Monovalent and Multivalent Vaccines

VaxArray® Influenza Potency Assays

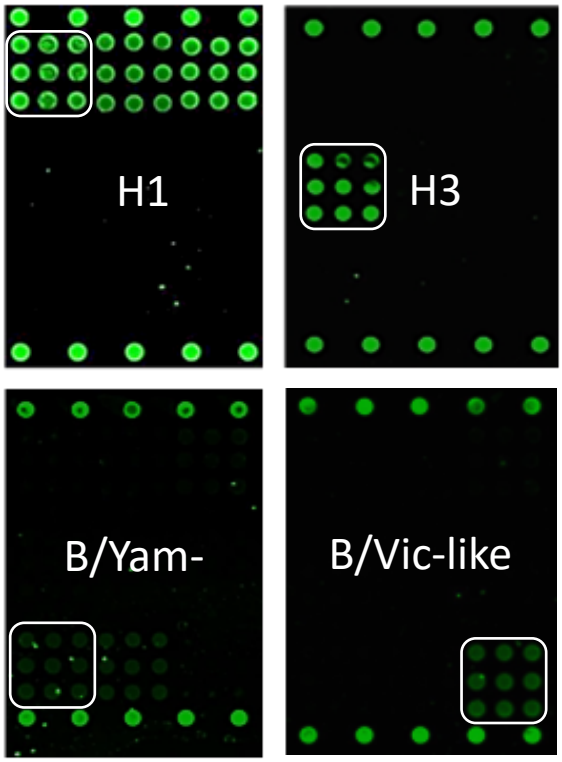
Overview

The VaxArray Seasonal Hemagglutinin Potency Assay is a new tool for hemagglutinin (HA) protein quantification based on a panel of subtype-specific but broadly reactive monoclonal antibodies (mAbs). Multiple antibodies against seasonal A/H1, A/H3, B/Yamagata-like and B/Victoria-like strains are printed in an array format on a glass substrate. Signal readout for this multiplexed immunoassay is based on fluorescence from conjugated polyclonal or monoclonal antibody labels.

Monovalent

Figure 1 shows representative fluorescence images for monovalent Bulk Drug Substance (BDS) samples analyzed on a VaxArray Influenza Microarray Slide. The antibodies used to quantify the protein are highlighted in a white box. Samples were quantified against reference antigens (rHA) used as calibration standards. Quantitative results are summarized in **Figure 2**, with standard error from replicate measurements.

Figure 1 - Representative Fluorescence Images for Monovalent Bulk Drug Substances



Multivalent

A significant advantage of the VaxArray Influenza Assay over ELISA and SRID is the ability to work with a variety of sample types on a single analytical platform. In addition to the specific measurement of monovalent BDS samples, VaxArray allows users to simultaneously analyze all components in trivalent or quadrivalent vaccine products. For example, **Figure 2** shows representative fluorescence image of multiplexed analysis of all components within a quadrivalent formulation (constructed from a mixture of monovalent BDS), where the white boxes outline the mAbs used to quantify each component. The error for quadrivalent formulation is 12% RSD, based on

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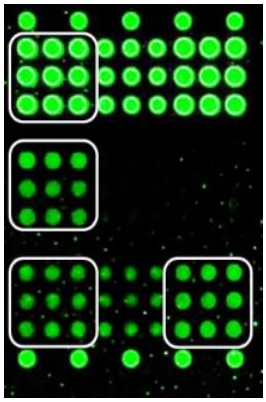
the average relative precision determined in separate studies. Despite the fact that multiplexed quantification was conducted three months after the initial BDS measurements, within error the results were equivalent to those reported for the monovalent BDS (with the exception of A/CA HA for which a new label antibody was tested).

A variety of trivalent vaccines have also been evaluated. Representative fluorescence images are shown in Figure 3 for vaccines produced by the four major manufacturers over a range of years.

Figure 2 - Representative Image and Results Summary for Multiplexed Quantification of HA in Quadrivalent Formulation



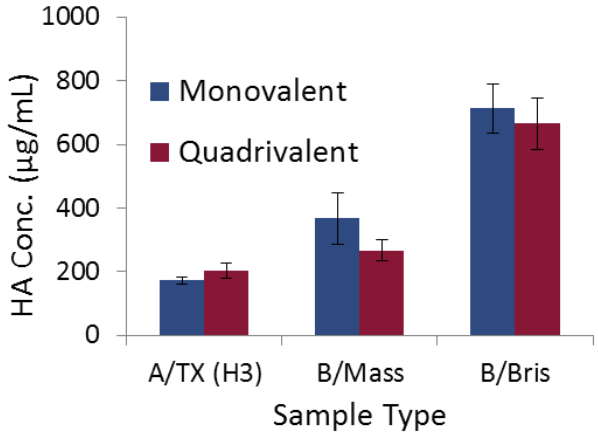
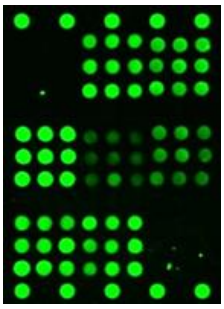
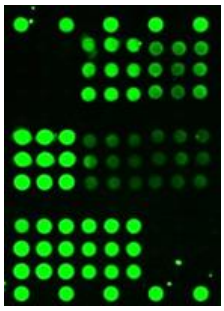


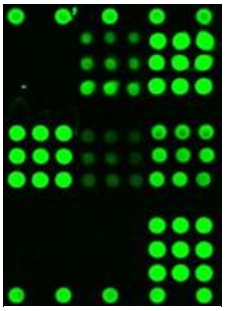
Figure 3 - VaxArray Images for Multiplexed Analysis of Trivalent Vaccines



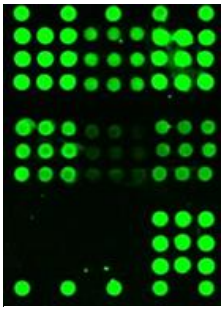
A/Brisbane/59/2007
A/Urug/716/2007
B/Florida/04/2006
2008-2009
Sanofi Fluzone



A/Brisbane/59/2007
A/Urug/716/2007
B/Brisbane/3/2007
2008-2009
GSK Fluarix



A/Solom. Is./3/2006
A/Wisc/67/2005
B/Malaysia/2506/04
2007-2008
Novartis Fluvirin



A/CA/7/2009
A/Vic/210/2009
B/Brisbane/60/2008
2010-2011
CSL Afluria

Summary

The ability of VaxArray to accurately quantify both monovalent and multiplex samples in a single assay provides a dramatic advantage in comparison to other platforms. This level of multiplexing is not possible with ELISA or SRID.

In addition, a single VaxArray Influenza experiment generally allows for 8-24 individual samples to be analyzed simultaneously.

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