

# **Diagnosis at the Point of Care with a Smartphone Dongle**

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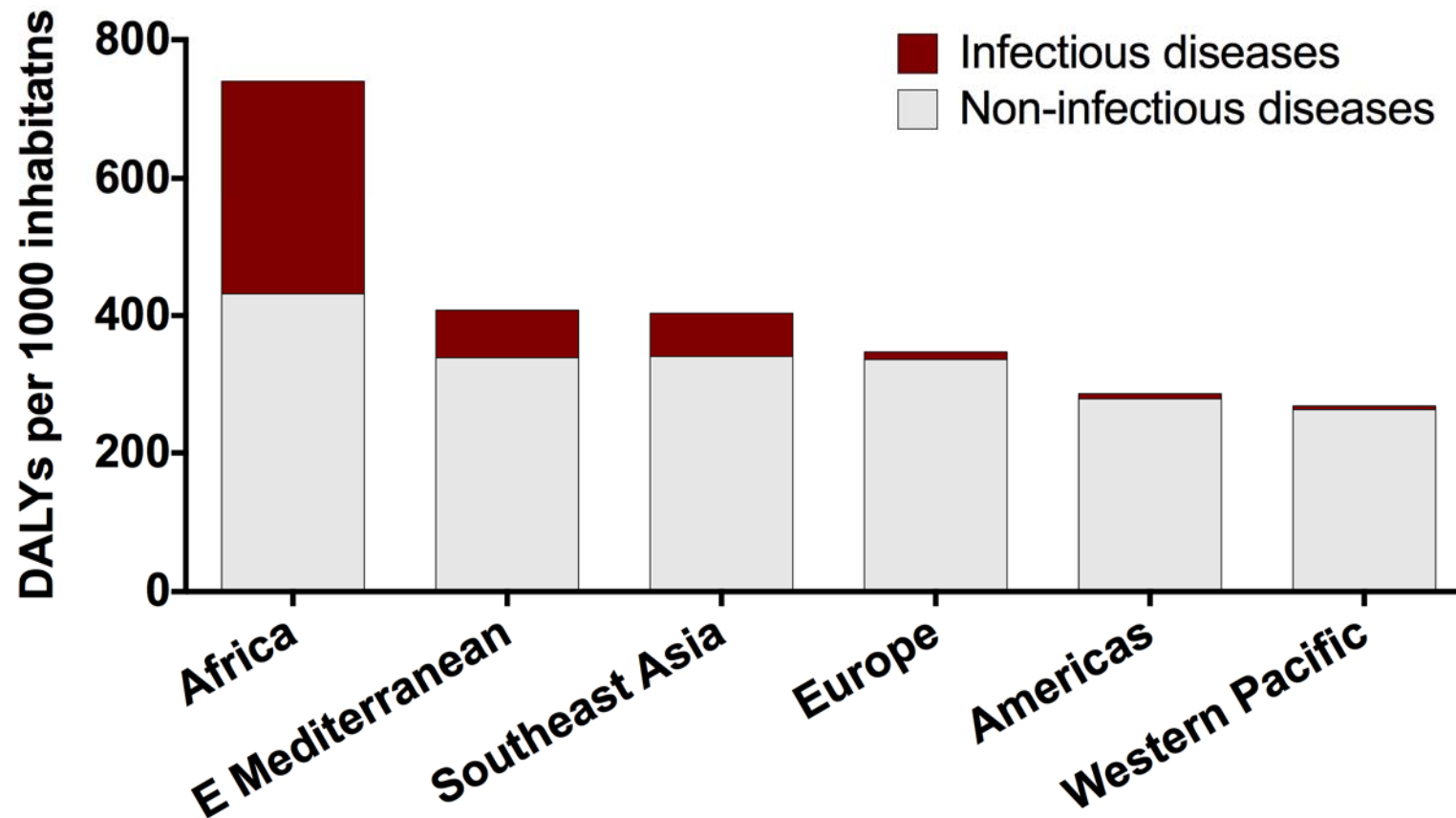
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# Learning objectives

- 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.

# Worldwide disease burden



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

# Vast differences in resources

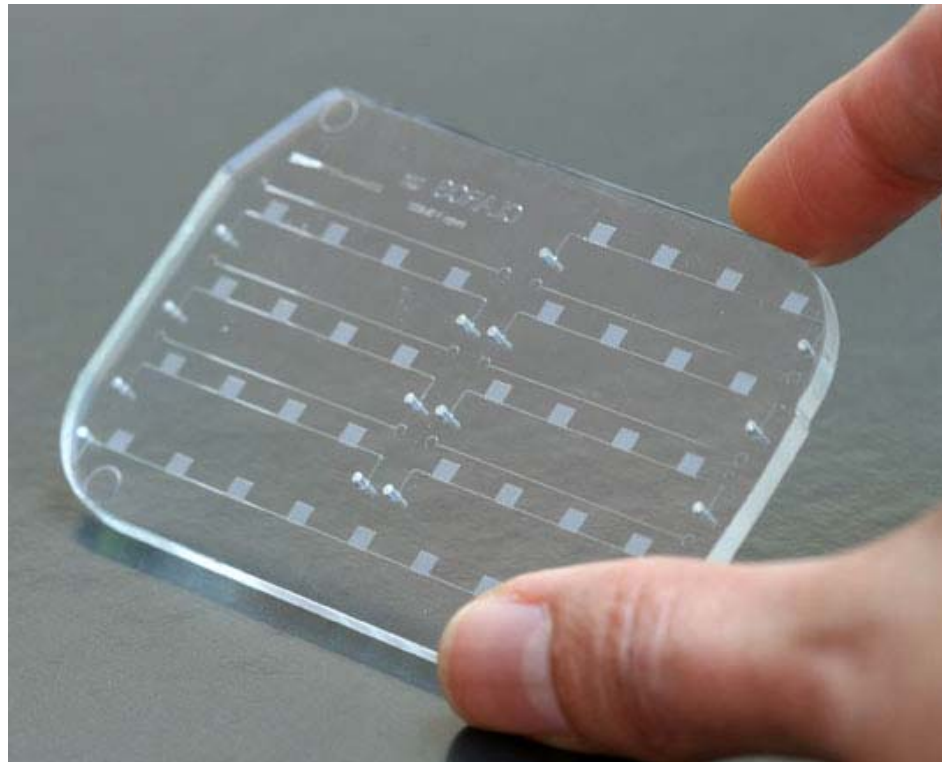


High resource setting



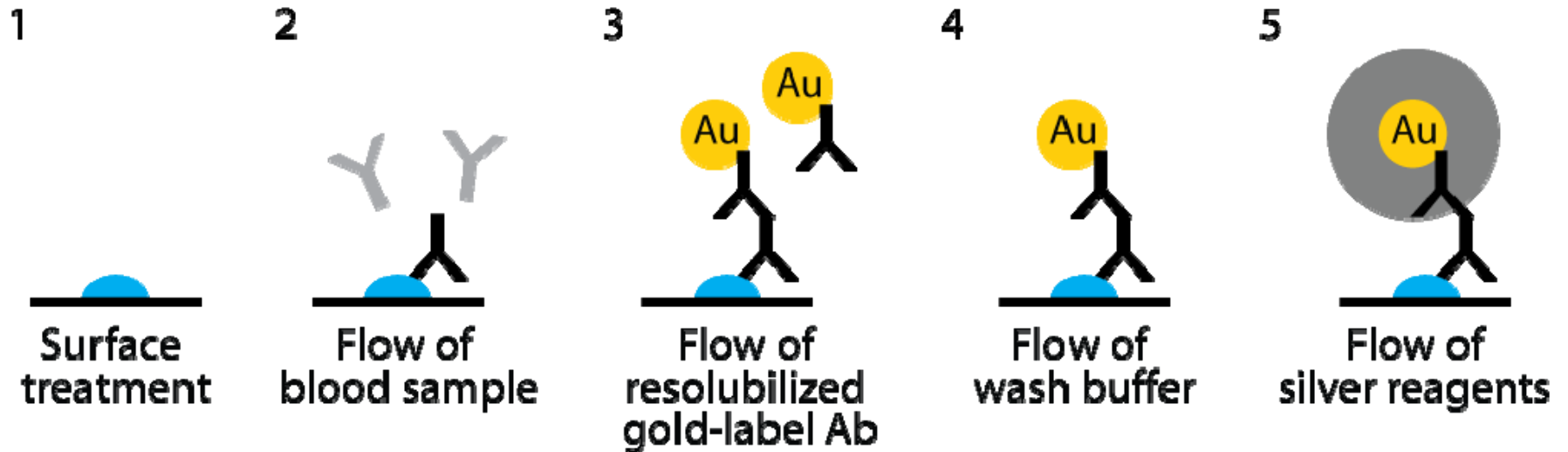
Low resource setting

# Microfluidics miniaturizes assays



Fast reaction time, low sample volume, low reagent consumption

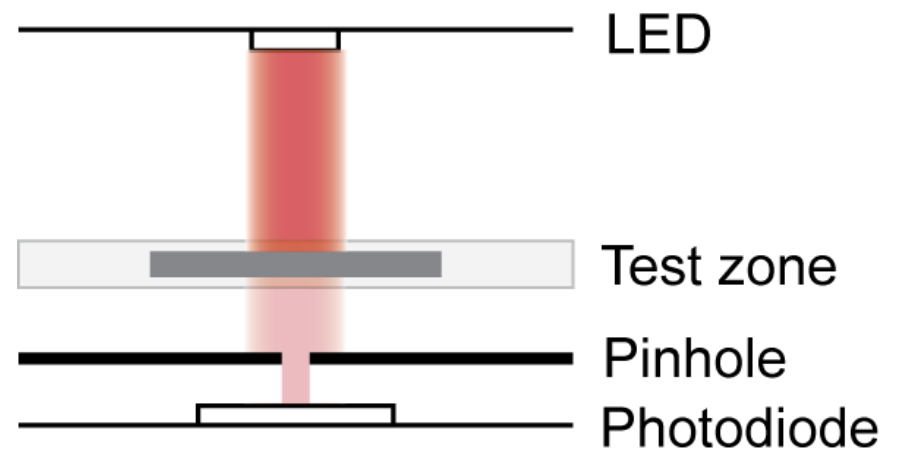
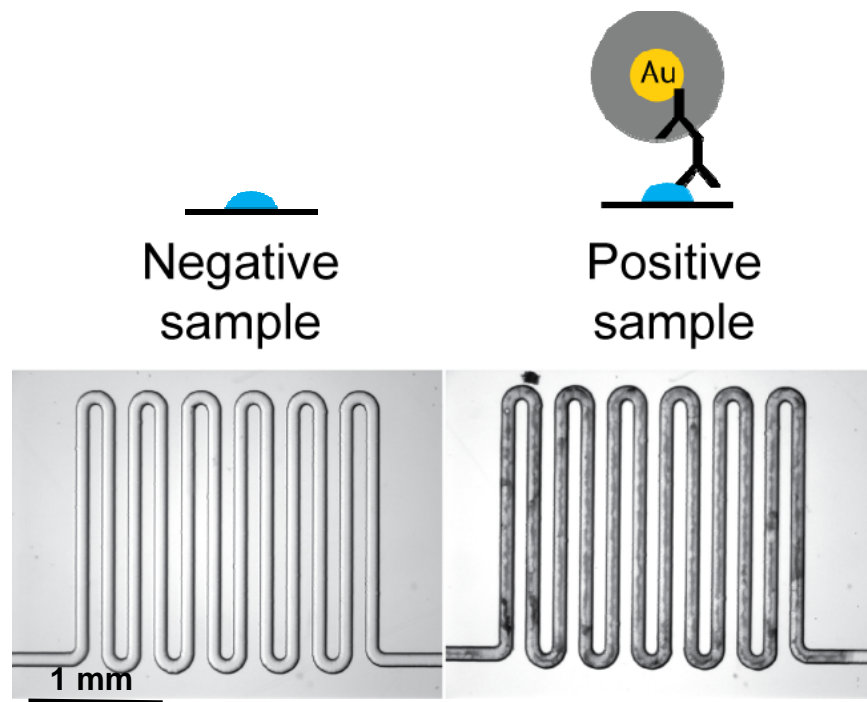
# Microfluidics-based immunoassay



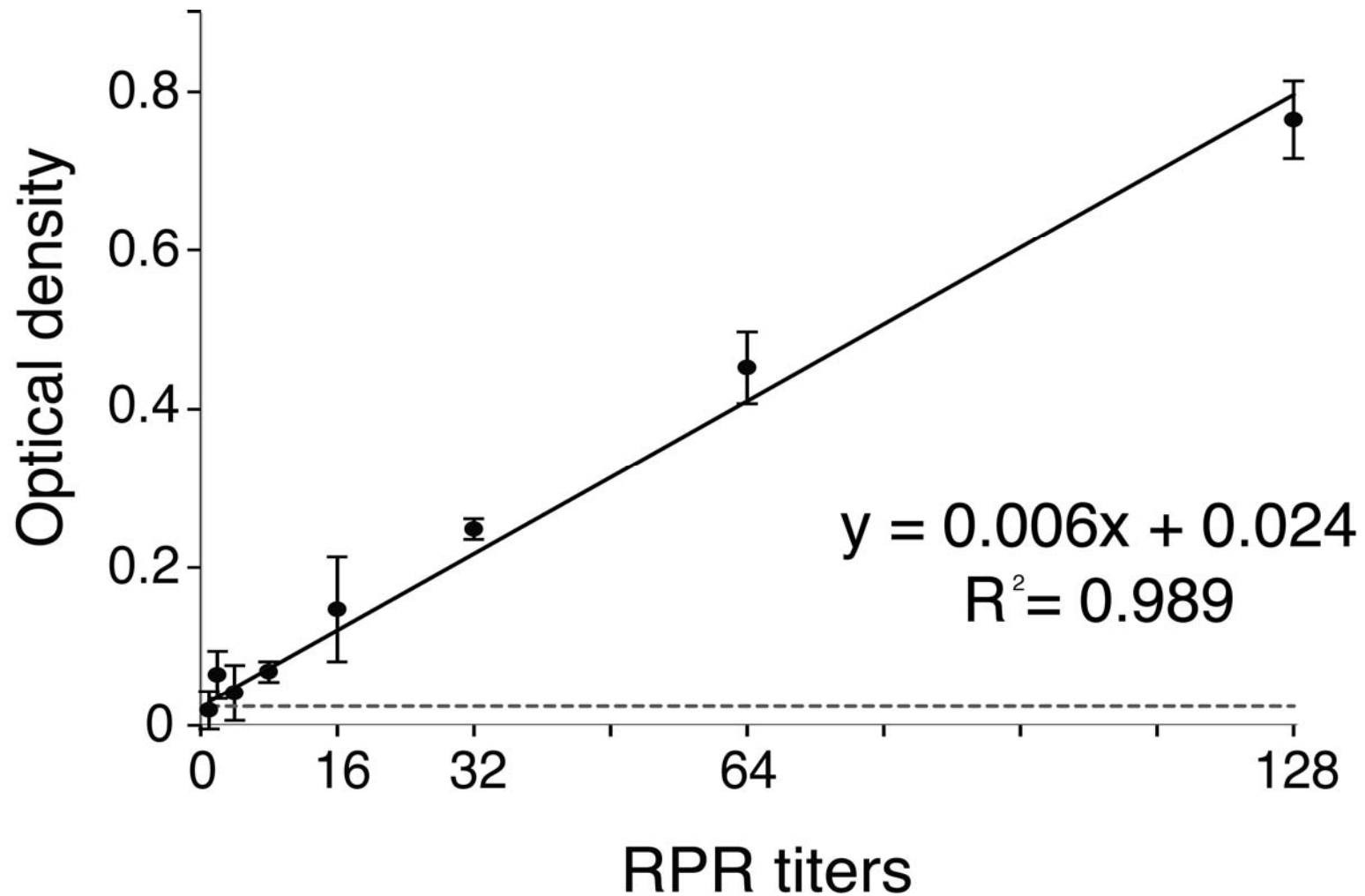
## Triplex: antenatal care panel

- HIV (gp41, gp36, O-IDR)
- Syphilis treponemal (r17)
- Syphilis non-trep (cardiolipin)

# Quantitative optical detection

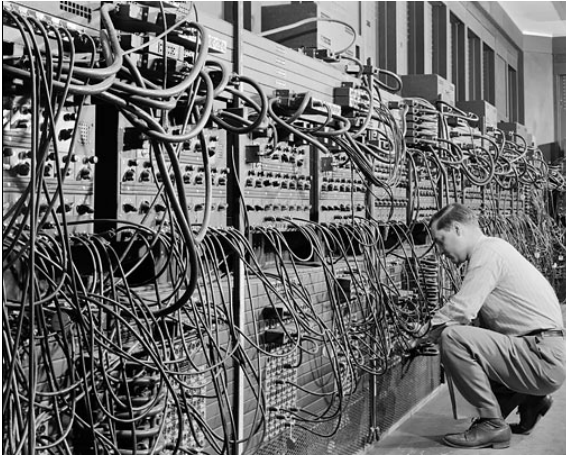


# Quantitative optical detection





# Boom in consumer electronics



1946



2007

- Processor
- GPS
- Camera
- Gyroscope

Smartphones are powerful tools enabled by advancements in semiconductor technology.

# 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.

# Smartphone dongle

## Power-free vacuum

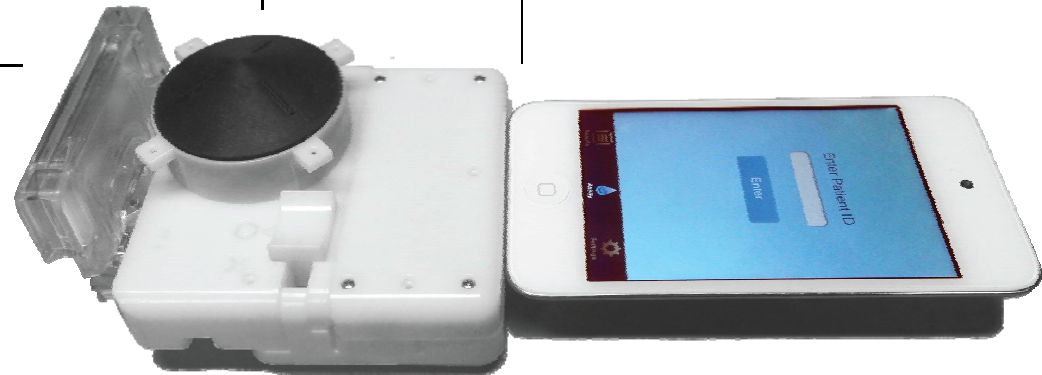
- Low-power
- Reduced price

## Audio jack power/data

- Portable power source
- Universal interface

## Microfluidic test

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



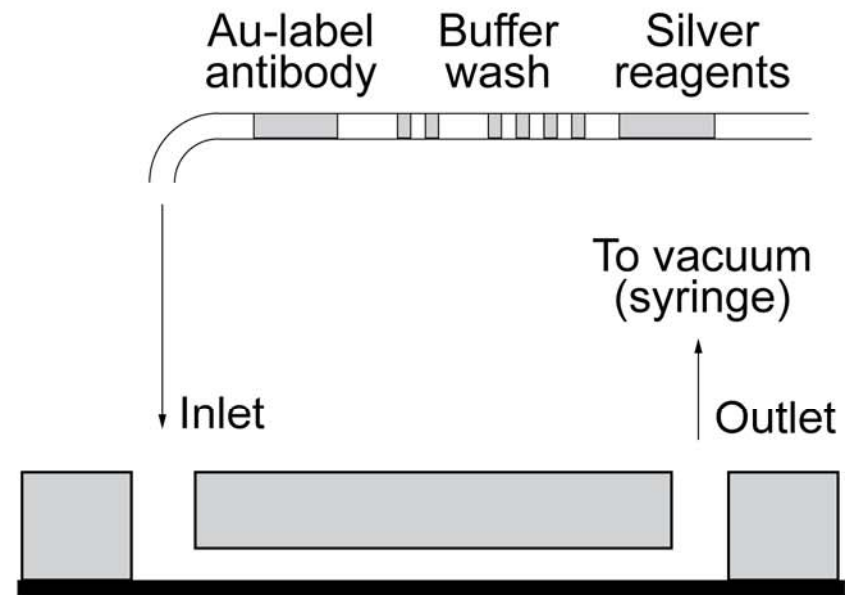
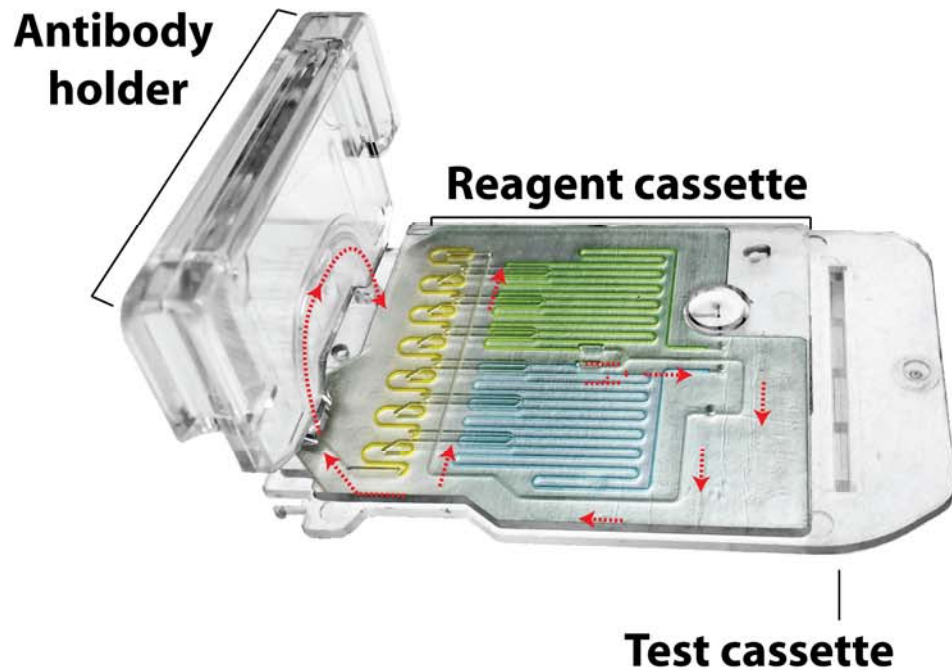
## Low-cost optics

- Objective readout
- Reduced price

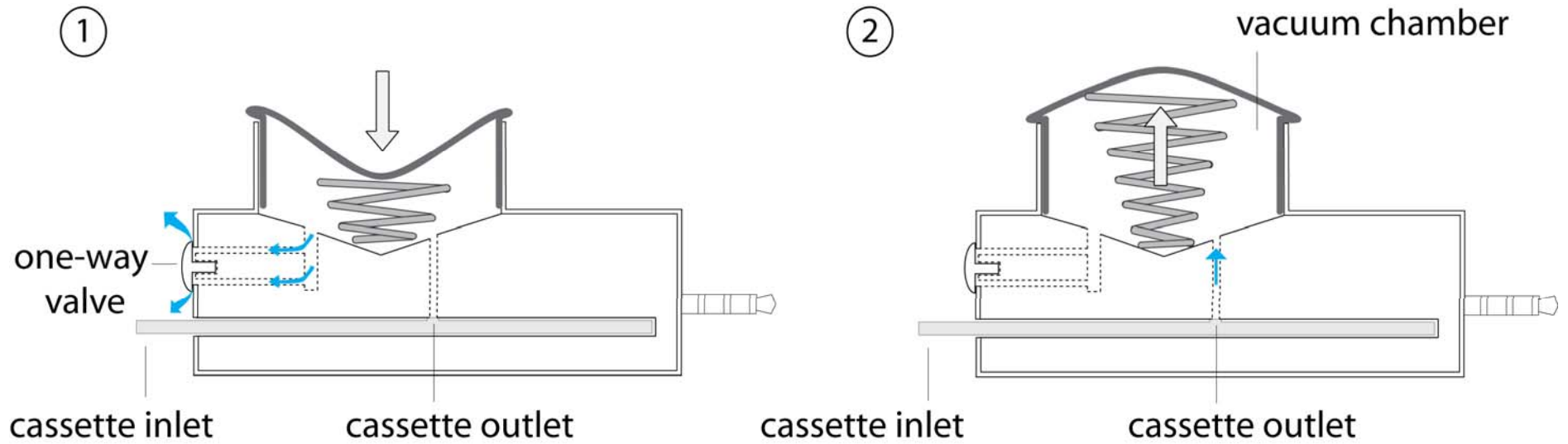
## User-friendly app

- Low training burden

# Automated reagent handling



# Power-free fluid flow



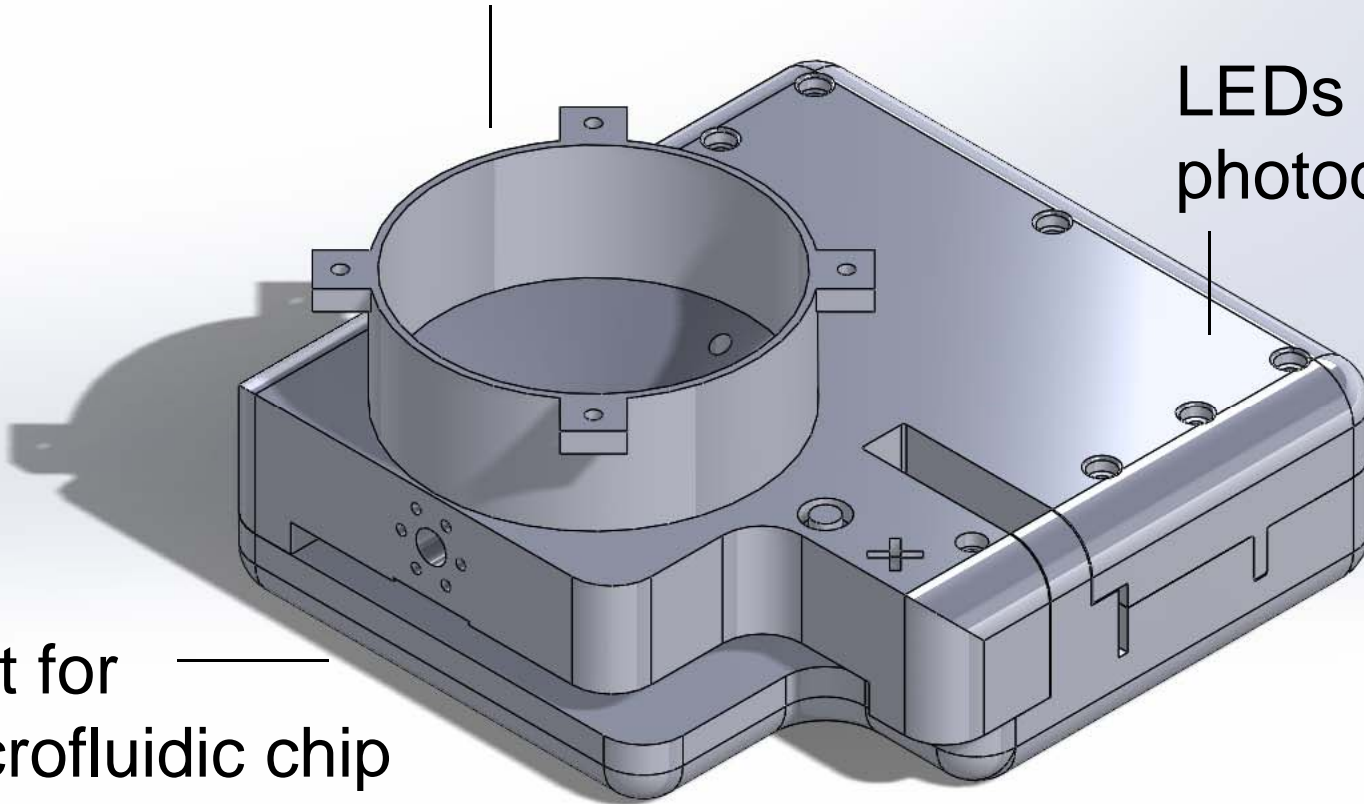
# 3D printed dongle case

7cm x 5cm x 5cm, 130 gm

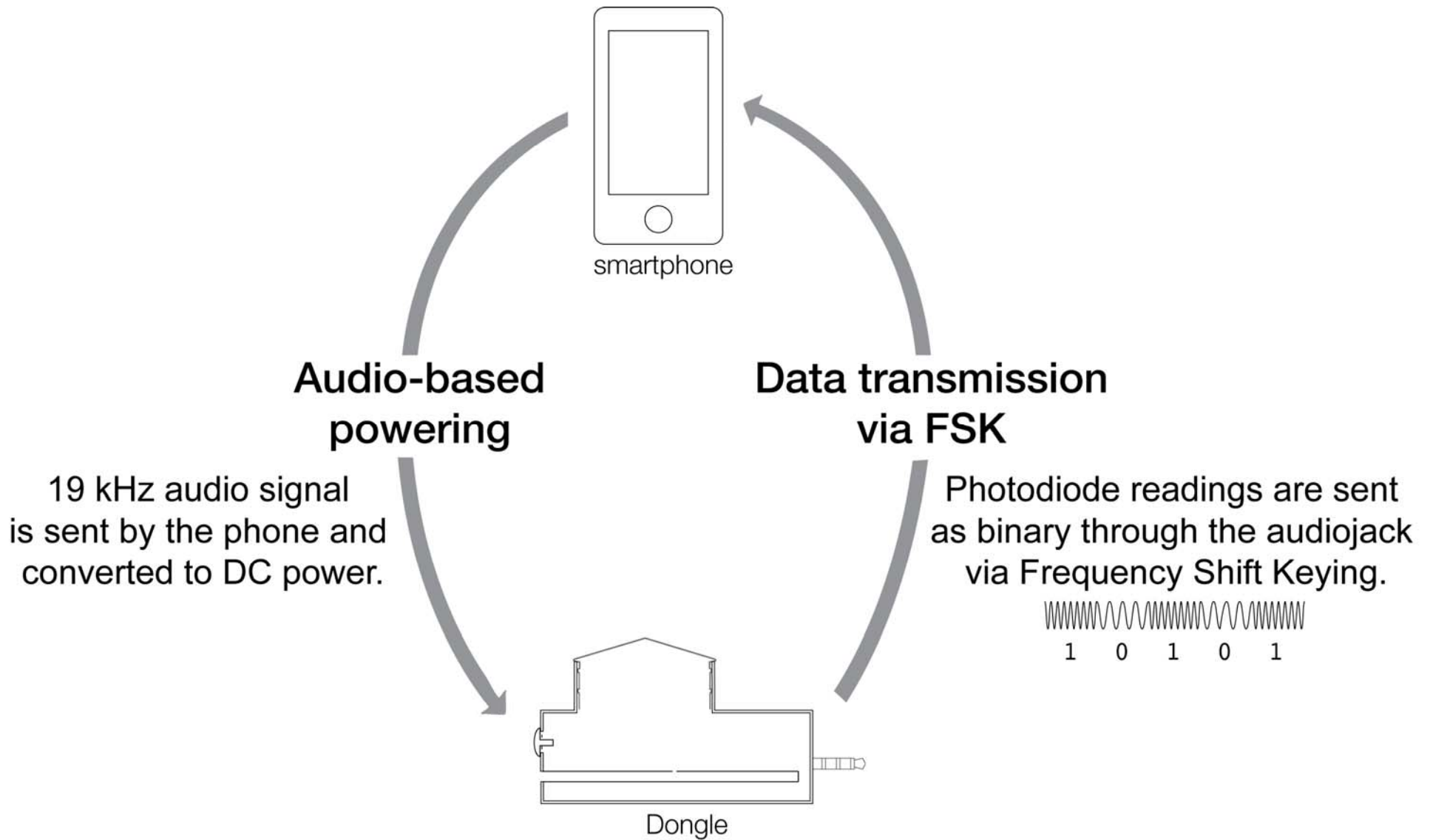
Vacuum chamber

LEDs and  
photodiodes

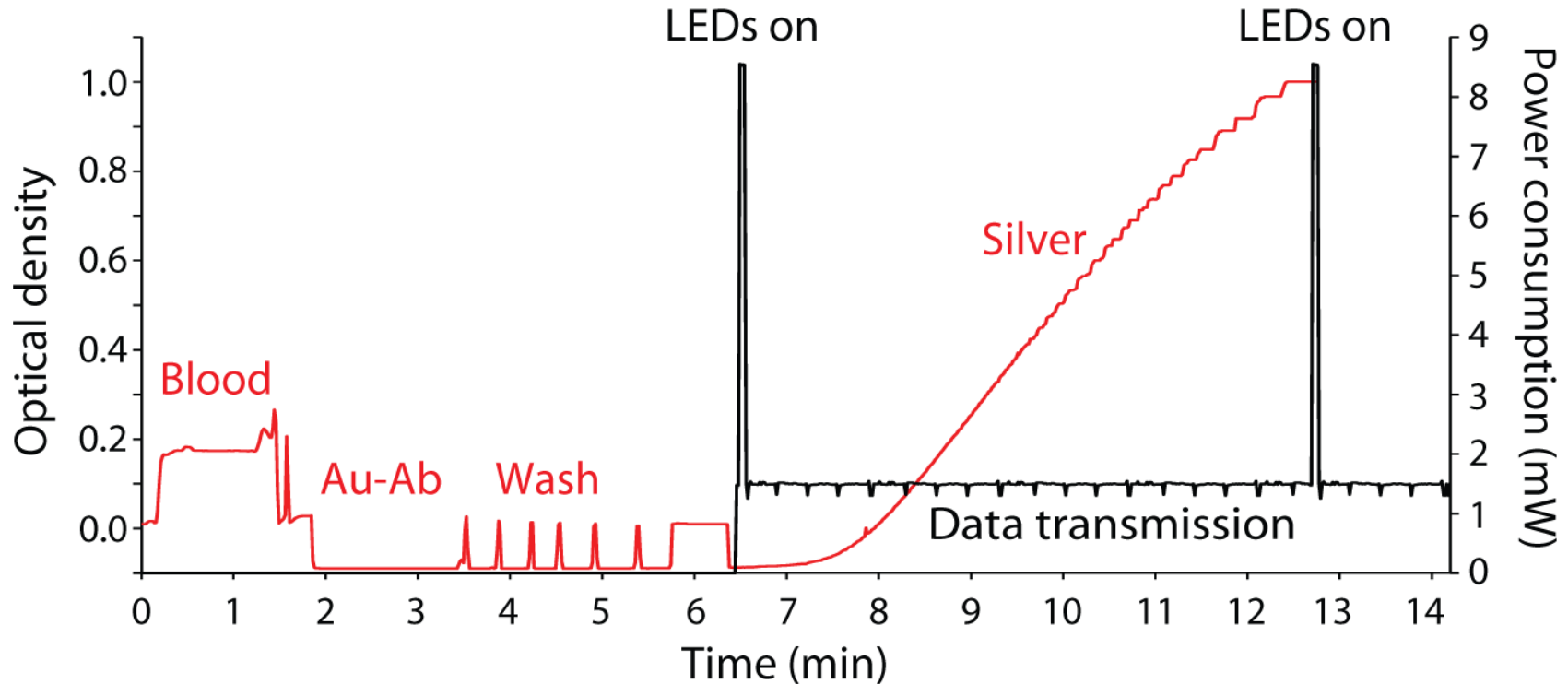
Slot for  
microfluidic chip



# Audiojack powering and data transmission



# Extremely-low power consumption



Average 1.6mW

0.22mW per test



# In-app directions

Enter Patient ID

Enter


1	2 ABC	3 DEF
4 GHI	5 JKL	6 MNO
7 PQRS	8 TUV	9 WXYZ
	0	✕

Back PHASE I

3) Insert cassette into the dongle.

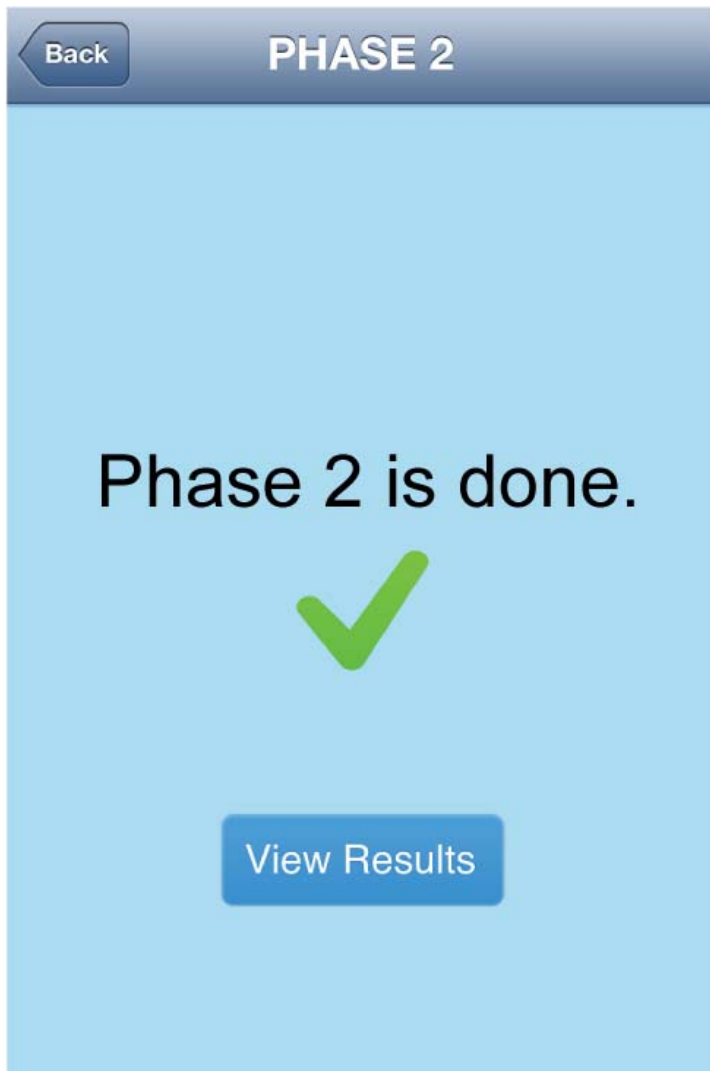


4) Press bulb fully to initiate vacuum.

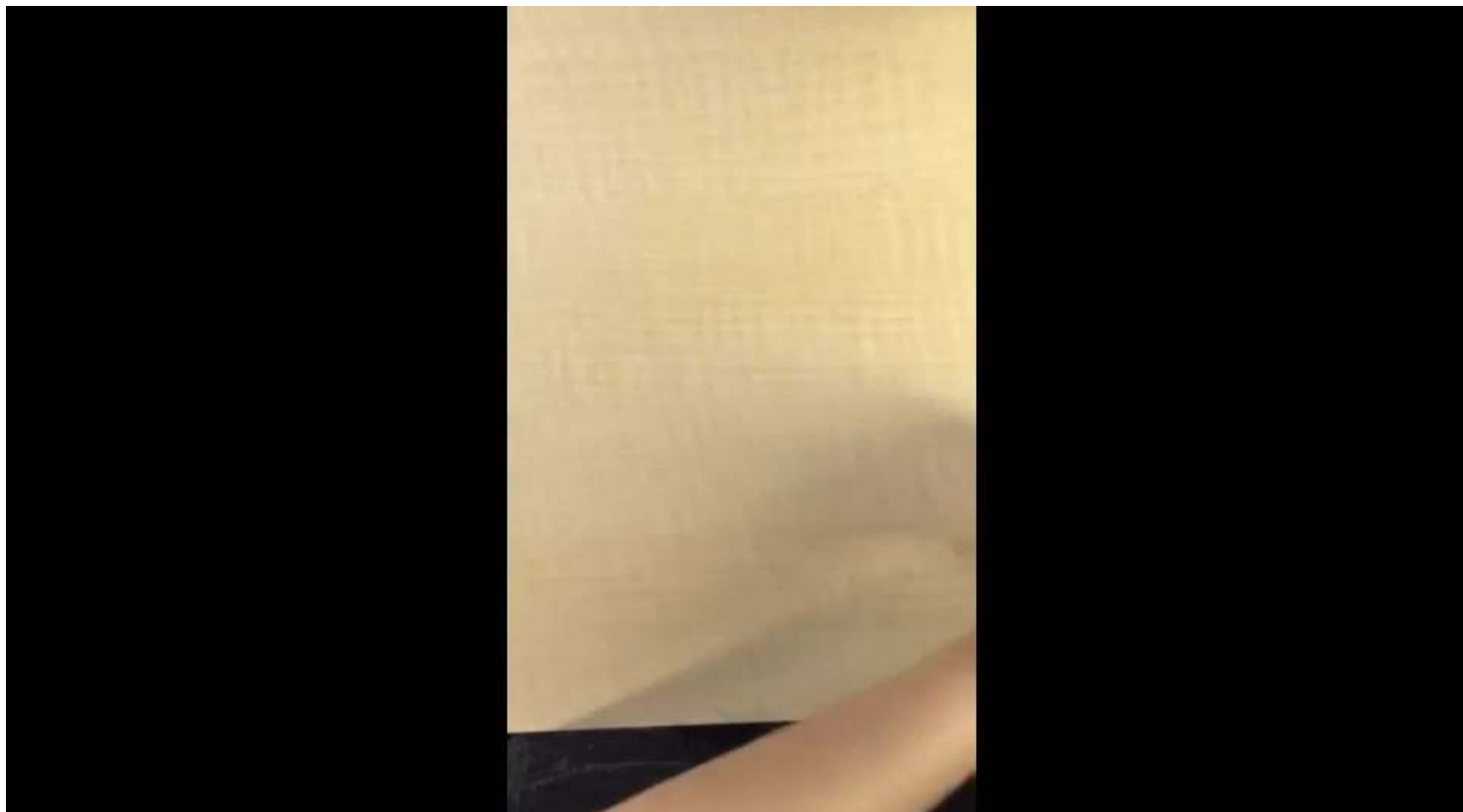


Start Phase 1

# Clear objective results



# Using the device

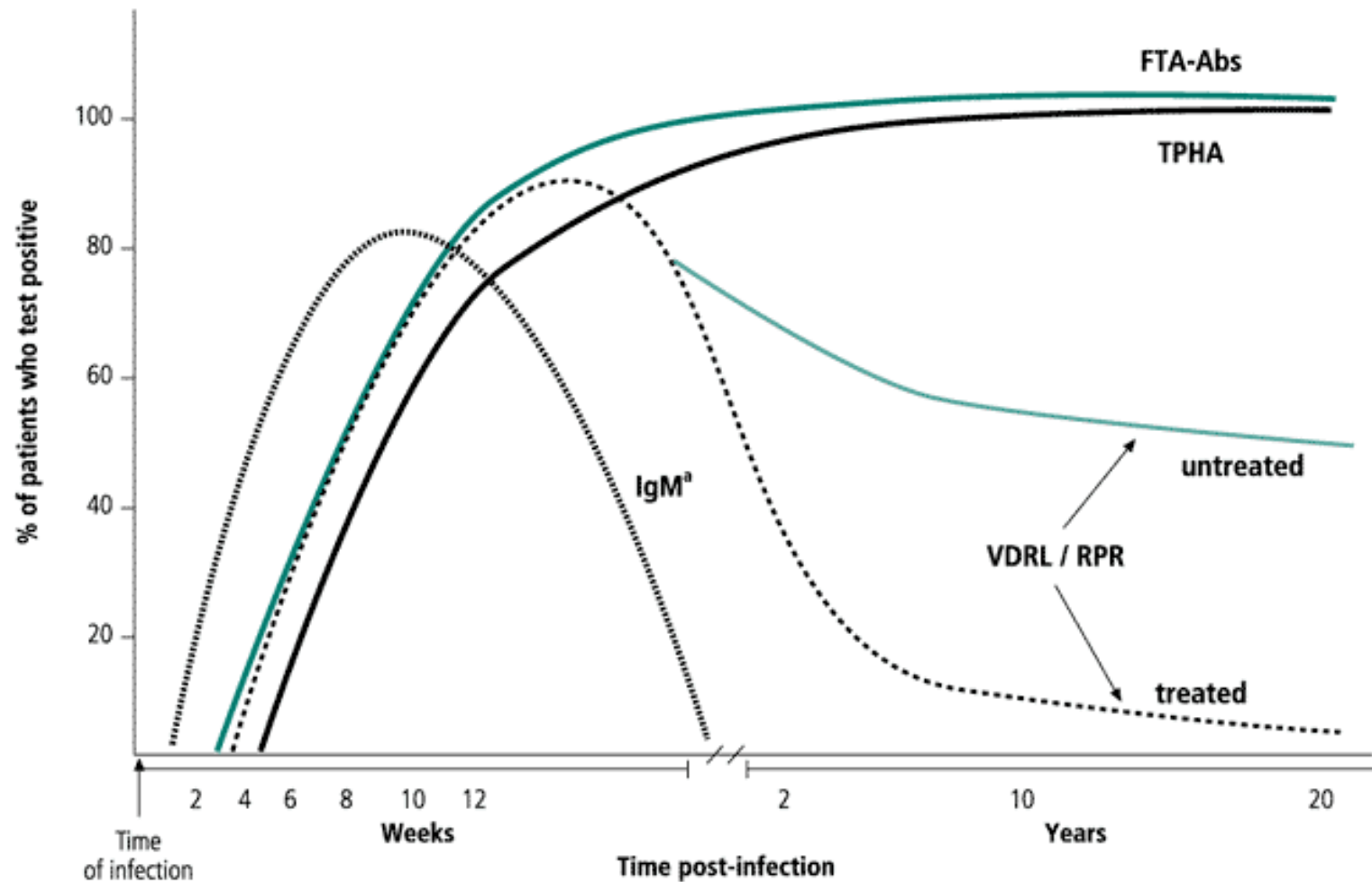


# Testing in the field

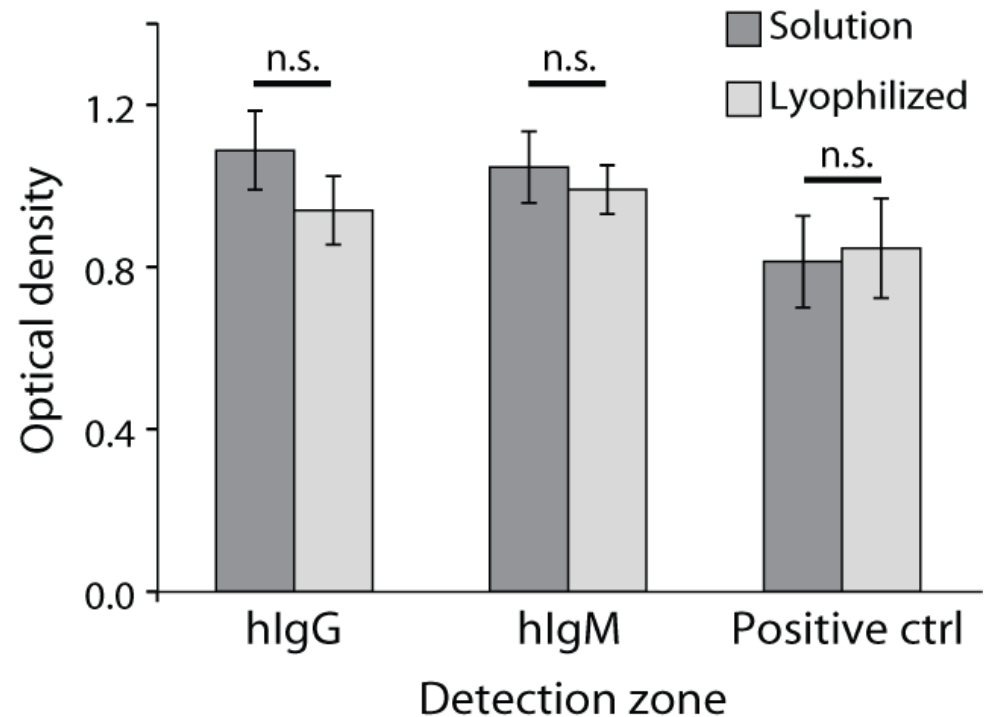
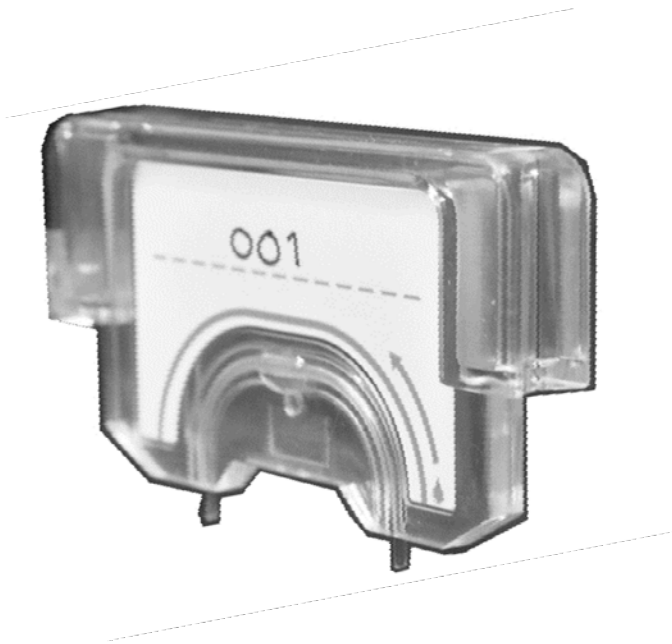
- Healthcare workers used our devices in 3 clinics around Kigali, Rwanda.
- This testing represents first trial with:
  - Target end-users
  - Fingerprick whole blood



# Treponemal and Non-treponemal markers

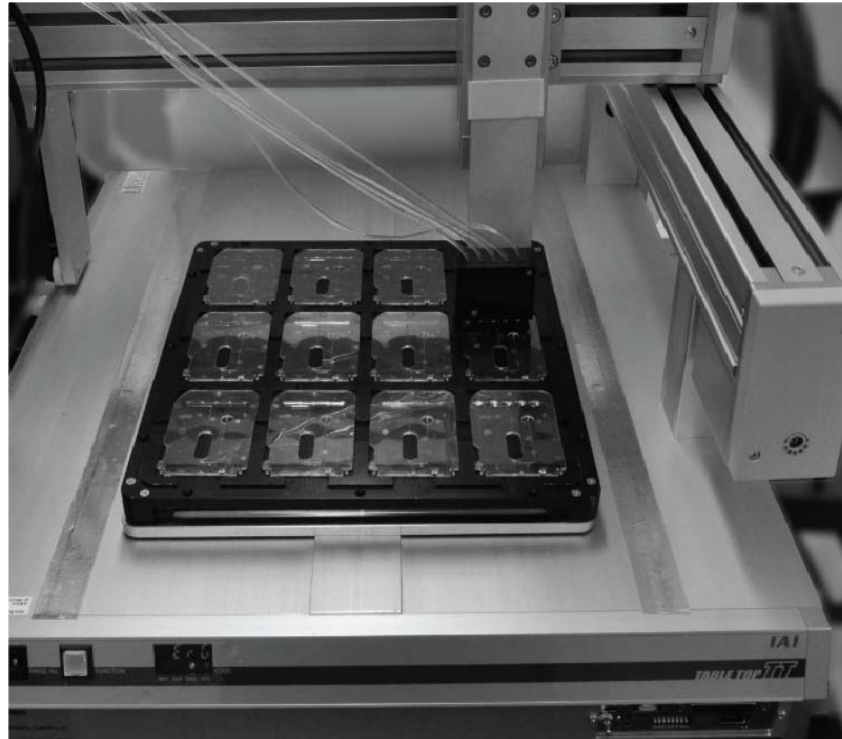


# Lyophilized gold secondary antibodies



Lyophilizing antibodies provided increased stability and portability.

# Prepared microfluidic tests at Columbia



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

## Study participants: patients

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



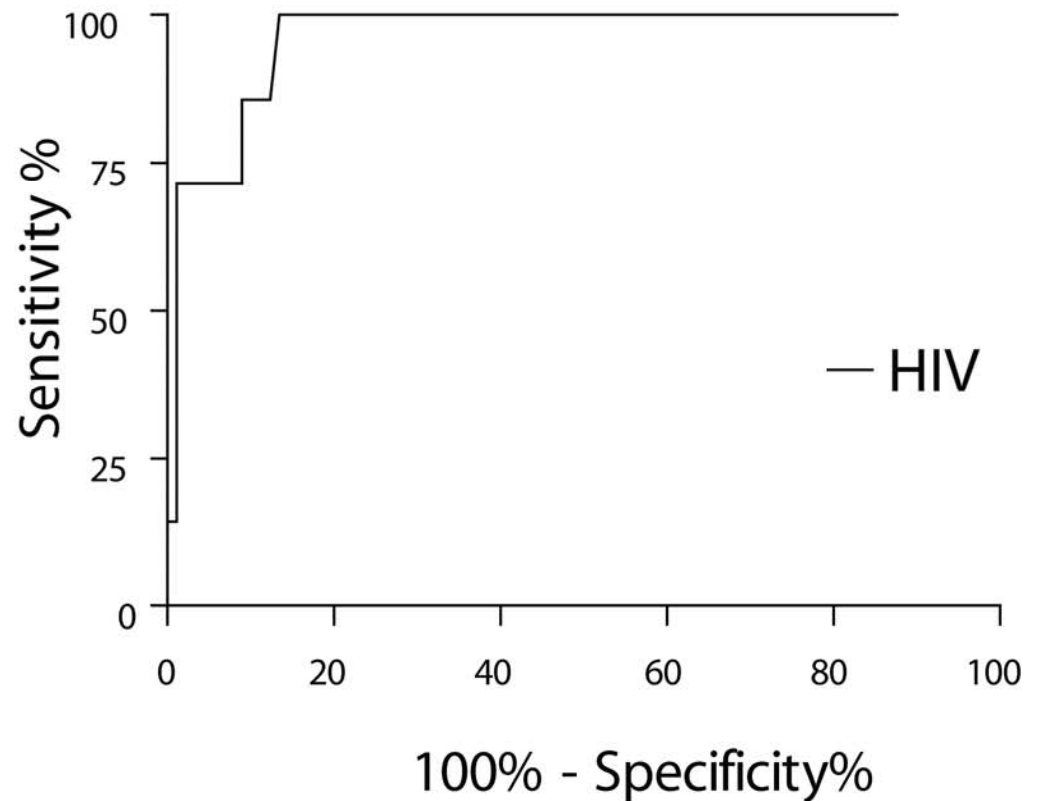
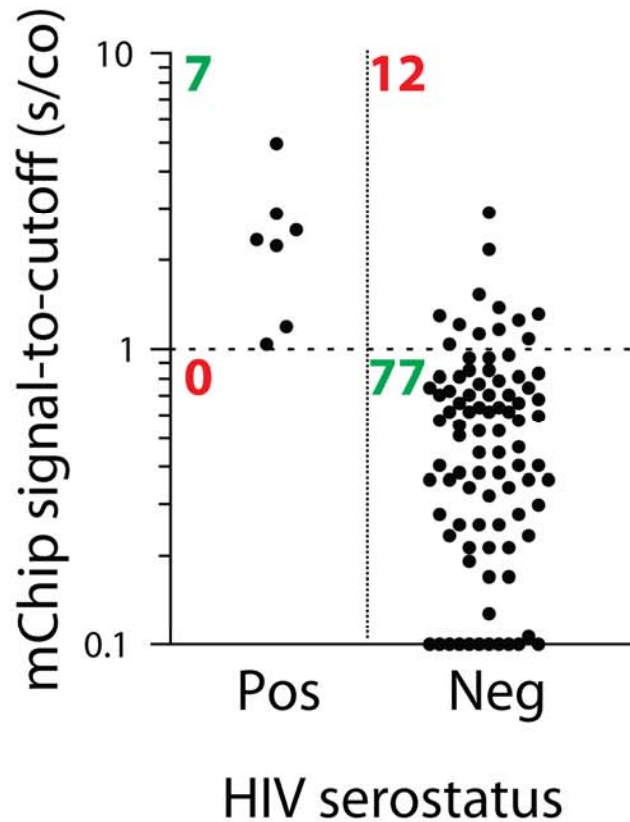
# Study participants: healthcare workers

<b>Healthcare workers</b>	<b>(n = 5)</b>
<i>Background</i>	
Laboratory technicians	5
Experience with RDT	5
Experience with fingerprick	5
Nursing education	3

Received 30 minute training

- Visual demonstration and individual practice

# Fingerprick testing: HIV

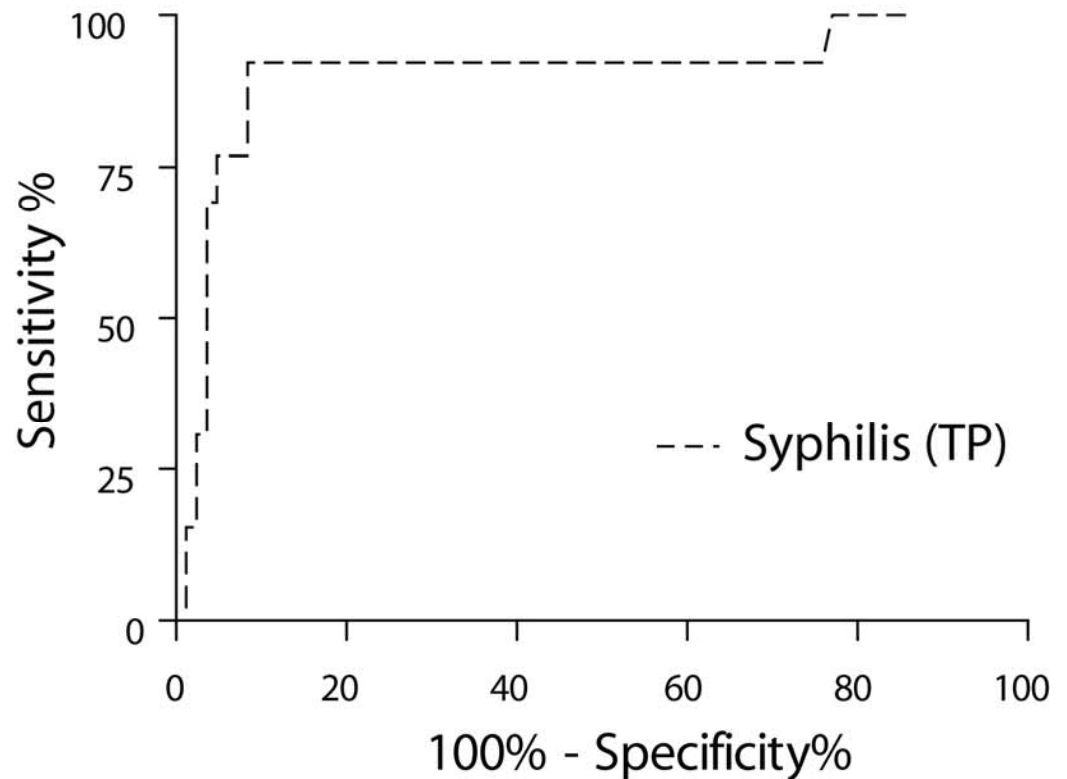
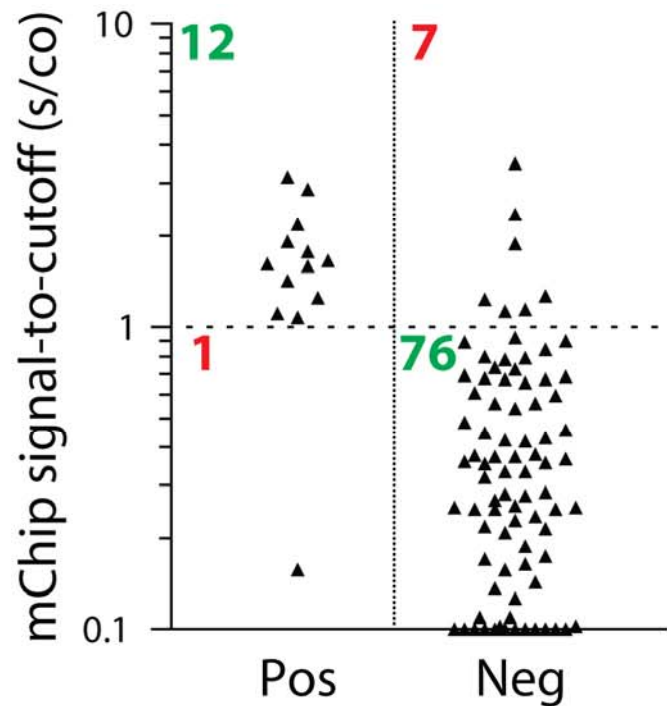


Reference test: HIV ELISA

Sensitivity: 100% (59-100)

Specificity: 87% (78-99)

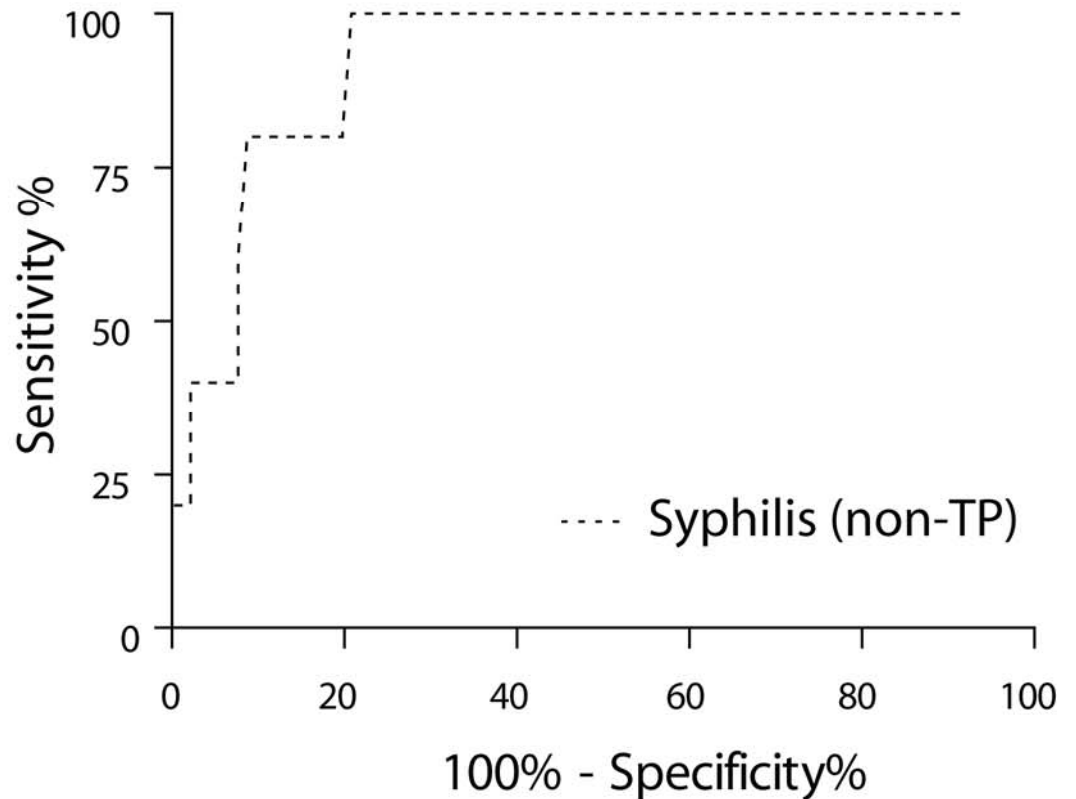
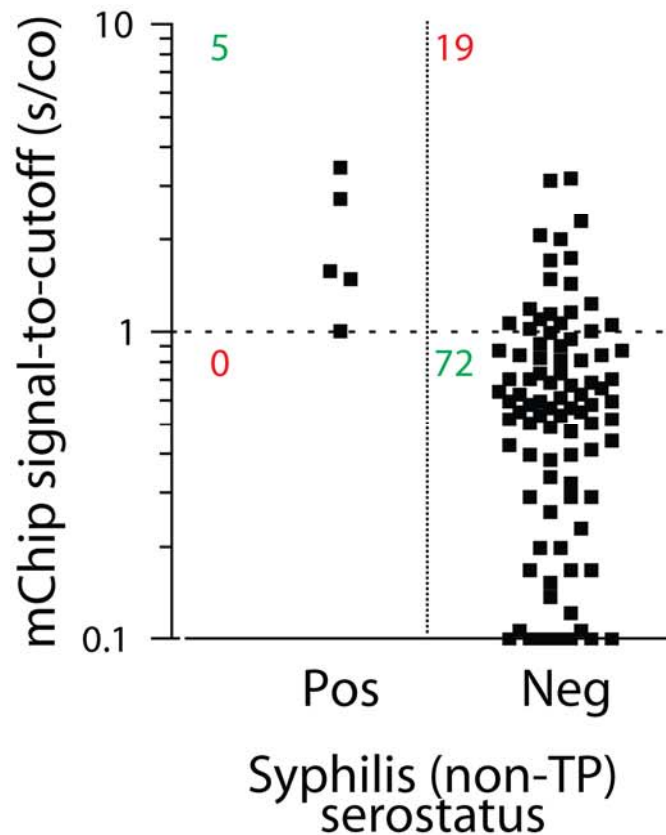
# Fingerprick testing: Treponemal syphilis



Reference test: TPHA

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

# Fingerprick testing: Non-treponemal syphilis

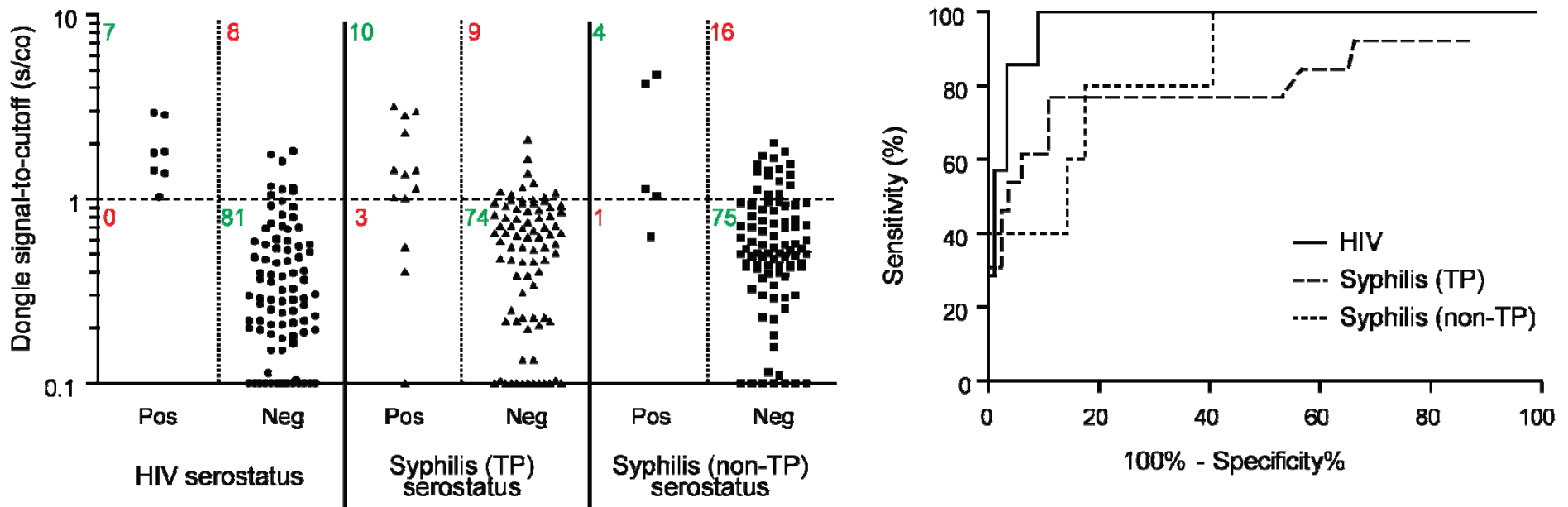


Reference test: RPR

Sensitivity: 100% (48-100)

Specificity: 79% (69-87)

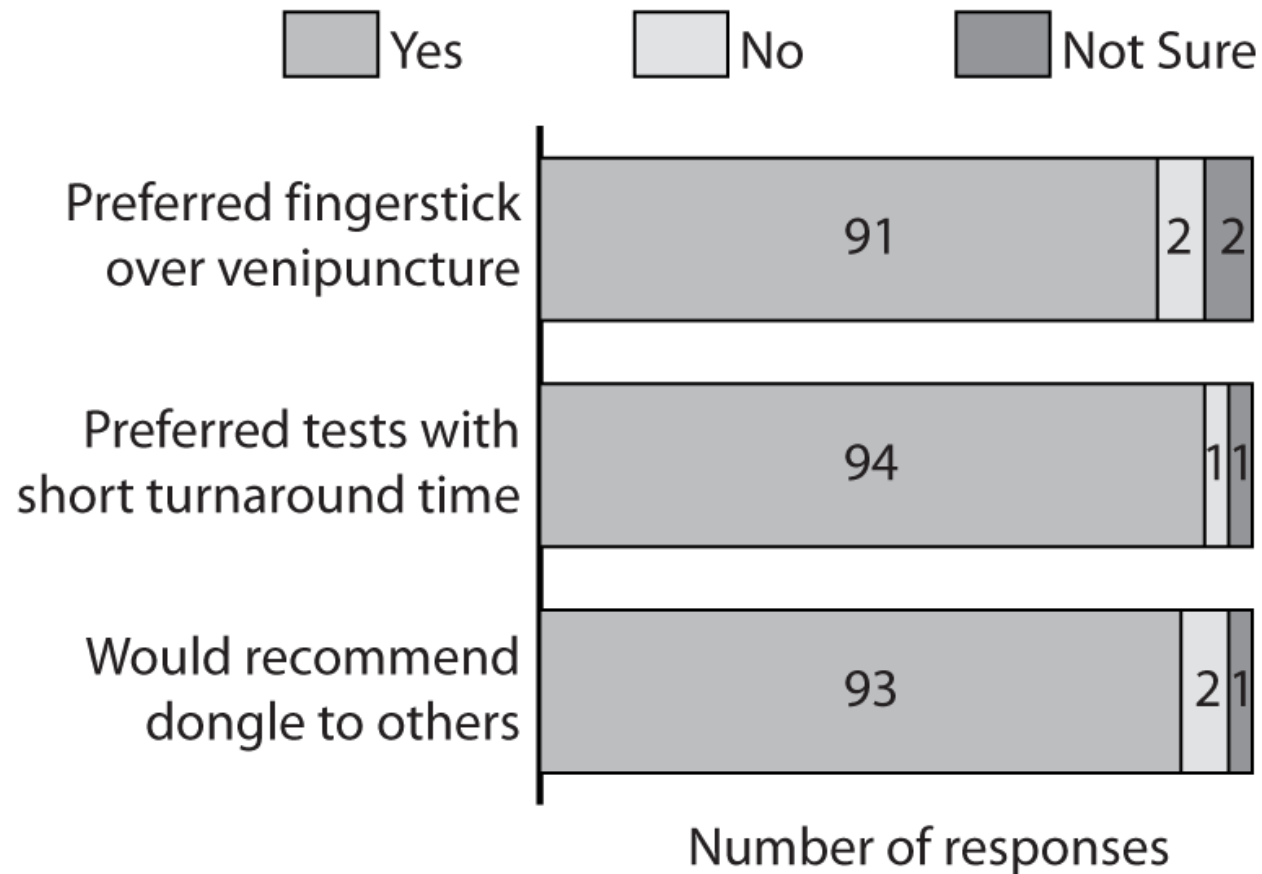
# Venipuncture testing: showed similar results



	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)

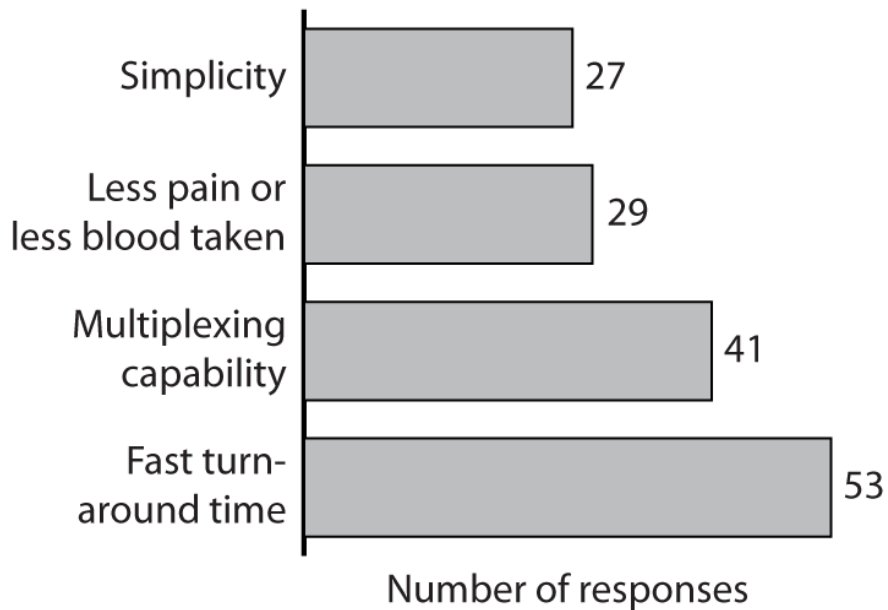
# Patient feedback

## Overall dongle preference

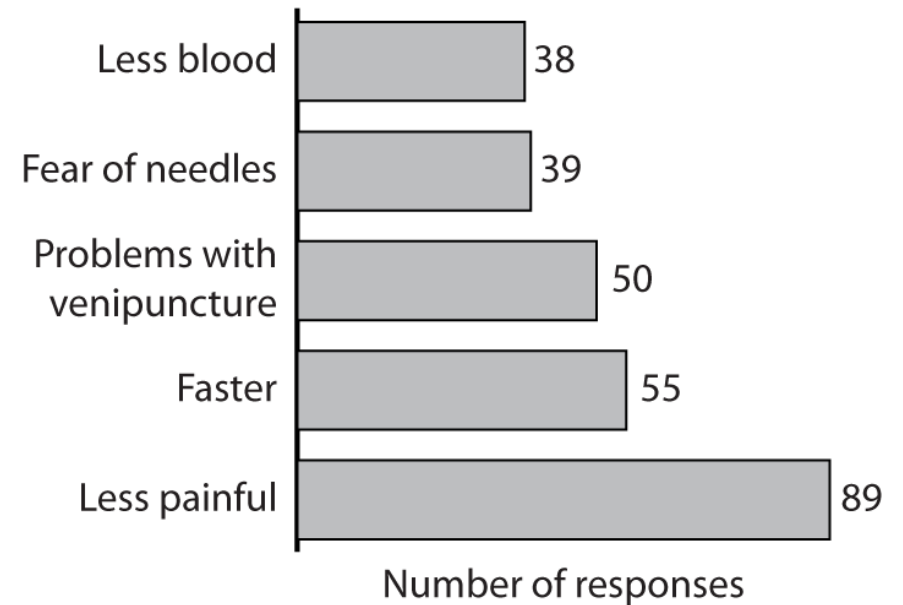


# Patient feedback

Dongle recommended based on:



Fingerprick preference based on:



# 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



# 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.

# Acknowledgements

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