



# POINT OF CARE BLOOD ANALYSIS SYSTEMS

Paige Fischer and Andy Jacobson

# PROPOSAL

- ▶ Platform that utilizes both microfluidic and lateral flow technology
- ▶ Allow for several different blood analysis tests to be evaluated at once
- ▶ Faster, more accurate, and robust results
- ▶ Devices could be modified to work in different medical arenas
- ▶ Needs of developing and developed world can be met

# BUSINESS OPPORTUNITY

- ▶ \$13.7 billion per year industry in 2010
- ▶ Annual growth of 8 to 9% predicted to 2016
- ▶ Central Testing Facilities annual cost is \$50 billion
- ▶ **\$13 per device cost**
- ▶ Building opportunity
- ▶ Main device development for the developing world
- ▶ To increase prosperity possibly develop an at home diagnostic test for the developed world

References

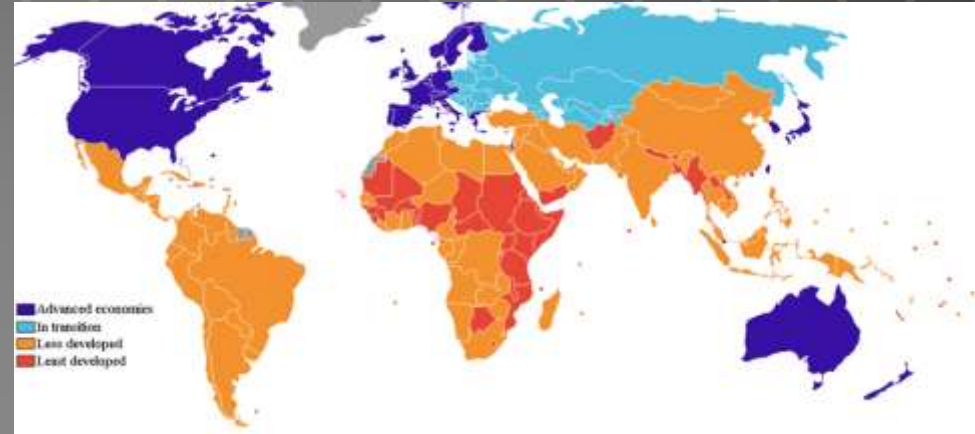
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# DEVELOPING COUNTRIES

## CHALLENGES

- ▶ Electricity and running water
- ▶ Transport and Storage
- ▶ Waste disposable
- ▶ Calibration



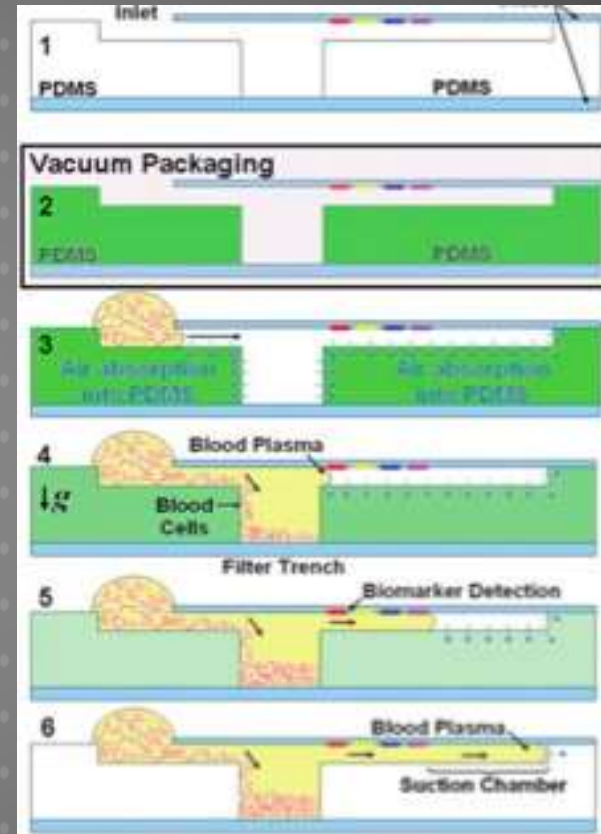
## BENEFITS

- ▶ World healthcare improvement
- ▶ Better understanding of diseases
- ▶ Better use of existing technologies



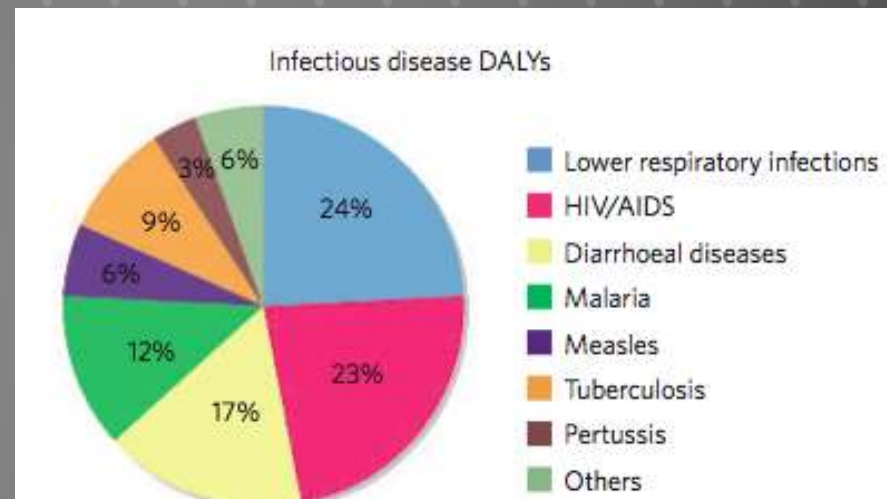
# DEVICE TECHNOLOGY

- ▶ Separate RBCs from plasma
- ▶ Filtration Trenches
  - ▶ Diameter= 2mm
  - ▶ Inlet Channel height= 80 $\mu$ m
  - ▶ Trench Depth= 2mm
- ▶ Material- Plastic
- ▶ Vacuum
- ▶ Tests take between 10 and 30 minutes
- ▶ Decreases costs through optimization



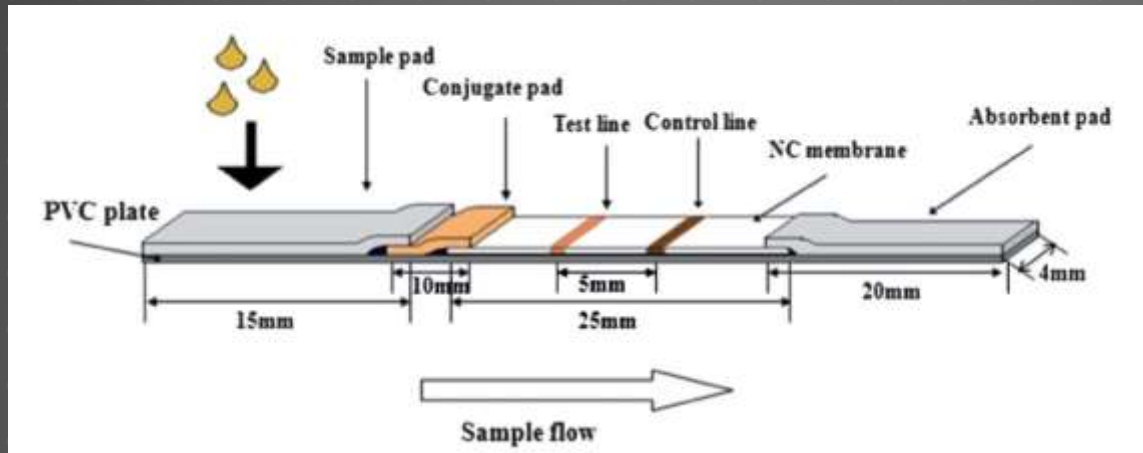
# DISEASES

- ▶ Human Immunodeficiency Virus (HIV)
- ▶ Hepatitis B
- ▶ Tuberculosis
- ▶ Syphilis
- ▶ Malaria





# LATERAL FLOW TEST STRIP

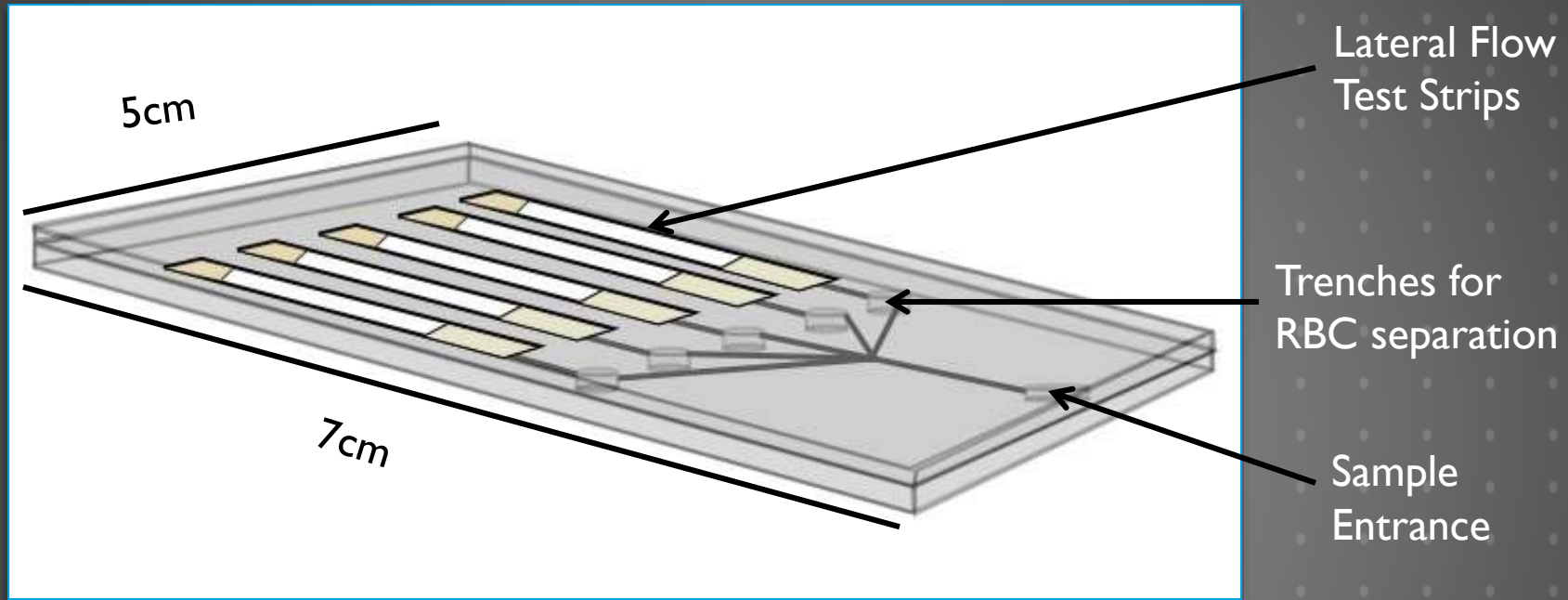


- ▶ Conjugation of Particles
- ▶ Conjugate Pad
- ▶ Test Strip
- ▶ Absorbent pad



Lou, S., et al. A gold nanoparticle-based immunochromatographic assay: The influence of nanoparticulate size. *The Royal Society of Chemistry*. Vol 137, 1171-1181. 2011.

# DEVICE



- ❖ Our device would be designed to be small and easy to use.

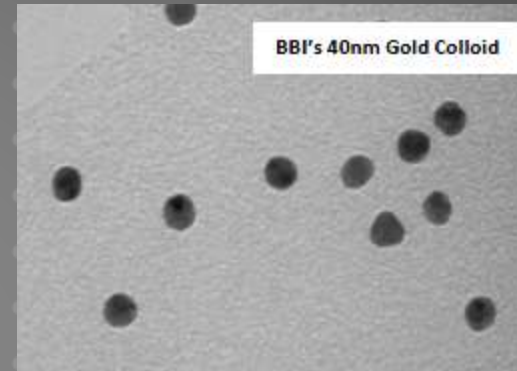


# REAGENTS

Disease	Reagent Needed for Detection	Type of Reagent
HIV	Gp36 and Gp41	Peptides
Hepatitis B	Anti-HbsAG	Surface antibody
Tuberculosis	Anti-MPB64	Monoclonal antibody
Syphilis	T. pallidum recombinant antigen p15, p17, p47	Recombinant antigen
Malaria	Anti-pfHRP2	Monoclonal antibody

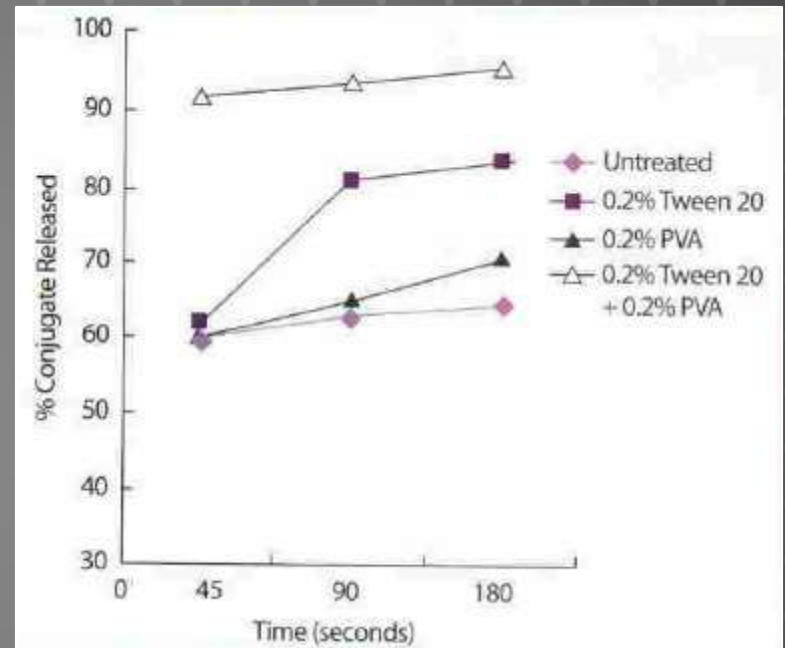
# CONJUGATE PARTICLES

- ▶ Colloidal gold nanoparticles
  - ▶ Stable, sensitive, and uniform shape and size
  - ▶ Small size, high sensitivity, and robust manufacturing methods
  - ▶ Surface easily modified
- ▶ Size and concentration
  - ▶ Depends on assay specifications
  - ▶ Larger size better affinity
  - ▶ Smaller size faster running speed
- ▶ 40nm colloidal gold nanoparticles



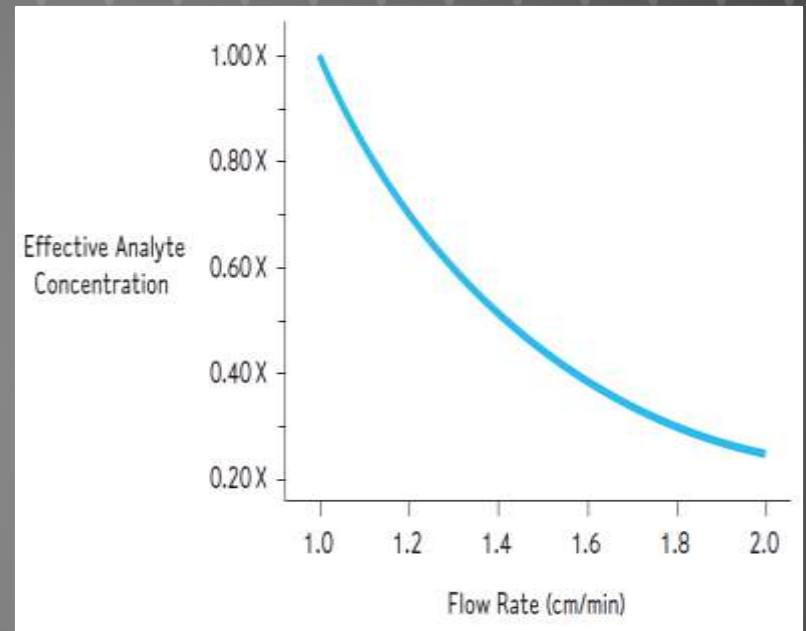
# CONJUGATE PAD

- ▶ Transport
  - ▶ Reagents and sample
- ▶ Properties of an Effective Pad
  - ▶ Low non-specific binding
  - ▶ Consistent flow characteristics
  - ▶ Consistent bed volume
  - ▶ Hydrophilic
- ▶ Common Materials
  - ▶ Glass fibers
  - ▶ Cellulose fibers
  - ▶ Polymers
- ▶ Blocking Agents



# TEST STRIP

- ▶ Purpose
- ▶ Properties of an Effective Strip
  - ▶ Capillary flow rate
    - ▶ Porosity
- ▶ Material
  - ▶ Nitrocellulose membrane
- ▶ Test Line
  - ▶ Pure antibodies
- ▶ Control Line
  - ▶ Anti-mouse goat protein



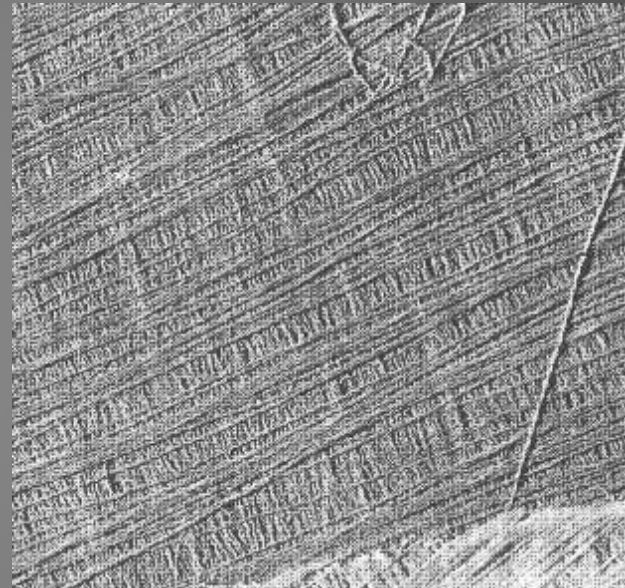
# ABSORBENT PAD

## ▶ Purpose

- ▶ Increase total volume entering the test strip
- ▶ Wash unbound particles away from test and control lines

## ▶ Materials

- ▶ Cellulose Fibers
  - ▶ Thickness
  - ▶ Compressibility
  - ▶ Manufacturability
  - ▶ Uniformity in Bed Volume



# SAMPLE AMOUNT

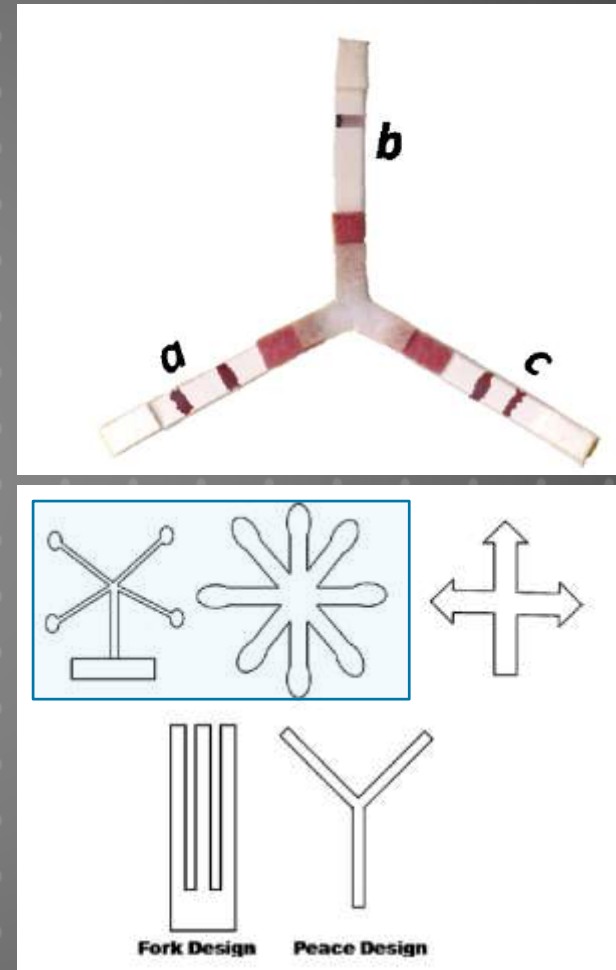
- ▶ 5 to 7  $\mu\text{L}$  per test strip
- ▶ 25-35  $\mu\text{L}$  per device





# ALTERNATIVE DESIGN

- ▶ Nitrocellulose membranes attached to round plastic support disc
- ▶ One sample loading pad with each strip having own absorbent pad
- ▶ Several different design options
- ▶ Can adjust for smaller sample volumes
- ▶ Currently designed for three devices



# ECONOMICS

	\$/device	Amount/ device ( $\mu\text{g}$ )	Cost/year, m\$/yr
Disease Reagents	6.78	4.24	40.70
Goat anti-mouse IgG	2.5	25	15
Gold nanoparticles	0.57	0.2 $\mu\text{L}$	3.402
Pad Elements	0.72	---	4.310
Manufacturing Cost	0.67	---	3.25
Additional Chemicals	0.5	---	3
<b>Total Cost</b>	<b>11.74</b>	<b>29.24</b>	<b>69.66</b>

- ❖ Each device requires very small amounts of material creating minimal costs

# ECONOMICS

	Cost/Profit
Equipment Cost	37.7m\$
FCI	20.69m\$
Price per device	\$13.00
Margin per device	\$1.26
NPV0	36.28m\$
NPV10	12.84m\$
IRR	20%

- ❖ **These economic conditions allow Sanguis to make a profit while selling devices for a minimal margin.**

# 510(K) CLEARANCES

- ▶ New Device
  - ▶ Must be equivalent to a device already placed onto the market
  - ▶ Must be safe and effective
- ▶ Steps
  - ▶ Pick 'predicate device'
  - ▶ Obtain data that device performs at the same level as 'predicate device'
  - ▶ Submit all data and design specifications to FDA
- ▶ Must be submitted 90 days prior to release

# FUNDING

- ▶ Red Cross
- ▶ Grants (University Setting)
- ▶ Program for Appropriate Technology in Health (PATH)
- ▶ Bill & Melinda Gates Foundation
- ▶ US National Institute of Allergy and Infectious Disease

QUESTIONS??



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