VaxArray® Polio Assay:
A Multiplexed Alternative to Traditional D-Antigen ELISA

Overview and Key Performance Data

The VaxArray Polio Assay is a new tool for measuring poliovirus D-antigen content in monovalent and multivalent vaccine samples using serotype-specific human monoclonal antibodies for capture and a monoclonal antibody label. The human capture antibodies are printed in an array format on glass, with detection via a fluorescent labeled human monoclonal antibody that universally binds D-antigen. With a time to result as little as 1 hour, the VaxArray Polio Assay provides an excellent alternative to the commonly used but cumbersome D-antigen ELISA assay. **Figure 1** shows a schematic of the assay detection principle, microarray layout, and representative fluorescence images.

VaxArray Polio Assay Features

- Time to result in 1 hour
- Multiplexed D-antigen quantification of types 1, 2, and 3 for a variety of polio vaccines
- Same human antibodies being evaluated as universal reagents for inactivated Sabin vaccines (sIPV)
- Adjuvant compatible

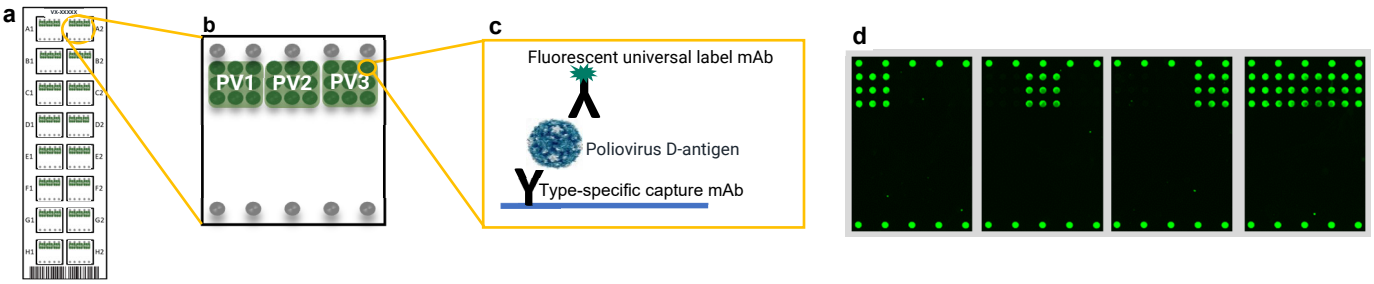

Figure 1: (a) VaxArray Polio Assay slide layout, (b) microarray layout schematic showing poliovirus types 1, 2, and 3 (PV1, PV2, PV3), (c) detection principle, and (d) representative fluorescence images of monovalent Sabin inactivated polio vaccine monobulk (types 1, 2, 3, and trivalent mixture at right).

D-antigen ELISA is the standard in vitro potency assay for inactivated polio vaccines, but the common use of "home brew" ELISA assays which are not standardized can add unnecessary variability to these analyses. The industry is moving towards improved reagents for D-antigen characterization of inactivated polio vaccines, particularly in light of increased use of the attenuated Sabin strains in inactivated polio vaccines (IPV or sIPV) to increase safety in manufacturing. Importantly, the VaxArray Polio Assay utilizes the same human monoclonal antibodies currently under consideration as universal reagents for characterizing sIPV vaccines[1,2]. The VaxArray Polio Assay can also be used for traditional IPV vaccines and for rapid antigen tracking in oral polio vaccine (OPV) as well.

The VaxArray Polio Assay provides comparable limits of quantification and linear dynamic range to ELISA, as shown in **Table 2**. However, the VaxArray solution provides the added benefits of a significantly reduced time to result and ability to multiplex all 3 antigens in a single, adjuvant compatible assay.

Table 2: VaxArray Polio Assay Limits of Quantification

Material	Type	LLOQ (D-Ag units/mL)	ULOQ (D-Ag units/mL)	Linear Dynamic Range
Trivalent sIPV mixture of monovalent bulks	1	0.40 (± 0.04)	27.2 (± 3.0)	68x
	2	0.20 (± 0.02)	18.0 (± 1.1)	90x
	3	0.10 (± 0.01)	50.2 (± 2.0)	502x
Trivalent cIPV IPOL vaccine	1	0.33 (± 0.03)	78.0 (± 7.8)	232x
	2	0.17 (± 0.02)	28.3 (± 0.6)	167x
	3	0.30 (± 0.03)	108.0 (± 7.6)	360x

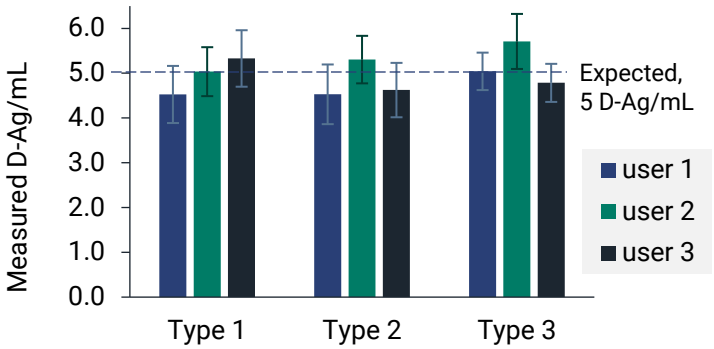

Figure 2: VaxArray Polio assay accuracy and precision in a 3-user, 3-day study of trivalent sIPV (each at 5 D-antigen units/mL). Error bars are ± 1 standard deviation of the average.

In addition, a precision and accuracy study was conducted in which three users analyzed a contrived trivalent sIPV mixture (5 D-Ag units/mL in each type) over each of three days, analyzing 8 replicates of the sample on each day (n=24 for each user). **Figure 2** shows the results generated in this study, with all 3 users obtaining % recovery of between 86 – 107% over all 3 types, and % RSDs of ≤ 15%.

Summary

Traditional D-antigen ELISA assays for characterization and in vitro potency testing of polio vaccines are time and labor intensive and suffer from assay-to-assay and lab-to-lab variability. The VaxArray Polio Assay provides a standardized, off-the-shelf alternative to ELISA that offers a rapid time to result of as little as 1 hour and performance equivalent to or improved over traditional ELISA. Polio vaccine manufacturers and researchers will benefit in saving time and money when using this assay for characterization of crude or in-process samples, and throughout the development process to final vaccine formulations.

Table 3: Major Benefits of VaxArray Polio Assay over Traditional D-Antigen ELISA Assays

Metric	Traditional D-Antigen ELISA	VaxArray Polio Assay	Improvement
Hands-on Time	2-3 hours	30 minutes	4-6x
Time to Result	24-48 hours	1 hour	~10-50x
Standardization	Home-brew/in-house assays	Global product/standardized reagents	Standardization reduces risk

References

1. Excerpted from Supplemental Information: Crawt, L. et al., *J. Inf. Dis.* **2020**, 221, 544-552.
2. Kouiavskaia et al., **2020**, *J. Virol. Meth.*, 276, 113785.

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