



ENABLING VACCINES & BIOTHERAPEUTICS

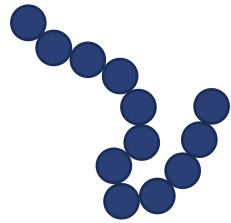
Highly Multiplexed, 30-minute VaxArray™ Immunoassay
for Pneumococcal Vaccine Antigen Characterization

April Ruka, PhD – Application Scientist

Complex Nature of Pneumococcal Vaccines

Pneumococcal vaccines require characterization of up to **24 polysaccharide serotypes**

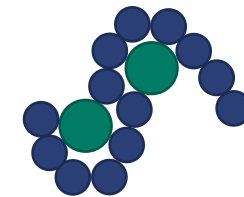
Pneumococcal Polysaccharide Vaccines (PPV)



Mixture of free polysaccharides of multiple serotypes



Pneumococcal Polysaccharide Conjugate Vaccines (PCV)



Mixture of multiple serotype polysaccharides bound to CRM197 carrier protein



Pneumovax® is a registered trademark of Merck Sharp & Dohme Corp.

Pneumovax™ is a registered trademark of Wyeth Pharmaceuticals LLC, a subsidiary of Pfizer Inc.

Challenges of CQA Testing for Multivalent PCV

580 Steps in Manufacturing*

678 Quality Tests*

2.5 Years to Manufacture*

IDENTITY

Nuclear Magnetic Resonance

- Costly Equipment
- Not compatible with conjugated samples

ELISA

- Singleplexed
- Extended time to result
- Requires high skill labor

QUANTITY

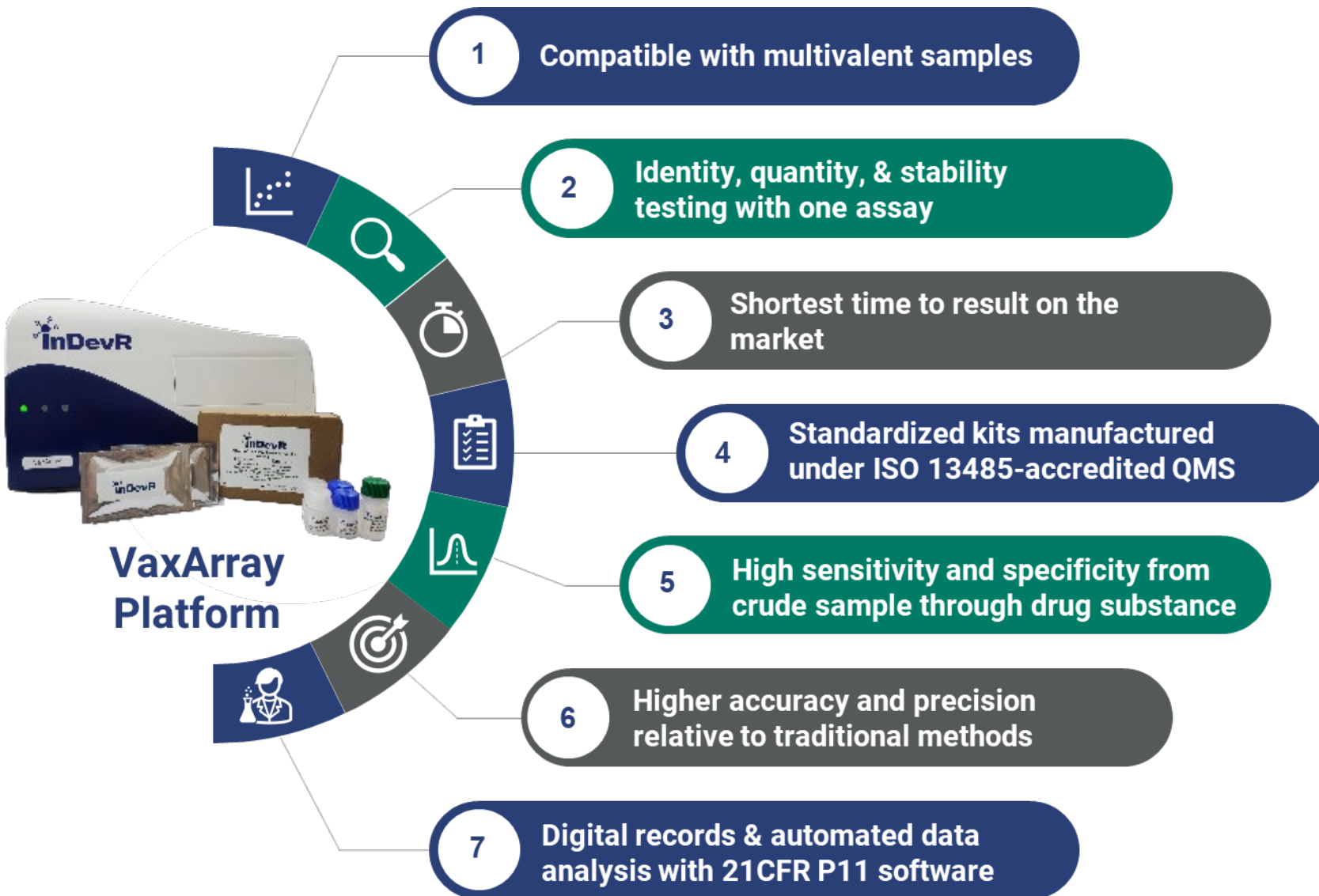
Anthrone Assay

- Non-specific, singleplexed
- Hazardous reagents

Bead-based Immunoassay

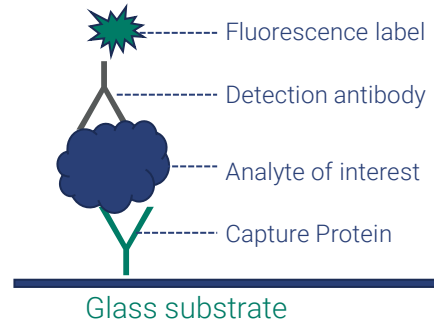
- Lengthy custom development
- Extended time to result
- Requires high skill labor

VaxArray for Rapid PCV Identity and Quantity Assay



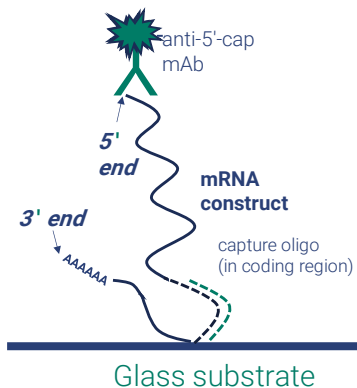
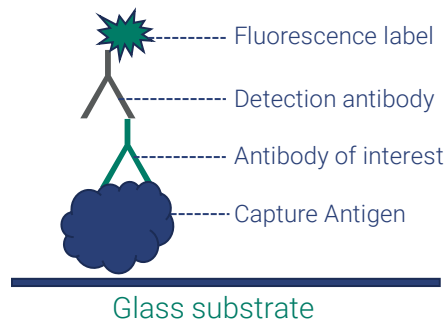
Multiplexed multivalent PCV identity and quantity testing in 30 minutes

Single Instrument, Multiple Assay Options



Measure Antigens

Measure Antibodies



Measure Nucleic Acids

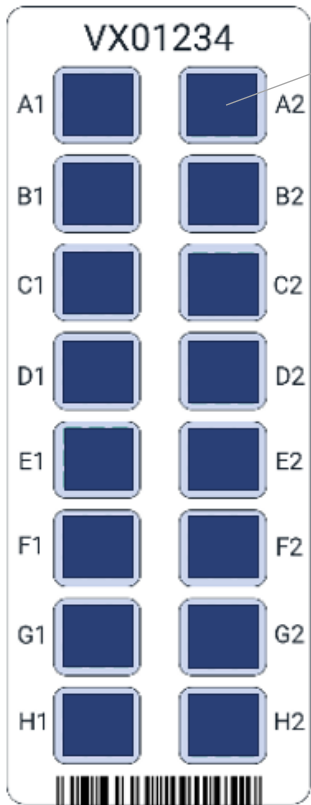
Platform Versatility

- Antibody, antigen, or oligo assays
- Reagent sparing microarray format
- High specificity and stability indicating
- Works with purified or crude samples

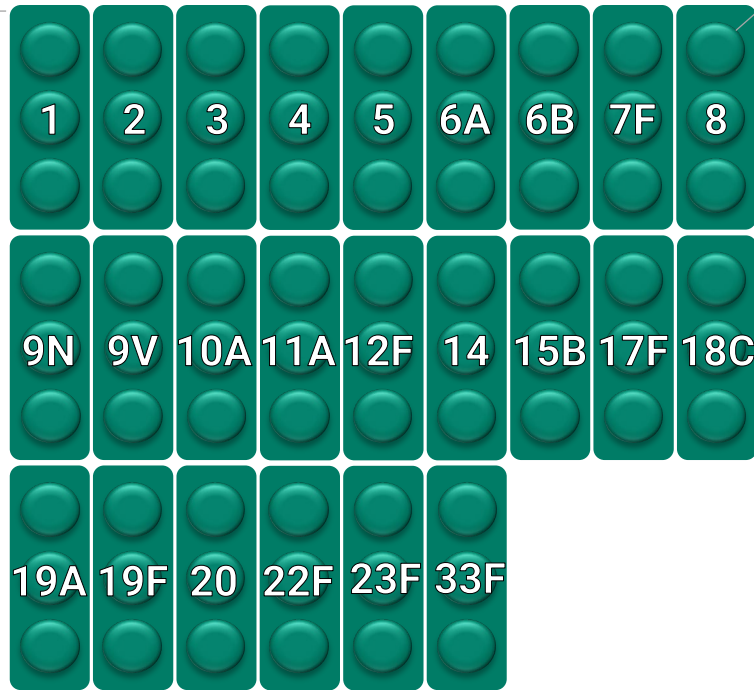
Proven Applications

- Polysaccharide based vaccines
- Split virus & subunit vaccines
- Recombinant proteins
- Virus-like particles (VLPs)
- Serology sample testing
- Nucleic acids

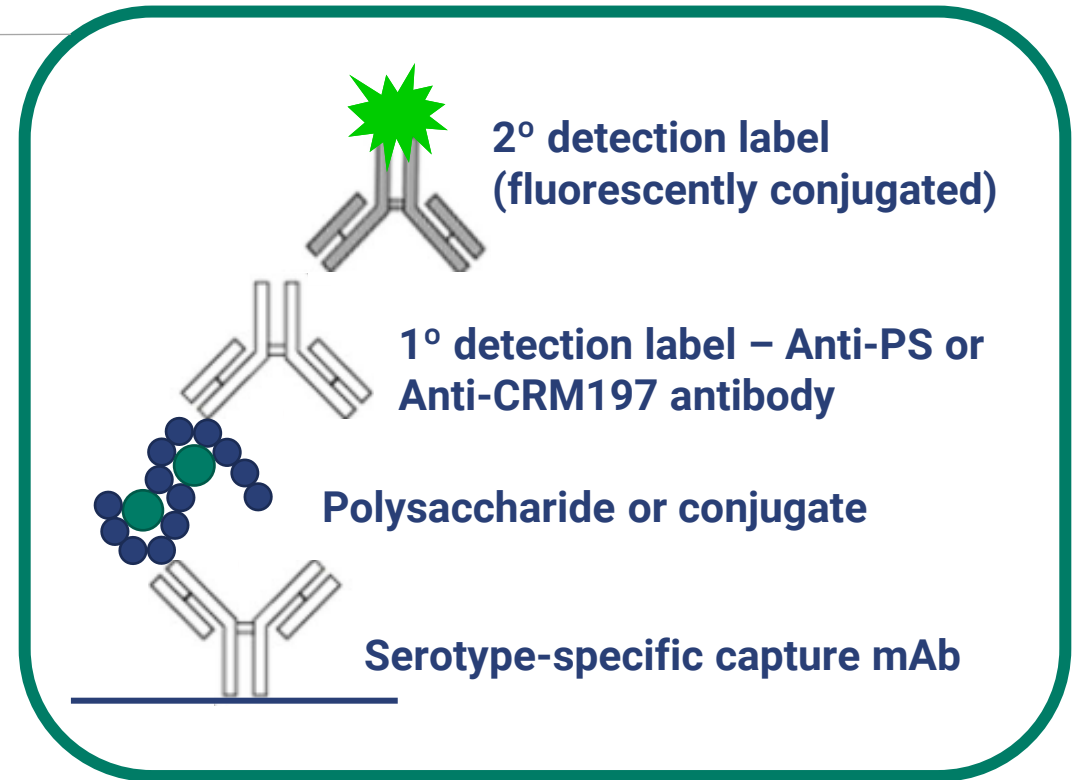
Pneumococcal Captures & Detection Mechanism



**Barcoded
VaxArray
Slide**

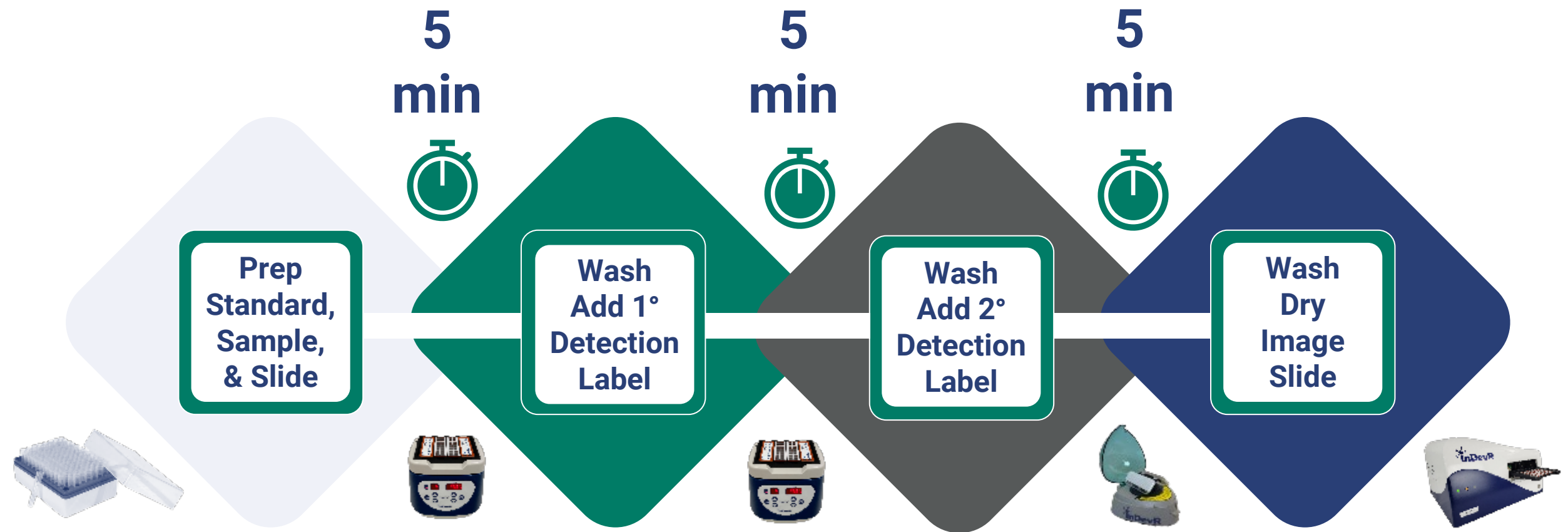


**Individual
Well
Format**



**Capture &
Detection
Principle**

Rapid & Simple VaxArray Assay Workflow



**Multivalent Polysaccharide Sample
Identity & Quantity Results in 30 Minutes**

VaxArray Slide Preparation on ArrayMax™



Slide Loading of Standard & Sample for Incubation



Transfer of Slide for Simple Washing Step



Centrifuge Drying of Slide in ArrayDry[®]

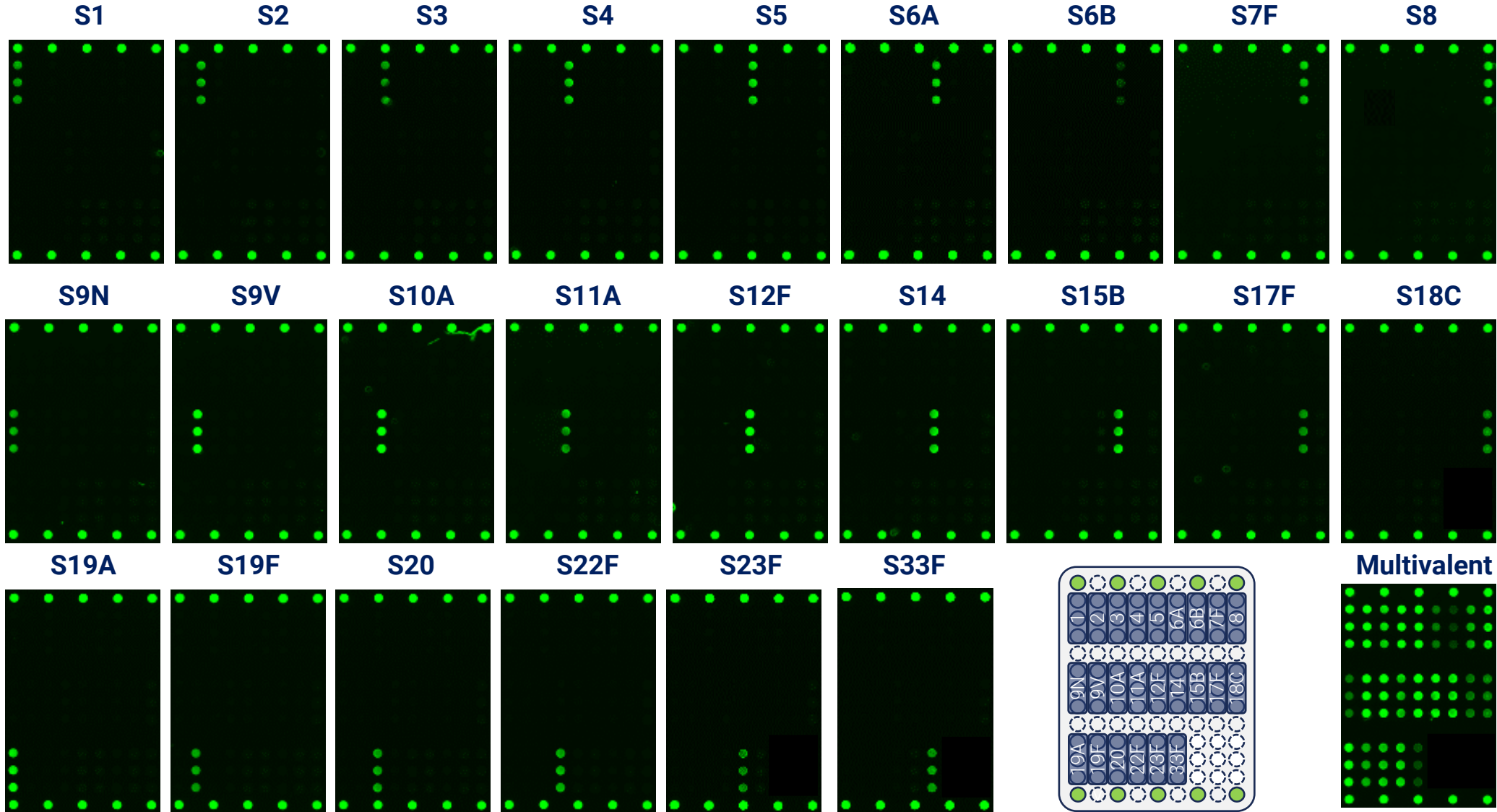


VaxArray Slide Imaging in Minutes

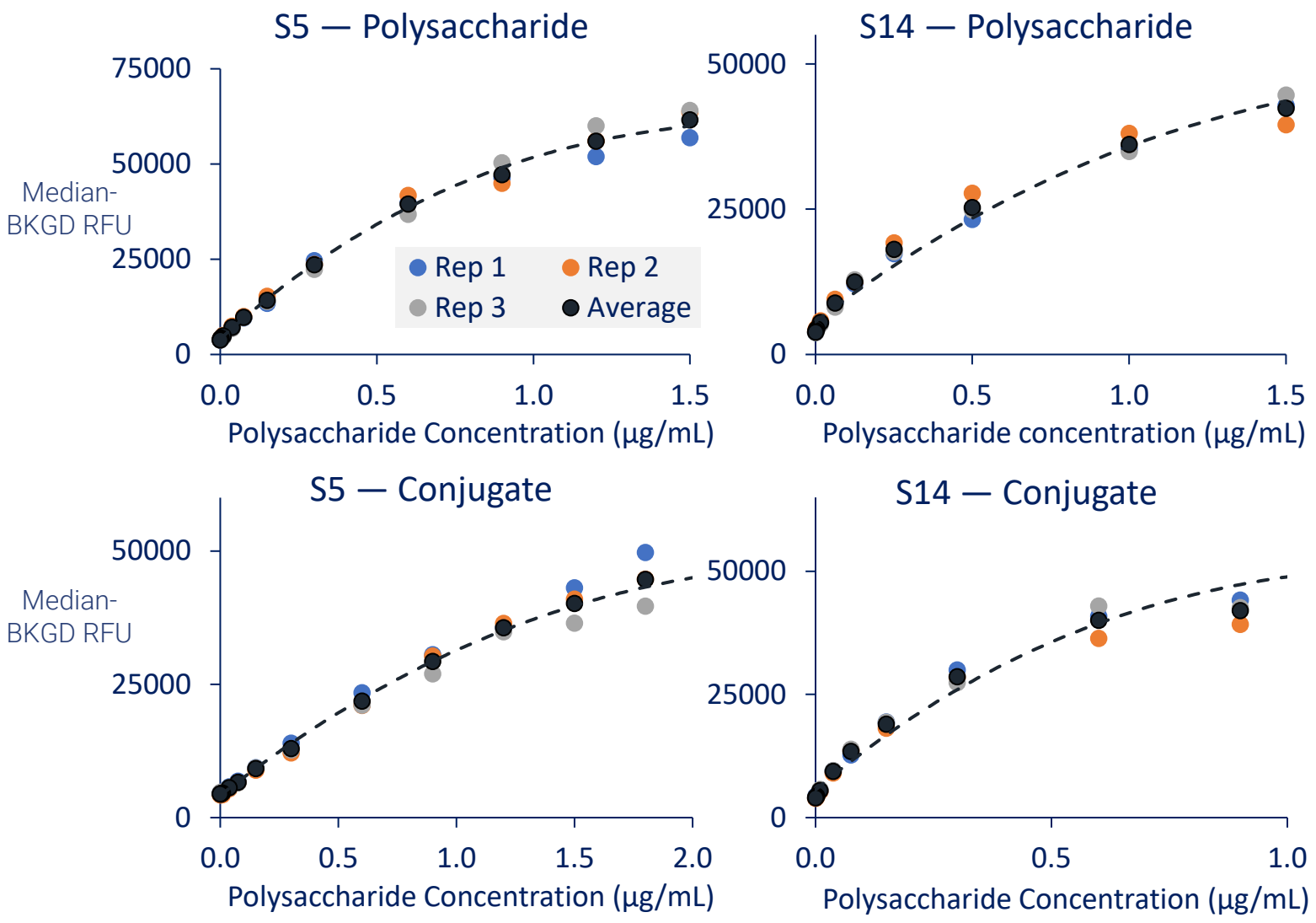


All 24 PS & Multivalent Analyzed in One Experiment

2 $\mu\text{g}/\text{mL}$ samples, labeled with 24-mix PS label



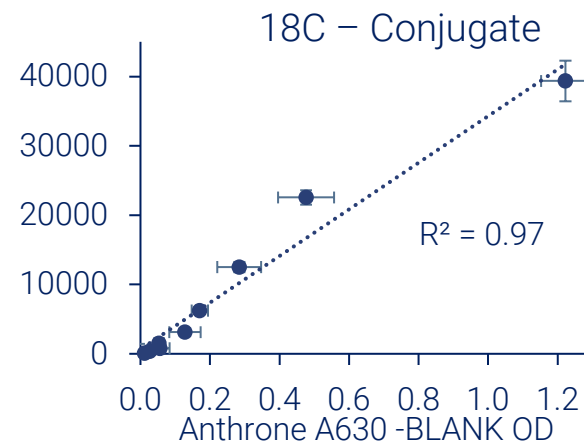
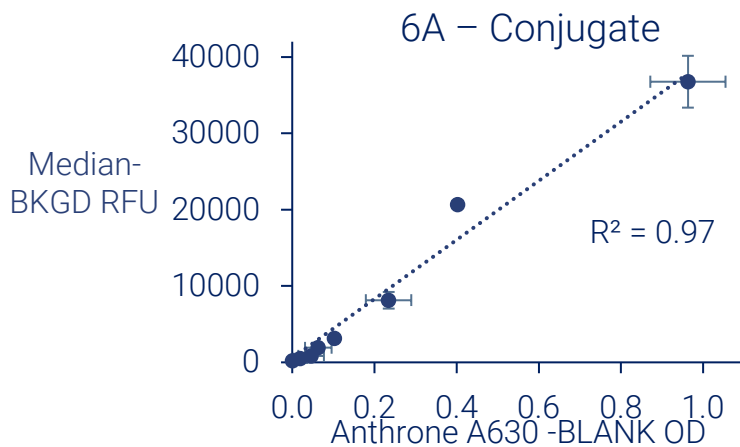
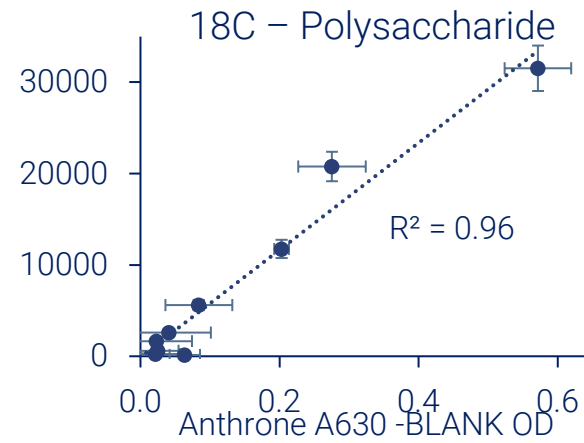
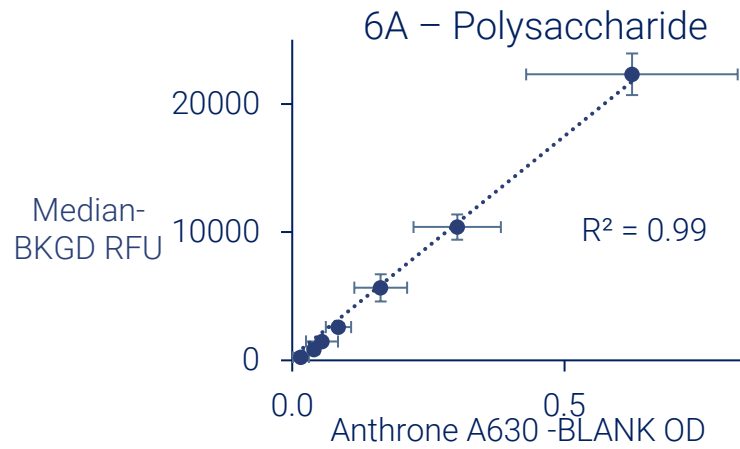
Precision for Both Free & Conjugated Samples



Data from median signal (RFU) vs. calculated µg/mL using a dilution series

New VaxArray v3.0 software has flexible curve fitting options typically used in immunoassays, such as 4 or 5 parameter logistic fit, or quadratic

Improved Accuracy & Precision Compared to Anthrone



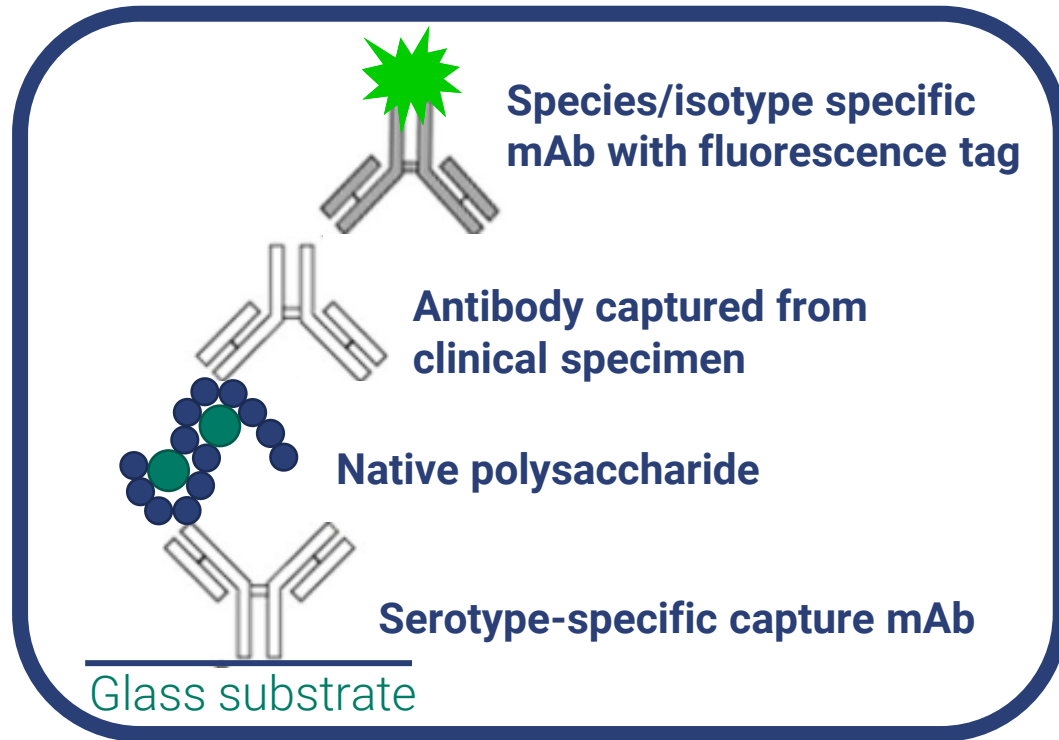
VaxArray and anthrone assays run with serial dilutions of serotype 6A and 18C

Both native PS and conjugate samples from same manufacturer

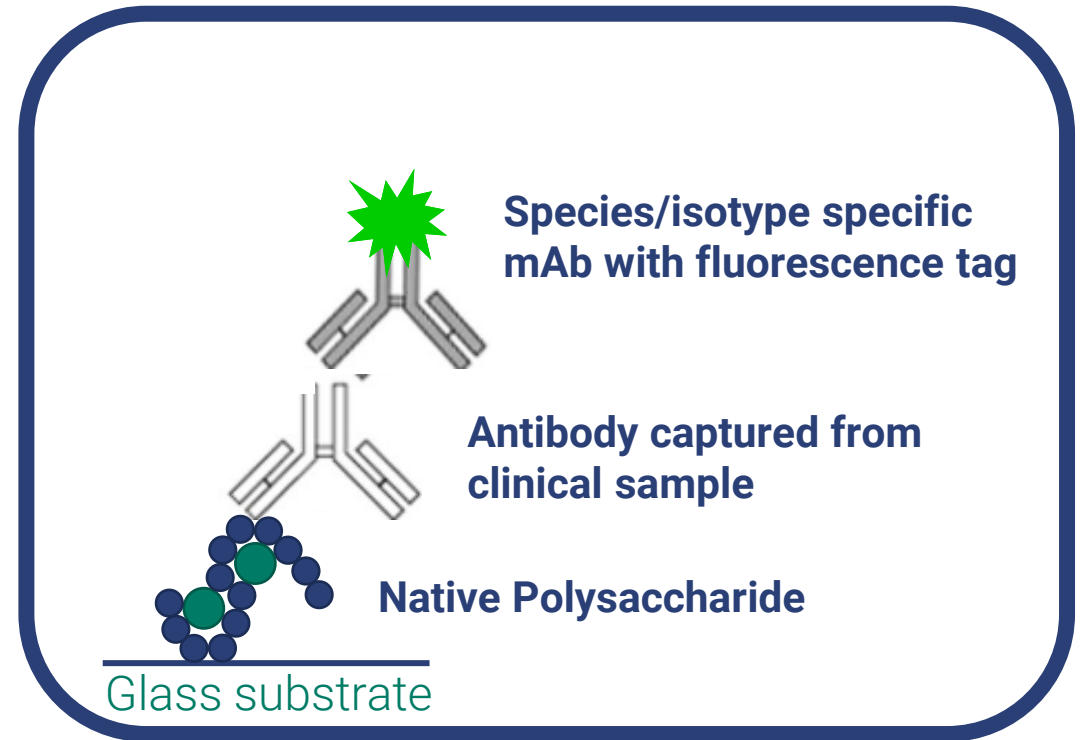
Assay responses are well-correlated for both materials

Error bars for VaxArray are significantly reduced (n=3)

Versatile Configurations for PCV SeroAssay

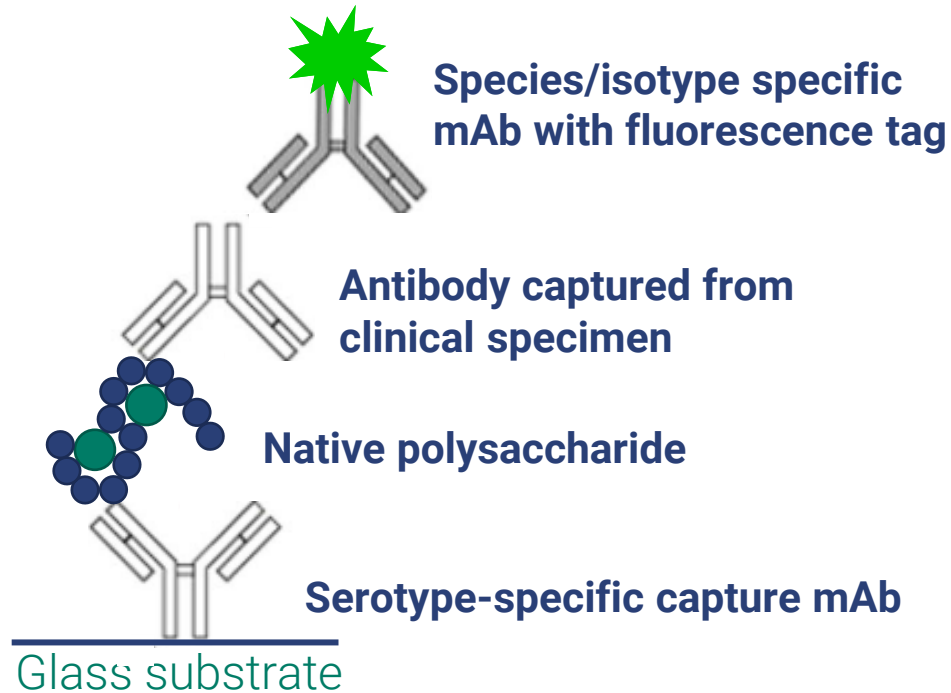


Option 1
Using off-the-shelf
PCV 2.0 assay kit



Option 2
Custom VaxArray kit with
polysaccharides printed on the slide

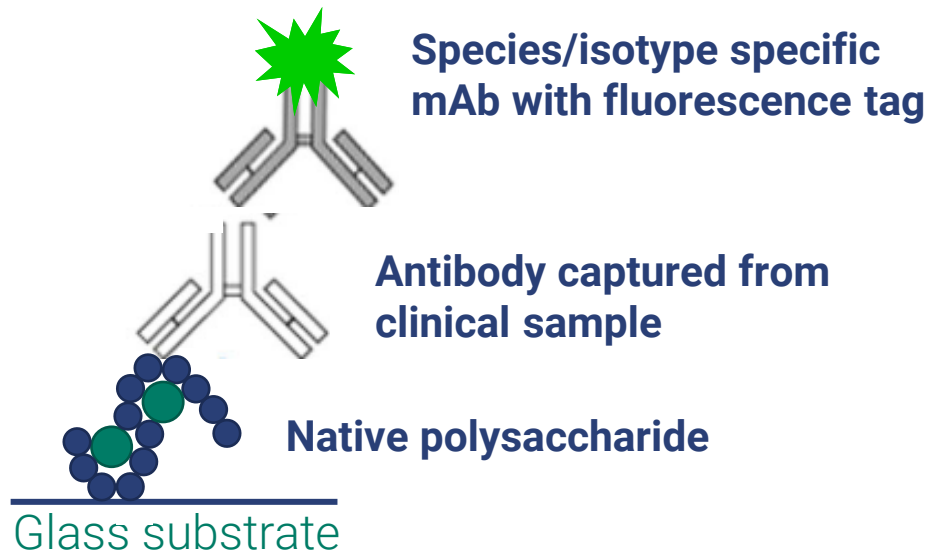
Proof-of-Concept Serology for Pre-clinical Studies



Option 1
Using off-the-shelf
PCV 2.0 assay kit

- **Rapid** path to **proof-of-concept** assay development using a commercially available kit for small sample numbers
- Ideal for **pre-clinical animal** testing of **non-human/non-mouse serum** samples

Fully Customized Assay for Pre-clinical Studies

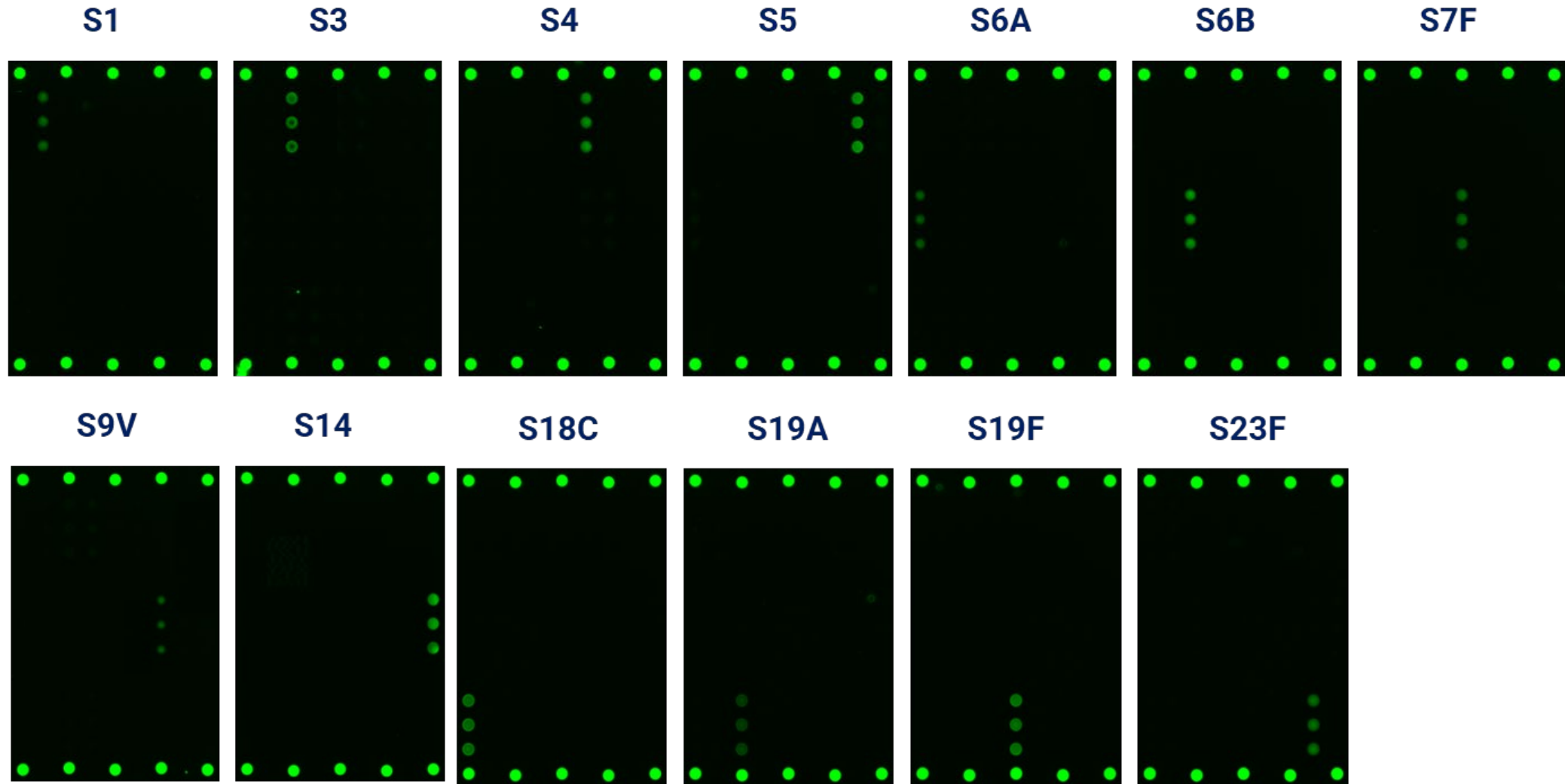


Option 2

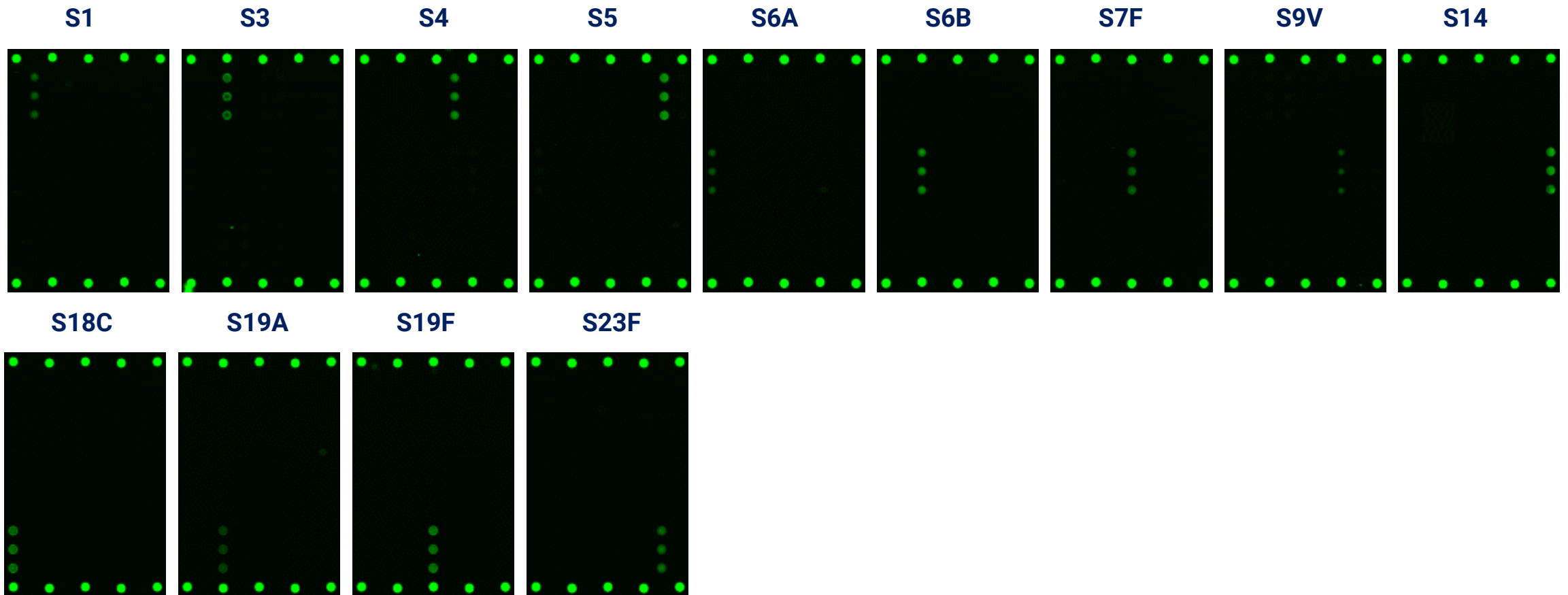
Custom VaxArray kit with polysaccharides printed on the slide

- **Fully developed custom** assay with configurable polysaccharide content
- Ideal for **pre-clinical** testing of **human/mouse serum samples**, and adaptable to other species

Antibody Response with High Specificity

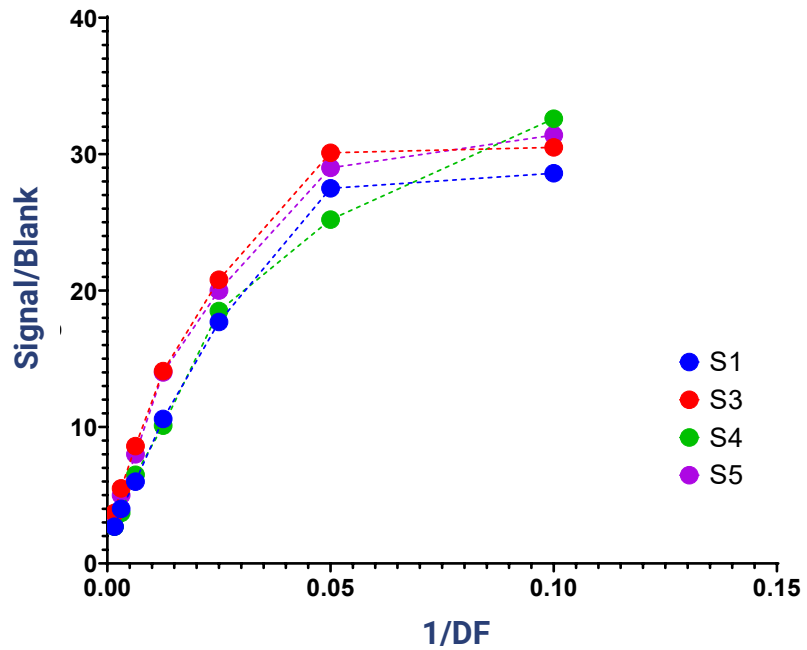


Antibody Response with High Specificity

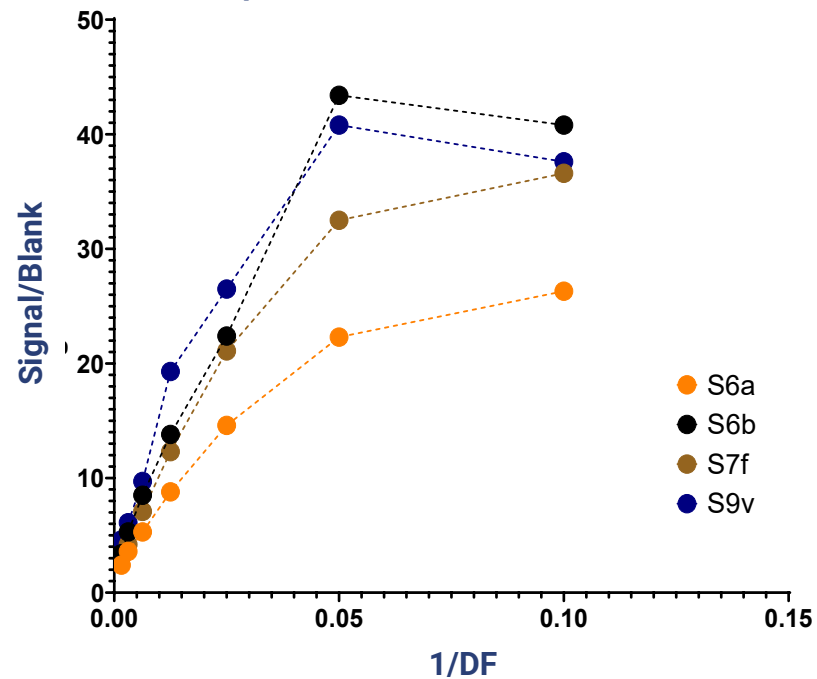


Dilution Curves with WHO Human Reference Serum

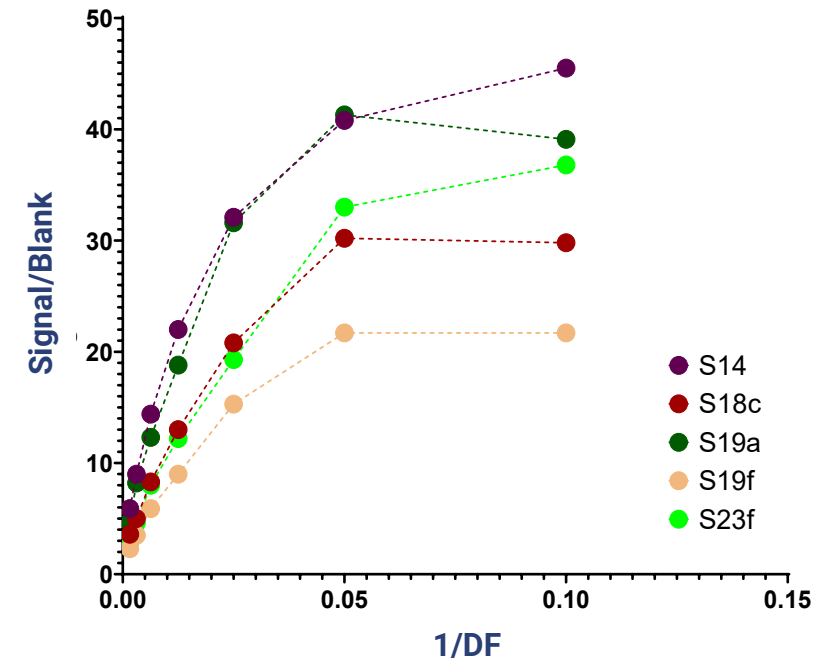
Response with Dilution of Reference Serum



Response with Dilution of Reference Serum



Response with Dilution of Reference Serum



Supporting Feasibility, Verification & Customization



VaxArray Platform

Assay kits for influenza, pneumococcal, coronavirus, polio, measles



Testing Services

For sample feasibility, orthogonal or outsourced answers



Custom Services

Custom multiplexed product to meet your specific project needs



Questions?



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