



## Enabling Theranostic applications at the Point of Primary Care

**Francesc Guasch**



**2010 Concertation and Consultation Workshop  
on Micro-Nano-Bio Convergence Systems (MNBS)  
Neuchâtel (Switzerland), February 15-16, 2010**

- 
- **Introduction to project TheraEDGE**
  - **Major achievements**
  - **Challenges**

[www.theraedge.org](http://www.theraedge.org)

 Single Molecule  
Detection at the **POCT**

**Theranostics**  
applications in  
Primary Care

Developing the  
future of **Molecular IVD**  
technology

- 4 Year Project
- Budget: 11 M€
- Consortium: 16 partners
- 9 Different Countries

## Theranostics & Personalized Medicine

- Project Number 216027
- Project start: 01-03-2008
- Coordinator: Biokit S.A. (Spain)

 **TheraEDGE**



**Systemlab**

**NTE SENER**



 **UNIVERSITY OF CAMBRIDGE**

 **tekever**  
technologies for the evernet



**biokit**

**IMM**



**CLÍNIC BARCELONA**  
Hospital Universitari

 **Universiteit Antwerpen**



**MDC**

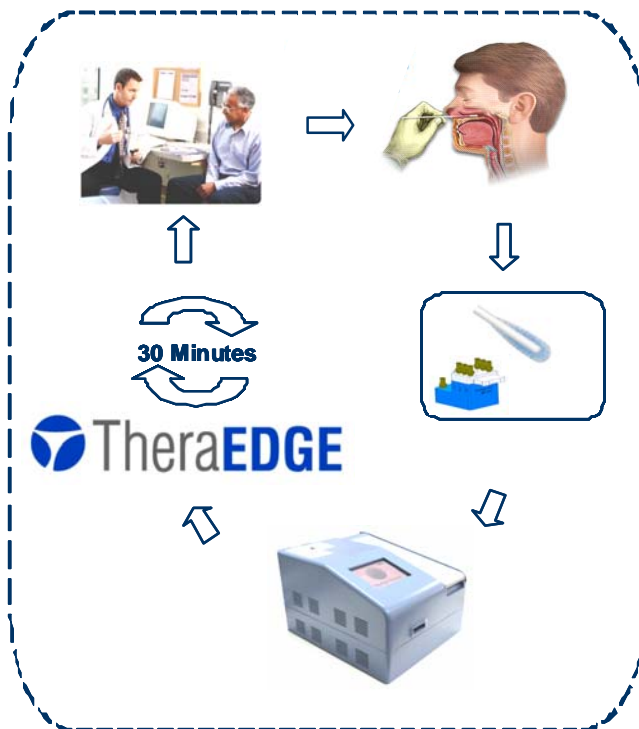
**CRAC**  
 **Ridgeback**



- A molecular diagnostics platform with ultra high sensitivity and specificity designed for primary care use (POCT)
- Detect and identify the organisms causing CA-LRTI, and to verify if this organism is resistant to commonly used antibiotics



*Pneumonia  
Bronchitis  
Emphysema*



1. Reduced antibiotic use and cost per patient
2. Minimized adverse drug events
3. Real time patient monitoring

TheraEDGE

## TheraTEST - *Analytical Platform*

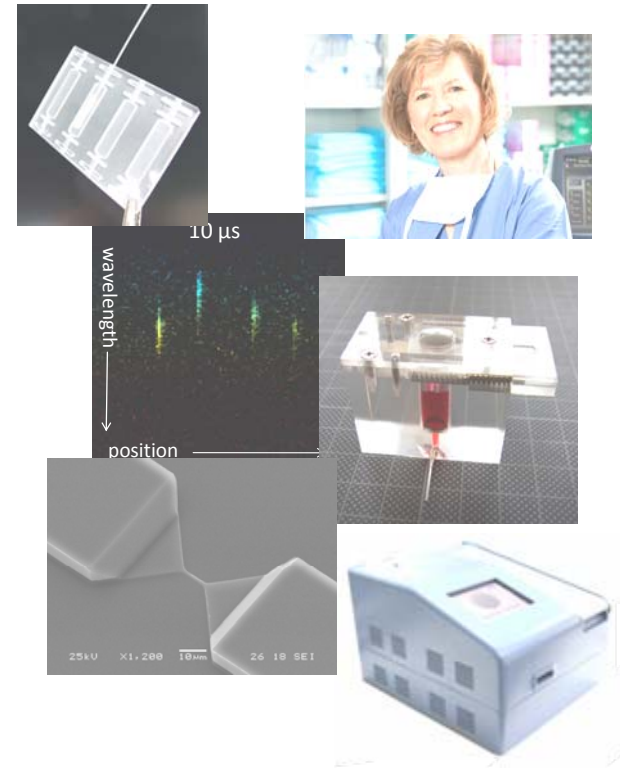
Single Molecule Detection  
Disposable Cartridge

## TheraPOC - *Operational Platform*

Universal Control Module  
PnP & Semantic interoperability

## TheraGUIDE - *Therapeutic platform*

Convergent IT for HIS-LIS  
Expert Systems



 **TheraEDGE**

**Preliminary Analysis**

*Feasibility and performance  
assessment*

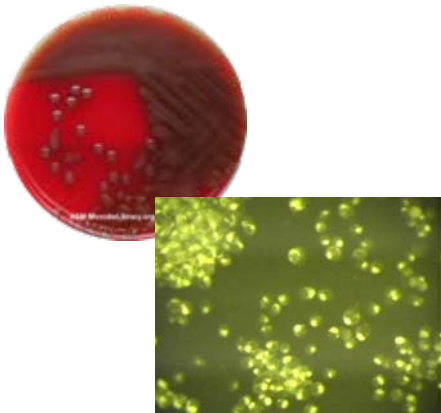
**Specifications Definition**

*Systems and interfaces  
definition & specifications*

**Concept Design and Breadboards**

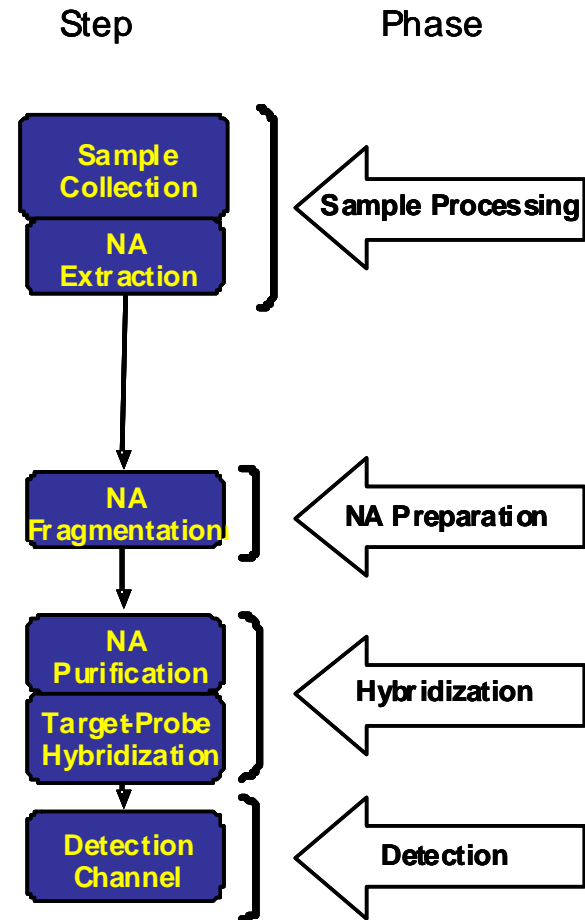
*Trade-off and concept selection*

- **Collaboration with GRACE**
  - **A great source to obtain User Requirements for primary care**
  - **Feedback and guidance on key medical procedures throughout Europe**
- **Selection of most relevant etiological agents causing CA-LRTI (European Survey)**
- **Determination of thresholds for colonization/infection levels**



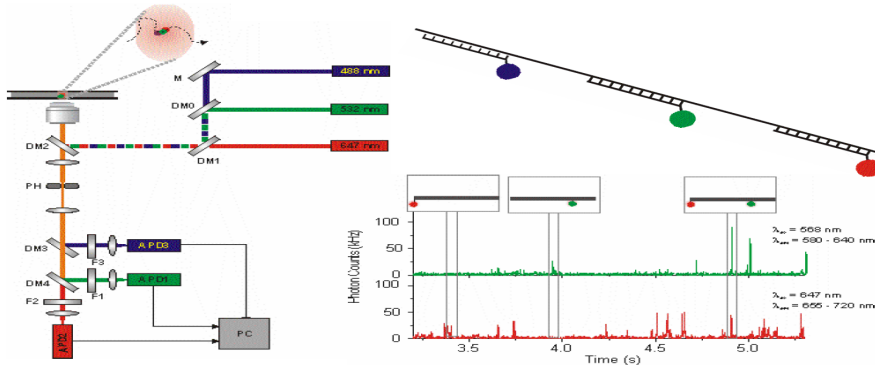
- **Dramatic simplification of bioassay into a few steps**
- **Current baseline is compatible with POCT requirements (Simplicity & Cost)**
- **Multiplexed assay with Time to Result under 30 minutes**

## Four Step Process



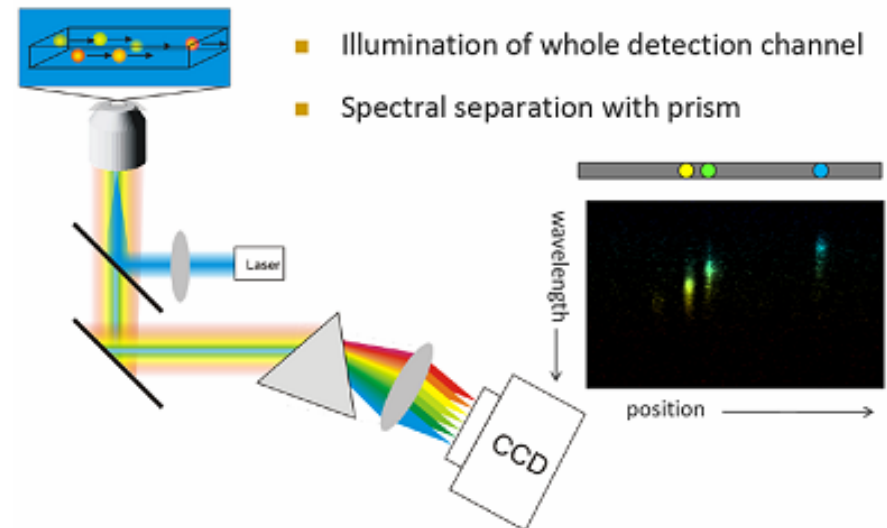
## Detection with Confocal Approach

- Single molecule detection in flowing channels demonstrated
- Detection period of 10 minutes
- Active interface (Instrument-Cartridge)

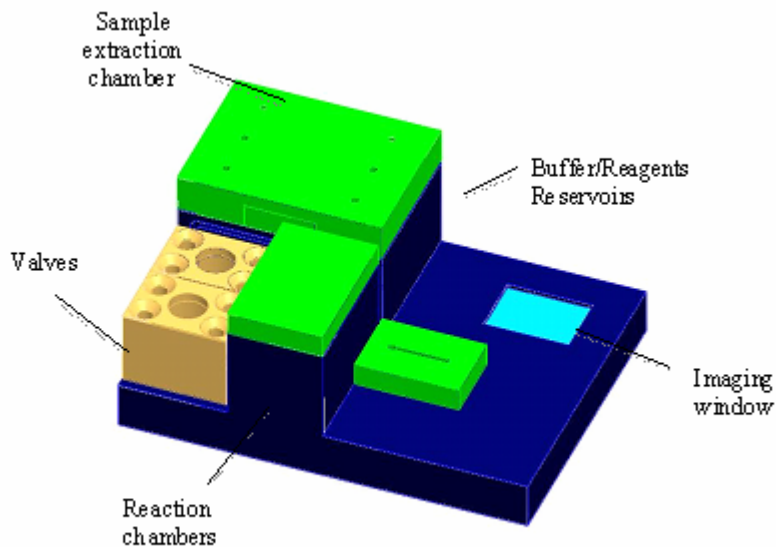


## Detection with Spectral Approach

- Simpler implementation in a POCT device
- Passive interface (Instrument Cartridge)
- Ag nanocluster-stained polymer beads

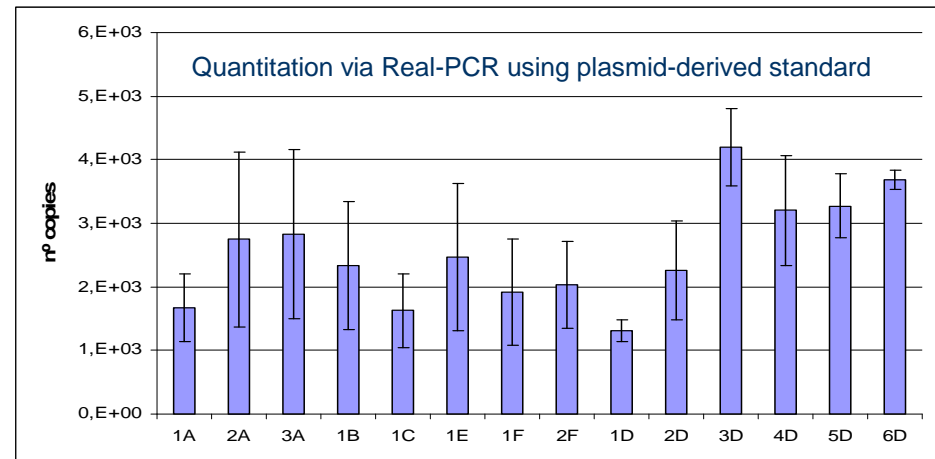


- All elements of the disposable cartridge have been prototyped and tested
- An integrated design (preliminary) of the cartridge is already available
- All evidence indicates that the final design will be injection molding compatible
- No wet interfaces to instrument with all reagents on board



## Biocompatibility Evaluations

14 Polymers exposed to 0.5 fmoles (3000 copies) of genomic DNA for 30 minutes

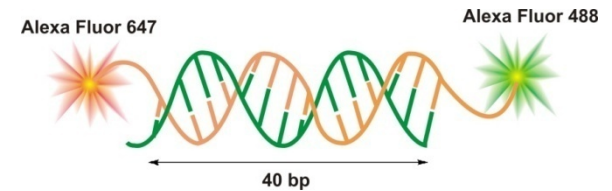


➤ Probe labeling

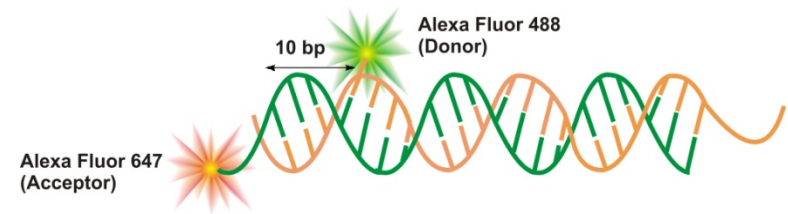
➤ Increase Sensitivity

➤ Reduce background

## Dual Excitation



## FRET



➤ Hybridization

➤ Minimize reaction time

➤ Reduce non-specific binding

➤ Prevent beads aggregation

➤ Detection system

➤ Simplification

➤ Cost minimization

# Thank you for your attention



- **Systelab Technologies (Spain)**
- **University of Antwerp (Belgium)**
- **Biokit (Spain)**
- **University of Bielefeld (Germany)**
- **IMM Mainz (Germany)**
- **University of Twente (The Netherlands)**
- **University of Cambridge (UK)**
- **University of Barcelona (Spain)**
- **Technical University of Dresden (Germany)**
- **Medical Device Consultancy (UK)**
- **Tekever (Portugal)**
- **Ridgeback (Italy)**
- **Clinic Hospital of Barcelona (Spain)**
- **University of Linköping (Sweden)**
- **Clinical Research Associates & Consultants (Slovakia)**
- **NTE-Sener (Spain)**