CAFOE 2013.

Translational Development of Clinical Diagnostic Platforms

Vincent Gau

GeneFluidics
Revolutionizing Molecular Analysis

1

CAFOE 2013.

TRANSLATIONAL DEVELOPMENT OF CLINICAL DIAGNOSTIC PLATFORMS

Improving the quality of human life with advanced engineering technologies.

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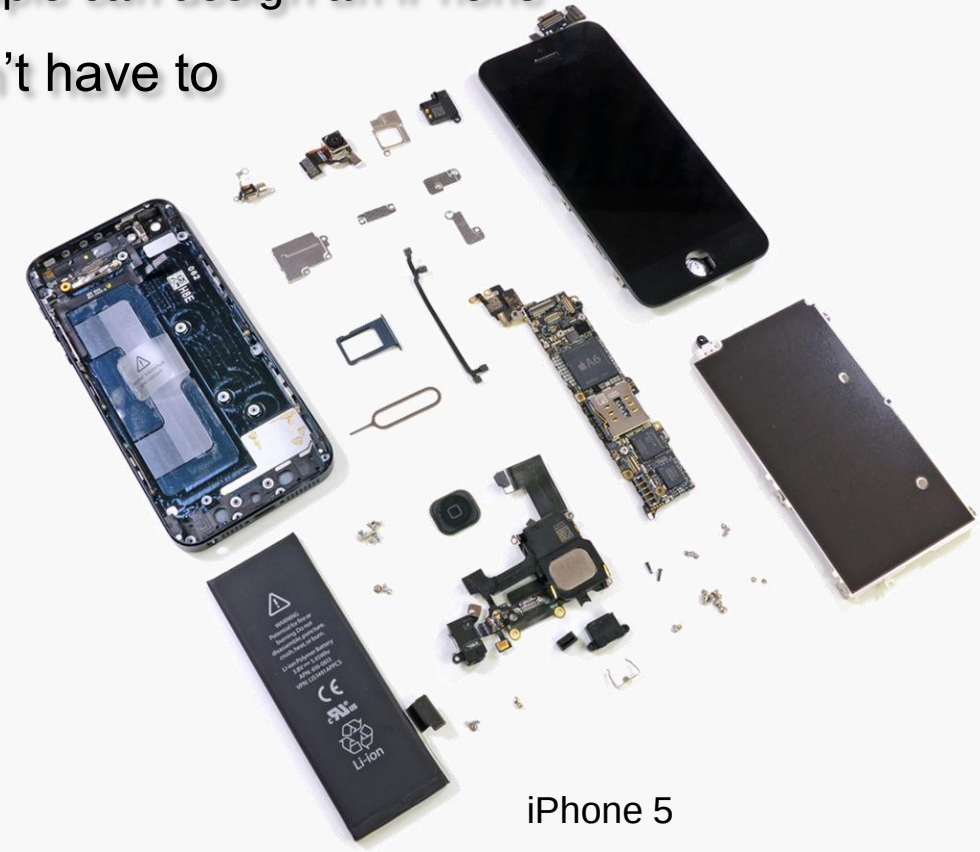
Not many people can design an iPhone

And you don't have to



iPhone 5

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2 Win-win situation with open platform

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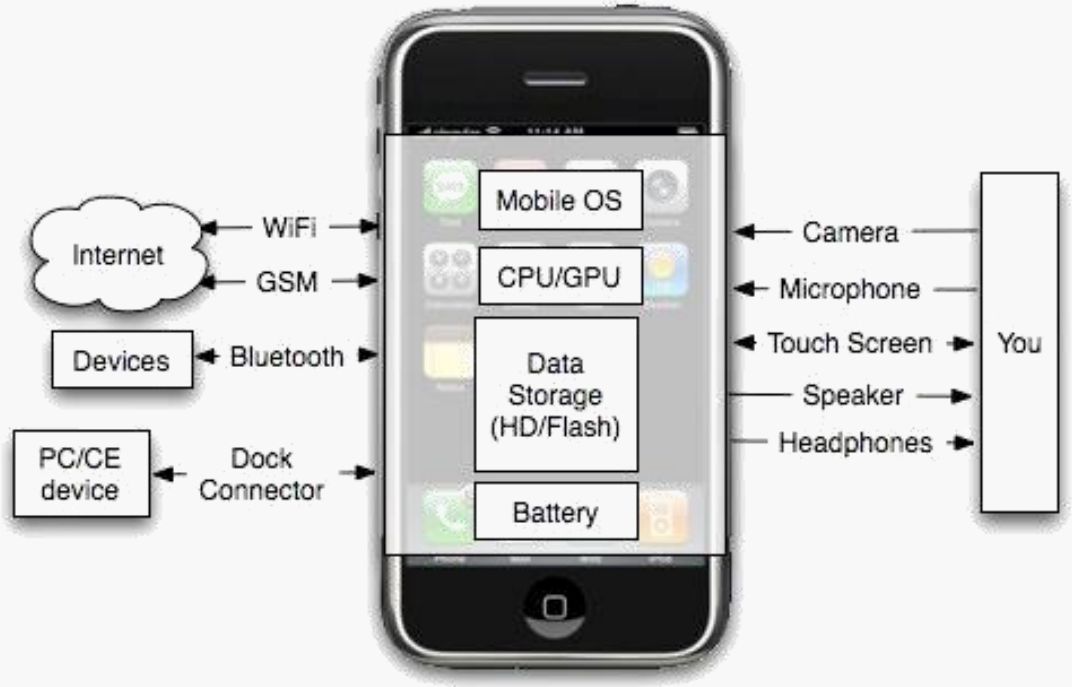
3 Modularization and Standardization



Modularization: functional, graphic and user interface design

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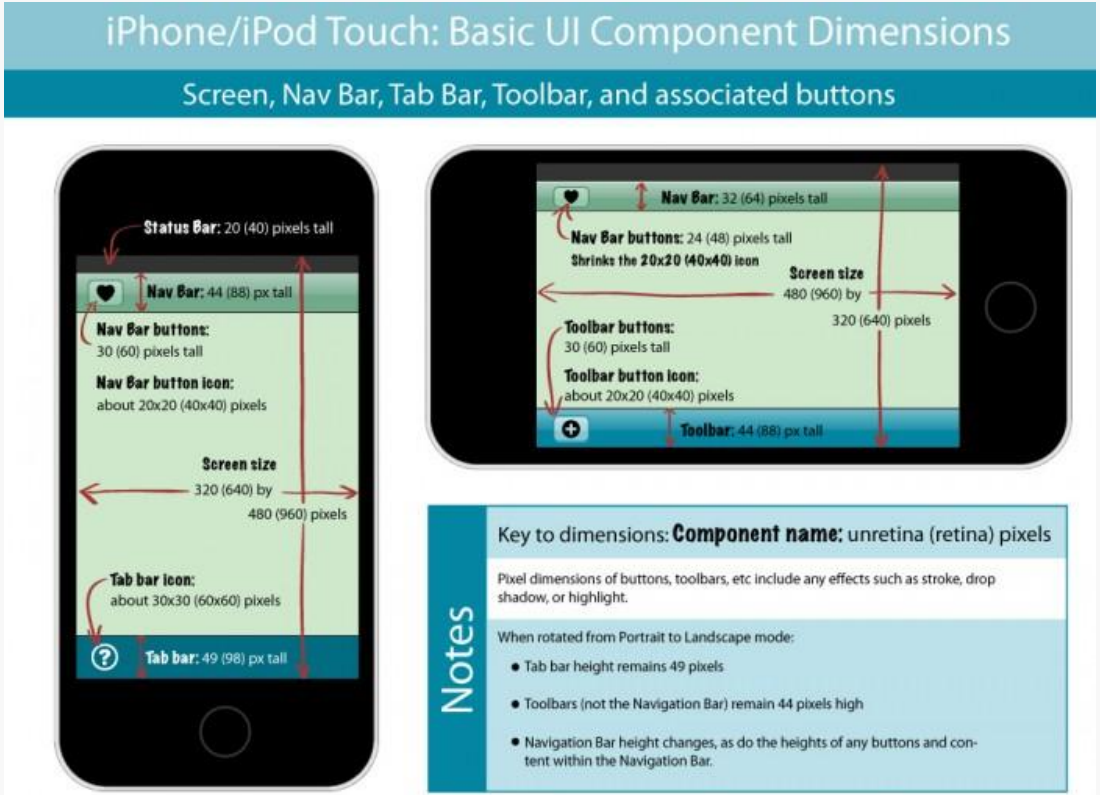
3 Modularization and Standardization



Standardization: design rules and recommendations

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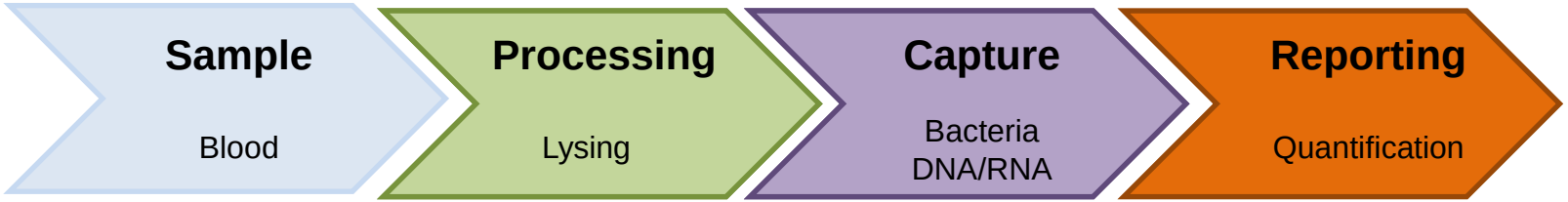
3 Modularization and Standardization



Specimen tested
blood,
serum,
plasma,
urine,
saliva,
CSF,
sputum,
milk,
meat juice

Genetic Assay
C. trachomatis
E. coli
H. influenzae
K. oxytoca
K. pneumoniae
P. aeroginosa
P. mirablis
Salmonella spp.
S. pneumoniae
Enterovirus
SARS
Kanamycin resist.

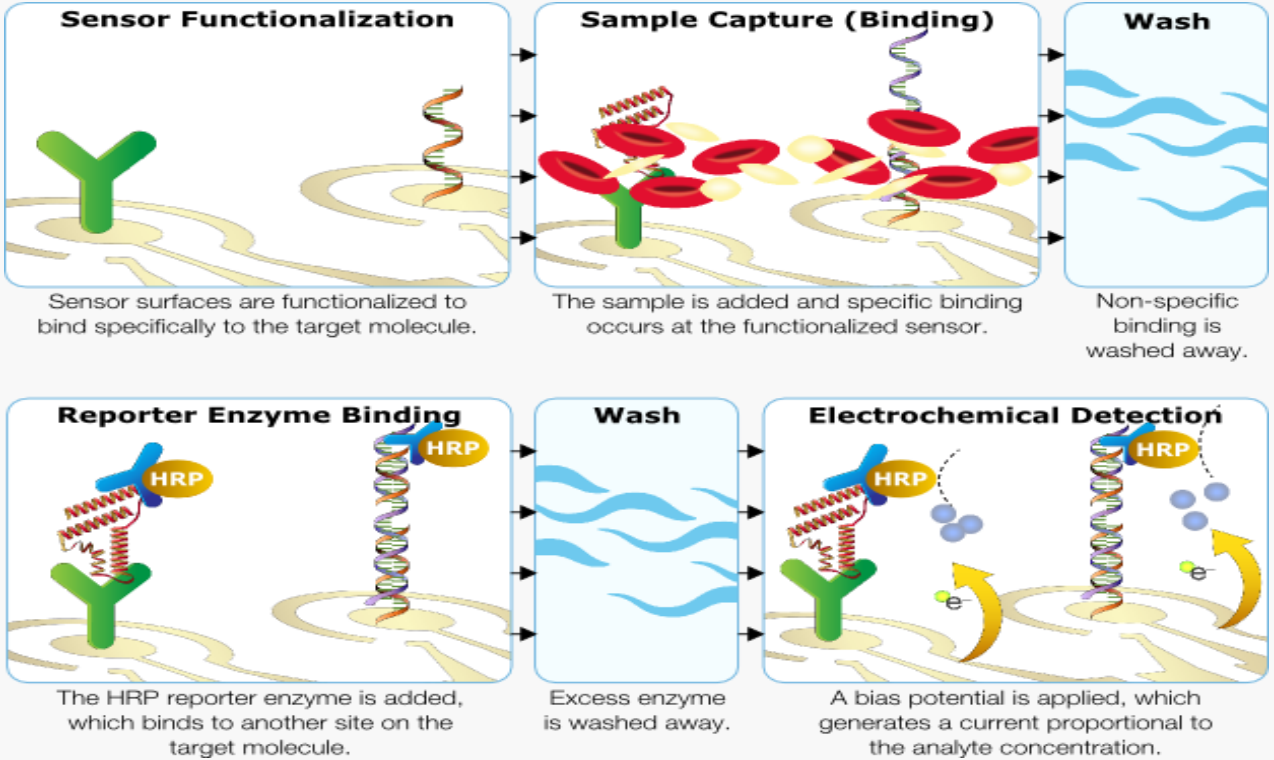
Immunoassay
HIV
SARS

Clinical Chemistry
Glucose
pH

Genetic Assay
Factor V Leiden
HPFH
IL-8
MCP-1
PML/RARa
Sickle cell
SNPs
TREC

Immunoassay
CA-125
FGF
HP-alpha
IL-8, IL-10
Osteopontin
PSA
T4
Troponin-I
VEGF
IL-6
Insulin
PSA

4 Universal Affinity-based Assay



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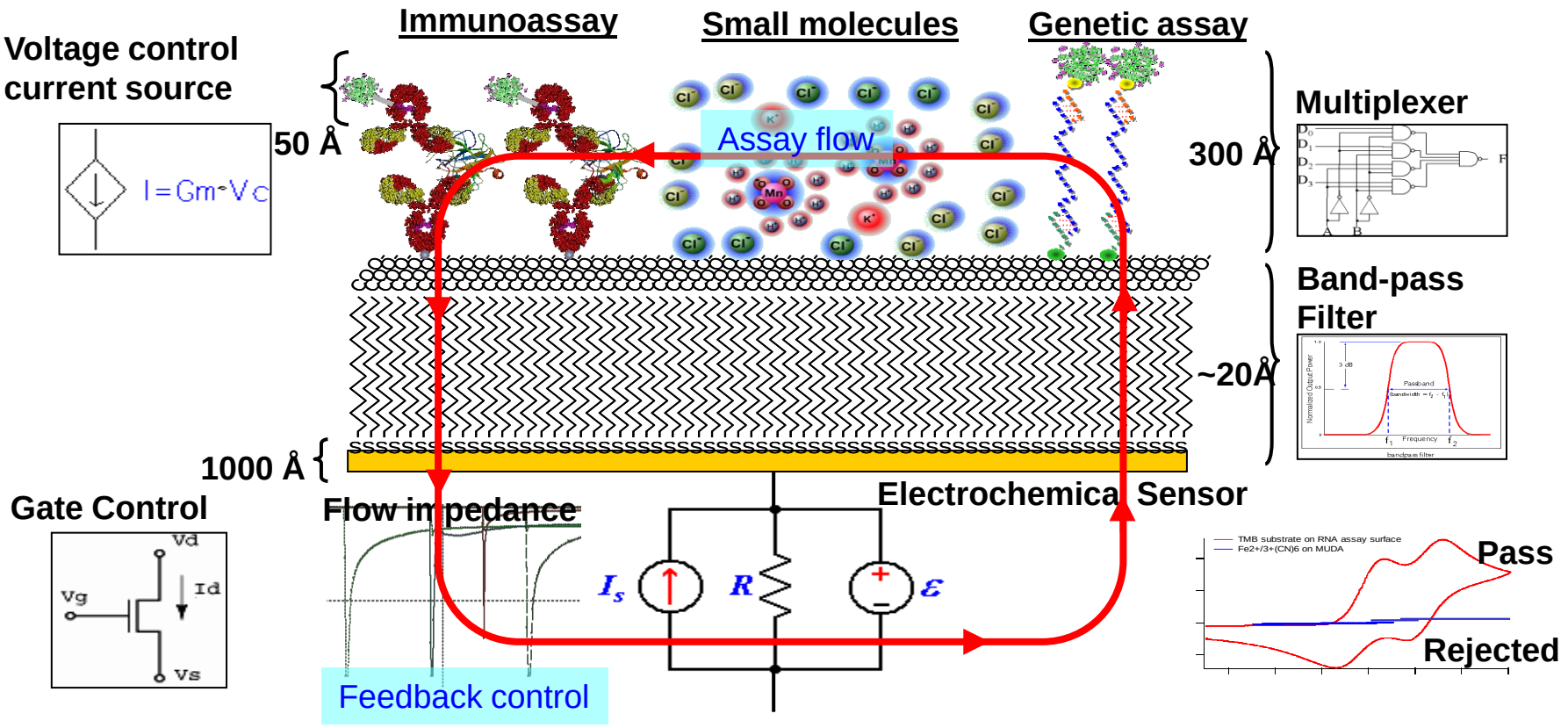
Bioelectronics with real-time flow impedance internal control



4 TRANSLATIONAL.

Lab Automation

The Robotic System is designed to automate procedures that typically require extensive labor by skilled technicians.

Reader

The reader is the first affordable multi-channel electrochemical workstation.

Sensor

16 independent assays can be performed on each sensor chip with different systems.

POC

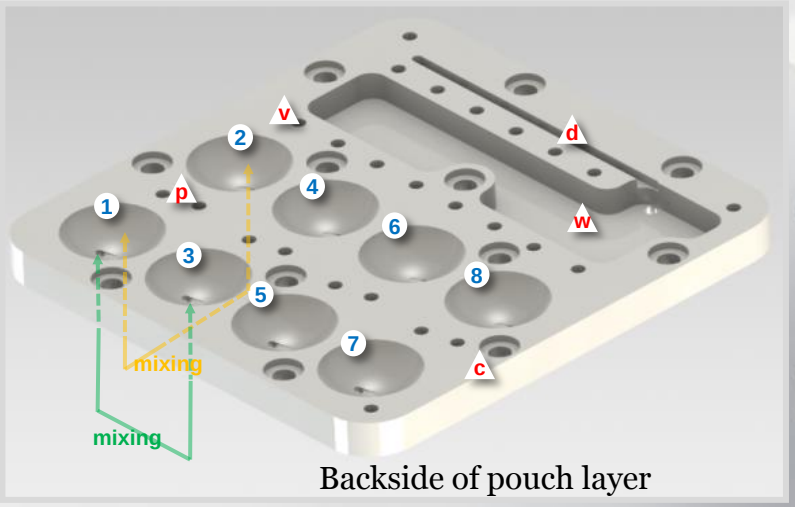
The POC system consists of a self-contained, disposable microfluidic cartridge and a sensing and control instrument.

Cartridge

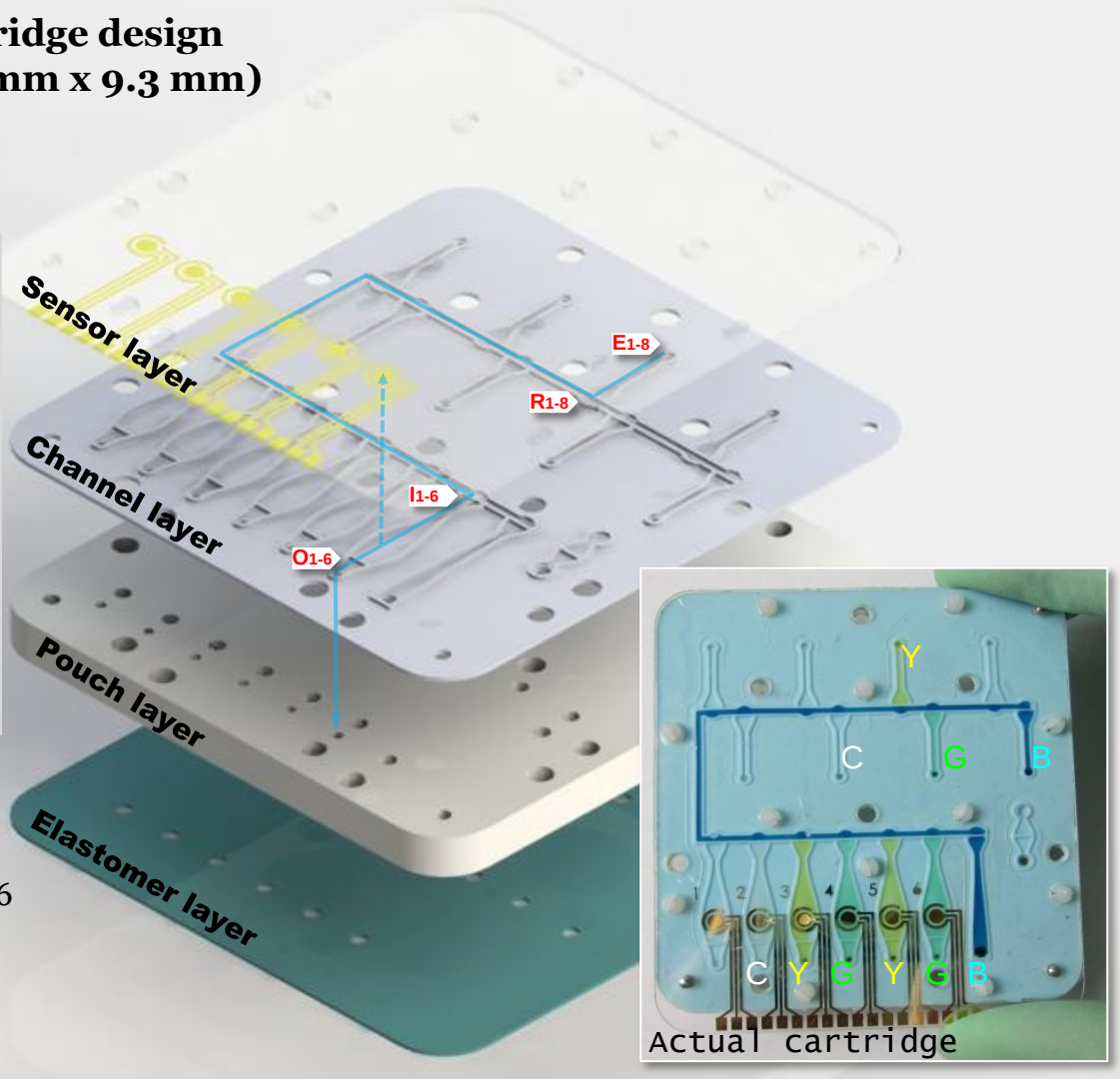
The microfluidic cartridge integrates reagent storage and fluid-handling components to achieve ultra-sensitive, multiplexed detection.

Original cartridge design (72 mm x 76 mm x 9.3 mm)

- c Clamping holes
- w Waste chamber
- v Vertical channels
- d Waste draining
- p Pneumatic control



Backside of pouch layer



Actual cartridge

1. Sample pouch
2. Culture media pouch
3. Lysis pouch
4. Probe pouch
5. Wash pouch
6. Enzyme pouch
7. Tween wash pouch
8. Substrate pouch

- S1-6 Sensor 1-6
- B1-6 Sensor chamber 1-6
- R1-6 Reagent valve 1-8
- I1-6 Inlet valve 1-6
- O1-6 Outlet valve 1-6
- E1-6 Reagent inlet 1-8

Product Overview | Specifications | Downloads | CAD Model | Accessories | Videos | Request Quote | Reviews

3D Rapid Prototyping Service

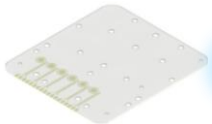
Pathogen Identification (ID) | Multiplexed Molecular Analysis | Antimicrobial Susceptibility Testing (AST) | LOGIN

Electrochemical sensor layer (MM21A-ES)

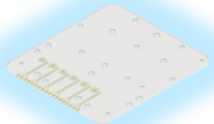
Working electrode: 4 mm²
Sensor: 3 channels
Configuration: identical
Product #: MM21A-ES43

Working electrode: 4 mm²
Sensor: 4 channels
Configuration: identical
Product #: MM21A-ES44

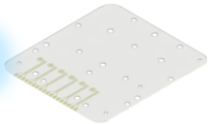
Working electrode: 2.4 ,9.6 mm²
Sensor: 6 channels
Configuration: alternating
Product #: MM21A-ES26



Working electrode: 9.6 mm²
Sensor: 6 channels
Configuration: identical
Product #: MM21A-ES96

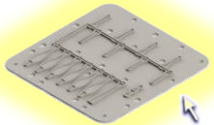


Working electrode: 4.0 mm²
Sensor: 6 channels
Configuration: identical
Product #: MM21A-ES46



Working electrode: 2.4 mm²
Sensor: 6 channels
Configuration: identical
Product #: MM21A-ES26

Elastic channel layer (MM21A-EC)



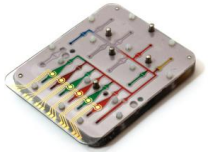
Chamber width: 4.5 mm
Neck width: 0.75 mm
Height: 1.0 mm
Product #: MM21A-EC47

Chamber width: 2.5 mm
Neck width: 0.75 mm
Height: 0.5 mm
Product #: MM21A-EC27

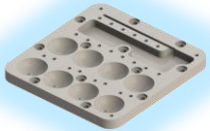
Chamber width: 4.5 mm
Neck width: 0.75 mm
Height: 0.5 mm
Product #: MM21A-EC48

Chamber width: 6.0 mm
Neck width: 0.75 mm
Height: 0.5 mm
Product #: MM21A-EC67

Chamber width: 6.0 mm
Neck width: 1.25 mm
Height: 0.5 mm
Product #: MM21A-EC61



Reagent storage layer (MM21A-RS)



Volume: 540 µL
Pouch number: 8
Configuration: identical
Product #: MM21A-RS58

Volume: 390 µL
Pouch number: 8
Configuration: identical
Product #: MM21A-RS38

Volume: 285 µL
Pouch number: 8
Configuration: identical
Product #: MM21A-RS28

Volume: 170 µL
Pouch number: 8
Configuration: identical
Product #: MM21A-RS18

Volume: 125 µL
Pouch number: 8
Configuration: identical
Product #: MM21A-RS08

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Product Overview | Specifications | Downloads | CAD Model | Accessories | Videos | Request Quote | Reviews

3D Rapid Prototyping Service

LOGIN

Notice: You must be logged in to download CAD Models.

Multiplexed molecular analysis assay cartridge (MM21A) – Elastic channel layer (MM21A-EC47)

Sizing Options

Sensor chamber geometry

4.5 mm x 0.75 mm x 1.0 mm

chamber width x neck width x height
2.5 mm x 0.75 mm x 0.5 mm
2.5 mm x 1.25 mm x 1.0 mm
4.5 mm x 0.75 mm x 0.5 mm
4.5 mm x 0.75 mm x 1.0 mm
6.0 mm x 1.25 mm x 0.5 mm
6.0 mm x 1.25 mm x 1.0 mm

Number of sensor chamber

6

Number of reagents

8

Total waste volume (µL)

4,000

Temp

Yes

Hydrophilic coating

Casein

Outgasing condition

3D Preview | CAD Download

Schematic | 3D Preview | CAD Download

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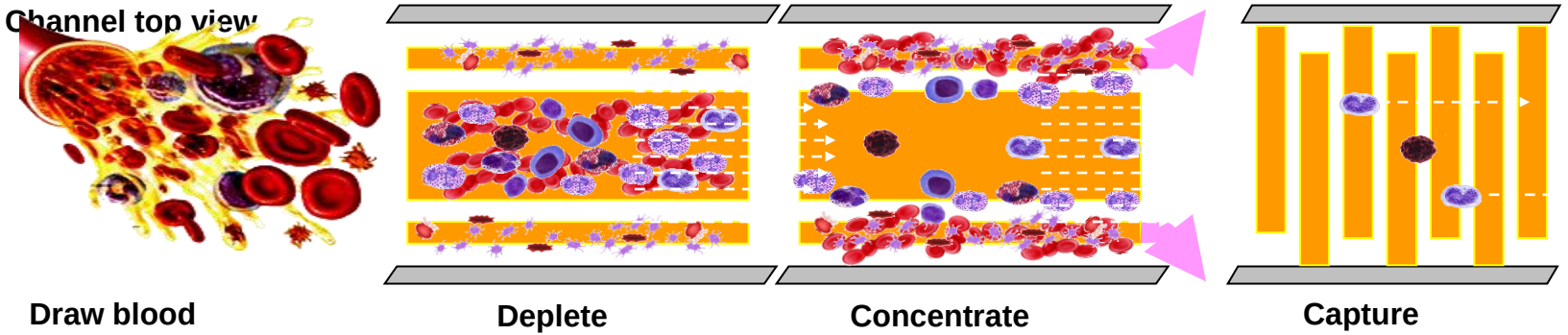
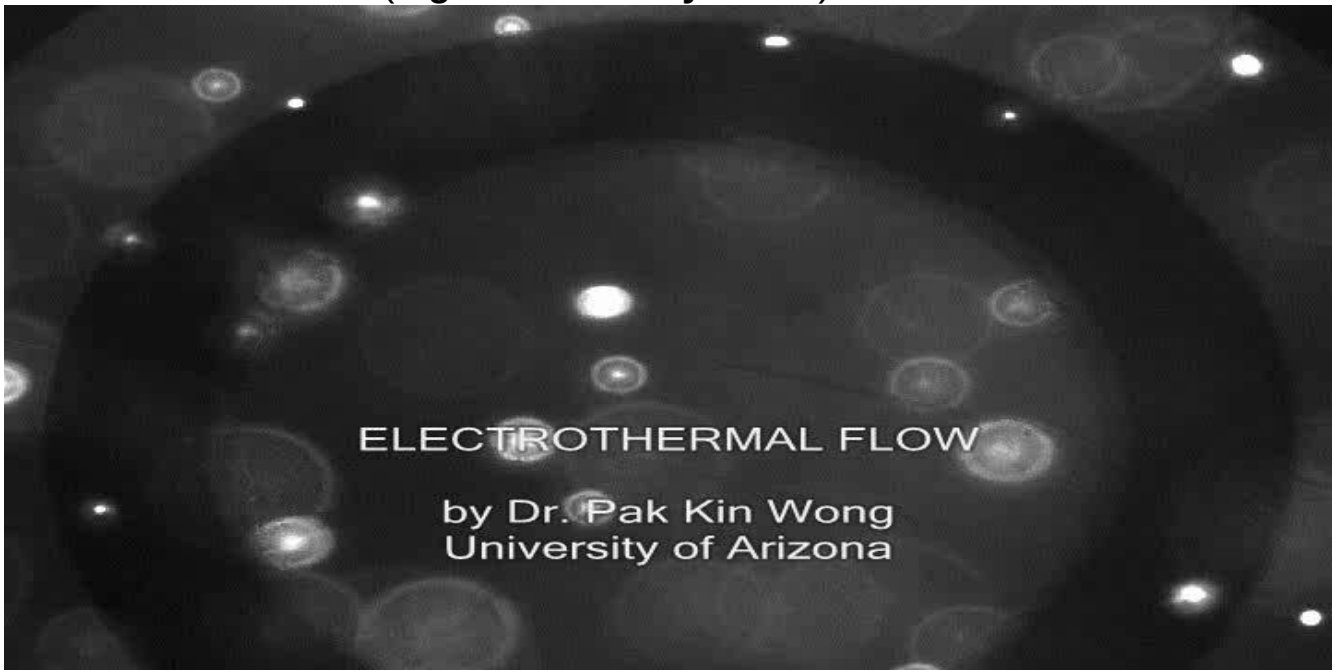
Blood cells (~ 45.7 % of whole blood)	**Erythrocytes** 45% of whole blood, 4M-6M/ mL in concentration	**Leukocytes** 0.7% of whole blood, 9-17 mm in size, 4,000-11,000 / mL in concentration			**Agranulocytes**, ~9-17 mm in size ,25% in volume of leukocyte		**Platelets** 2-5 mm in size 150k-500k / mL concentration
		Granulocytes, ~9-12 mm in size, 68.5% in volume of leukocyte					
	~8 mm in size	Basophils, 0.5%	Eosinophils, 3%	Neutrophils, 65%	Lymphocytes	Monocytes	
Plasma (~ 54.3 % of whole blood)	**Water**	**Electrolyte**	**Proteins**		**Lipids & amino acids**		**Others**
	~92% of plasma	~0.8% of plasma Na+, 135 - 145 (mmol/L) K+, 3.0 - 5.0 (mmol/L) Cl-, 98 - 108 (mmol/L) HCO3-, 22 - 30 (mmol/L)	~6-8% of plasma Albumins, 3.5-5.0 g/dl Immunoglobulins, 1.0-1.5 g/dl Fibrinogens, 0.2-0.45 g/dl Enzymes, proenzymes, hormones		LDL cholesterol, 2-3.4 mmol/L HDL cholesterol, 0.9-2.2 mmol/L Triglycerides, 0.6-1.7 mmol/L Amino acids, varies 0-730 mmol/L		Urea, 1.2-7 mmol/L Glucose, 3.8-6.1 mmol/L pO_2, pCO_2



Electrokinetic Mixer with AC Electrothermal (ACET) flow

ACET induced vortices (**high conductivity buffer**)



Many 3-D vortices were generated around the electrode over a large area
Joint development with University of Arizona

Mixing Enhancement with ACET Induced Vortices

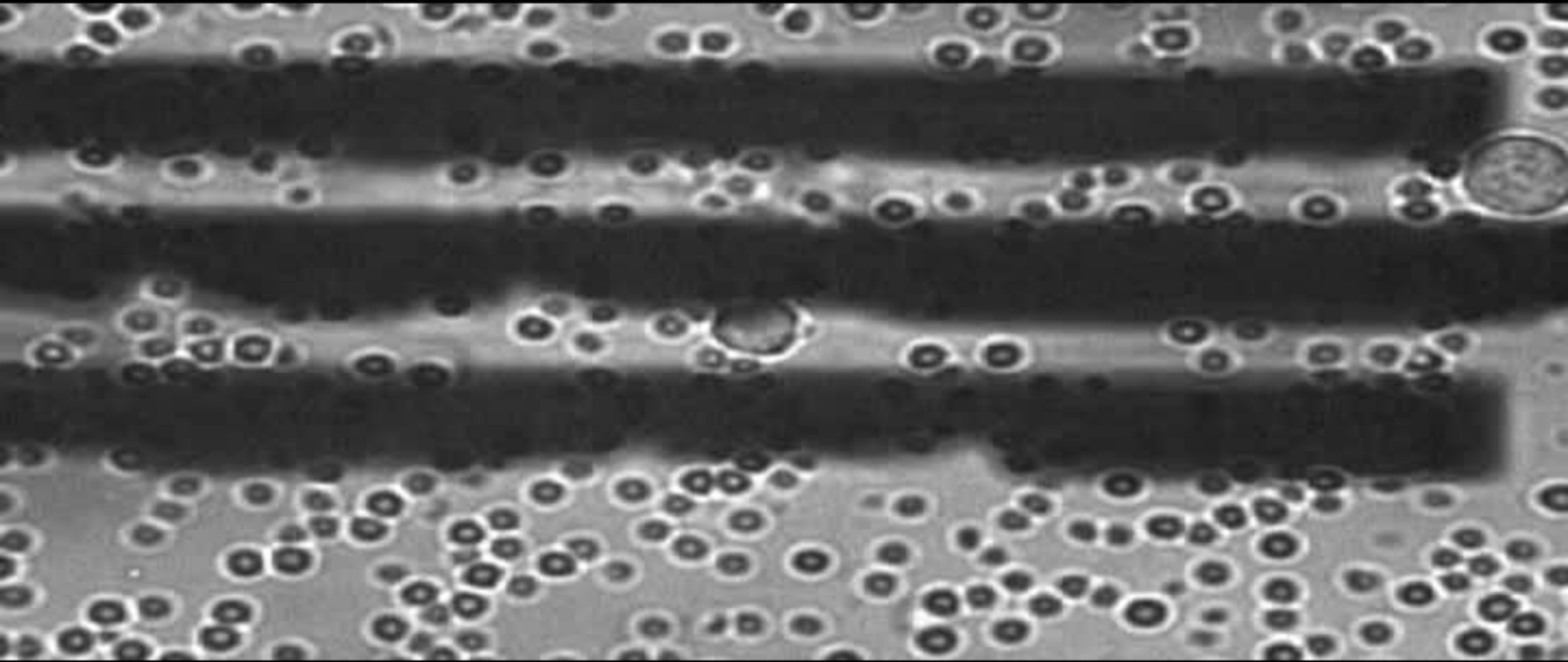
High Conductivity Buffer (1 S/m)

DI water (10 mS/m)

6 Vpp ; 200 kHz

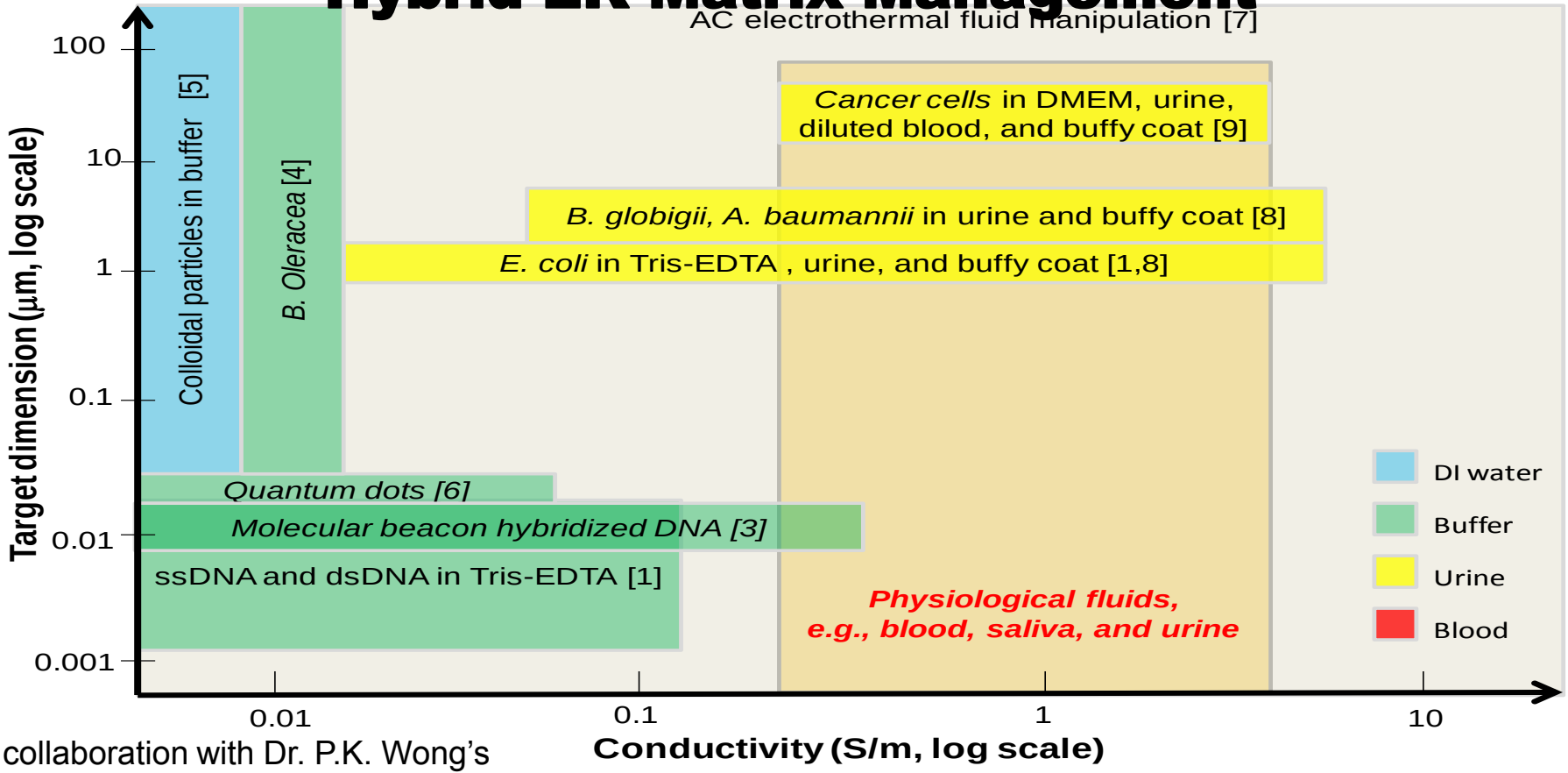
Mixing of fluid streams was dramatically enhanced with ACEO-induced vortices with an applied voltage of 10 V_{pp} and 500 Hz.

Joint development with University of Arizona



Isolation of CTC from blood cells

Hybrid EK Matrix Management



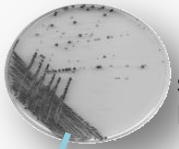
In collaboration with Dr. P.K. Wong's group at University of Arizona

Hybrid EK Matrix Management

Target	Ref	Conductivity, S/m	Medium	Function	Journal	Year
Collidal particles, E. coli, dsDNA, ssDNA	[1]	< 0.1	Tris-EDTA buffer	Concentration, depletion	Analytical Chemistry	2004
Review article	[2]	NA	NA	NA	IEEE/ASME TRANSACTIONS ON MECHATRONICS	2004
Molecular beacon hybridized DNA	[3]	<0.5	Tris/HCL	Focusing	Journal of American Chemical Society	2005
Brassica oleracea	[4]	<0.1	MEA buffer	Electrodeformation	Journal of Buommechanics	2005
2- 2000 μm colloidal particles and E. coli	[5]	<0.01	DI water	Separation, Mixing, and Concentration	Nanotechnology	2009
Quantun dots	[6]	<0.1	DI water	Concentration and separation	Journal of Physical Chemistry	2009
Conductive solution	[7]	0.01 – 20	EDTA (0.01 - 22 S/m)	Fluid motion	Journal of Association for Laboratory Automation	2010
E. coli, B globigii, A. baumannii	[8]	0.1 -10	Urine and buffy coat	Concentration	Lab on a Chip	2011
Cancer cells and 16S rRNA	[9]	1-10	Urine, diluted blood, and buffy coat	Concentration, trapping and isolation	Unpublished data (submitted)	2011

In collaboration with Dr. P.K. Wong's group at University of Arizona

EVIDENCE-BASED DIAGNOSTICS FOR PROPER CARE.



standard
Pathogen ID

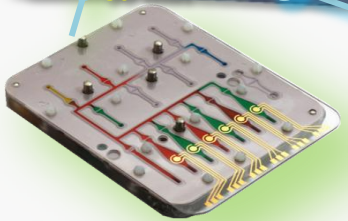
standard
Phenotypic AST

30 min

90 min

18 hours

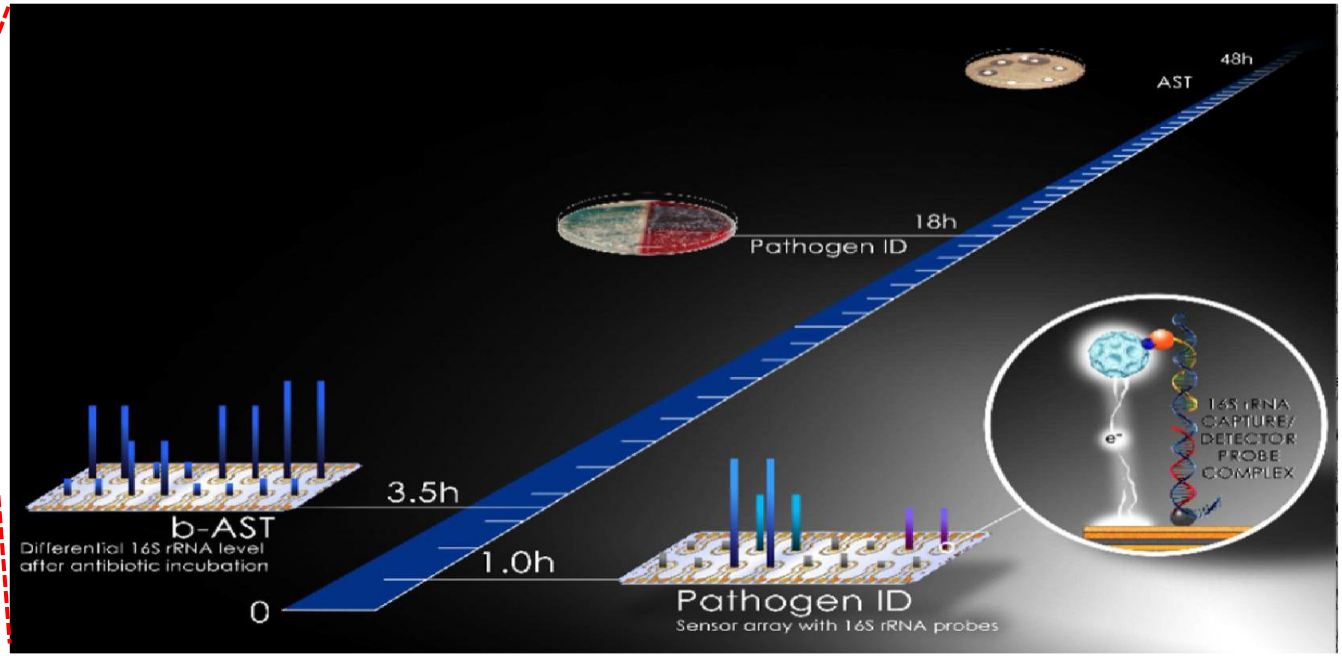
48 hours



Pathogen ID
cartridge

Phenotypic rapid AST system

COMPETITIVE ADVANTAGES.



Source: Journal of Urology, The 2011; 185:148-153 (DOI:10.1016/j.juro.2010.09.022)

Cover story and cover picture

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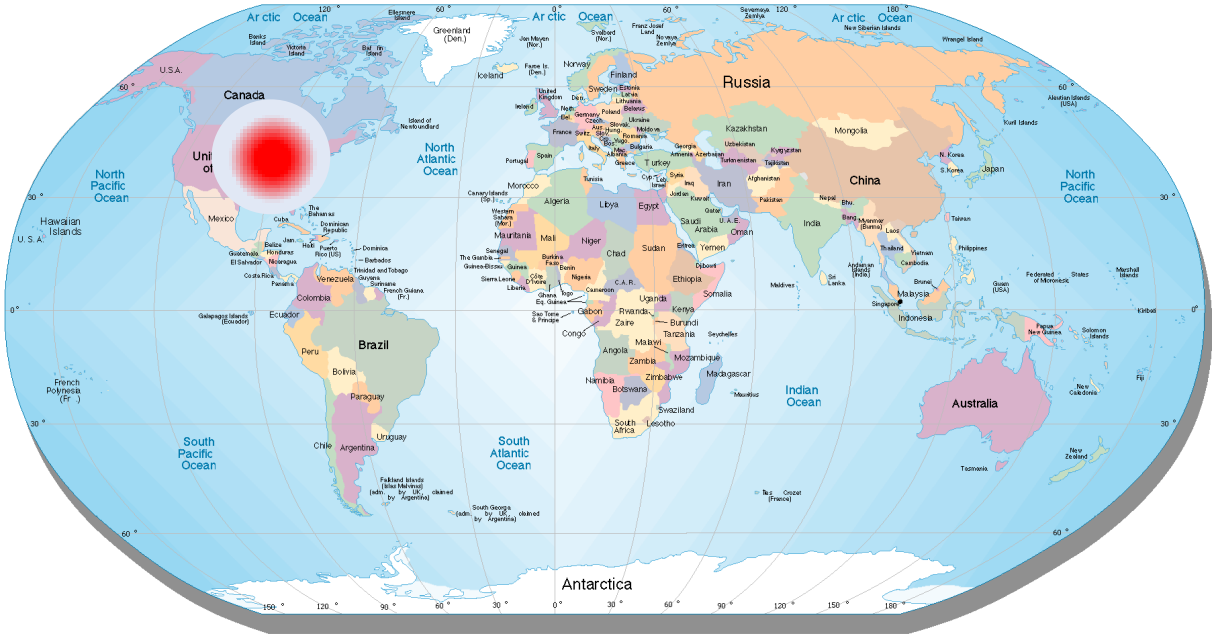

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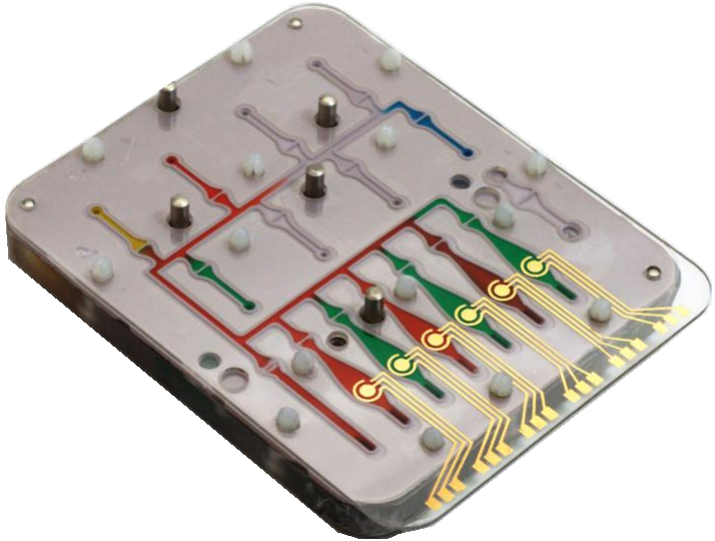
THANKS

Q&A.



Translational Technology Development

GeneFluidics' sensor technology enables quantification of nucleic acids and proteins in unprocessed samples on a single platform.