Diagnosis at the Point of Care with a Smartphone Dongle

Tiffany W. Guo, SB
Columbia University
Department of Biomedical Engineering
New York, NY

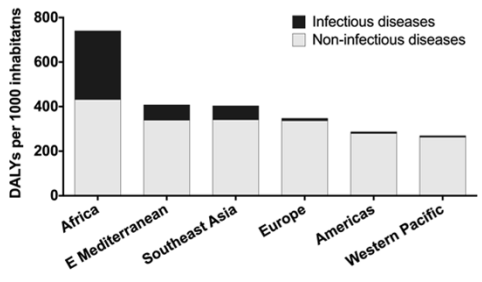
1

Learning objectives

- Explain benefits of using microfluidic technologies in point-of-care (POC) devices.
- Describe utility of smartphones in expanding access to point-of-care diagnostics.
- Identify opportunities and advantages of early testing with target users.

2

Worldwide disease burden



Adapted from: WHO Global burden of Disease (GBD). Geneva: WHO; 2012.

3

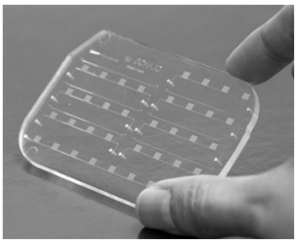
Vast differences in resources

High resource setting

Low resource setting

4

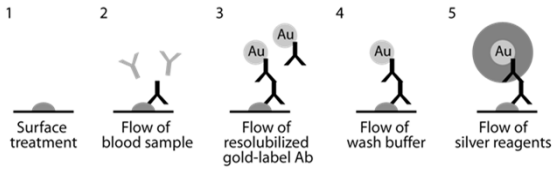
Microfluidics miniaturizes assays



Fast reaction time, low sample volume, low reagent consumption

5

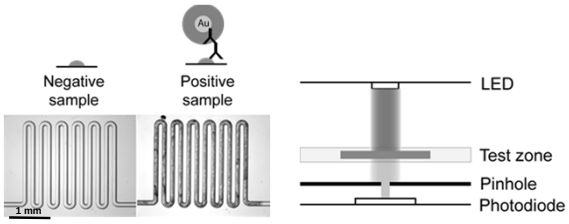
Microfluidics-based immunoassay



Triplex: antenatal care panel
- HIV (gp41, gp36, O-IDR)
- Syphilis treponemal (r17)
- Syphilis non-trep (cardiolipin)

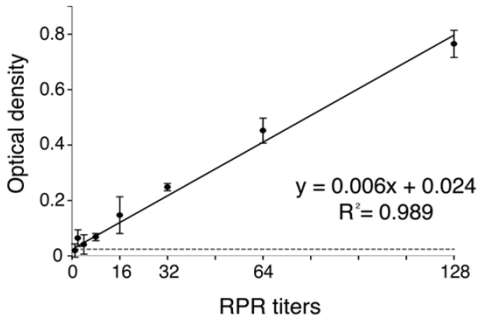
6

Quantitative optical detection



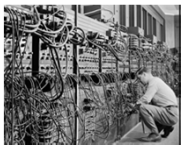
7

Quantitative optical detection



8

Boom in consumer electronics



- Processor
- GPS
- Camera
- Gyroscope

1946 2007

Smartphones are powerful tools enabled by advancements in semiconductor technology.

9

Coupling microfluidics with smartphones

- Smartphones
  - Fast **computing** power
  - Interactive interface for **training/education**
  - **Communication** to centralized databases

The combination of **microfluidics** and **smartphone** technology has the potential to bring previously inaccessible diagnostic technology to the point of care.

10

Smartphone dongle

Power-free vacuum
- Low-power
- Reduced price

Audio jack power/data
- Portable power source
- Universal interface

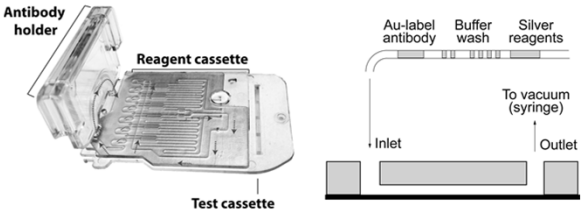
Microfluidic test
- 15 min assay time
- Auto-reagent handling
- Multiplexing

Low-cost optics
- Objective readout
- Reduced price

User-friendly app
- Low training burden

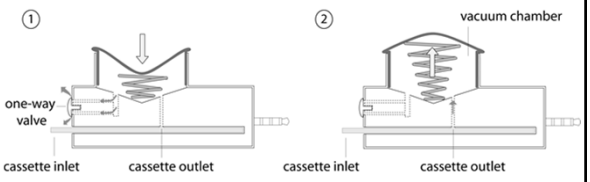
11

Automated reagent handling



12

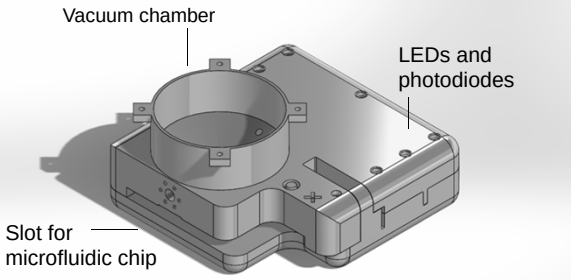
Power-free fluid flow



13

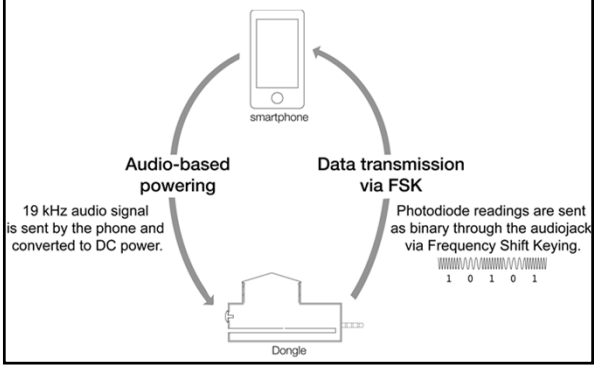
3D printed dongle case

7cm x 5cm x 5cm, 130 gm

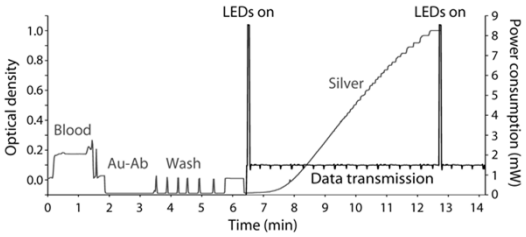


14

Audiojack powering and data transmission



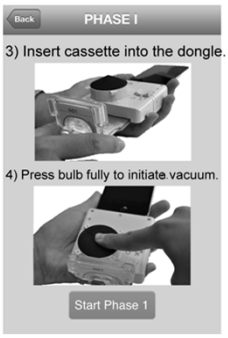
Extremely-low power consumption



Average 1.6mW 0.22mW per test

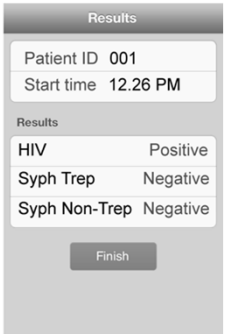
16

In-app directions



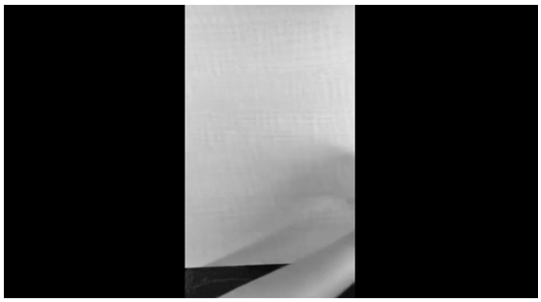
17

Clear objective results



18

Using the device



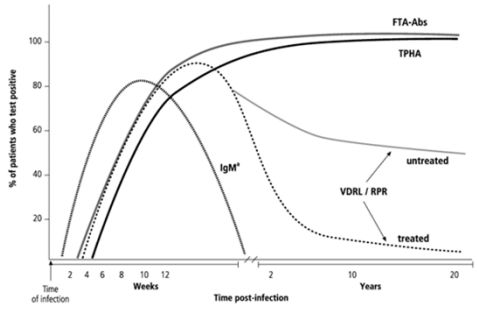
19

Testing in the field

- Healthcare workers used our devices in 3 clinics around Kigali, Rwanda.
- This testing represents first trial with:
  - Target end-users
  - Fingerprick whole blood

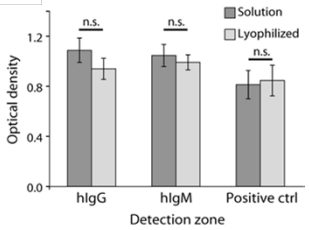
20

Treponemal and Non-treponemal markers



21

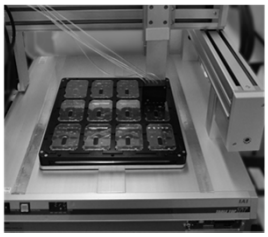
Lyophilized gold secondary antibodies



Lyophilizing antibodies provided increased stability and portability.

22

Prepared microfluidic tests at Columbia



The robotic arm helped to create large consistent batches (100 microfluidic cassettes).

23

Study participants: patients

Patients	***(n = 96)***
Average age	31 (21-62)
Gender	
Male	40
Female (preg)	56 (23)
Clinic	
VCT (Voluntary counseling and testing)	52
PMTCT (Prevention of mother to child transmission)	38
GC (General consultation)	6

24

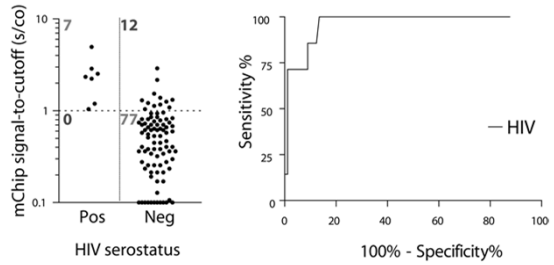
Study participants: healthcare workers

Healthcare workers	*(n = 5)*
Background	
Laboratory technicians	5
Experience with RDT	5
Experience with fingerprick	5
Nursing education	3

Received 30 minute training
- Visual demonstration and individual practice

25

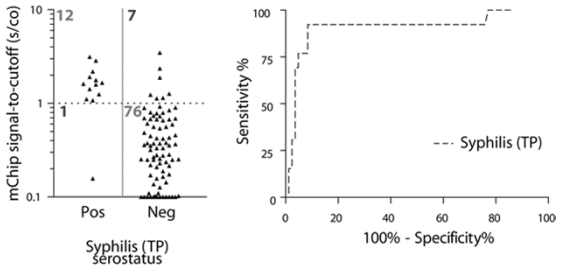
Fingerprick testing: HIV



Reference test: HIV ELISA
Sensitivity: 100% (59-100) Specificity: 87% (78-99)

26

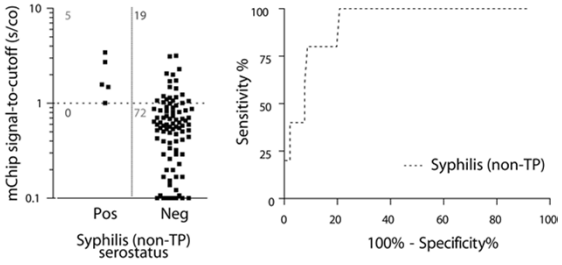
Fingerprick testing: Treponemal syphilis



Reference test: TPHA
Sensitivity: 92% (64-100) Specificity: 92% (83-97)

27

Fingerprick testing: Non-treponemal syphilis

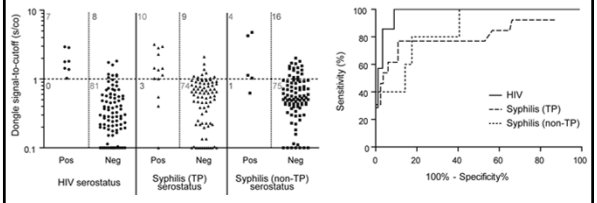


Reference test: RPR

Sensitivity: 100% (48-100) Specificity: 79% (69-87)

28

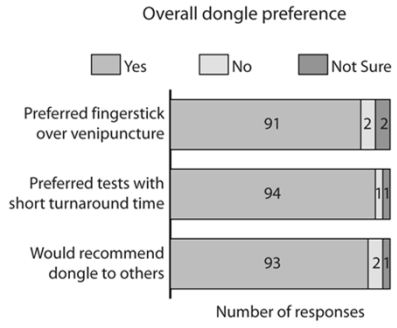
Venipuncture testing: showed similar results



	HIV	Syphilis (TP)	Syphilis (non-TP)
Reference test	HIV ELISA	TPHA	RPR
Sensitivity (95% CI)	100% (59-100)	77% (46-95)	80% (28-99)
Specificity (95% CI)	91% (83-96)	89% (80-95)	82% (73-90)

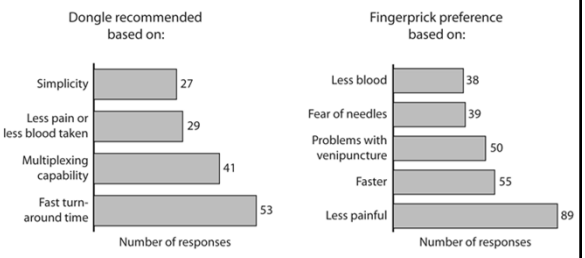
29

Patient feedback



30

Patient feedback



31

Healthcare worker feedback

- Felt it was simple to operate
- Valued multiplexing capability, objective read-out, fast turn-around
- Suggested use in low patient-volume settings (mobile clinics)
- Suggested use as back-up test in power outages

32

Conclusions

- Healthcare workers could operate the assay after a short **30 minute training**.
- The device showed **comparable results** to other diagnostic tests run in the field.
- Testing in the intended setting gave us **valuable feedback** from the user.
- **Smartphones** and **low-power engineering** enabled truly POC diagnostic testing.

33

Acknowledgements

Sia Lab, Columbia University
Tassaneewan Laksanasopin
Samiksha Nayak
Archana Sridhara
Owolabi Olowookere
Fanxing Meng
Shi Xie
Paolo Cadinu
Curtis Chin
Natalie Chee
Jiyoon Kim
Sau Yin Chin

Advisor: Samuel Sia

Rwandan collaborators
Veronicah Mugisha
Placidie Mugwaneza
Elisaphane Munyazesa
Sabin Nsanzimana

External collaborators
Jessica Justman (ICAP)
Vincent Linder (OPKO)
David Steinmiller (OPKO)
Dr. Alex Rai (CUMC)

Funding
Columbia MSTP
USAID Saving Lives at Birth Transition Grant

34