

Axela: Accelerating Biomarkers through Research to Diagnostics

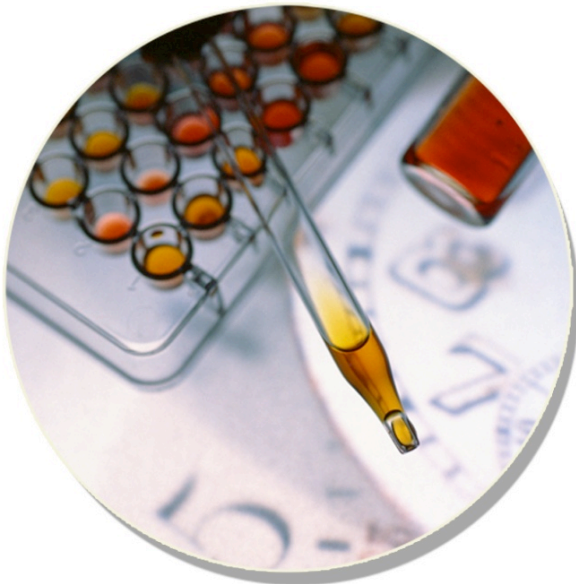
Paul Smith
p.smith@axela.com



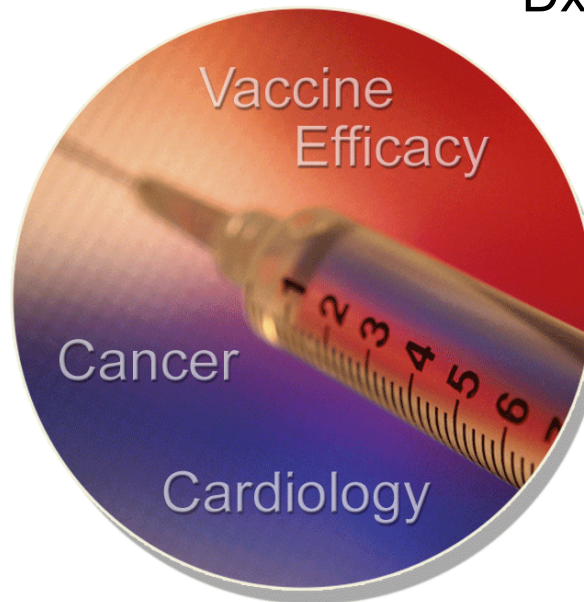
Axela's Business Strategy

Enabling Leader in Personalized Medicine Research

Research Tools & Clinical Research Today - Tomorrow's Personalized Dx



Significantly improve efficiency of post discovery biomarker assay development and validation



Capitalize on game changing methods for interpreting molecular interactions in health research



Leverage proprietary technology advantage to deliver novel diagnostics

The Opportunity in Personalized Medicine

Clinical research and diagnosis is hampered by the limited information derived from current test methods



Axela provides new dimensions to Biomarker Testing

Initial focus on Oncology and Infectious Diseases

Enabled by Diffractive Optics Technology

Leverage more information from a single test

Multiplex Quantitation +
Avidity
Isotype
Isoforms
Modifications

Biomarker Panels
Early Detection and Stage
Immune Status
Direct Virus and Bacteria

Real Time *Plus* Multiplexing

Combines applications of interaction, bead and plate immunoassay in a single point of science platform

Interaction applications ***Plus*** “real world” samples

Protein Multiplexing ***Plus*** “pick and play” flexibility

New Dimensions in Biomarker Testing

Early diagnosis

- autoantibodies: level and avidity, high sensitivity biomarker analysis

Complexity of Disease and Diagnosis

- mix and match multiplex

Rapidly Emerging Biomarkers/Pathogens

- common platform for development and deployment

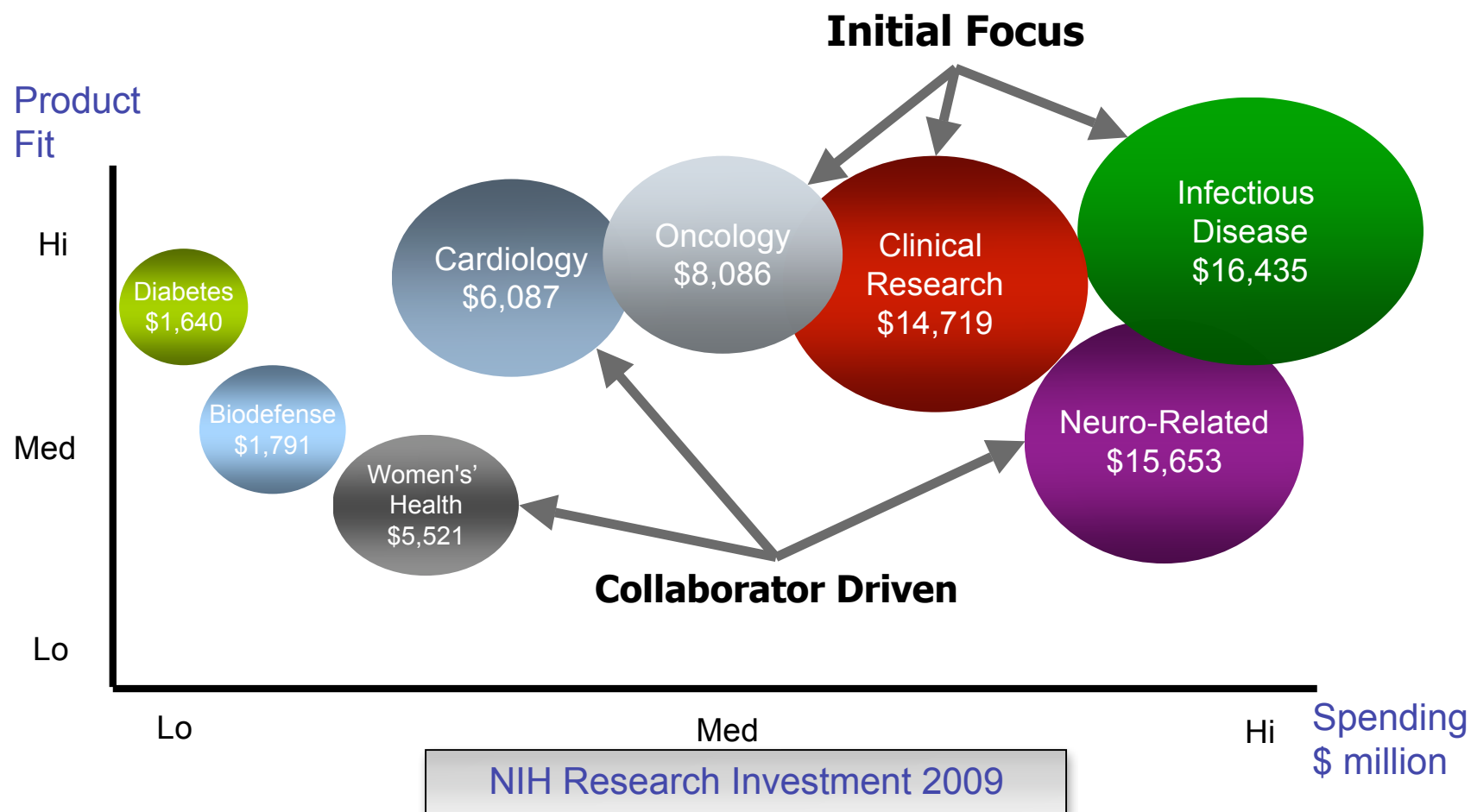
Full Characterization of marker/virus/bacteria

- disease detection plus serology (titer/avidity/isotype), biomarker quantitation plus isoforms/PTM's

Prevention

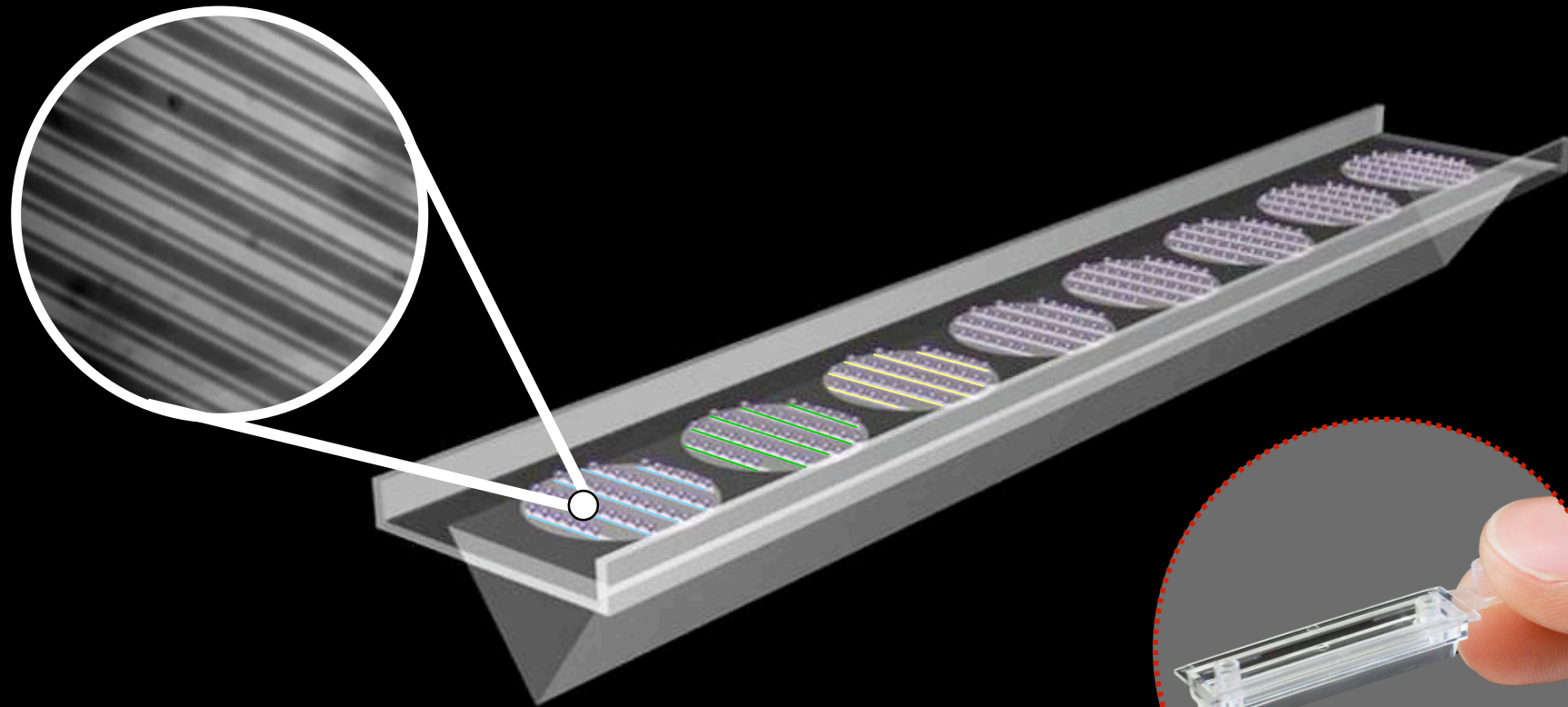
- direct vaccine response monitoring, immunogenicity

NIH Spending Relative to Axela Focus

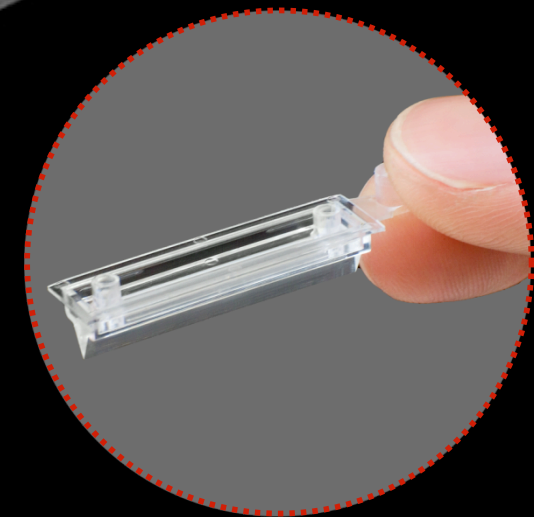


Diffractive Optics Technology

dotLab® Sensors



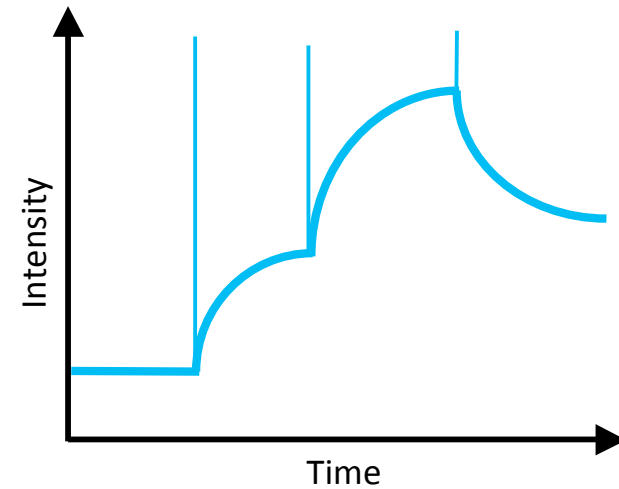
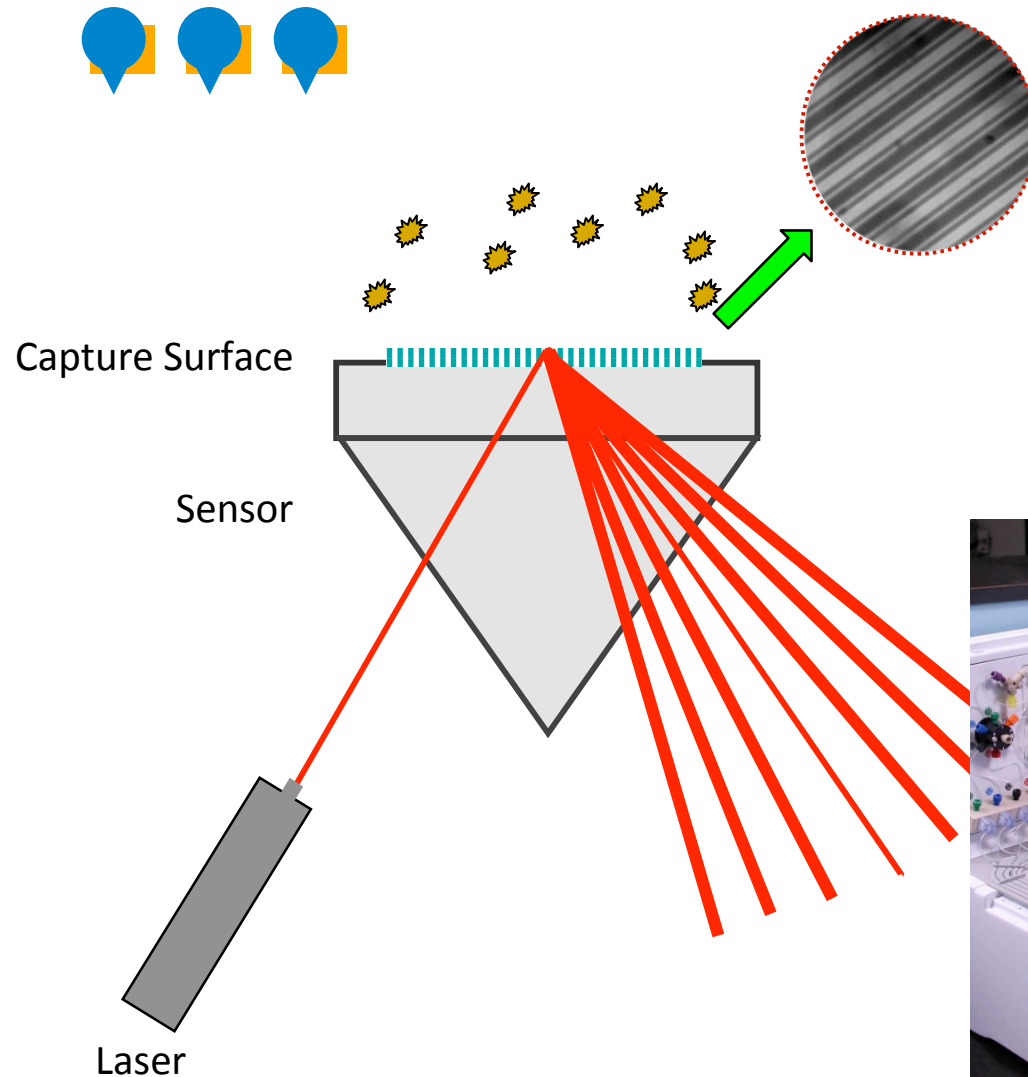
Ligand (*e.g.* antibodies) is immobilized onto dotLab Sensors in specific line patterns that form a diffraction grating



dotLab® Sensor

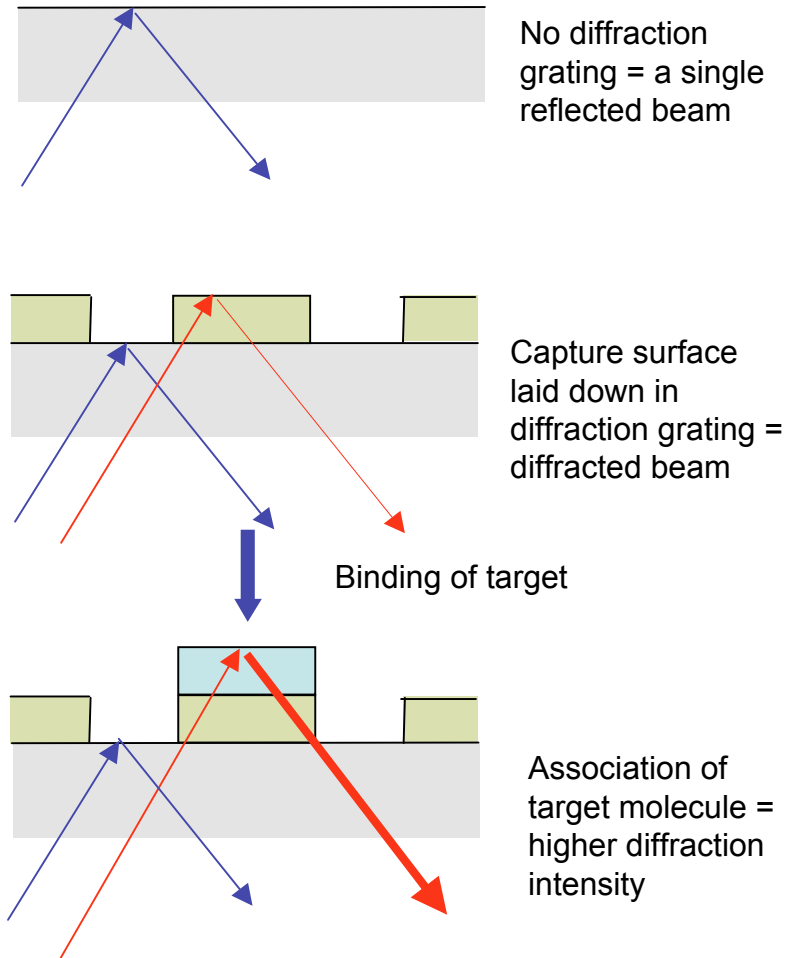
Diffractive Optics Technology

Combining Affinity Capture with Diffractive Optics

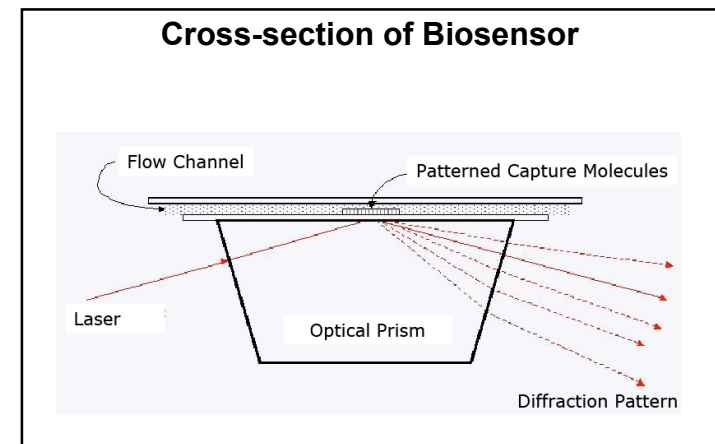


Diffraction Optics Technology

Inherent Self-referencing adds greater flexibility

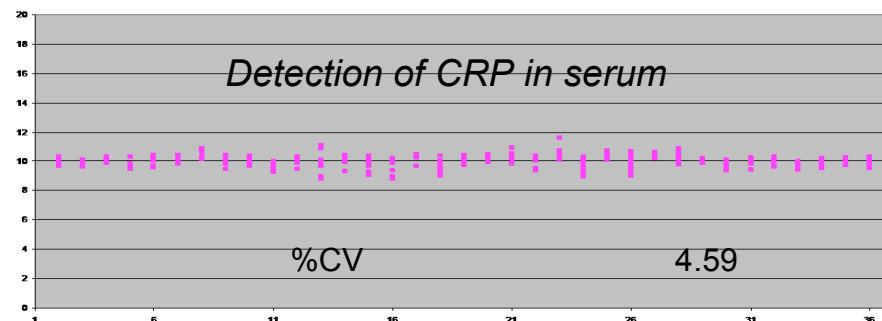
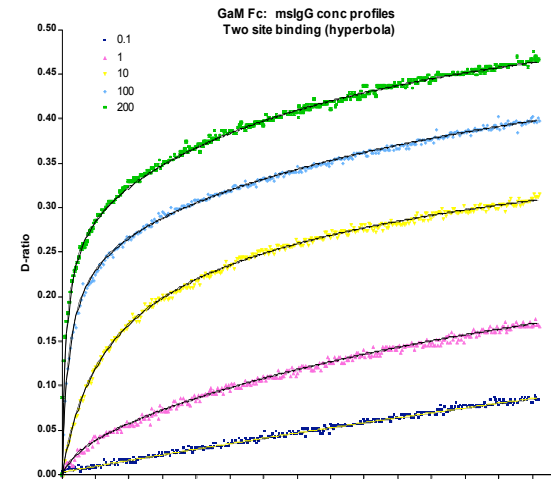
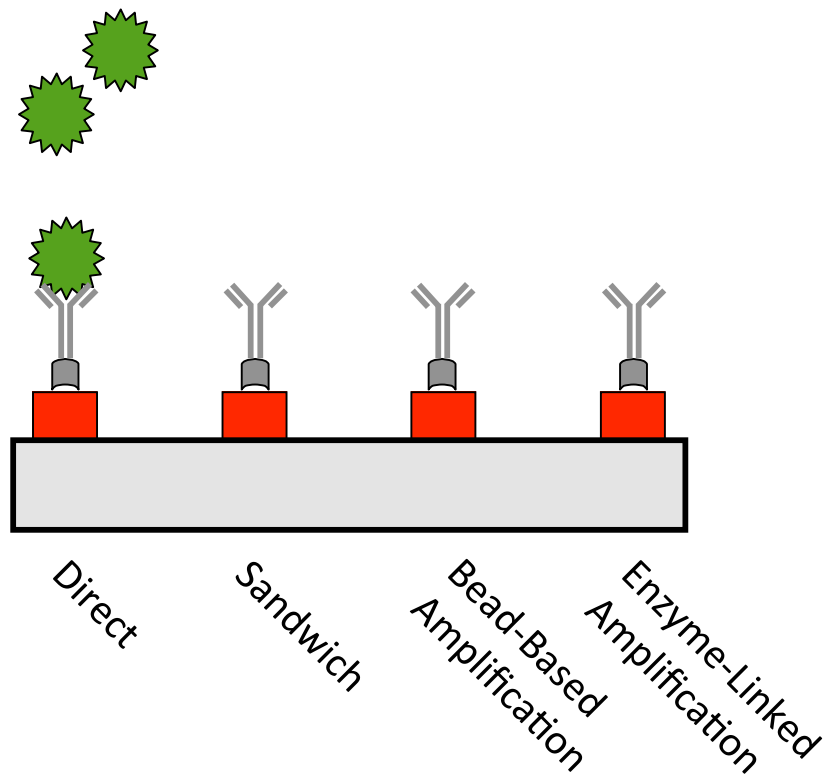


- Reduced impact of non-specific binding
- Allows direct measurement in complex media
- No requirement for separate reference channel
- Allows broad range of experimental formats
- Removes flow artifacts and allows vigorous mixing
- Significantly reduces sample volume requirements



Real-time plus flow & multiple assay formats: Direct Detection

Label free, direct detection
Rapid and Precise

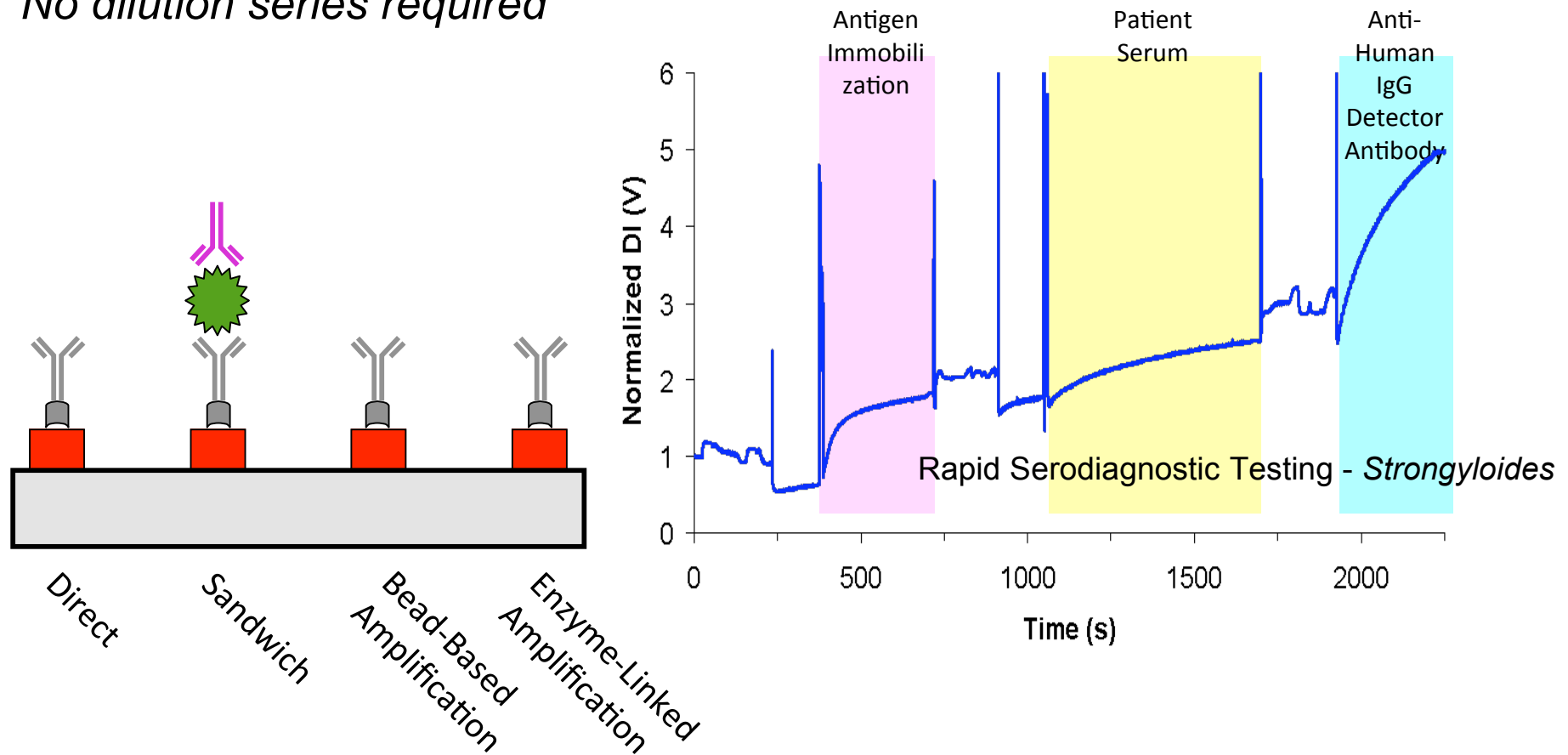


Real-time plus flow & multiple assay formats:

Sandwich Assay Provides Specificity

Rapid quantitation

No dilution series required

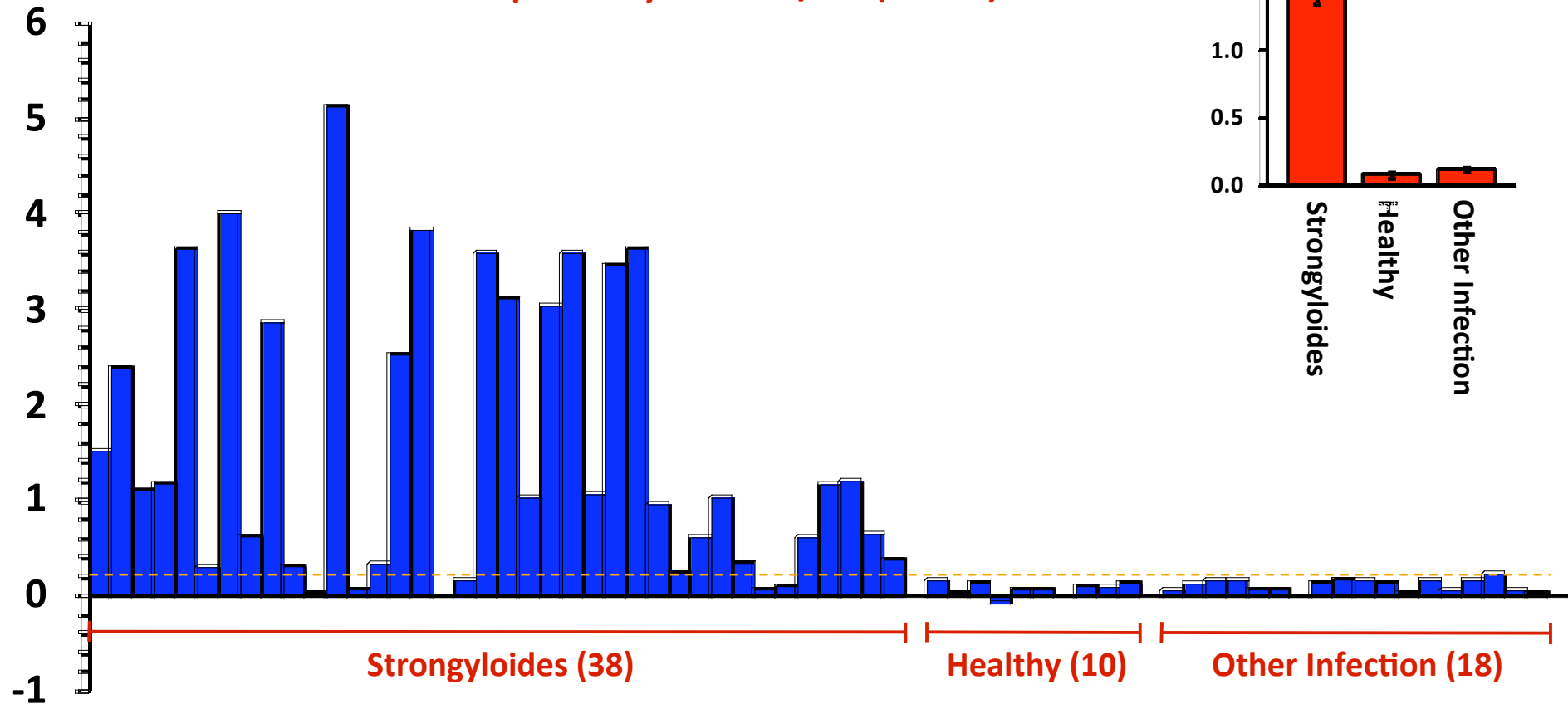


Strongyloides Serological Assay

Patient antibody titre summary

Sensitivity – 32/38 (84.2%)

Specificity – 27/28 (96.4%)

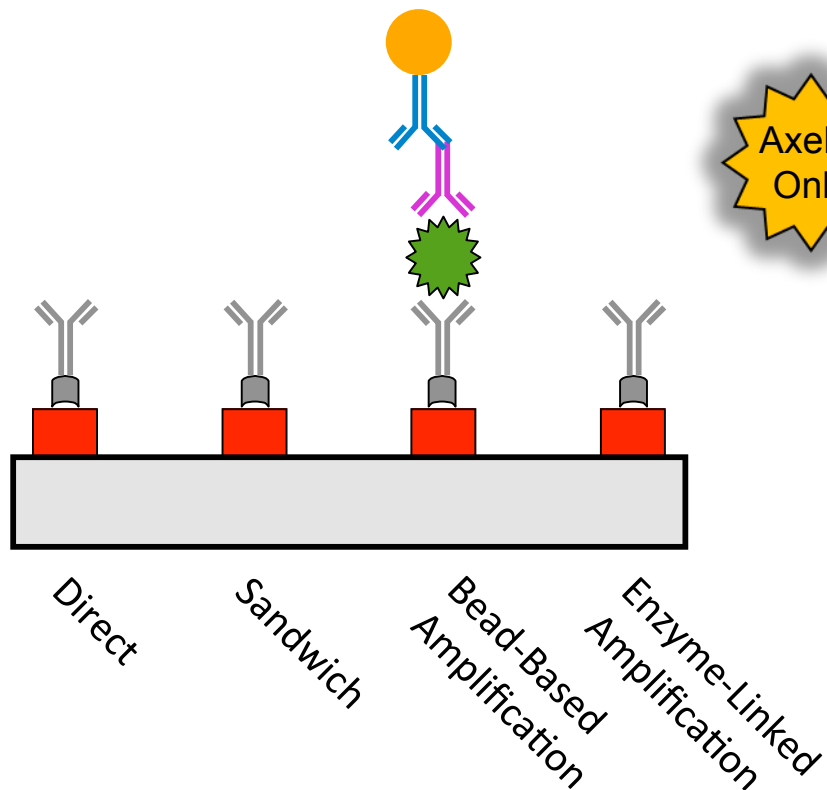


Collaborator: Dr. Momar Ndao, National Reference Centre for Parasitology/McGill University

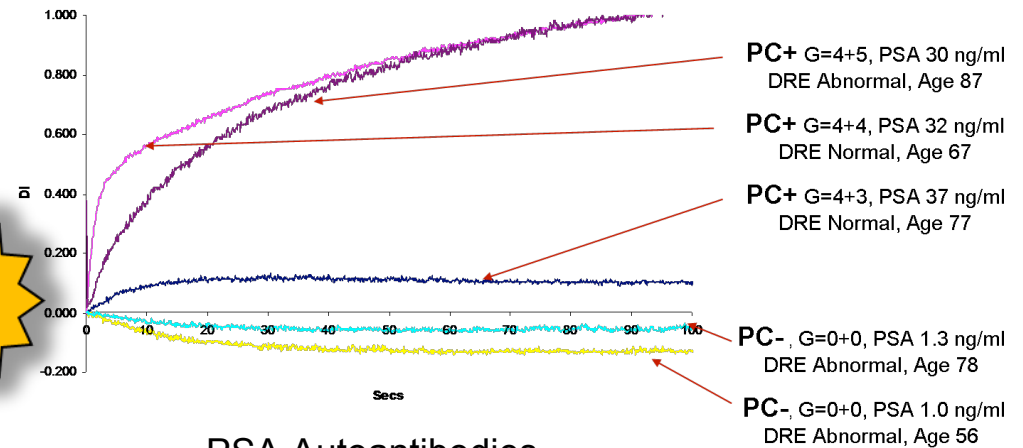


Real-time plus flow & multiple assay formats: Bead Based Amplification for High Sensitivity

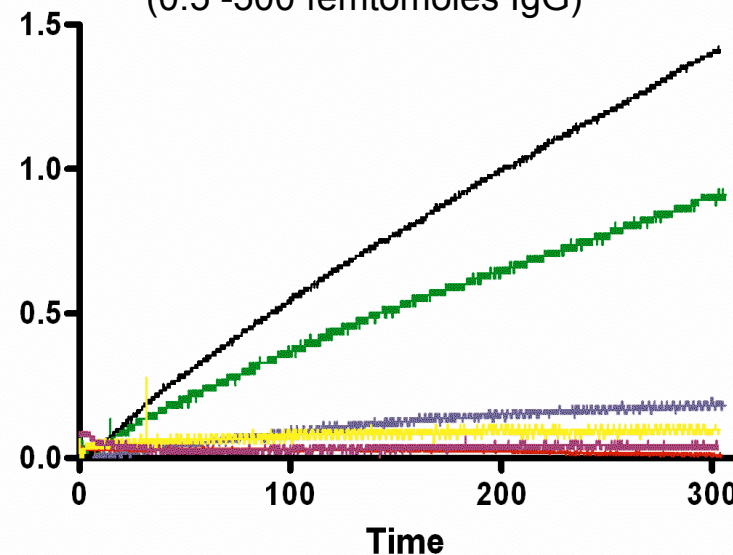
*Direct characterization of
autoantibodies for early disease
detection*



Binding Curves for Serum (8 ul) to immobilized r-PSA

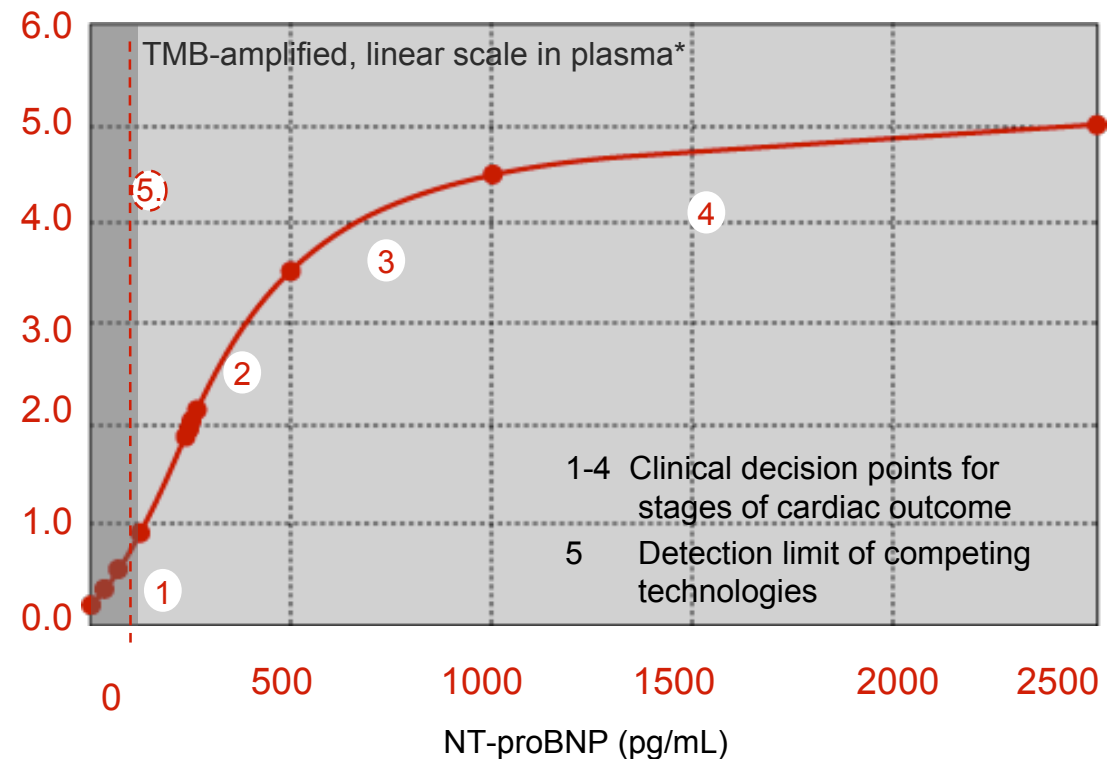
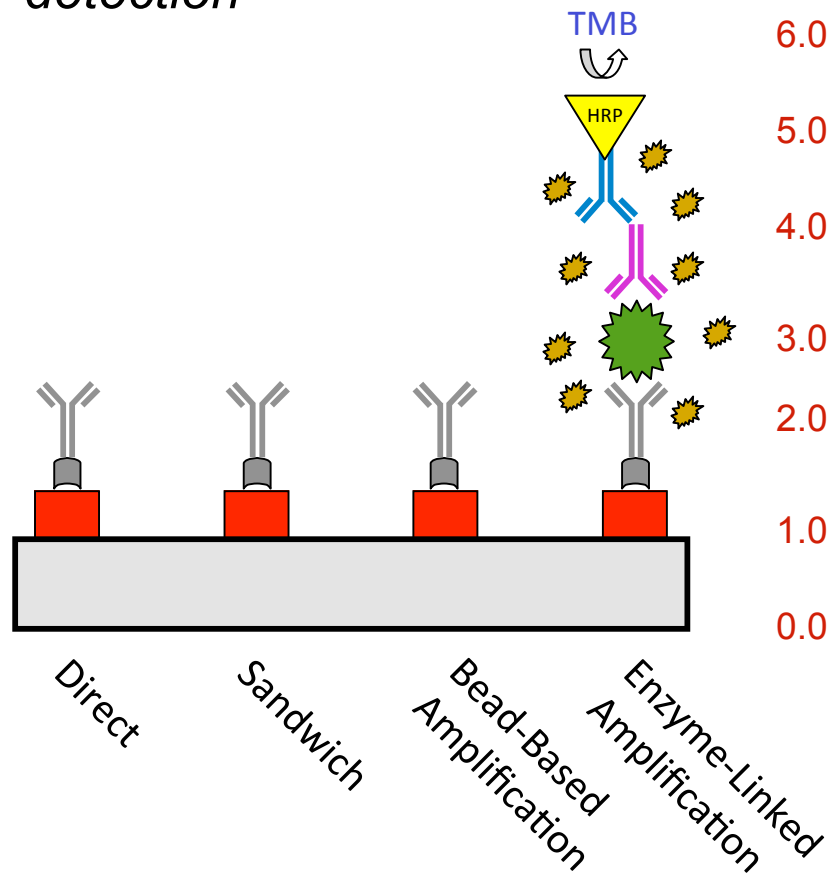


PSA Autoantibodies
(0.5 -500 femtomoles IgG)



Real-time plus flow & multiple assay formats: Universal Enzyme Signal Enhancement

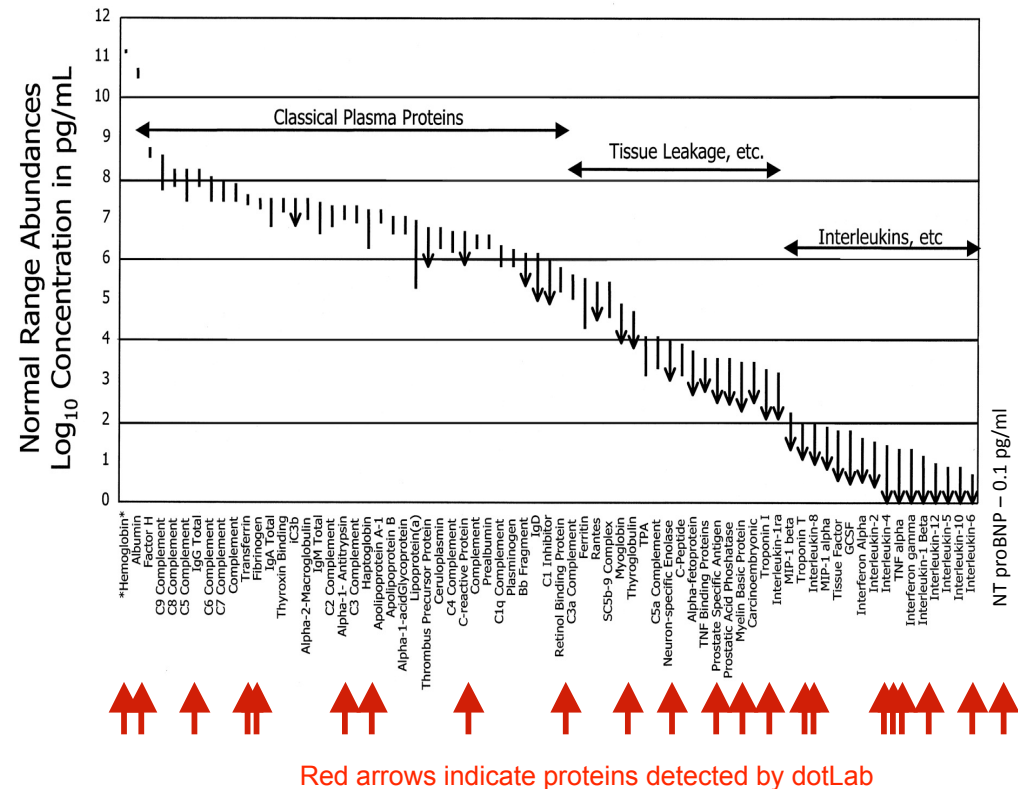
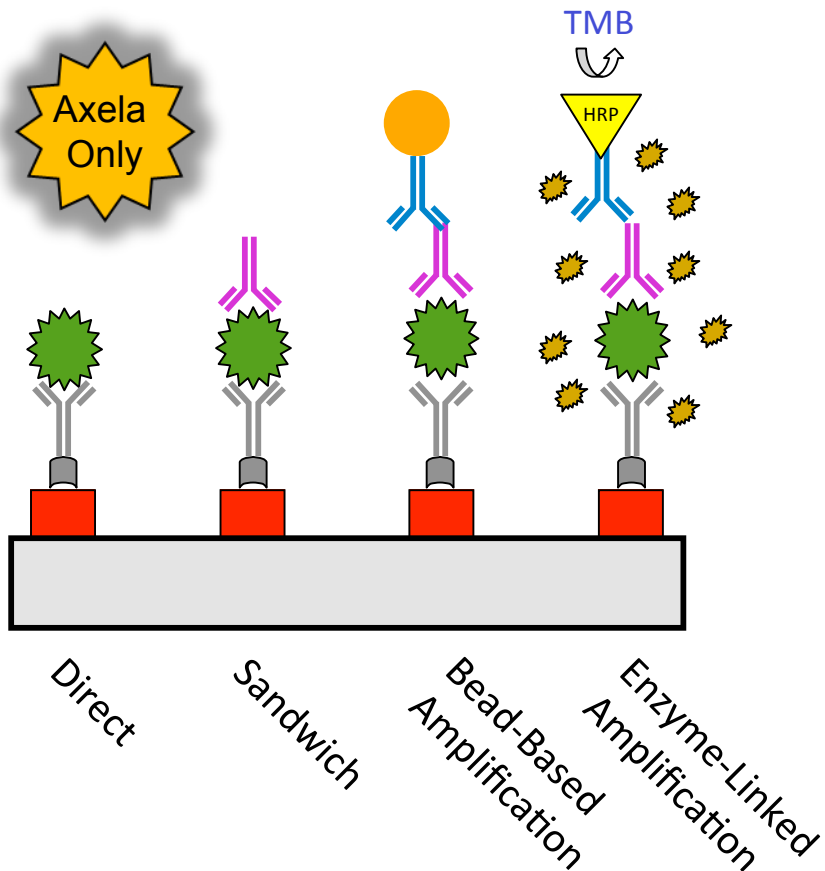
High sensitivity biomarker
detection



Real-time plus flow

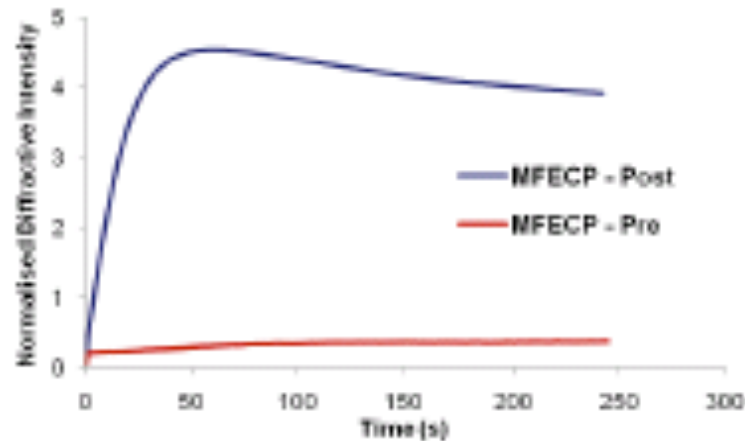
Multiple Assay Formats Provide Unmatched Dynamic Range

Addresses the entire serum proteome:
multiplex independent of abundance

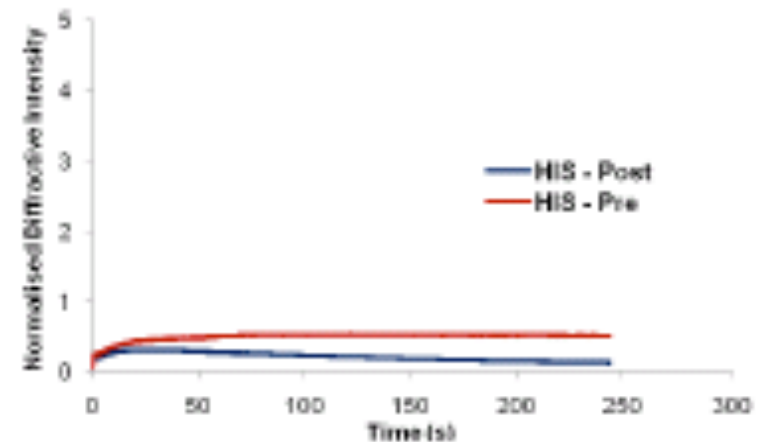


Direct Immunogenicity monitoring – epitope specific

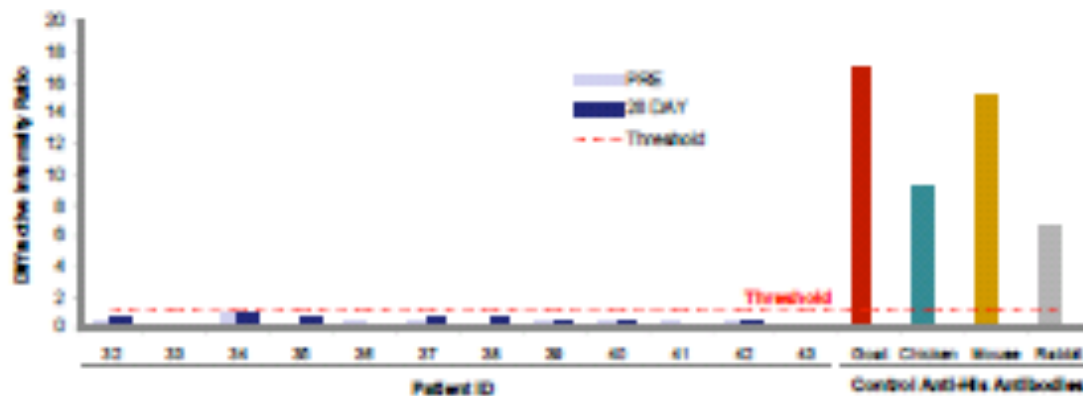
Anti-MFECP response



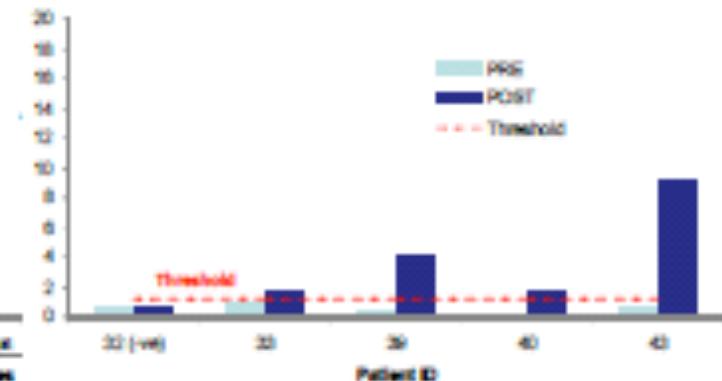
Anti-His response



Human anti-His response



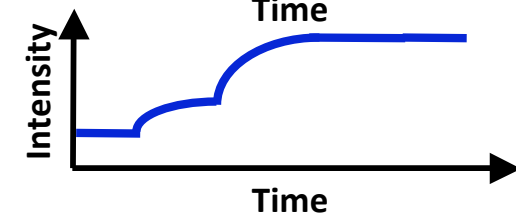
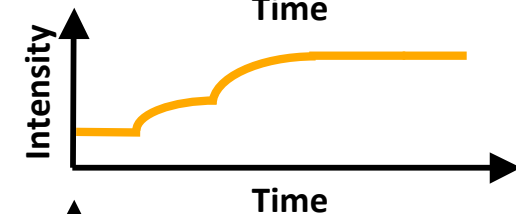
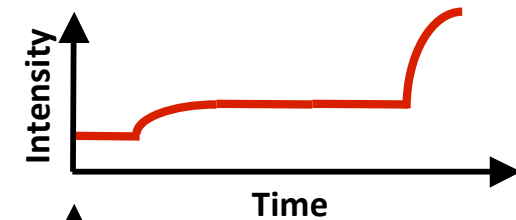
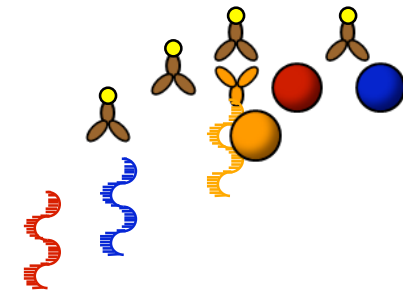
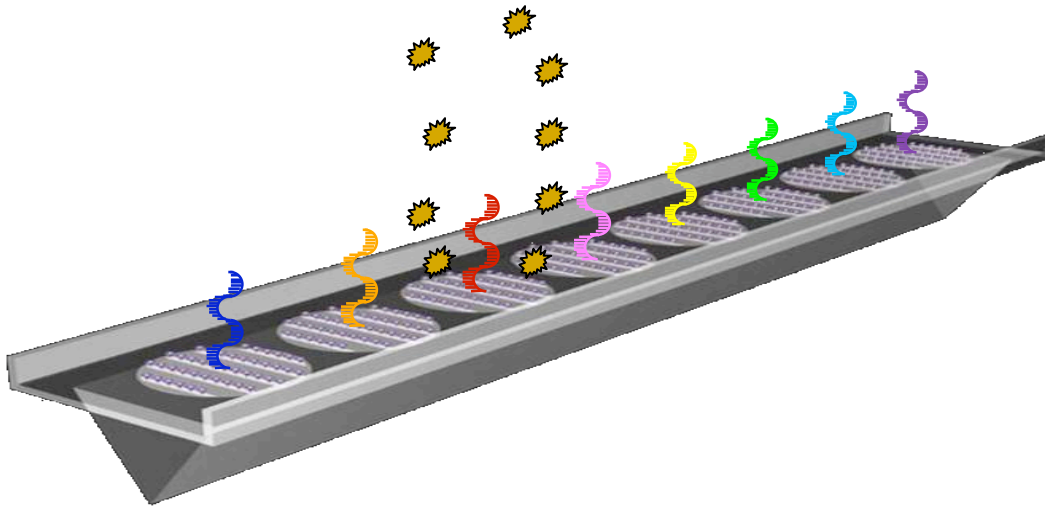
Human anti-MFECP response



panelPlus Sensors

User configurable panels using addressable reagents

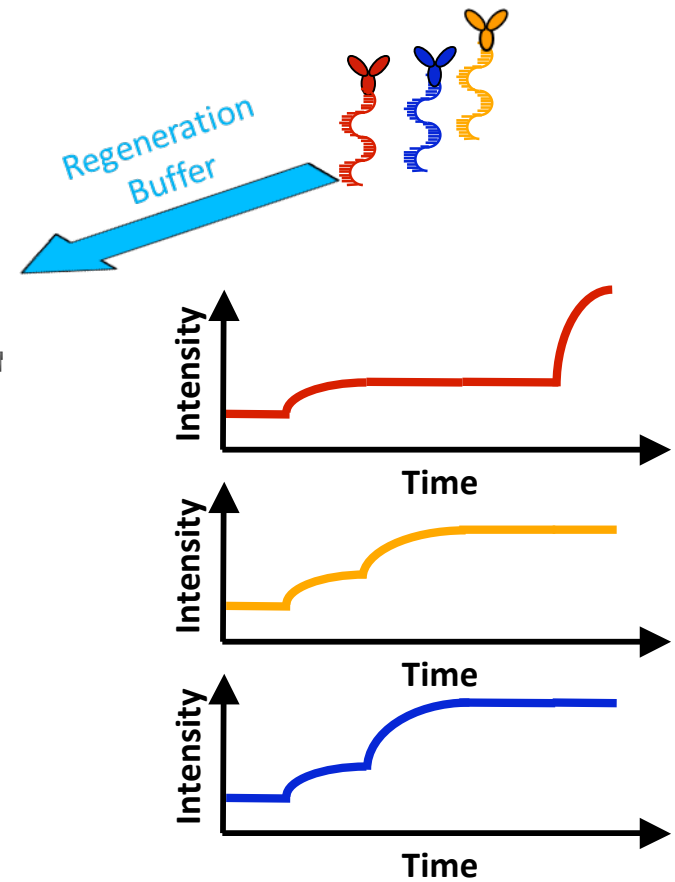
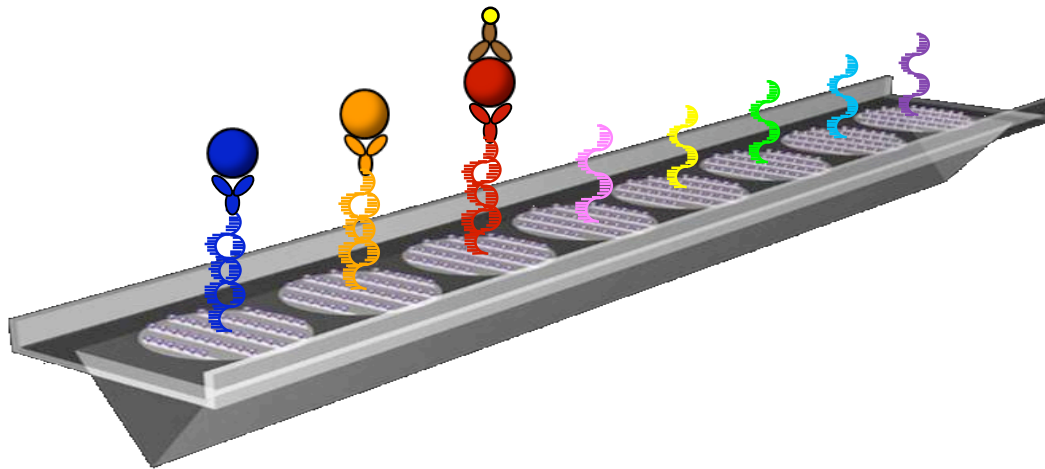
1. Off-Line Analyte Conjugation
or Selection From Pre-Conjugated Menu
2. Hybridization
3. Sample Incubation
4. Amplification (if necessary)



panelPlus Sensors

User configurable panels using addressable reagents

1. Off-Line Analyte Conjugation
or Selection From Pre-Conjugated Menu
2. Hybridization
3. Sample Incubation
4. Amplification (if necessary)
5. Regeneration



Combine discoveries with well characterized biomarkers: **Speed Validation**

panelPlus Initial Menu

Oncology

AFP

CEA

CA125

CA15-3

CA19-9

PSA

PSA free

beta-hCG free

beta-2

Microglobulin

Infection Disease

H. Pylori (IgG, IgM)

TORCH:

Toxo IgG

Rubella IgG + IgM

CMV IgG + IgM

HSV-1 IgG + IgM

HSV-2 IgG + IgM

Toxo IgG + IgM

Marker Conjugation Kits to
include your own content

Cardiology

CK-MB

Fatty Acid Binding Protein

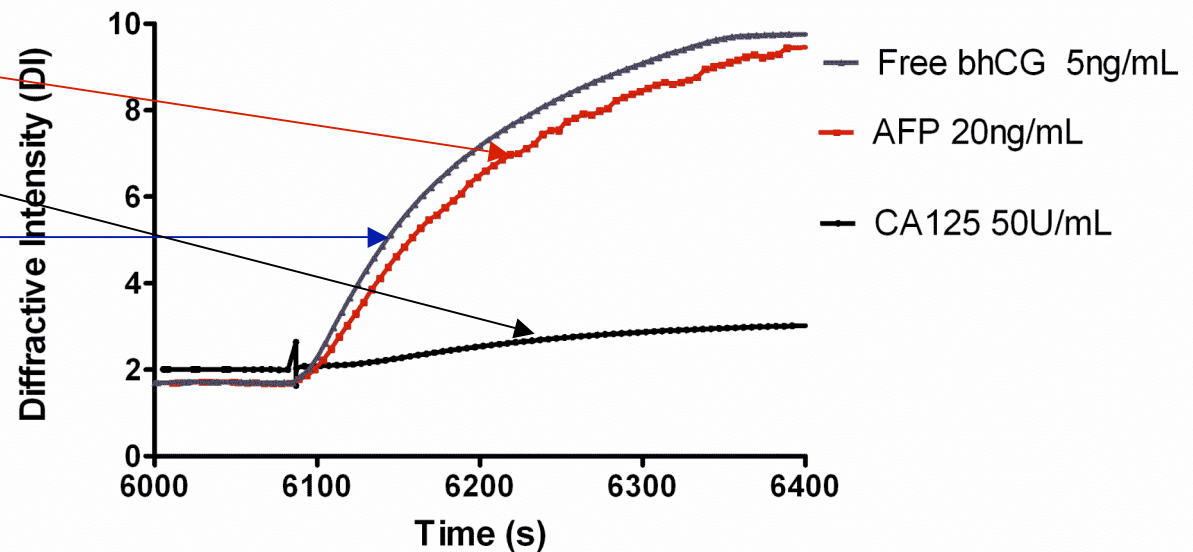
CRP

Troponin I

Myoglobin

MPO (Myeloperoxidase)

CA125/AFP/Free bhCG



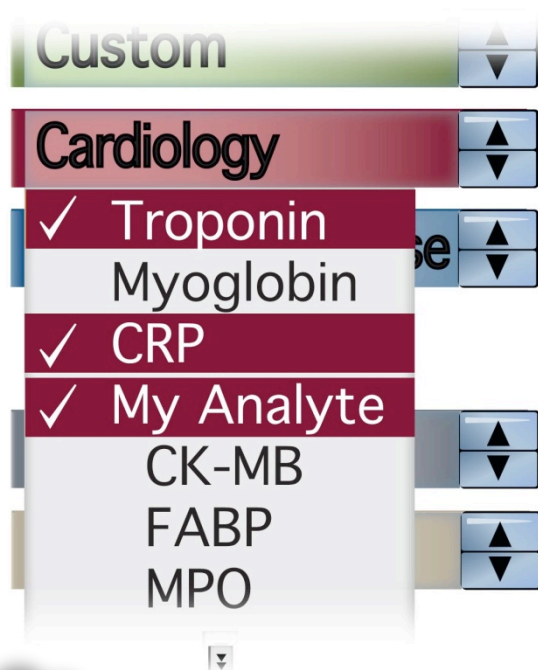
Ovarian Cancer Research Panel

Axela
Only

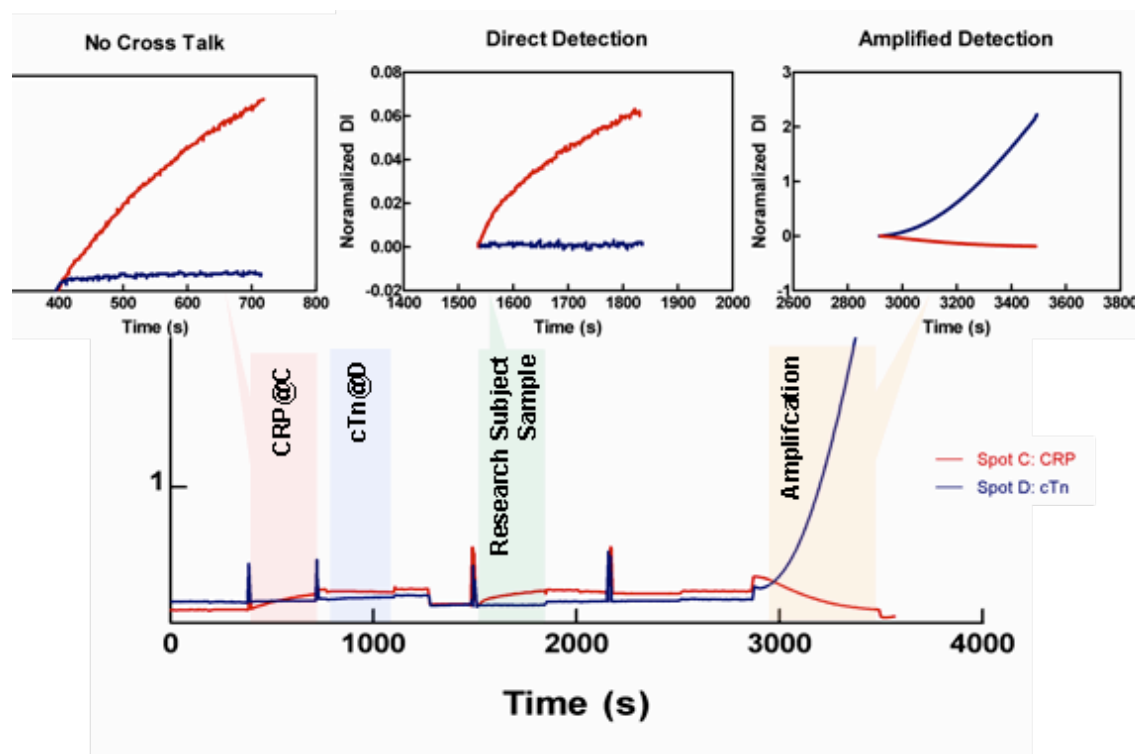
Preconfigured Assays **plus** Your Markers



Delivers Sensitivity plus Extended Dynamic Range



Analysis of CRP and Troponin I

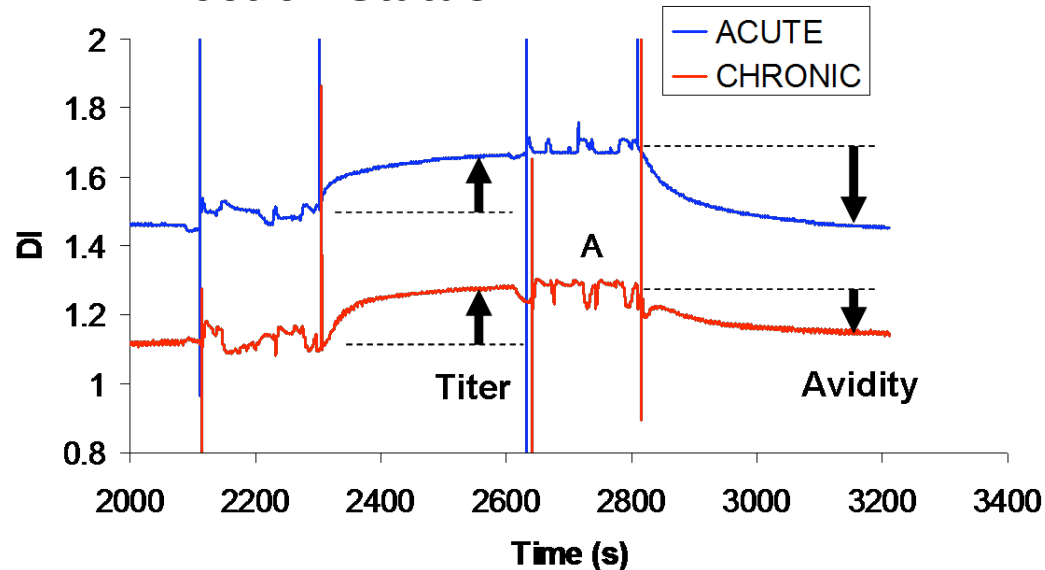


Measure High **plus** Low Abundance Markers Together

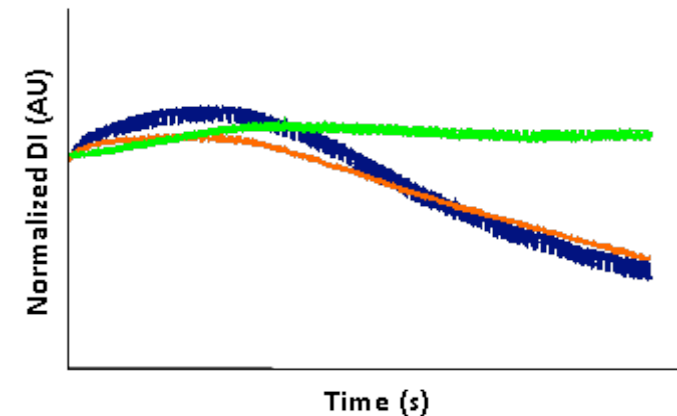
Real-time plus flow

Avidity in Clinical Samples

Infection Status

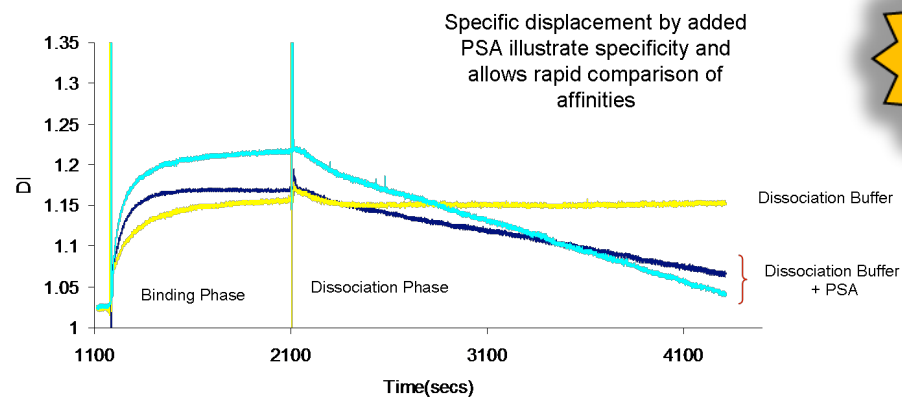


Vaccination Status



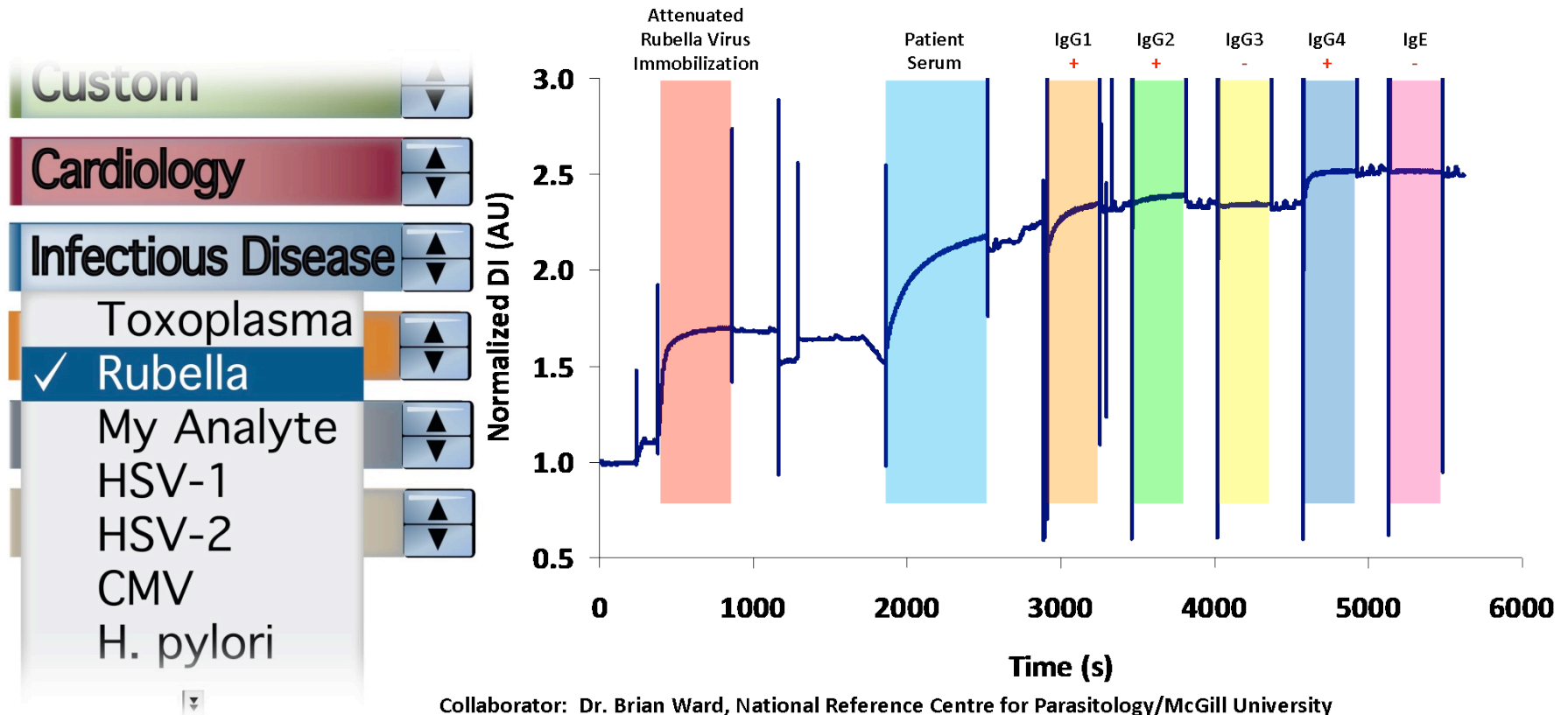
- Rubella Virus Competition (Patient 1)
- Rubella Virus Competition (Patient 2)
- Measles Virus Competition (Patient 1)

Disease Status



Saves 24-48 hours
Direct measurement of Avidity
vs calculated

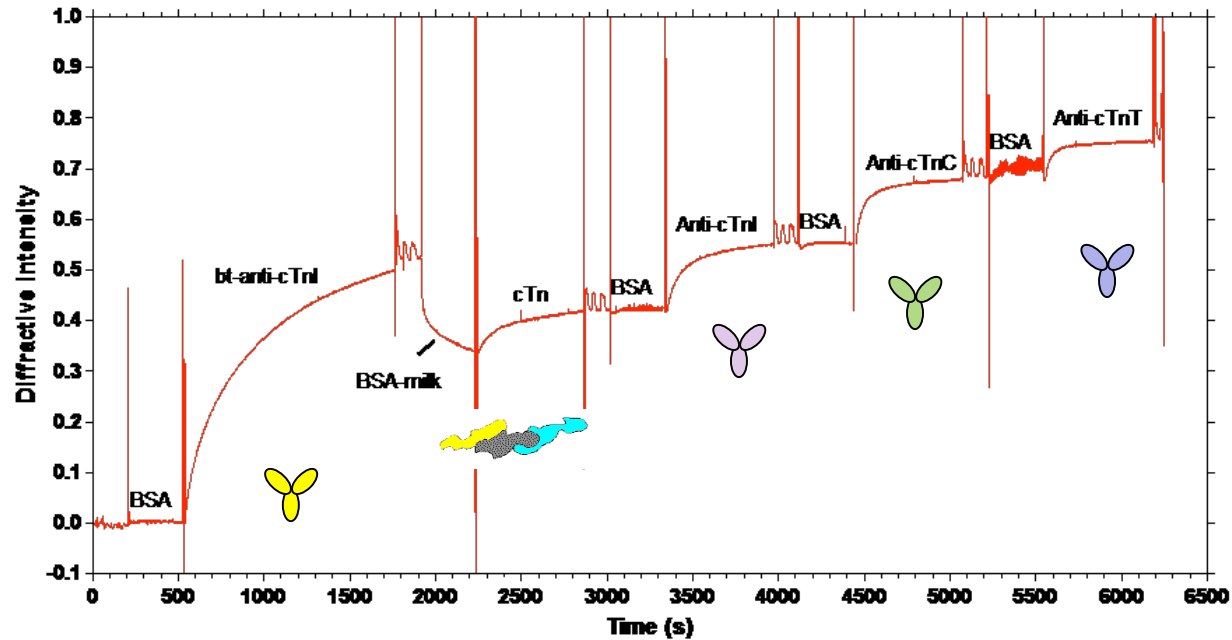
Quantitation plus another dimension of information: Avidity, Isoforms, Complexes, etc.



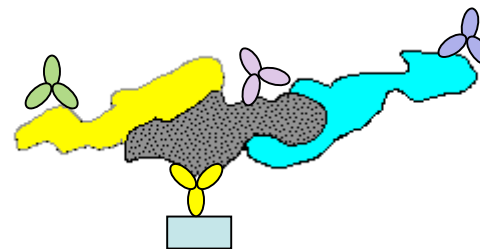
Axela
Only

Single Test replaces Multiple ELISA's

More Information: Protein Complexes and Isoforms

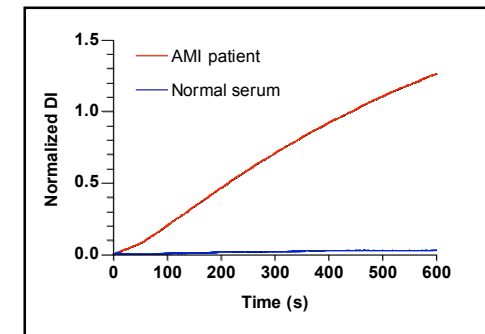


Sequential Probing:
Enables free and bound
measurements in the
same assay

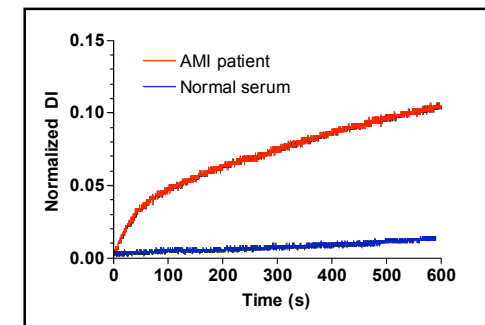


Surface pattern

Confirmation in serum from AMI patients



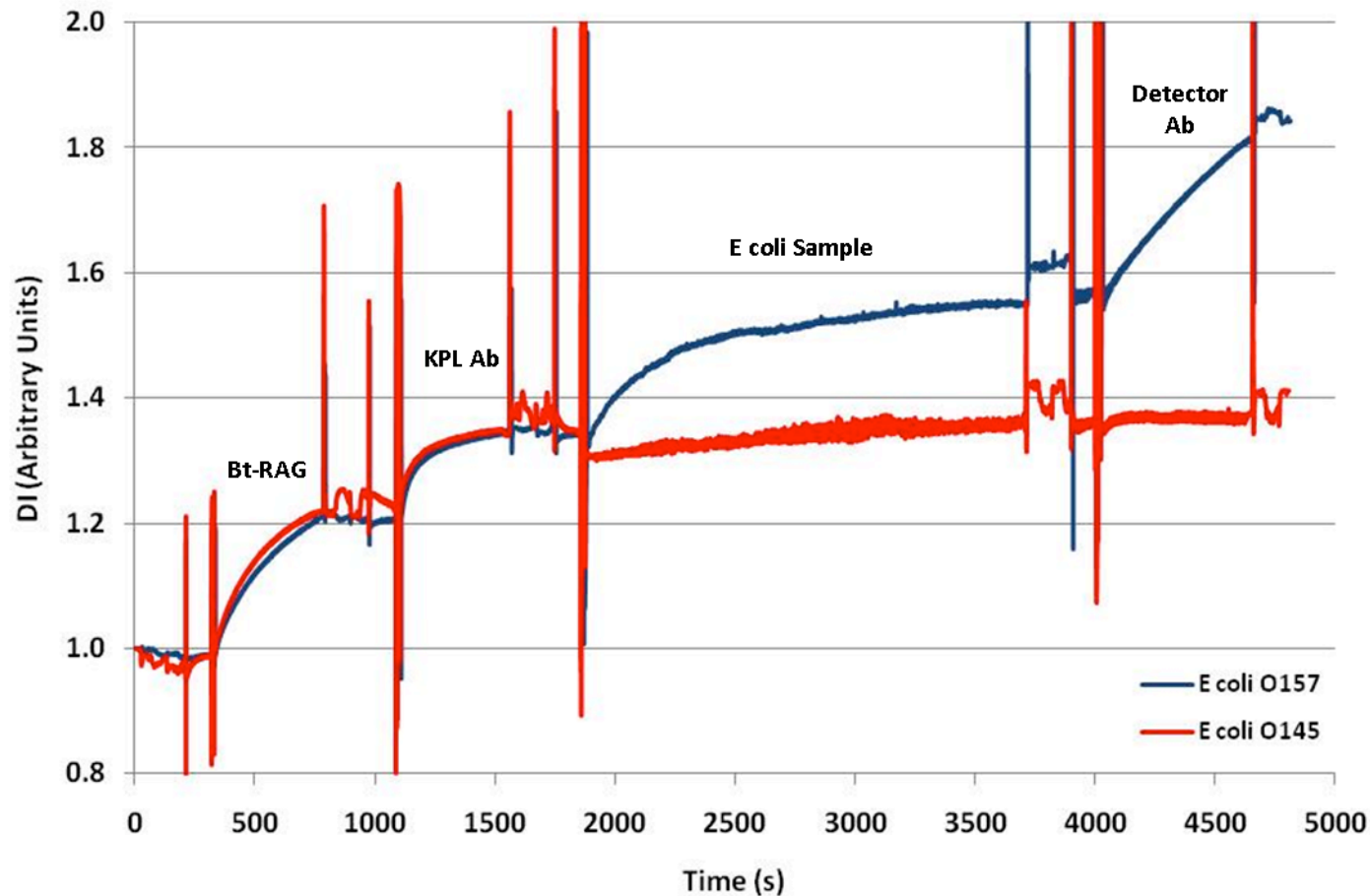
cTnI-cTnC complex



cTnI-cTnT complex

Direct Bacteria Capture

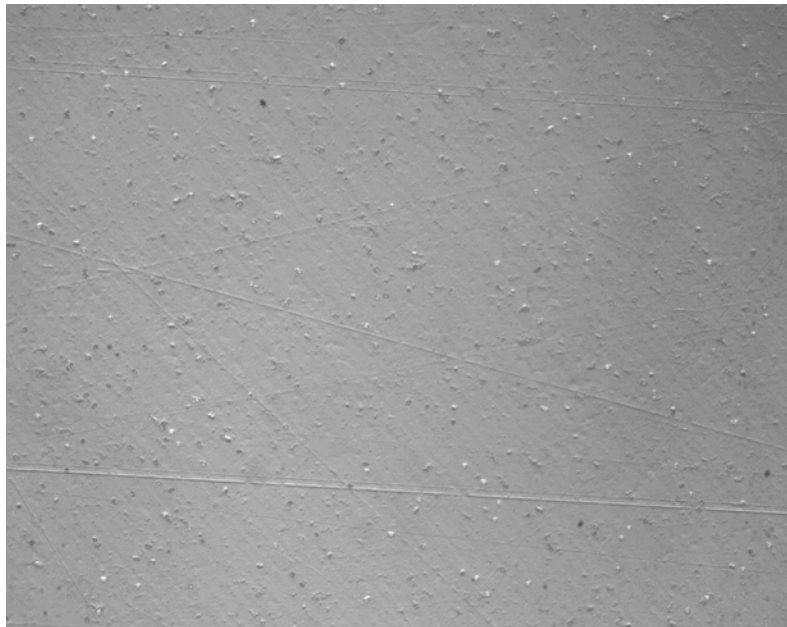
Antibody-based capture of E. coli O157:H7



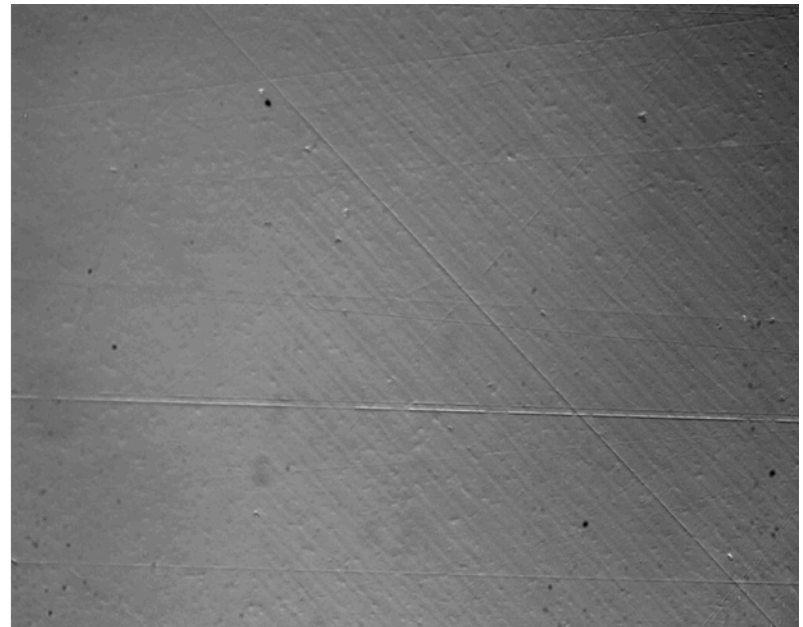
Collaborator: Dr. Kirsten Mattison, Health Canada

Direct Bacteria Capture

Antibody-based capture of E. coli O157:H7

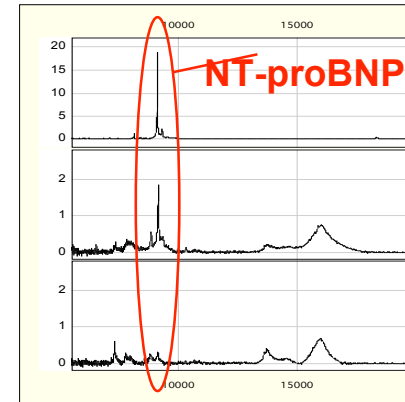
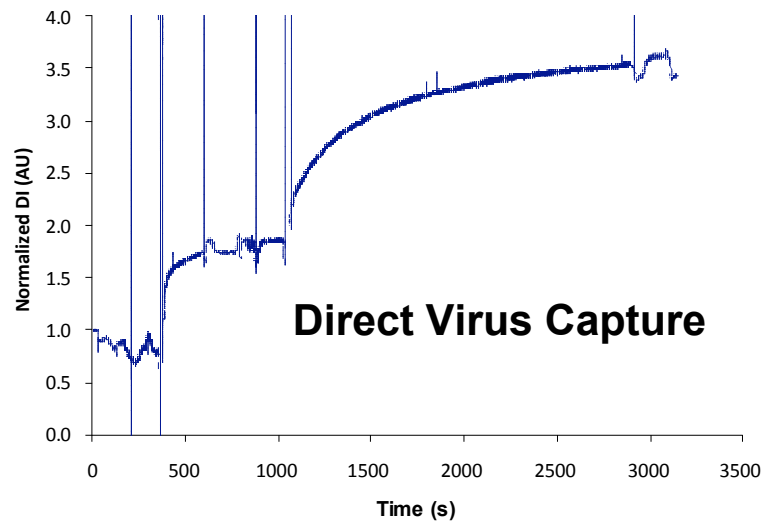


**E. coli O157
(Positive)**



**E. coli O145
(Negative)**

Real-time plus dot Technology: Broad scope of applications

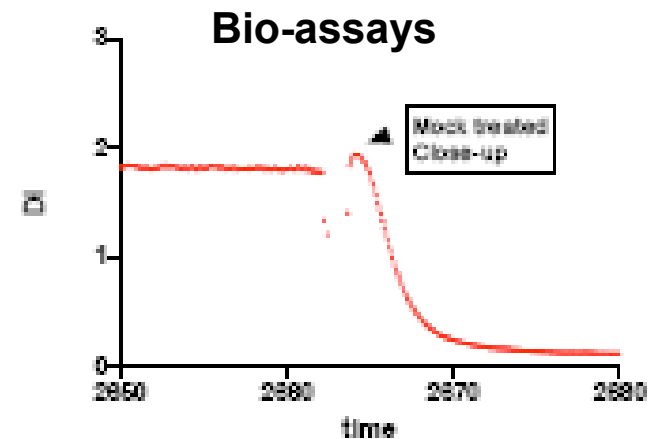
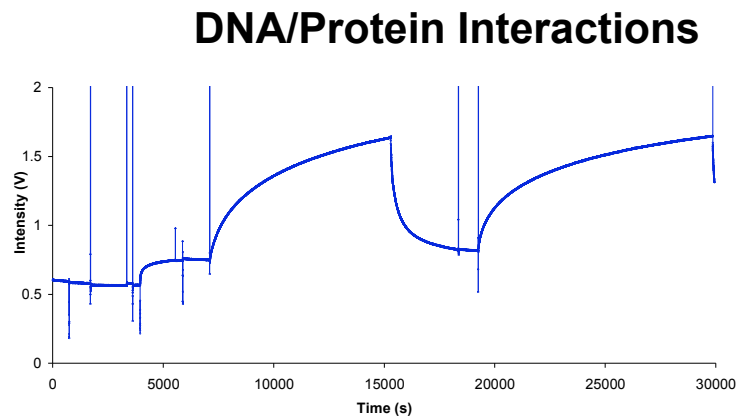


Purified NT-proBNP

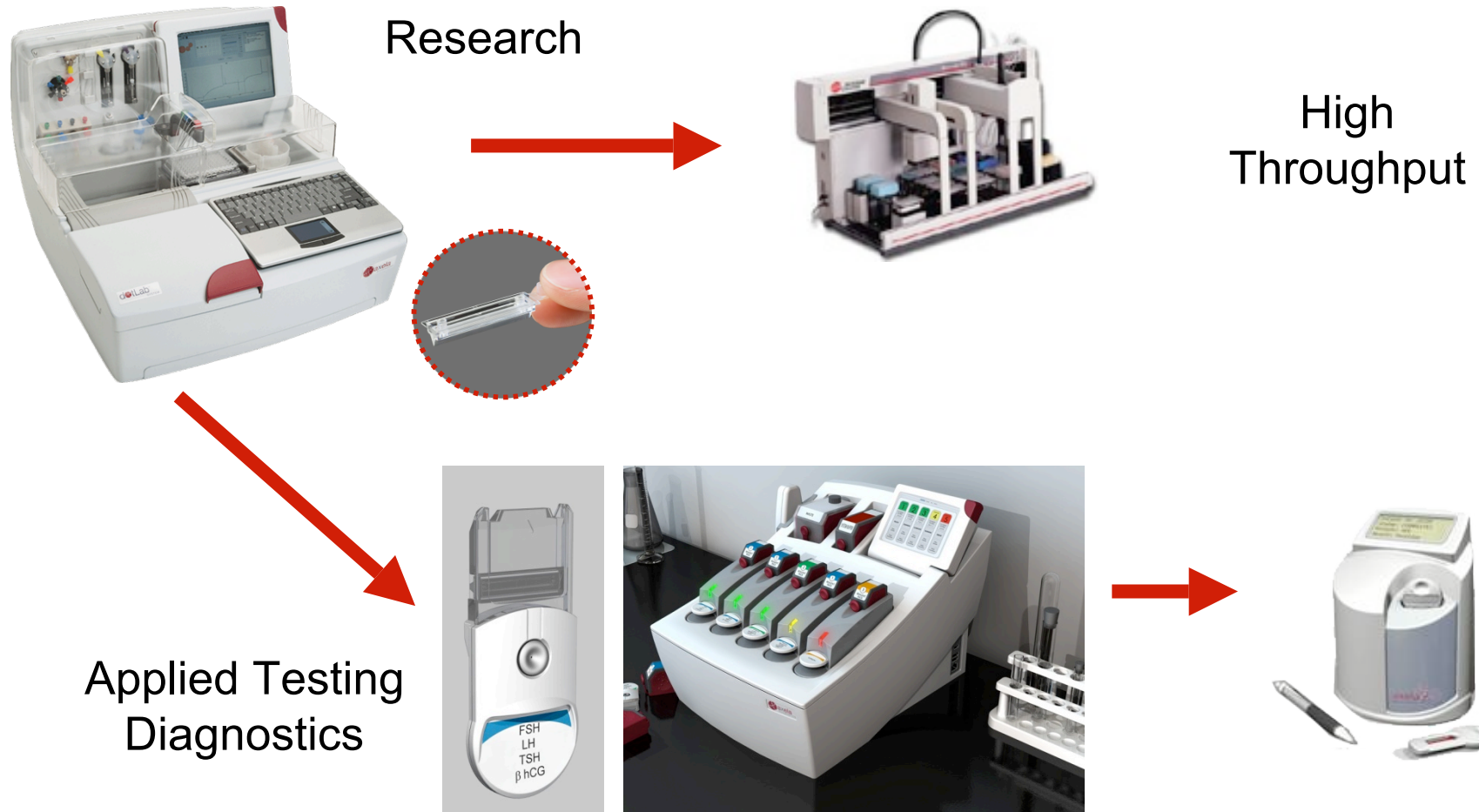
Positive
(6G11 Capture)

Negative
(anti-CRP Capture)

Characterization by MS



dot Technology: Multiple Platform Opportunities



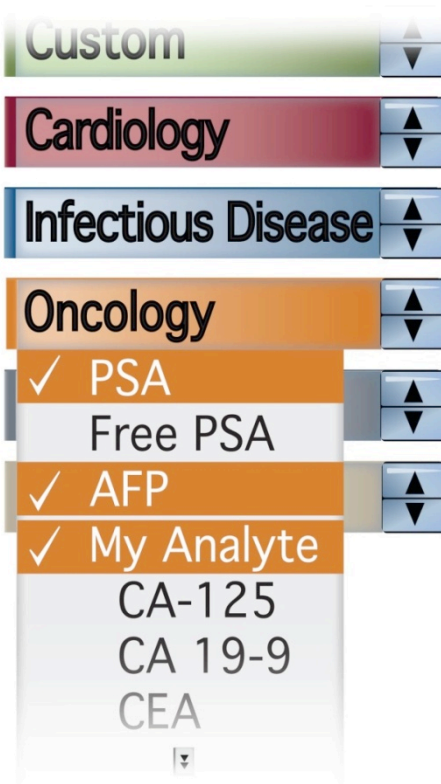
Common sensor format provides direct assay transfer

Axela Products

dotLab® System

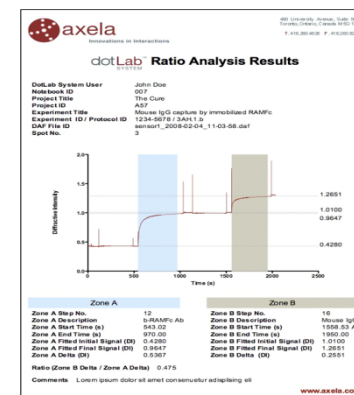


ELISA Validation Kits



Menu and Panels

Consumables

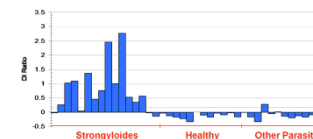
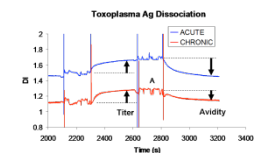
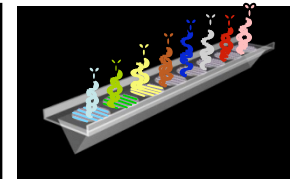
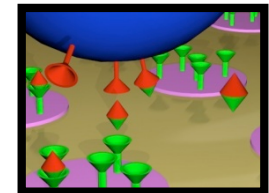
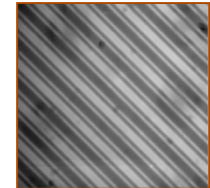
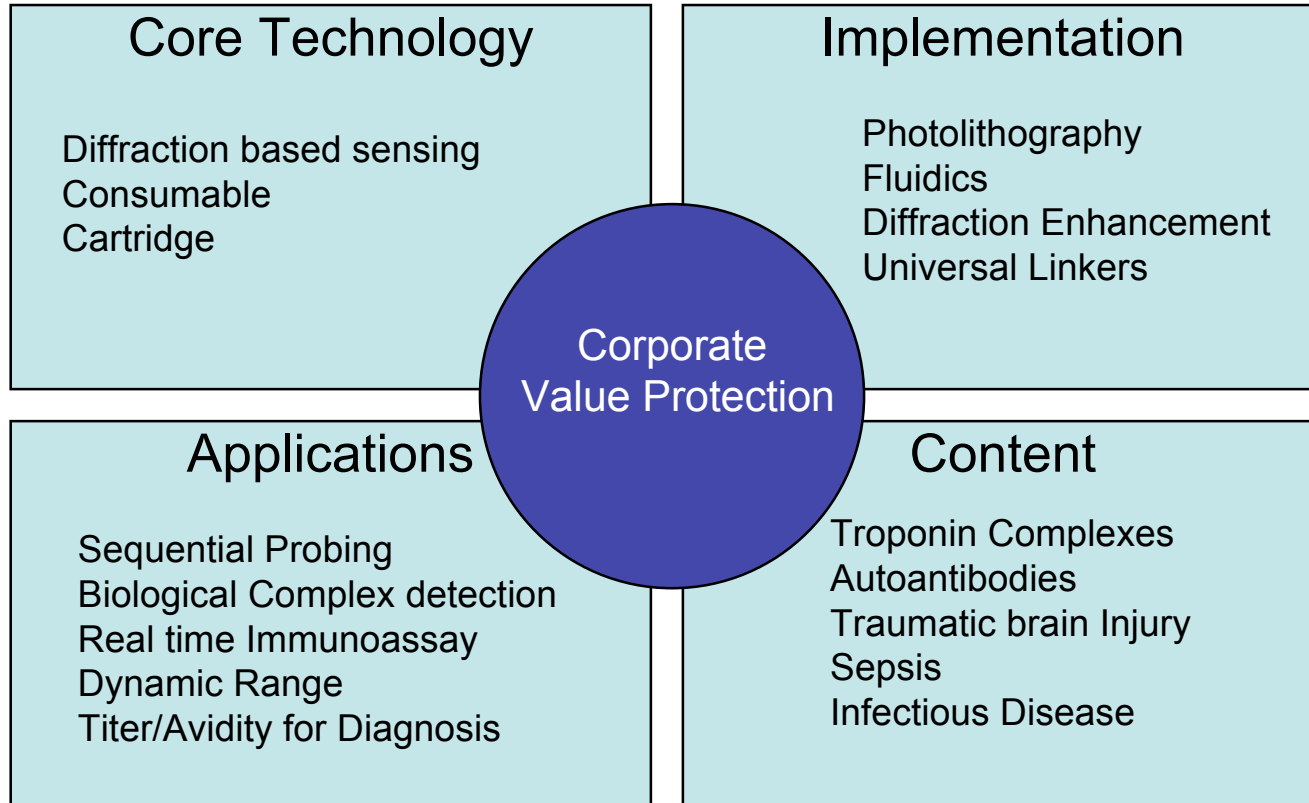


21 CFR part 11
Compliance Software



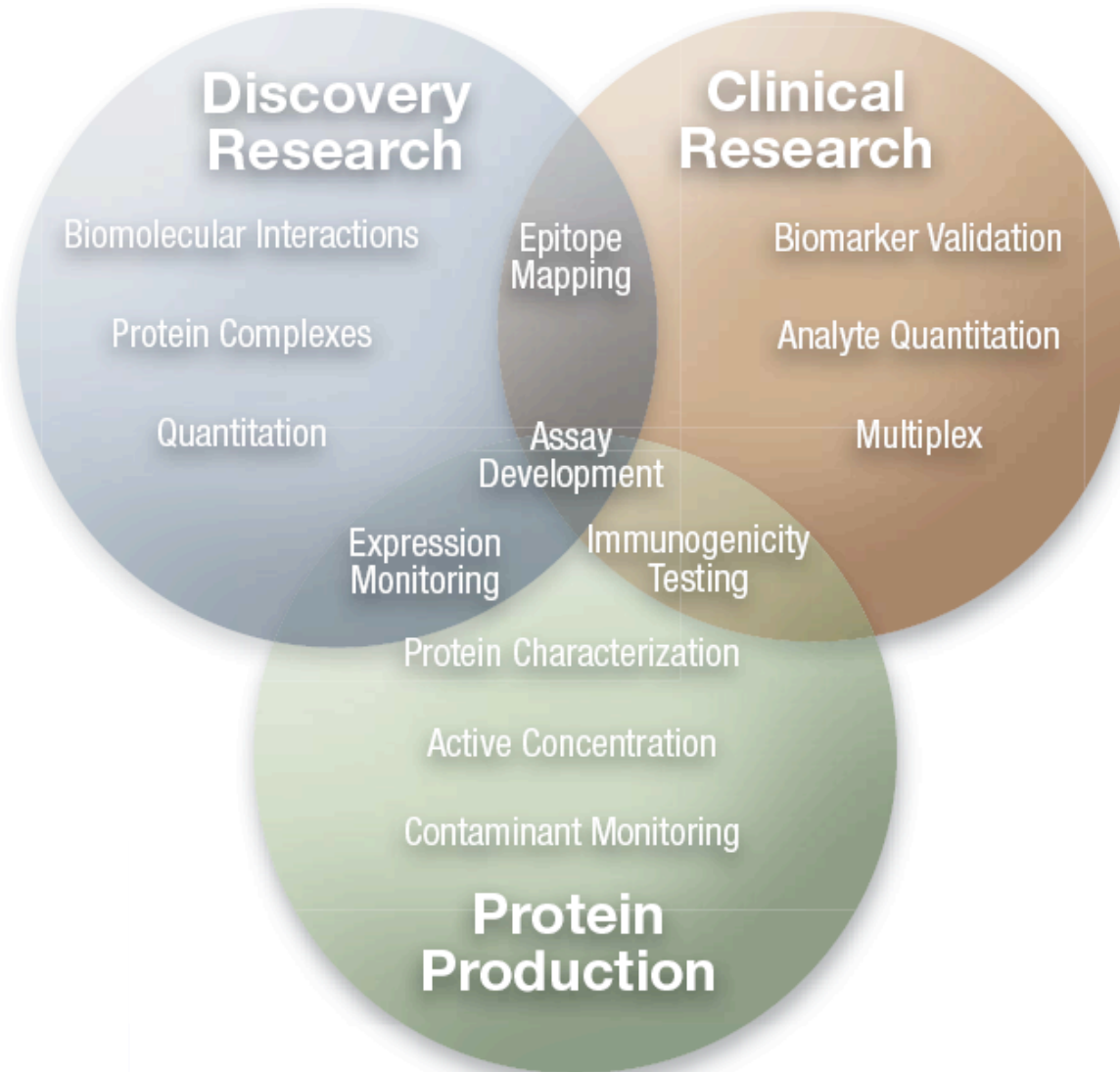
IP Strategy

>150 patents and applications



IP Sources
 Founder IP
 Axela Developed
 In-License

Applicable Research Markets



Axela Highlights

- **Diffraction Optics Technology:** Delivers mix and match multiplexing and avidity measurements in clinical samples. Unique to Axela
- **Technology validation by premier institutes:**
- **Strong IP position:** >150 patents and applications
- **No technology risk:** research product commercialized
- **Tremendous diagnostic opportunity:** leverage proprietary discoveries
- **Business model validated:** Troponin, Infectious Disease, Shaken Baby Syndrome
- **Robust content pipeline:** Proprietary markers and assay alliances

Become leader in research tools, leveraging applications & opportunities in personalized diagnostics



Multiplexing made simple



Get more information from every sample

Thank You!

www.axela.com

