Multiplexed POC System for HIV and Co-Infection Serodiagnosis

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Orlando, FL

Background

- **mBio Diagnostics, Inc., Boulder CO**
- **Collaboration with UCSD**
  - **Drs. Schooley and Benson**
- **Point-of-care (POC); low-cost, instrumented tests**
  - Global health focus

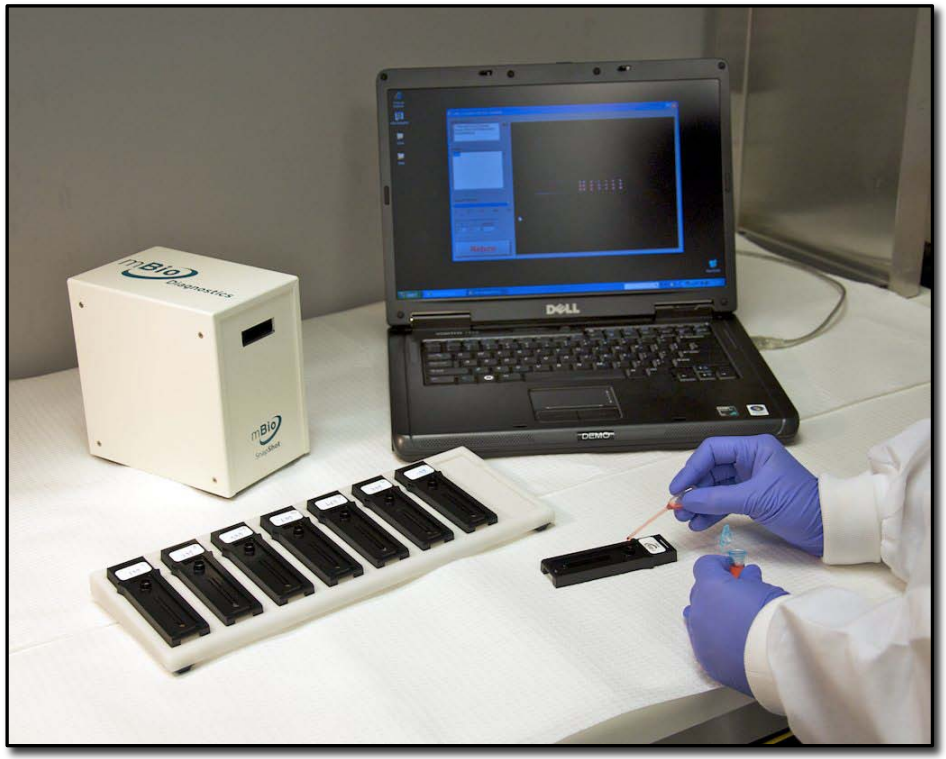
- **MAJOR THEMES**
  - **Multiplexed assay panels at point of care**
  - **Rapid test workflow & cost with lab quality output**

mBio SnapEsi™ System

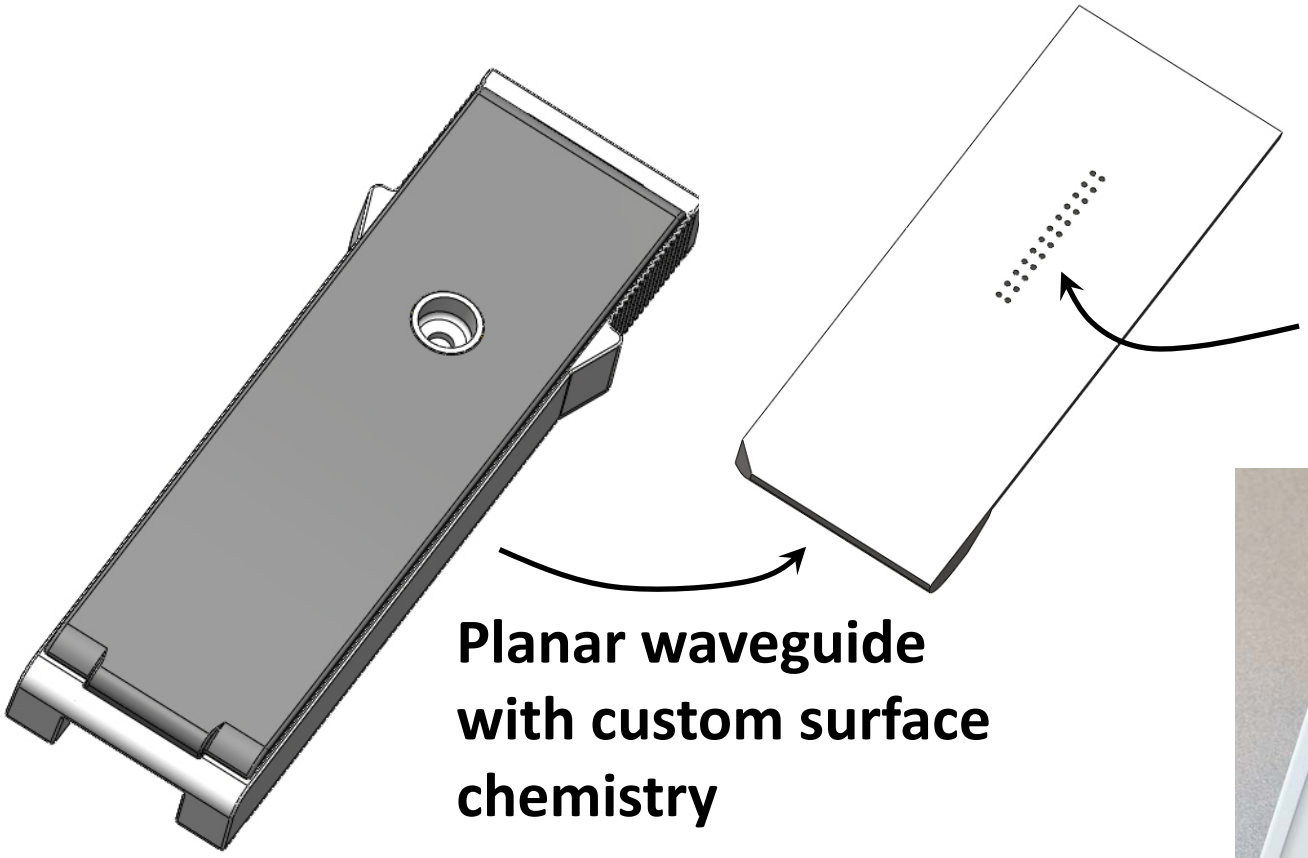
- Fluorescence immunoassays
- Digital and quantitative
- Designing for CLIA-waiver

Address limitations of visually read rapid tests

- **Interpretation**
- **Training; QA/QC**
- **Connectivity**



Multiplexed Serology Assay

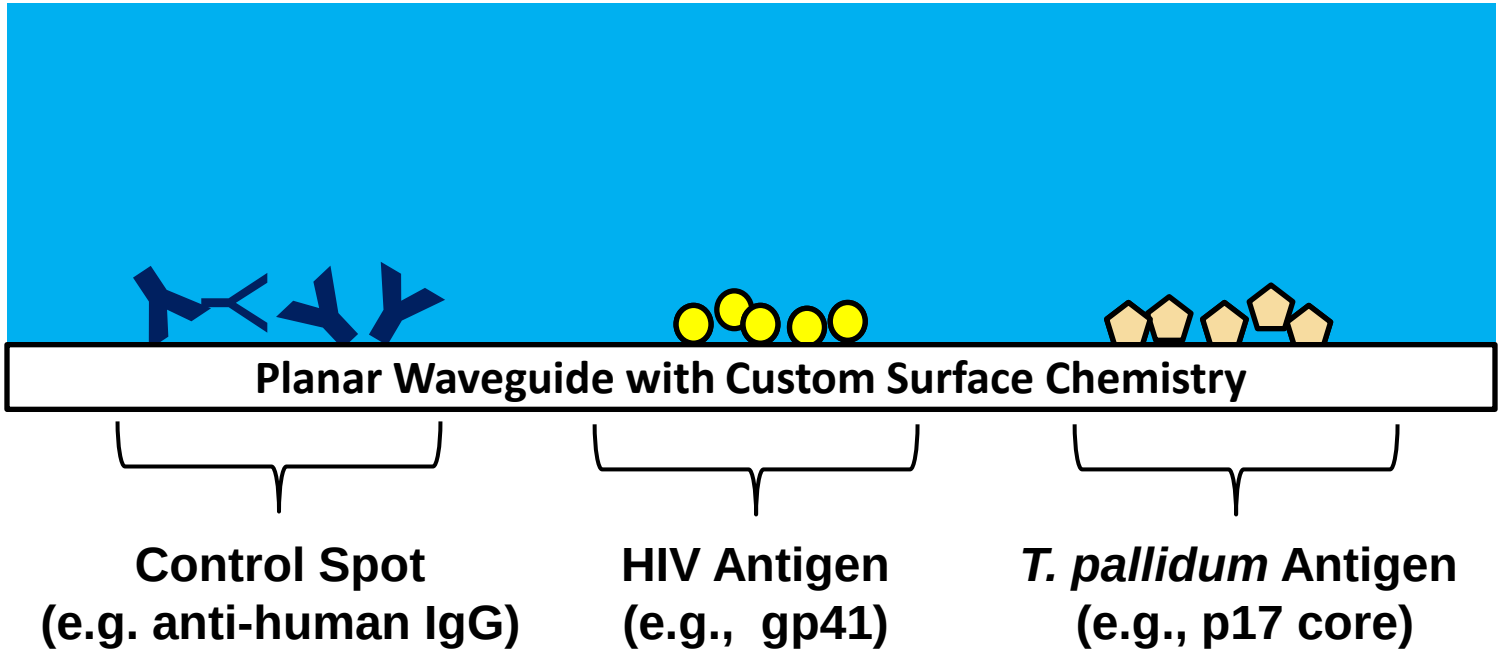


20 to 30 feature microarray

Planar waveguide with custom surface chemistry

Multiplexed Serology Assay

- **Low density microarray in fluidic channel**
  - Printed antigen spots
  - Sample and procedural controls
- **Detect antibodies in serum, plasma, blood**



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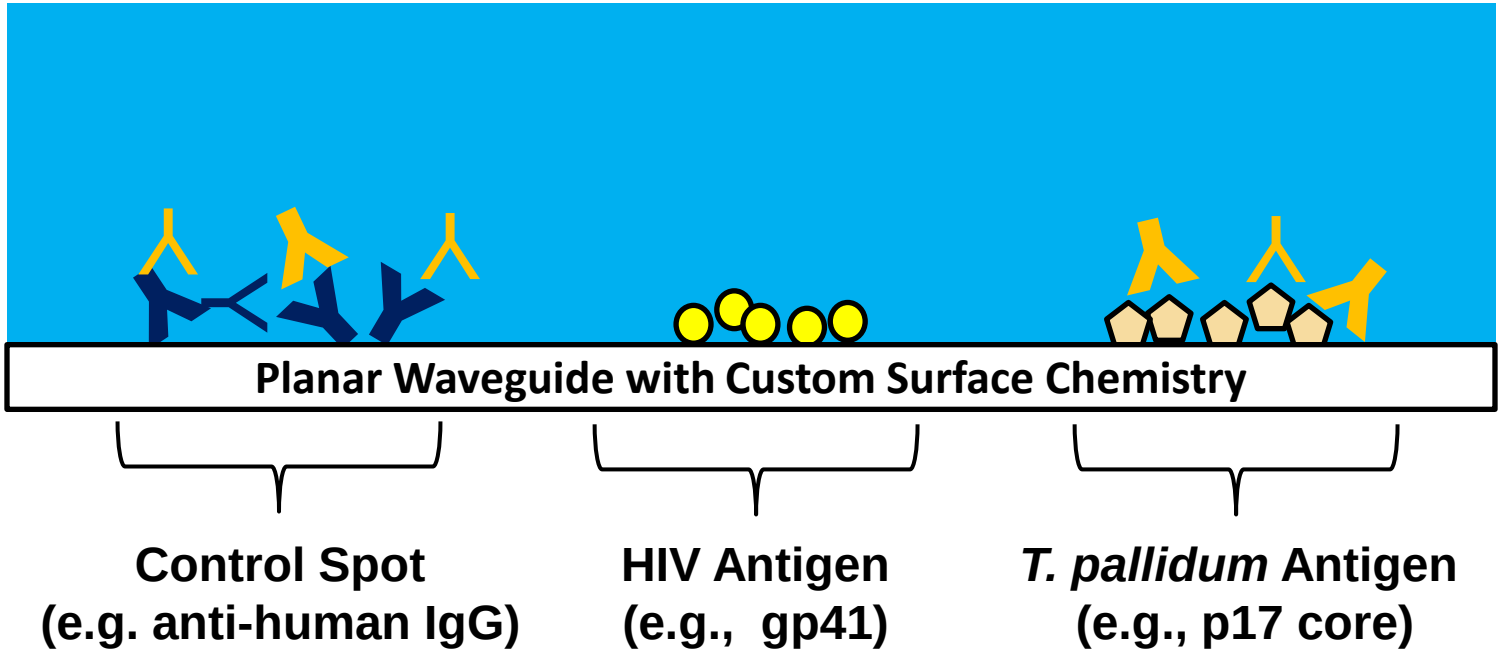

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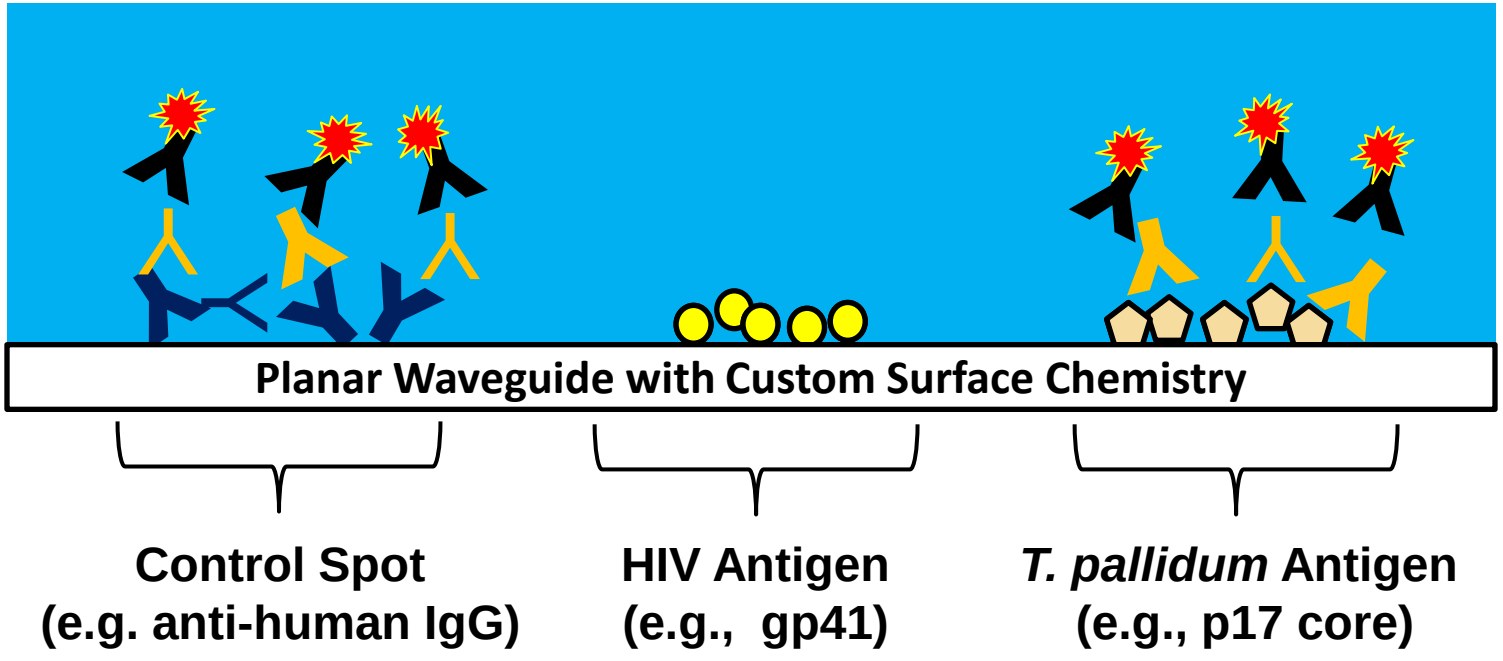
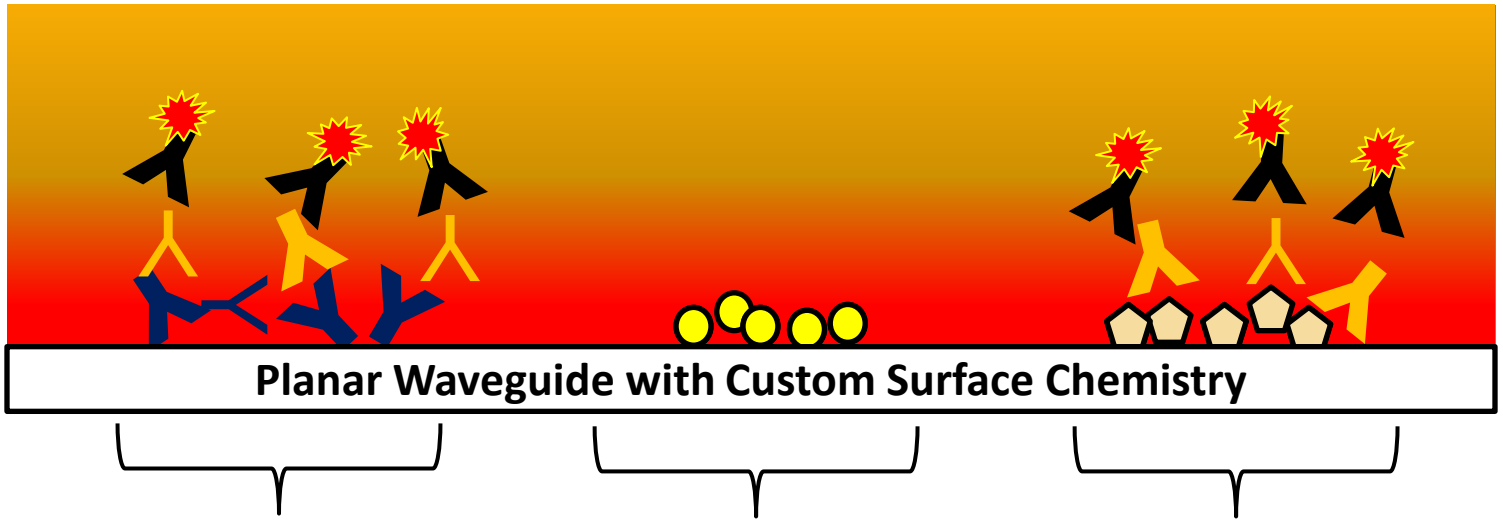
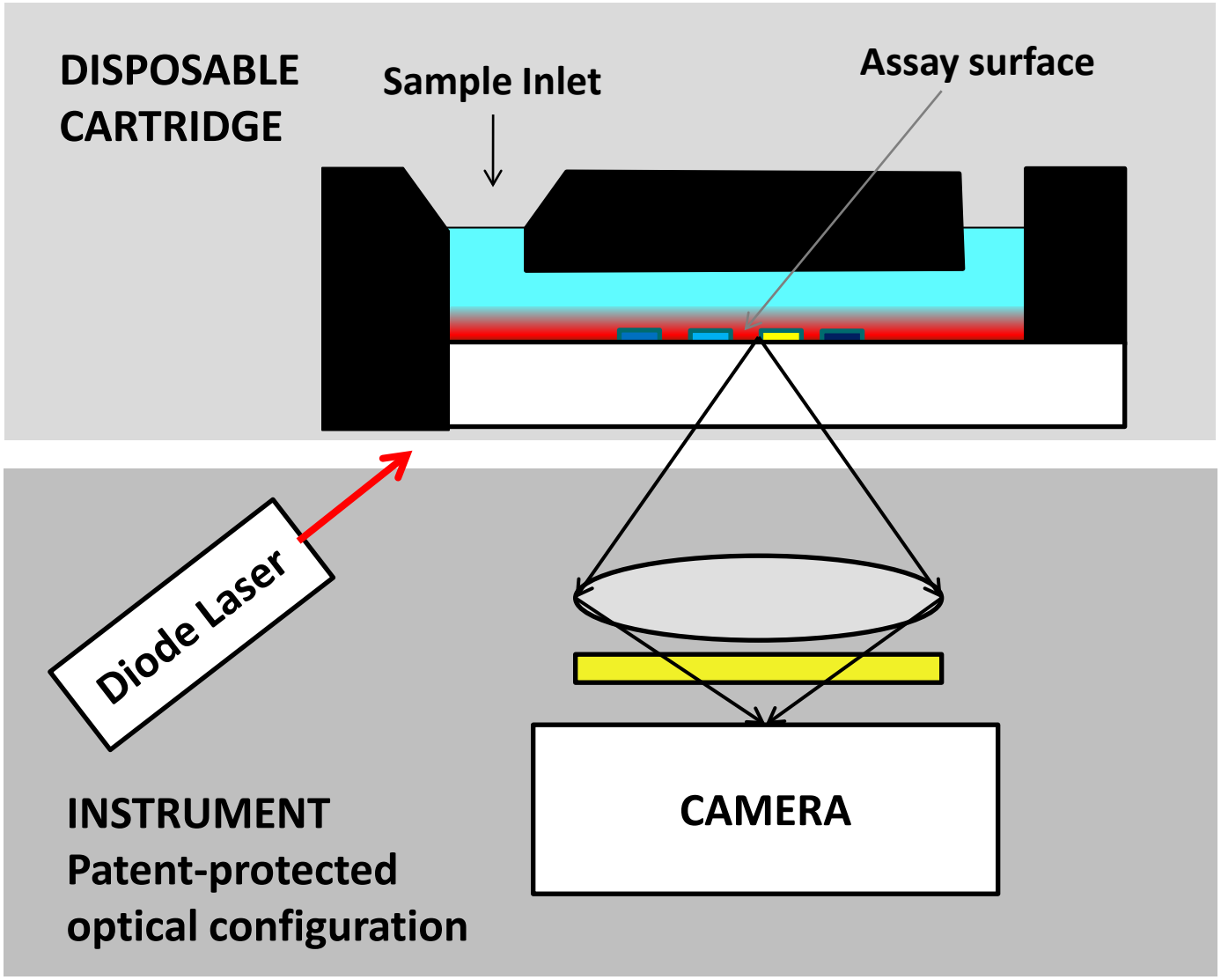


Multiplexed Serology Assay

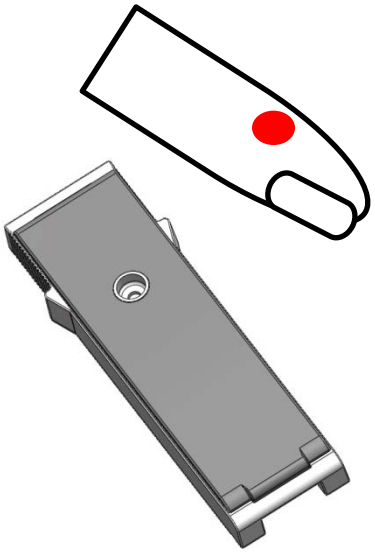
- Fluorescence imaging detection
- Patent-protected planar waveguide design
- Robust, reproducible illumination at very low cost

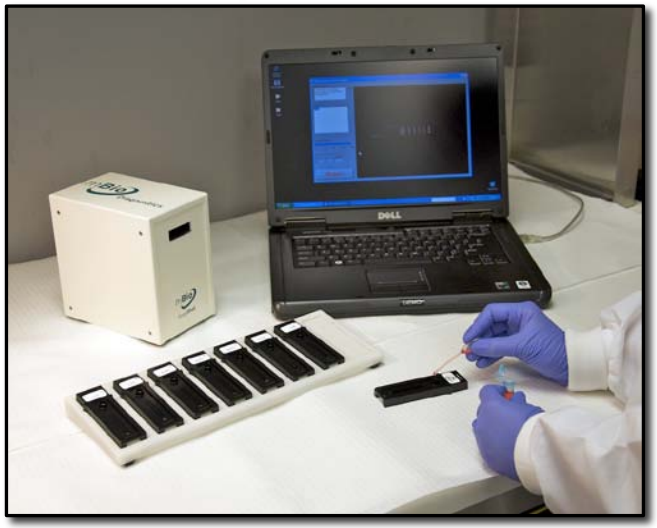


mBio SnapEsi™ System
Low Cost Fluorescence Imaging



SnapEsi™ HIV-1/Syphilis Workflow

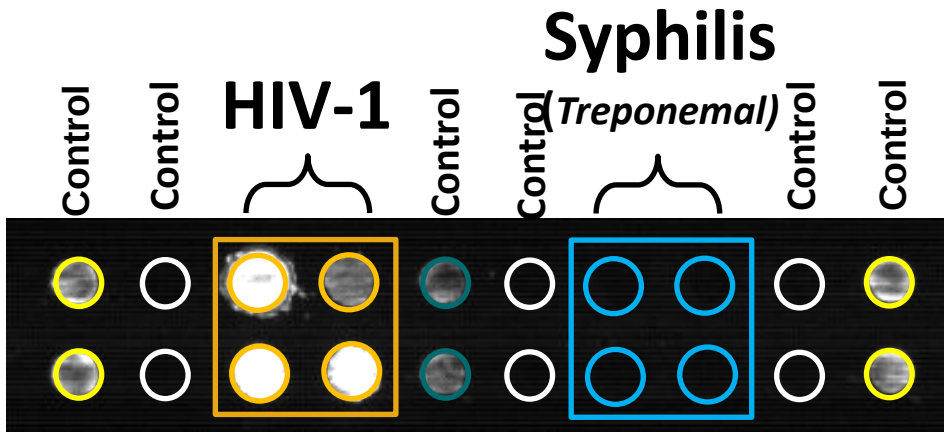




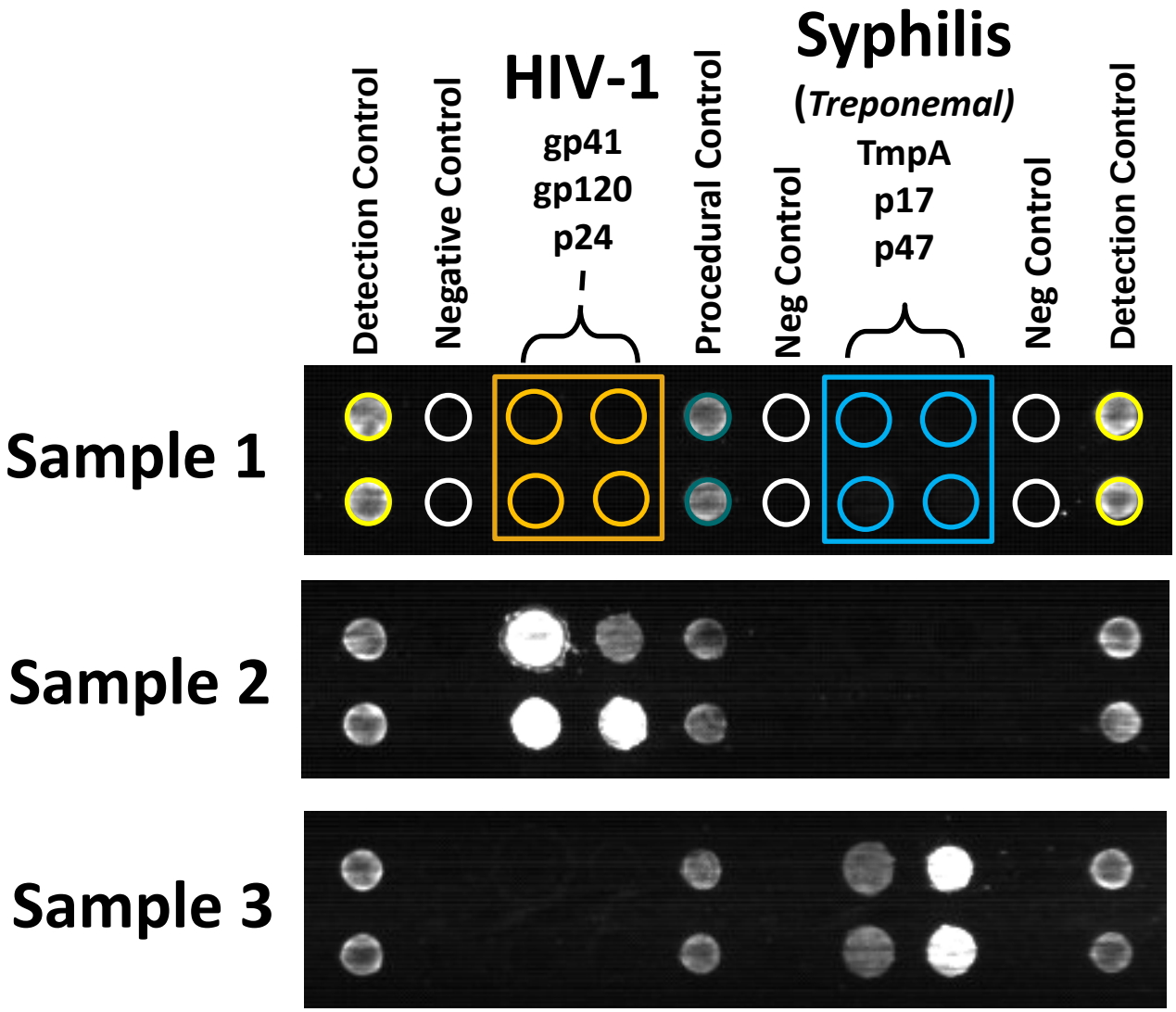
- **5 to 10 microliter sample**
- **Total assay time ~25 min**
- **Batch processing; one operator:**
  - 16 cartridges in parallel
  - 60 to 80 per shift
- **Read window: 10 min to hours**

SnapEsi™ Ab Reactivity Output

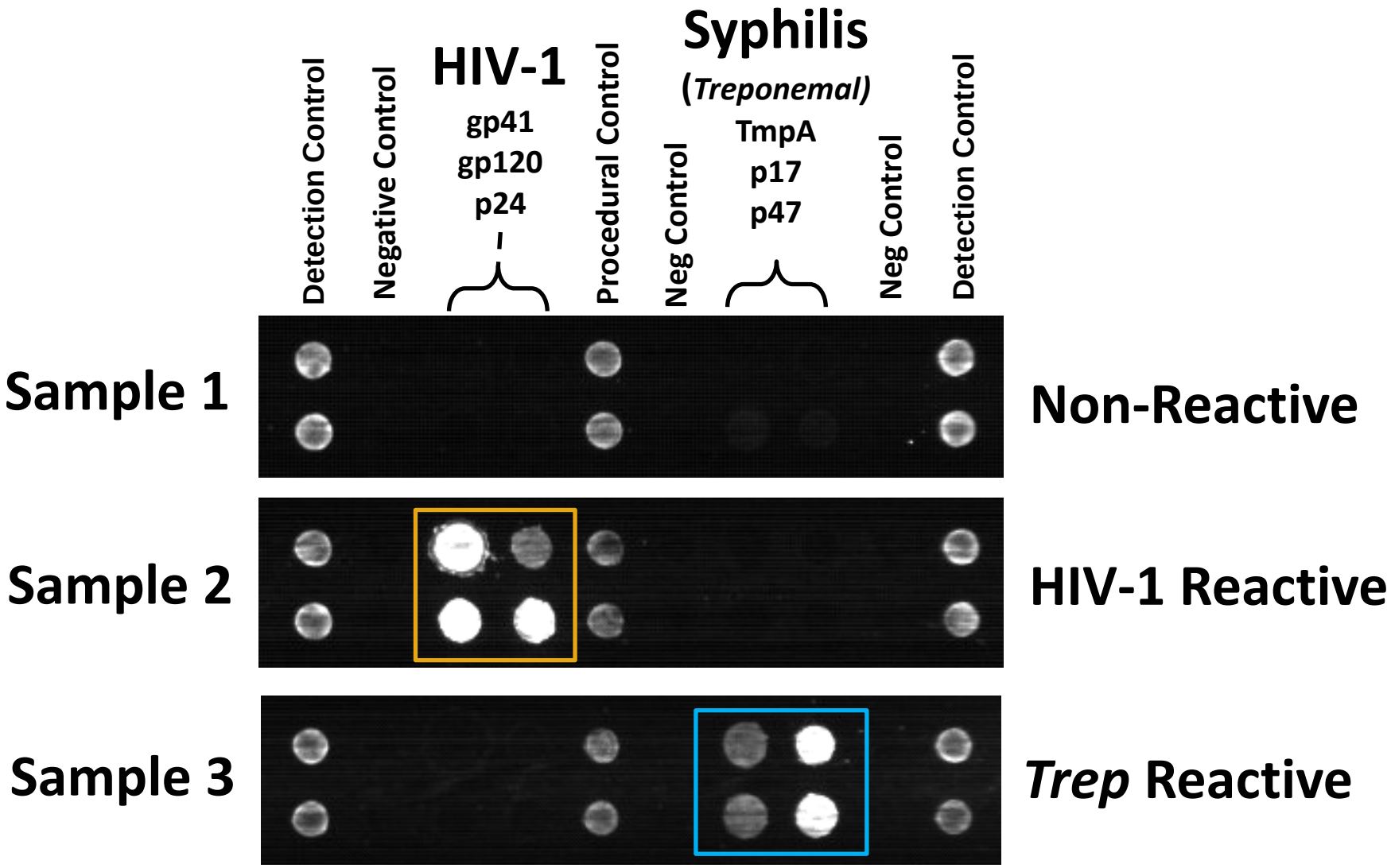
Pathogen	Status	Antibody Reactivity	Signal / Cutoff
HIV	POSITIVE	gp41	5.0
		gp120	5.4
		p24	7.8
T. pallidum	NEGATIVE	p47	0.0
		p17	0.0
		TmpA	0.0
Control	Good Test	Anti-Hu IgG	4.1



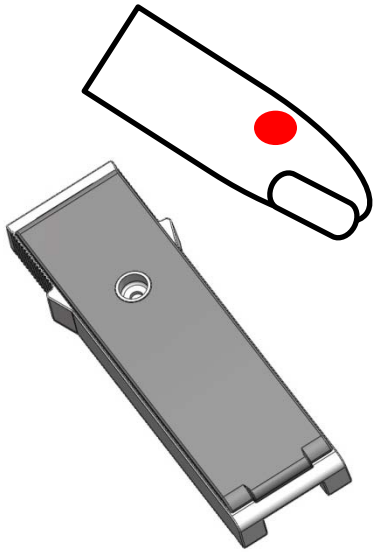
HIV-1 / Syphilis Combination Assay

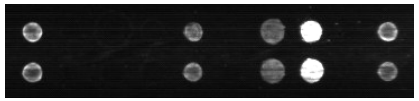


HIV-1 / Syphilis Combination Assay



Example Data Output
Treponemal Ab Reactive Sample





Pathogen	Status	Antibody Reactivity	Signal / Cutoff
HIV	NEGATIVE	gp41	0.0
		gp120	0.1
		p24	0.0
T. pallidum	POSITIVE	p47	5.7
		p17	3.7
		TmpA	8.8
Control	Good Test	Anti-Hu IgG	6.1

HIV-1/Syphilis Clinical Sample Results

- **Serum Samples from University of California San Diego Clinical Micro Lab** (Siemens ADVIA Centaur analyzer)
- **Commercial controls (including negatives)**

❖ **Sensitivity and Specificity based on same dataset used to establish cutoffs**

HIV		**n =**	**170**
True Pos	False Neg*	True Neg	False Pos
54	1	115	0
Sensitivity		**Specificity**	
98.2%		**100.0%**	

*Also negative on OraQuick®

HIV-1 Seroconversion Panel
PATH (Seattle, WA) Evaluation Result

		mBio SnapEsi™	Abbott EIA	Maxim Western Blot	Siemens Advia Centaur
Sample	**Days since 1st bleed**	**Result**	**s/co**	**Result**	**s/co**
PRB956-01	0	NEG	0.1	NEG	0.1
PRB965-02	5	NEG	0.1	NEG	0.1
PRB965-03	7	NEG	0.2	NEG	0.7
PRB965-04	12	POS	>17.7	IND	>50
PRB965-05	14	POS	>17.7	POS	>50
PRB965-06	21	POS	7.6	POS	>50
		PATH Result	**Package Insert Data**		

mBio SnapEsi Syphilis (*Treponemal*) Clinical Serum Sample Results

***T. pallidum* Positives**

- **46 confirmed *Trep*-positive (TPPA)**
- **45 SnapEsi POS; one indeterminate**
- **97.8% Sensitivity**

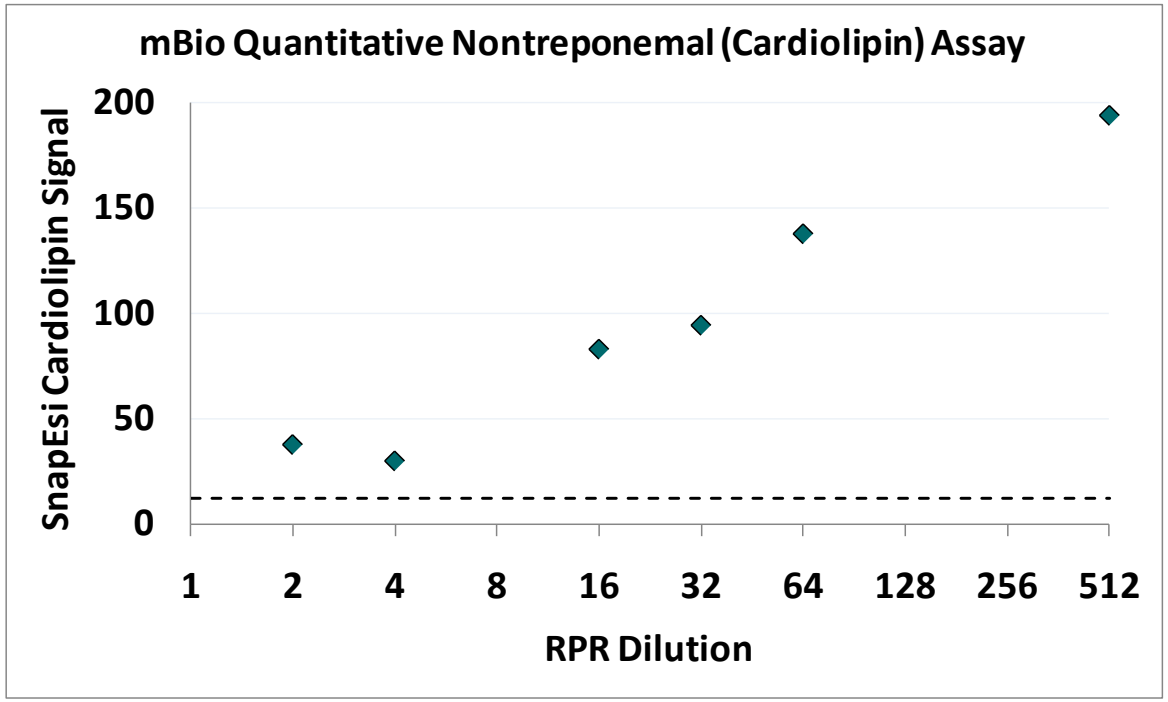
RPR Negatives

- **111 RPR negatives**
- **108 SnapEsi *Trep* NEG**
- **3 SnapEsi POS are likely resolved/treated infection**

SnapEsi™ Syphilis T/NT
(Treponemal / Nontreponemal)

- **Preliminary quantitative anti-cardiolipin results**

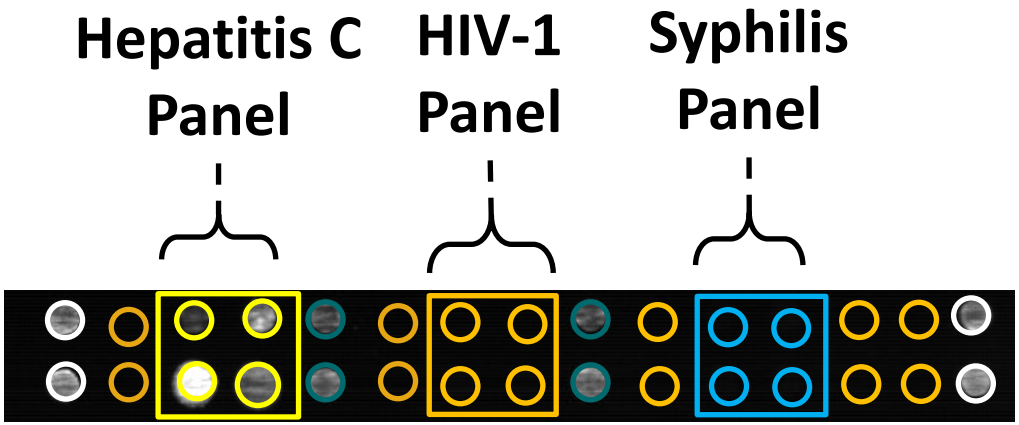
Anti-cardiolipin assay in same array as anti-*T. pall* assay



Dashed line is signal for pooled normal human serum.

mBio Development Pipeline:
Quantitative Antigen Detection & Panel Expansion

- Hepatitis B Surface Antigen (HBsAg)
- HIV-1 p24 direct antigen detection
- HIV-2 serology
- Hepatitis C serology



Summary

- Simple, low-cost fluorescence imaging system with disposable assay cartridge
- mBio focus: HIV, coinfection, global health apps

- **MAJOR THEMES**
  - Multiplexed assay panels at point of care
  - Rapid test workflow & cost with lab quality output

Acknowledgements - Collaborators

Clinical Collaborators:

Dr. Robert Schooley (UCSD)
Dr. Constance Benson (UCSD)
Dr. Sharon Reed (UCSD)

- Dr. Emilia Noormahomed (Mozambique)
- Dr. Roberto Badaro (Brazil)

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- Kurt Vogel