A novel tool to enable multivalent vaccine development for influenza and coronavirus

Chih-lung Fu, Damini Patel, Abeer Al-Ghouleh, Ph. D.

VaxArray Platform and Kits

Abstract

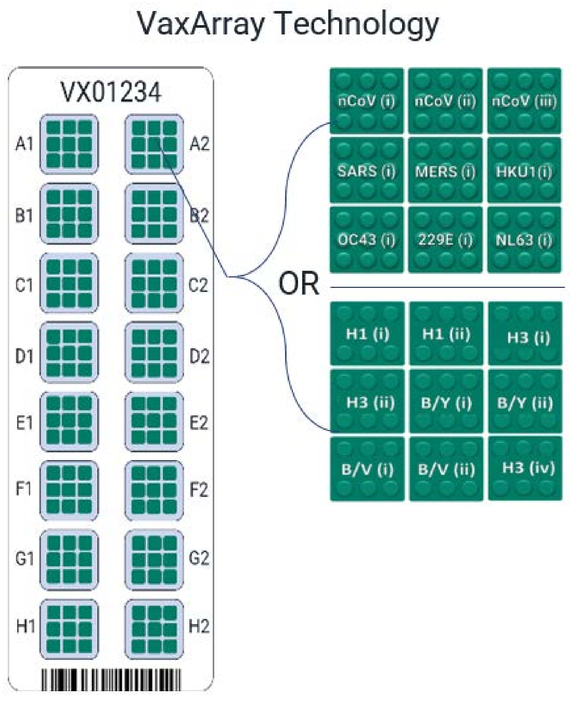
Influenza and coronavirus pose unique challenges in vaccine development. Continuous antigenic drift requires new reagents and tools for analytical assessment and this challenge can represent a bottleneck in vaccine production and virus eradication. Improved characterization assays for identity, potency, and stability are needed to replace cumbersome and inefficient methods such as SRID and ELISA, which can cause increased development time and higher manufacturing costs. A lack of standardized assays and reagents also leads to a missed opportunity to compare results across manufacturing sites and products and diminishes a coordinated global effort. InDevR seeks to eliminate these bottlenecks by providing a standardized, ready to use kit with reagents that are versatile for antigenic drift. The VaxArray® Portfolio offers a simple multiplex solution that is validated to ICH guidelines and is manufactured under ISO:13485 quality standards. The VaxArray system has been implemented for bioprocess improvement at several influenza and coronavirus vaccine manufacturing sites and has already gained traction with FDA and Health Canada submissions.

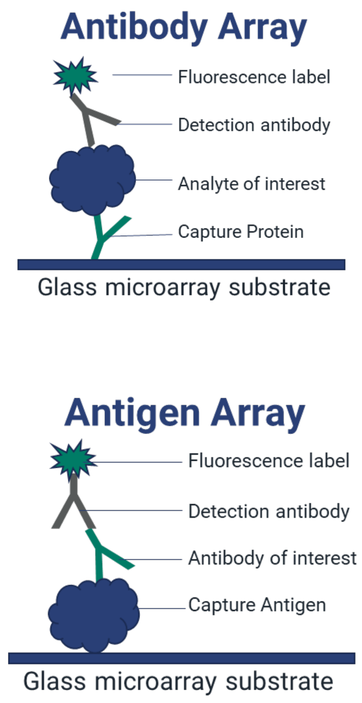
Methods and Materials

The VaxArray platform is a reagent sparing sensitive multiplexed fluorescent immunoassay for detection of antigens or antibodies in a total assay time of 1-2 hours. The assay principles are shown on the right.

Two potential use cases are shown below. On the left, a standard protocol was used to evaluate the potency of a quadrivalent influenza vaccine and accuracy is shown with respect to SRID. The VaxArray solution works well with egg, recombinant, and virus-like-particle vaccine technologies and is compatible with crude and adjuvanted drug substance and product.

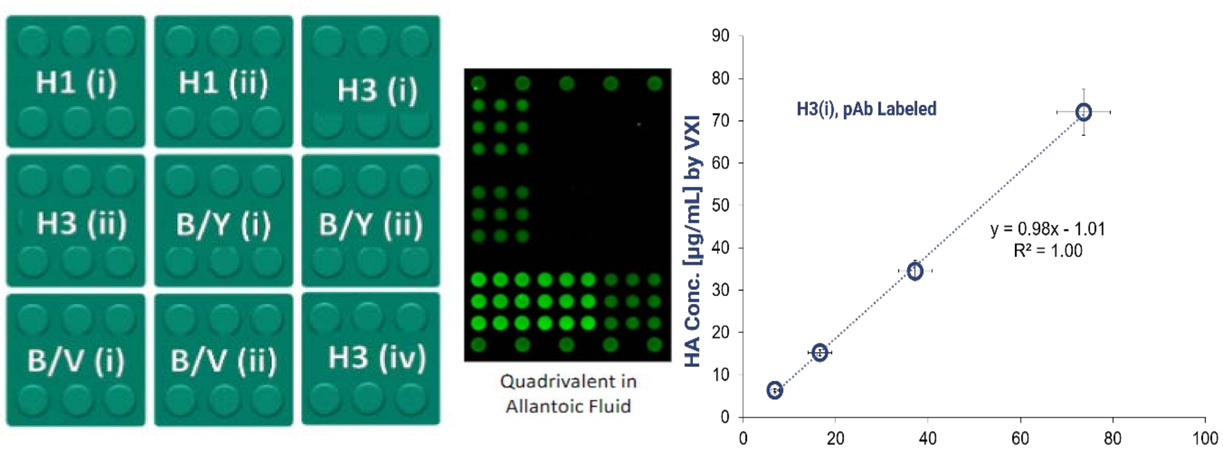
The system can also be used to determine pre-immunization status or post-immunization immunogenicity of participants during clinical trials, or can be used to characterize convalescent serum antibodies. On the right, the data shows sero history differences of clinical sample for variants of the coronavirus. The CoV SeroAssay provides a complete picture for understanding prior variant history and potential impact during clinical trials.





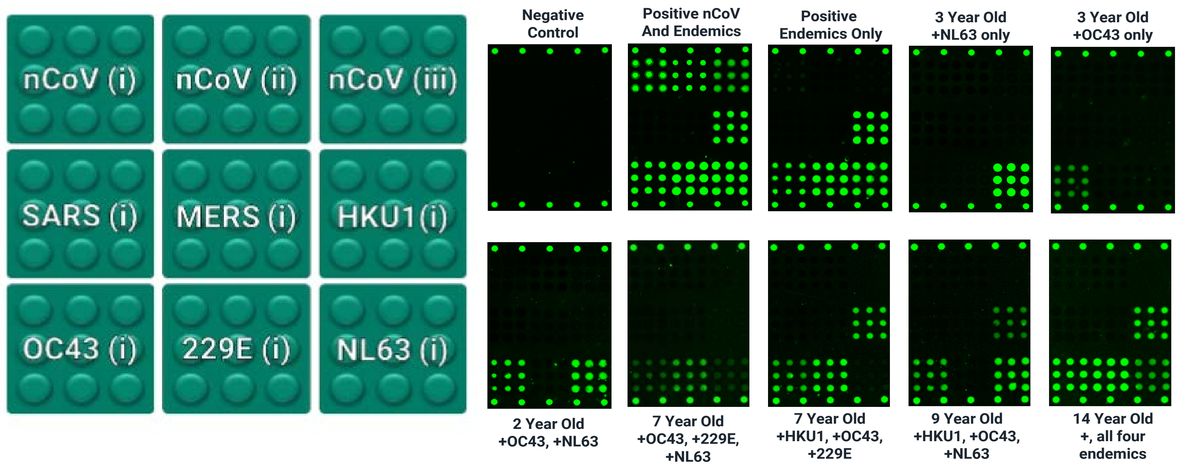
Seasonal Influenza Hemagglutinin Assay for Vaccine Development

Simultaneously evaluate potency and subtype specific identity of H1, H3, B/Yamagata-like, and B/Victoria-like HA antigens. All VaxArray Kits contain capture molecules that are both conformational and stability indicating. Strong correlation with SRID was also observed.



Coronavirus SeroAssay for Clinical Evaluation of Sero History

Analysis of pandemic and endemic human antibodies for SARS-CoV printed in replicate in a microarray format shown below, which enables simultaneous analysis of serum antibodies to 9 antigens. Coronavirus SeroAssay shows 98.5 % sensitivity and 100% specificity, when compared to infectivity status by RT-PCR.



Conclusion

The VaxArray platform offers standardized kits for vaccine development and clinical assessment of influenza, coronavirus, measles/rubella, polio, and more. Custom kits can easily be configured for additional vaccine areas and its analytical applicability can extend from vaccine development, bioprocess optimization, manufacturing QC, preclinical/clinical trials, or serosurveillance studies.

The VaxArray kits provide multiple benefits by measuring conformationally correct target analytes with high subtype specificity, and the multiplex assay format provides more answers simultaneously with less labor and reagent. These benefits are helpful as compared to HPLC assays. Faster assay development, with ~30 minutes hands-on time also offers advantages over SRID and ELISA methods.

	VaxArray	SRID	ELISA	HPLC
Time to Result	1-2 hours	2-3 days	8-24 hours	2-3 hours
Multiplexed	√	x	x	x
Ready to Use Kit	√	x	x	x
Functional Assay	√	√	√	x
Stability Indicating	√	√	√	x
Subtype Specific	√	√	√	x
In Process Samples	√	x	x	√
Adjuvated Samples	√	x	x	x
Sensitivity	High	Med	High	Med
Relative Cost	Low	Med	Low	Med