ENABLING VACCINES & BIOOTHERAPEUTICS

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

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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.
Prevnar™ 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

*According to Pfizer 2015 Annual Review*
VaxArray for Rapid PCV Identity and Quantity Assay

1. Compatible with multivalent samples
2. Identity, quantity, & stability testing with one assay
3. Shortest time to result on the market
4. Standardized kits manufactured under ISO 13485-accredited QMS
5. High sensitivity and specificity from crude sample through drug substance
6. Higher accuracy and precision relative to traditional methods
7. Digital records & automated data analysis with 21CFR P11 software

Multiplexed multivalent PCV identity and quantity testing in 30 minutes
Single Instrument, Multiple Assay Options

**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

**Measure Antigens**
- Fluorescence label
- Detection antibody
- Analyte of interest
- Capture Protein
- Glass substrate

**Measure Antibodies**
- Fluorescence label
- Detection antibody
- Antibody of interest
- Capture Protein
- Glass substrate

**Measure Nucleic Acids**
- mRNA construct
- 5' end
- 3' end
- Anti-5'-cap mAb
- Capture oligo (in coding region)
- Glass substrate
Pneumococcal Captures & Detection Mechanism

Barcoded VaxArray Slide

Individual Well Format

Capture & Detection Principle

Serotype-specific capture mAb

Polysaccharide or conjugate

1º detection label – Anti-PS or Anti-CRM197 antibody

2º detection label (fluorescently conjugated)
Rapid & Simple VaxArray Assay Workflow

1. Prep Standard, Sample, & Slide
2. Wash Add 1° Detection Label
3. Wash Add 2° Detection Label
4. Wash Dry Image Slide

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

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2 µg/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

- Glass substrate
- Native polysaccharide
- Serotype-specific capture mAb
- Antibody captured from clinical specimen
- Species/isotype specific mAb with fluorescence tag

**Option 2**
Custom VaxArray kit with polysaccharides printed on the slide

- Glass substrate
- Native Polysaccharide
- Antibody captured from clinical sample
- Species/isotype specific mAb with fluorescence tag
Proof-of-Concept Serology for Pre-clinical Studies

- **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

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Using off-the-shelf PCV 2.0 assay kit

- Antibody captured from clinical specimen
- Native polysaccharide
- Serotype-specific capture mAb
- Species/isotype specific mAb with fluorescence tag
- Glass substrate
Fully Customized Assay for Pre-clinical Studies

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

Option 2
Custom VaxArray kit with polysaccharides printed on the slide
Antibody Response with High Specificity
Antibody Response with High Specificity
Dilution Curves with WHO Human Reference Serum

Response with Dilution of Reference Serum

Signal/Blank

1/DF

Response with Dilution of Reference Serum

Signal/Blank

1/DF

Response with Dilution of Reference Serum

Signal/Blank

1/DF
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