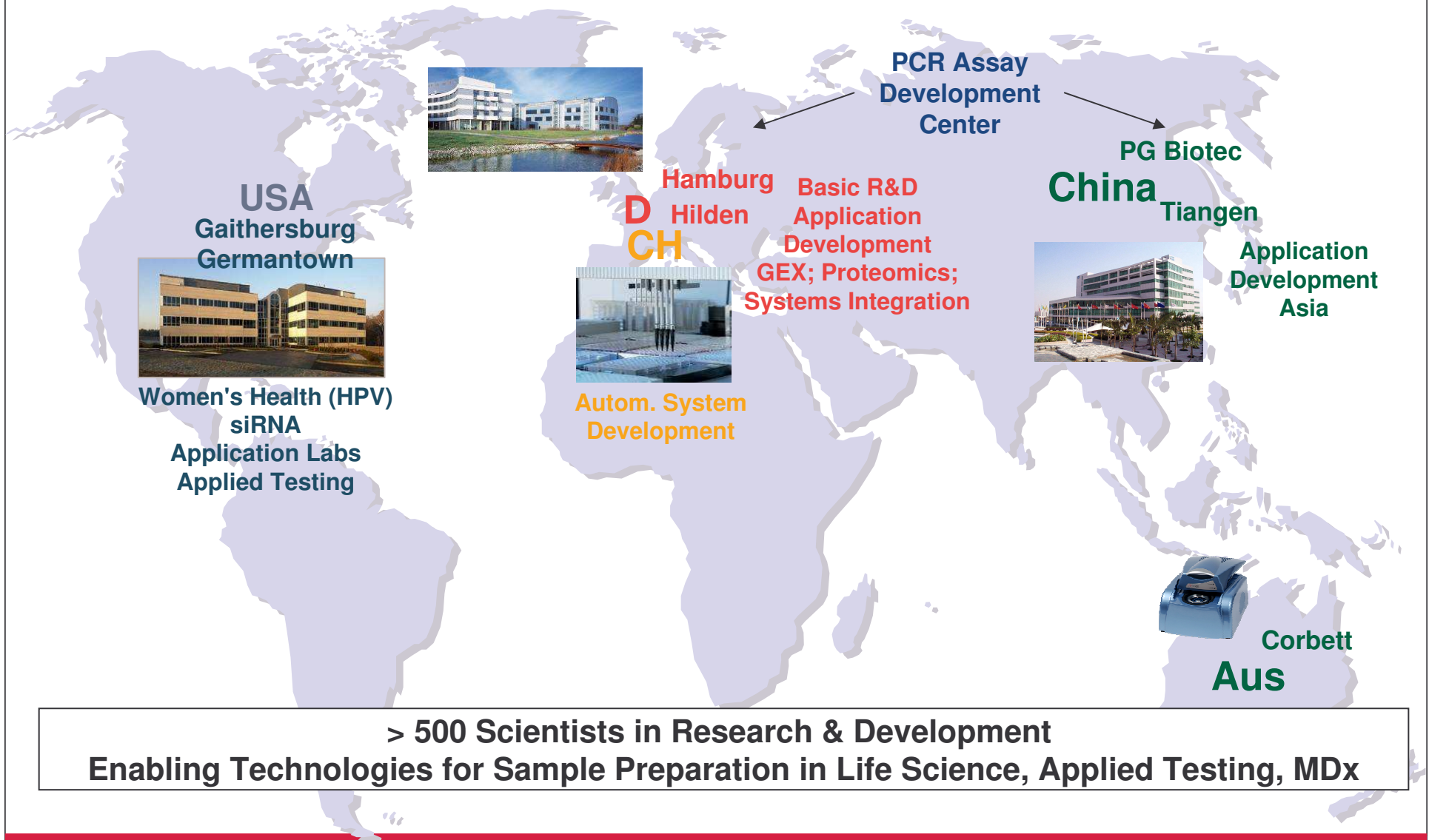


Thank You for Your Attention!





Global R&D Structure Based on Competence Centers



> 500 Scientists in Research & Development
Enabling Technologies for Sample Preparation in Life Science, Applied Testing, MDx