

Streamline
Bioprocess
Development,
Improvement
and Monitoring
with New Protein
Quantification Tool



Webinar for:

Developing
Countries
Vaccine
Manufacturer
Network

Presenter:

Kevin Kohlmeier

AGENDA



ABOUT INDEV



VACCINE
BIOPROCESS



ROLE OF
ANALYTICS



CURRENT
ANALYTICAL
LANDSCAPE



VAXARRAY FOR
BIOPROCESS
ANALYTICS



CONTACT
INFORMATION



Founded in 2003

Focused on development of next generation analytical tools

Documented success with bringing new technologies to market

The Importance of Vaccines

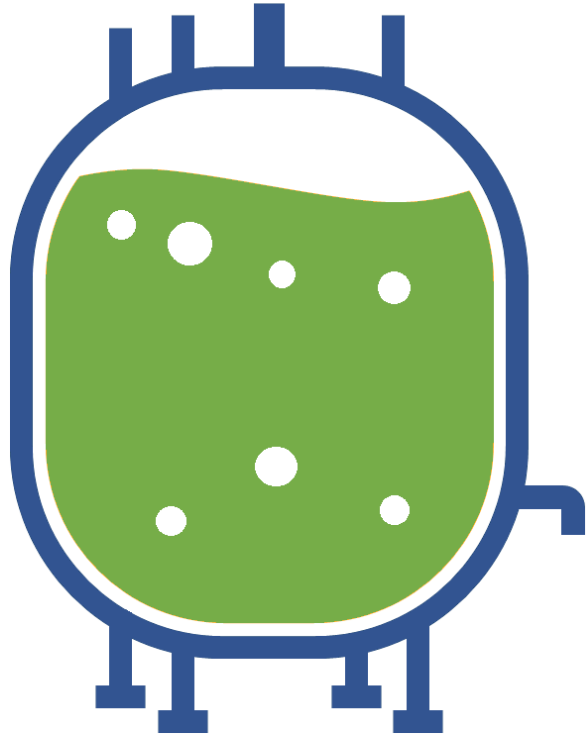
“With the exception of safe water, no other modality, not even antibiotics, has had such a major effect on mortality reduction...”

S. Plotkin, W. Orenstein, P. Offit, Vaccines (Saunders, Philadelphia, 5th ed. 2008).



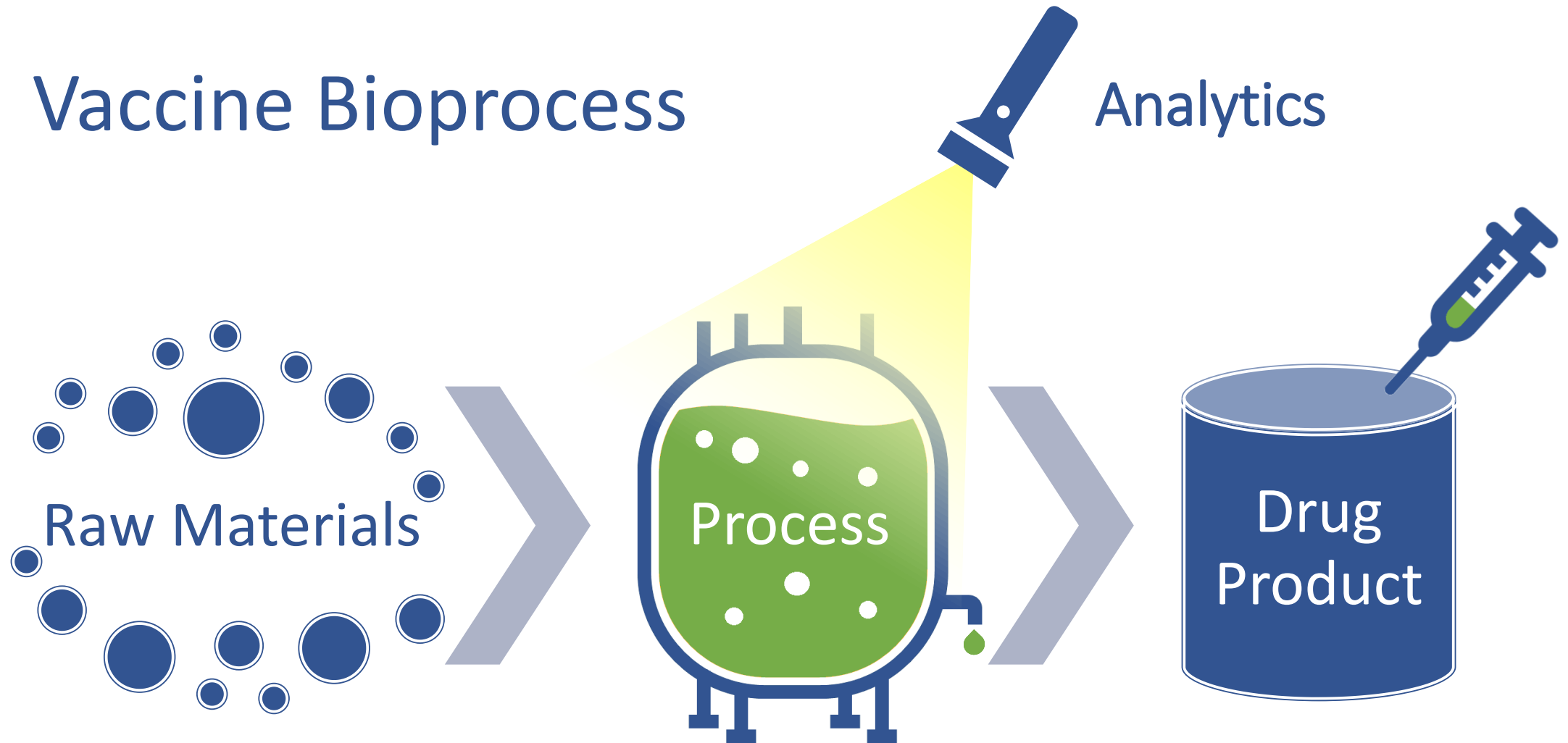
Challenges for Vaccine Manufacture

“Vaccine manufacture is one of the most challenging industries. Even the most basic manufacturing steps necessary to produce vaccines [...] are difficult to execute.”



PROCESS = PRODUCT

Vaccine Bioprocess



The Role of Analytics

In-Process

“Successful development of biopharmaceuticals depends on high-quality analysis [...]. Of particular benefit are analytical methods that can be applied not only to final purified samples, but also throughout production [...].”

The Role of Analytics

New Technologies

“The biological, immunological and physicochemical properties of the HA antigen should be verified using a wide range of state-of-the-art analytical methods.”

From European Medicines Agency’s ‘Guideline on Influenza Vaccines – Quality Module’, 2017

The Role of Analytics

Advantages

“A company with this capability [advanced analytics] has an enormous competitive advantage because of the manner in which technology issues can dominate vaccine development.”

Defining Performance

Understanding requirements for new methods

“The properties of an ideal assay for influenza vaccine would include the following.



1. *It would measure a biologically relevant parameter to give meaningful measurements of potency, stability and clinical effect.*



2. *It would be accurate and precise although the degree of accuracy and precision required is not specified.*



3. *It would be rapid to allow real time monitoring of processes.*



4. *It would be specific at least to the level of virus type and subtype.*



5. *It should have a wide dynamic range so as to measure low dosage forms and it should work on different vaccine types such as might be used in pandemics.”*

ANALYTICAL NEEDS



BIOLOGICALLY
RELEVANT



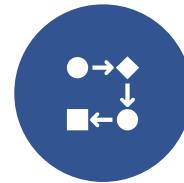
ACCURATE &
PRECISE



RAPID & HIGH
THROUGHPUT



QUANTITATIVE



COMPATIBLE
THROUGHOUT
PROCESS



OFF THE
SHELF



EASE OF
VALIDATION

Biological methods



Chromatography



Molecular methods



Immunoassays



Next Generation Technologies



The Analytical Landscape

Next Generation Technologies



The Analytical Landscape



The Analytical Landscape

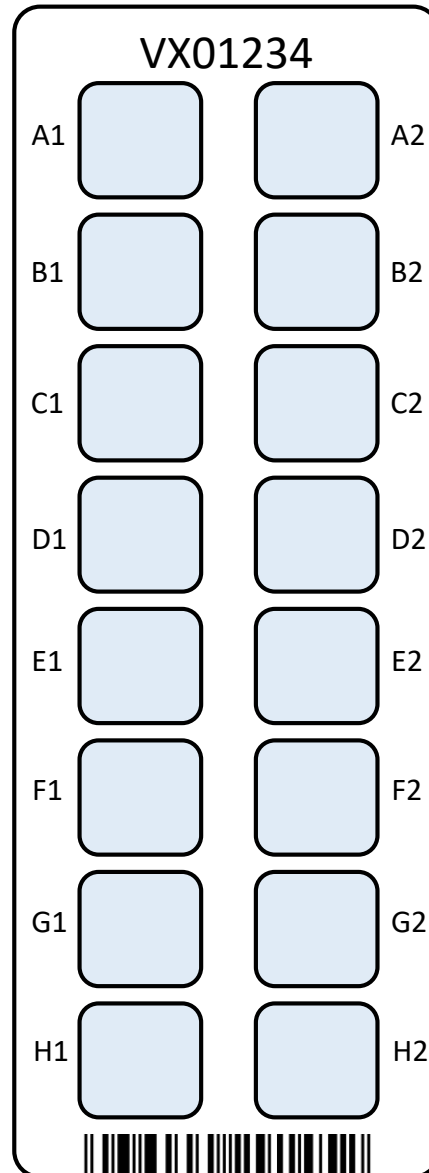


A new analytical
method for protein
quantification.

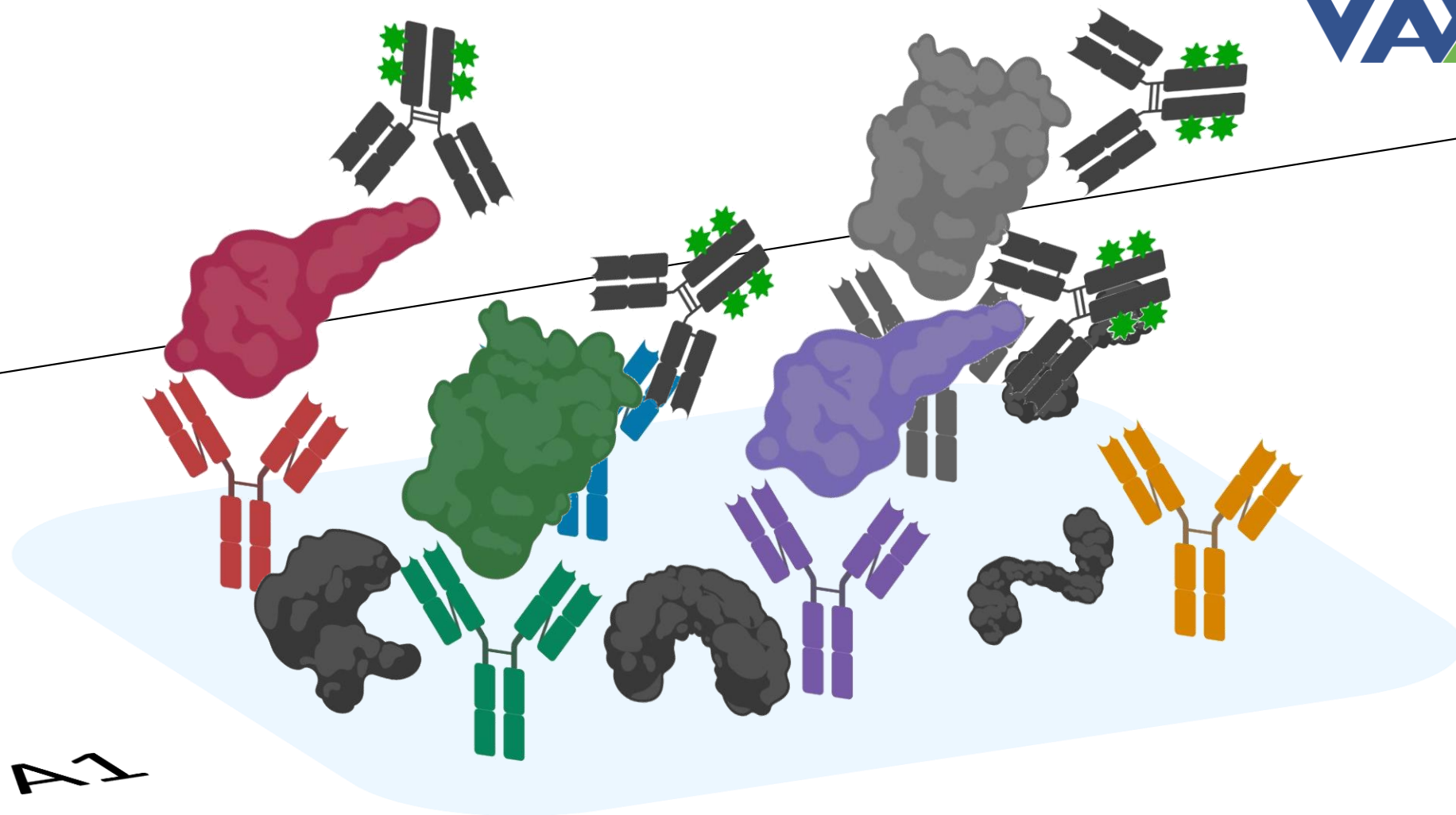


VAXarray®

A MULTIPLEXED
IMMUNOASSAY



A MULTIPLEXED
IMMUNOASSAY



A1

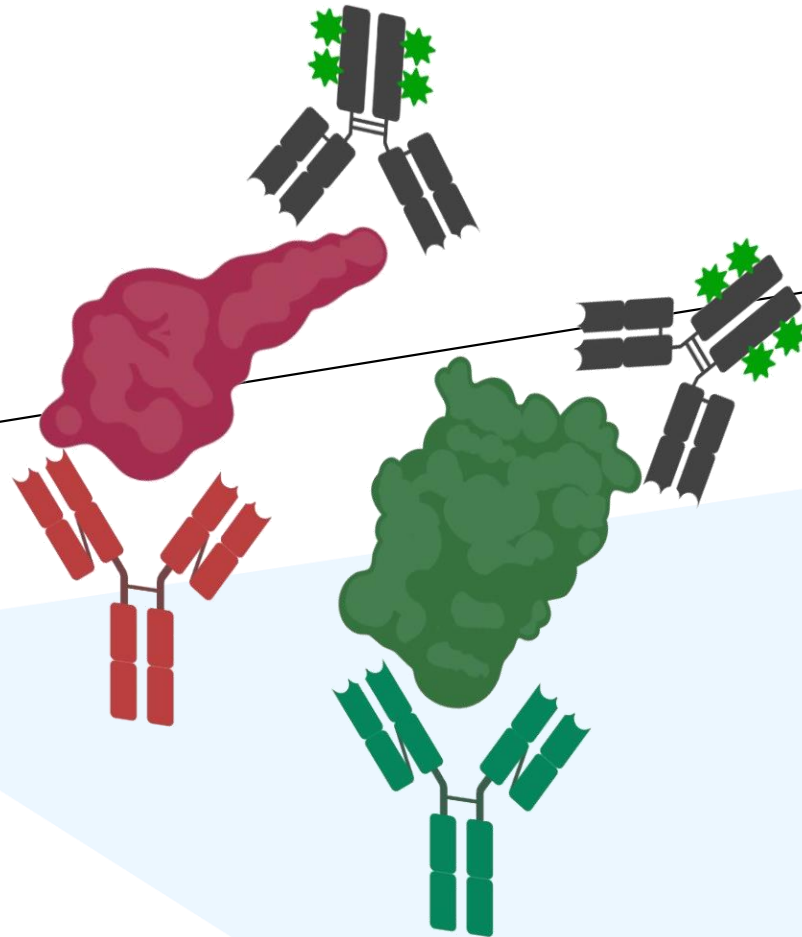


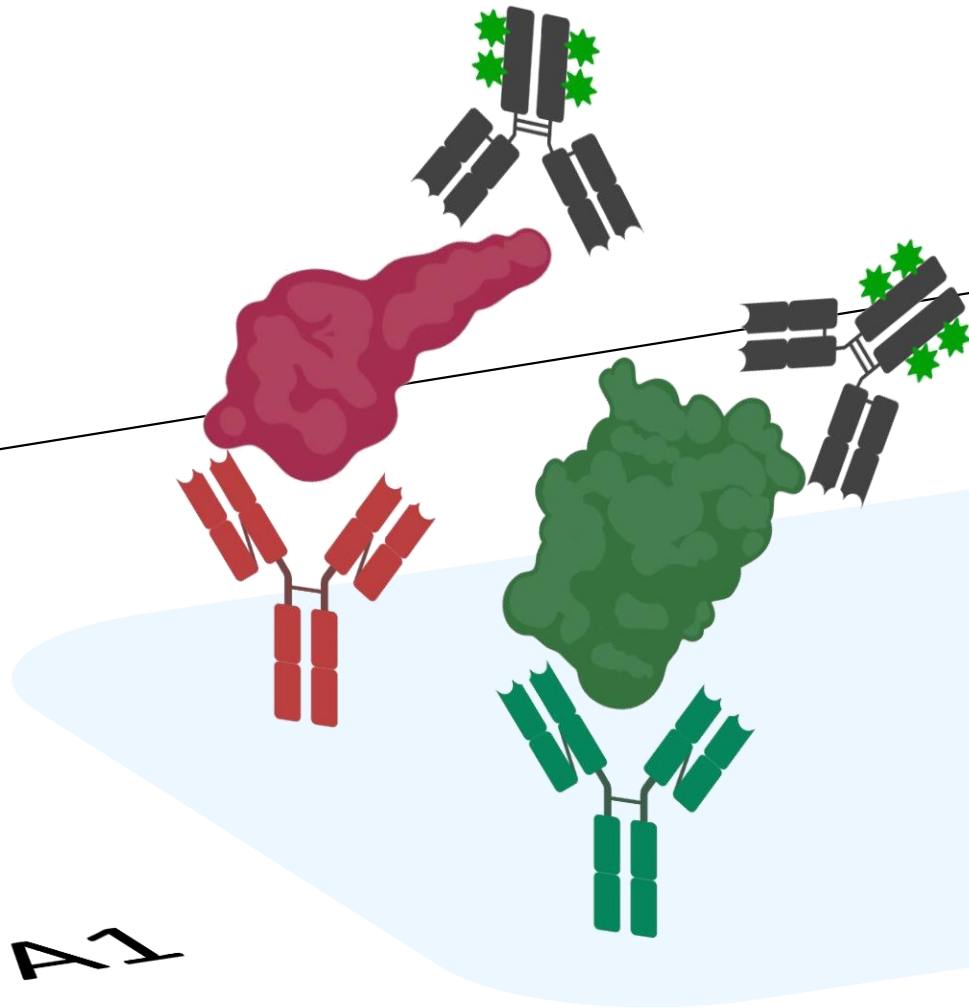
MULTIPLEXED

Multiple antibodies in a well

Quantification of multiple proteins simultaneously

A1





PROVEN TECHNOLOGY

Immunoassays are broadly used

Biologically relevant

Fluorescence detection



BIOLOGICALLY
RELEVANT



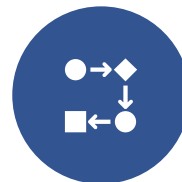
ACCURATE &
PRECISE



RAPID & HIGH
THROUGHPUT



QUANTITATIVE



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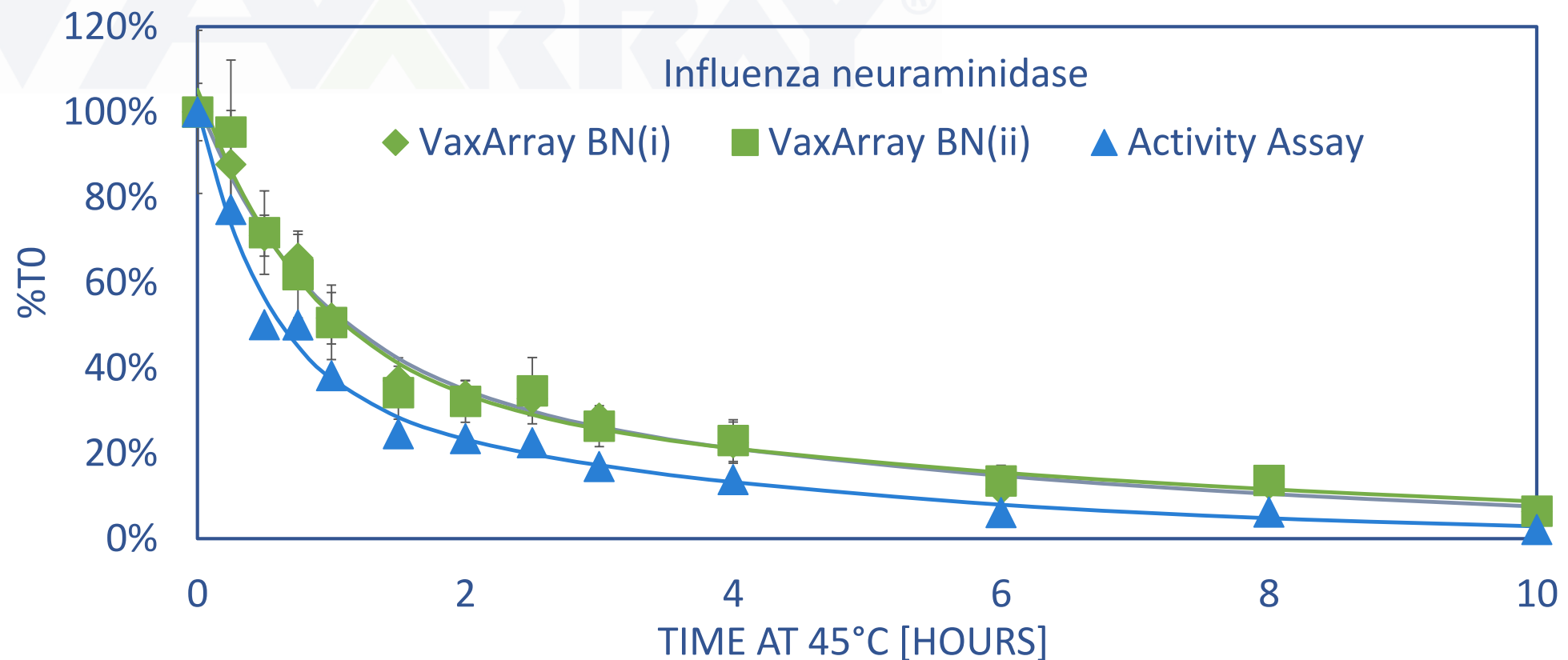


EASE OF
VALIDATION



BIOLOGICALLY RELEVANT

Stability Indicating



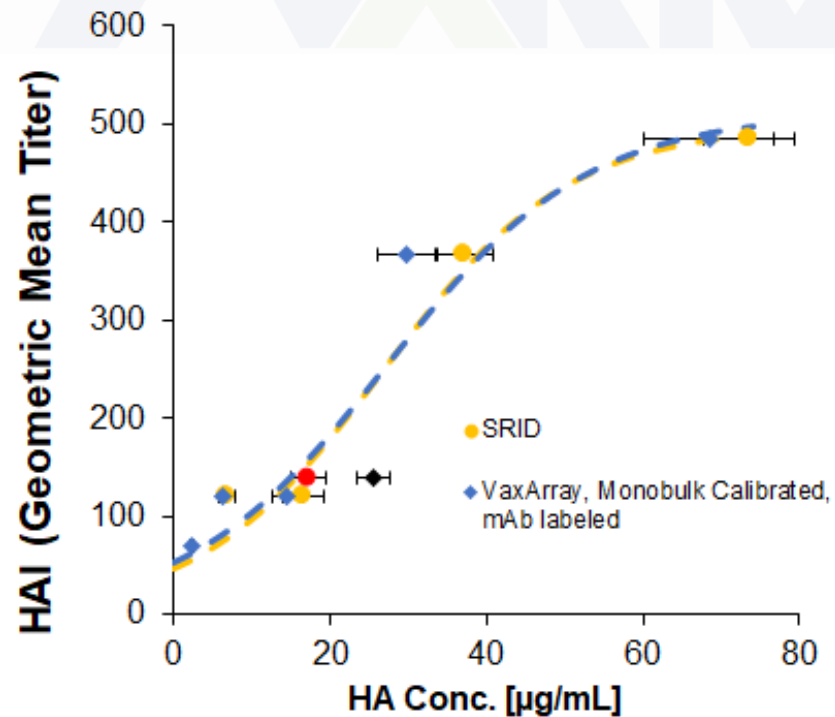
Byrne-Nash, R., 2019, 'A neuraminidase potency assay for quantitative assessment of neuraminidase in influenza vaccines', *Vaccines*, (2019)4:3



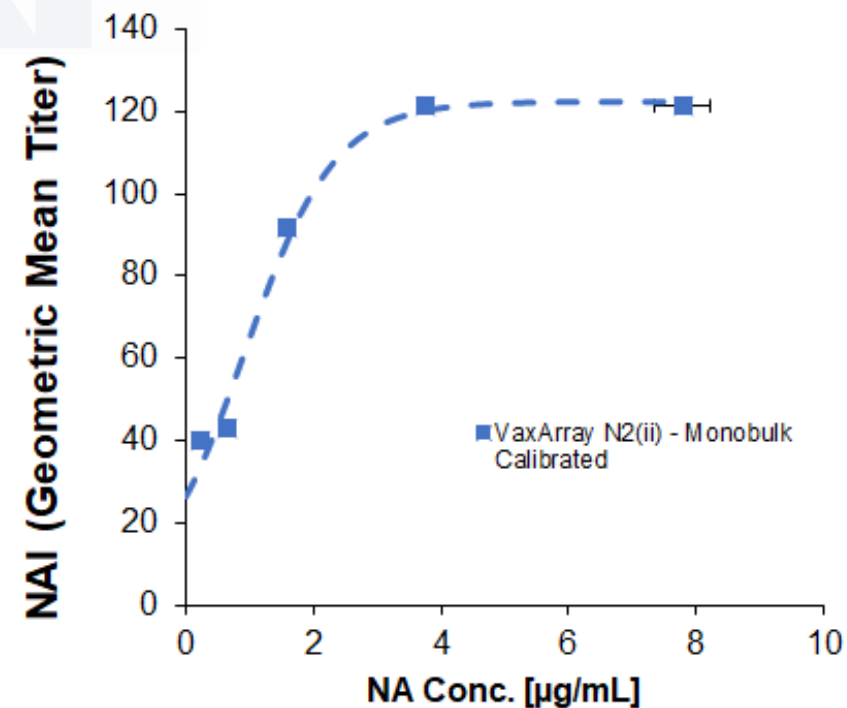
BIOLOGICALLY RELEVANT

Proven Indicator of Immunogenicity

VaxArray Seasonal HA Assay



VaxArray Seasonal **NA** Assay





BIOLOGICALLY
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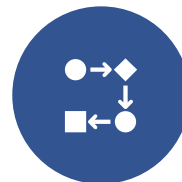
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THROUGHPUT



QUANTITATIVE



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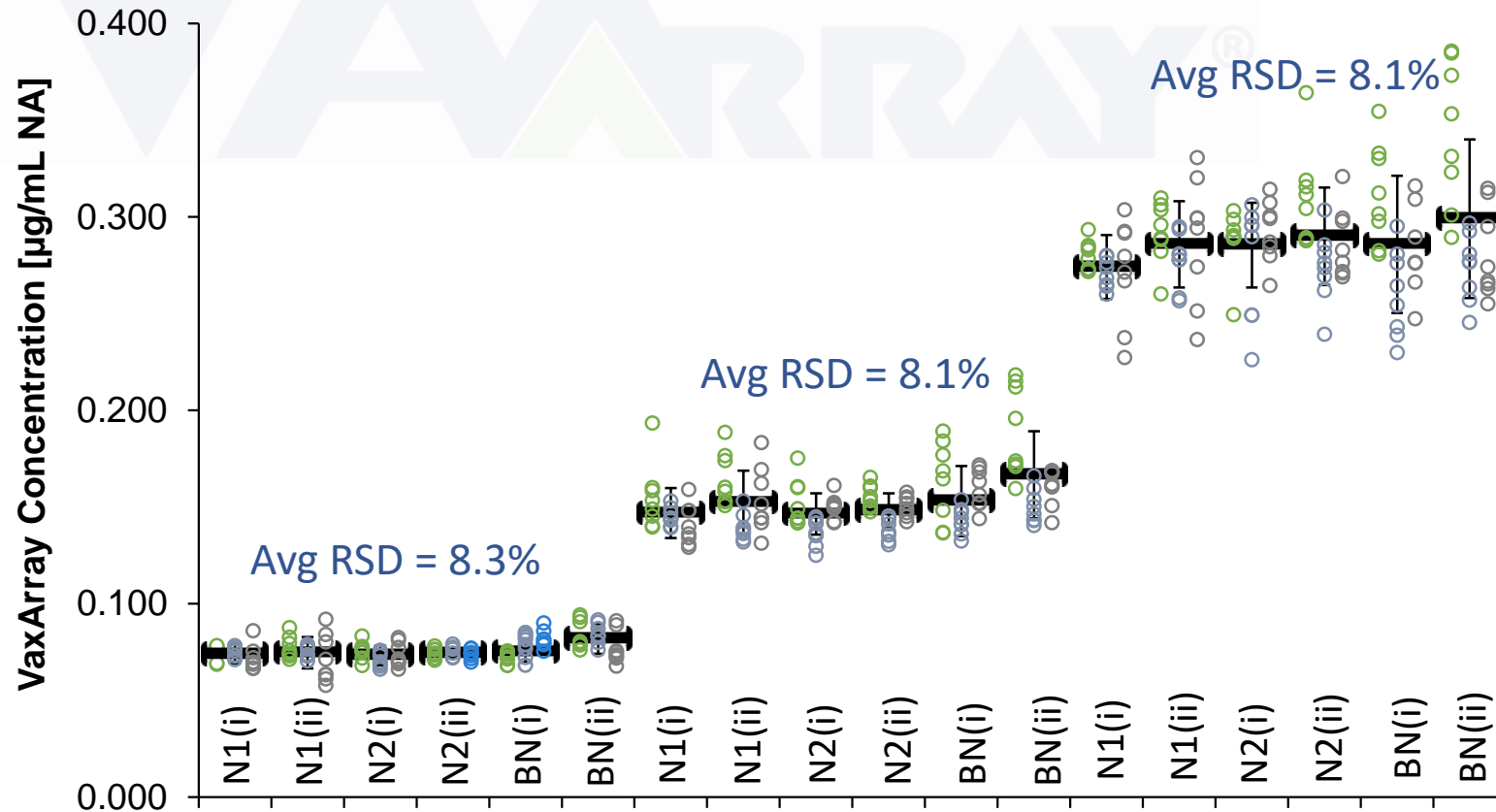
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ACCURATE & PRECISE



From ICH Guidelines:

Three days

Three operators

Three reagent lots

Two instruments



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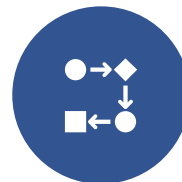
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EASE OF
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RAPID & HIGH THROUGHPUT

Simple. Easy to execute.

Two hour time to result

Process up to 64 samples at once

Easy washing steps

Minimal sample prep

Analysis in minutes





BIOLOGICALLY
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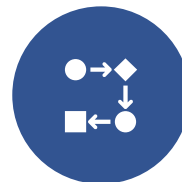
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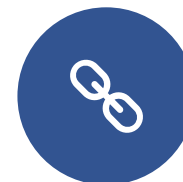
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COMPATIBLE
THROUGHOUT
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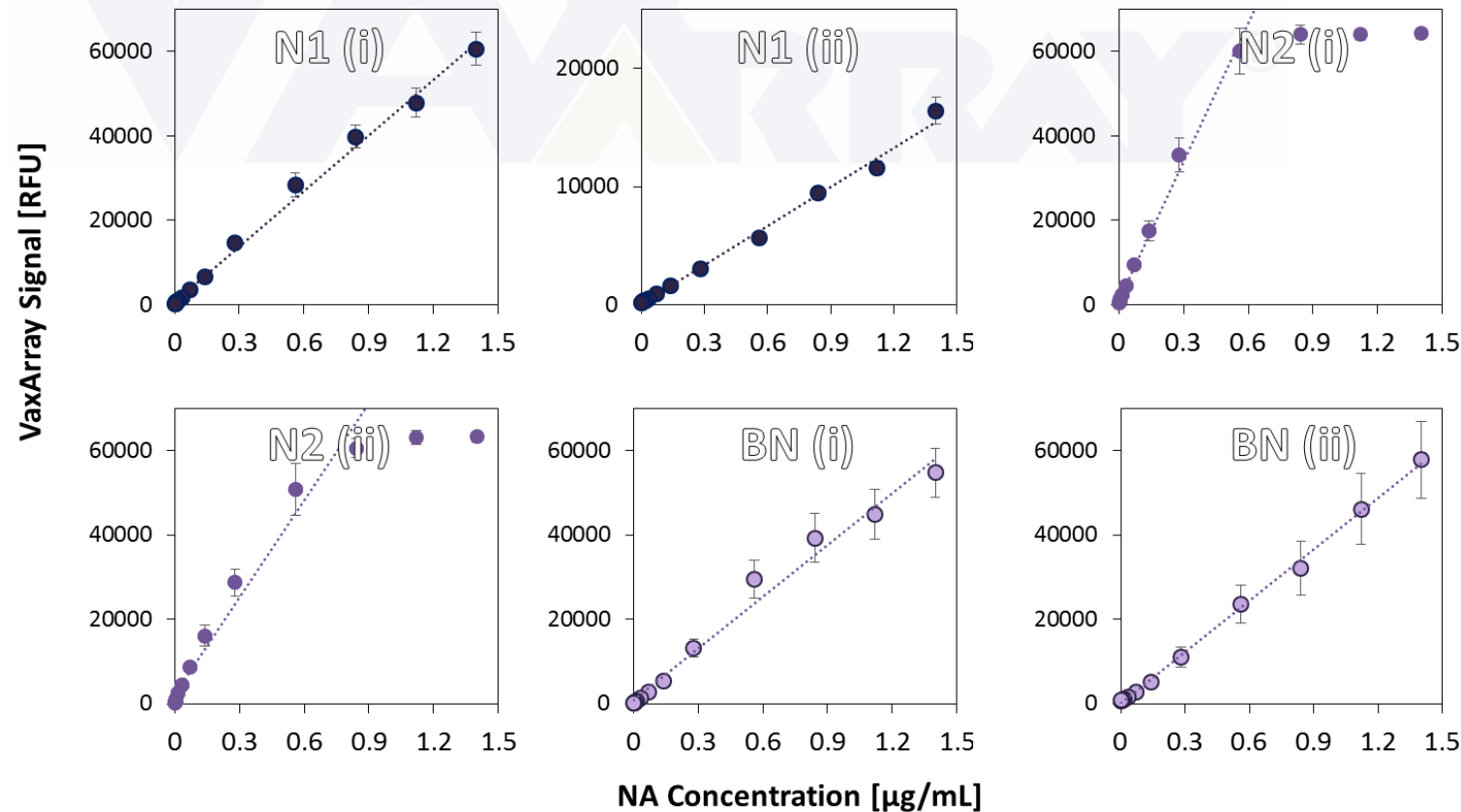
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EASE OF
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QUANTITATIVE



Broad linear range

Low limits of quantification

Exceptional sensitivity

Calibration using a variety of methods



BIOLOGICALLY
RELEVANT



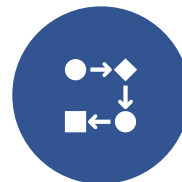
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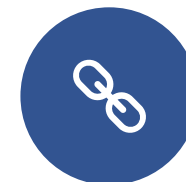
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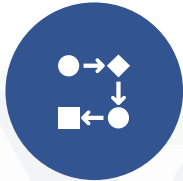
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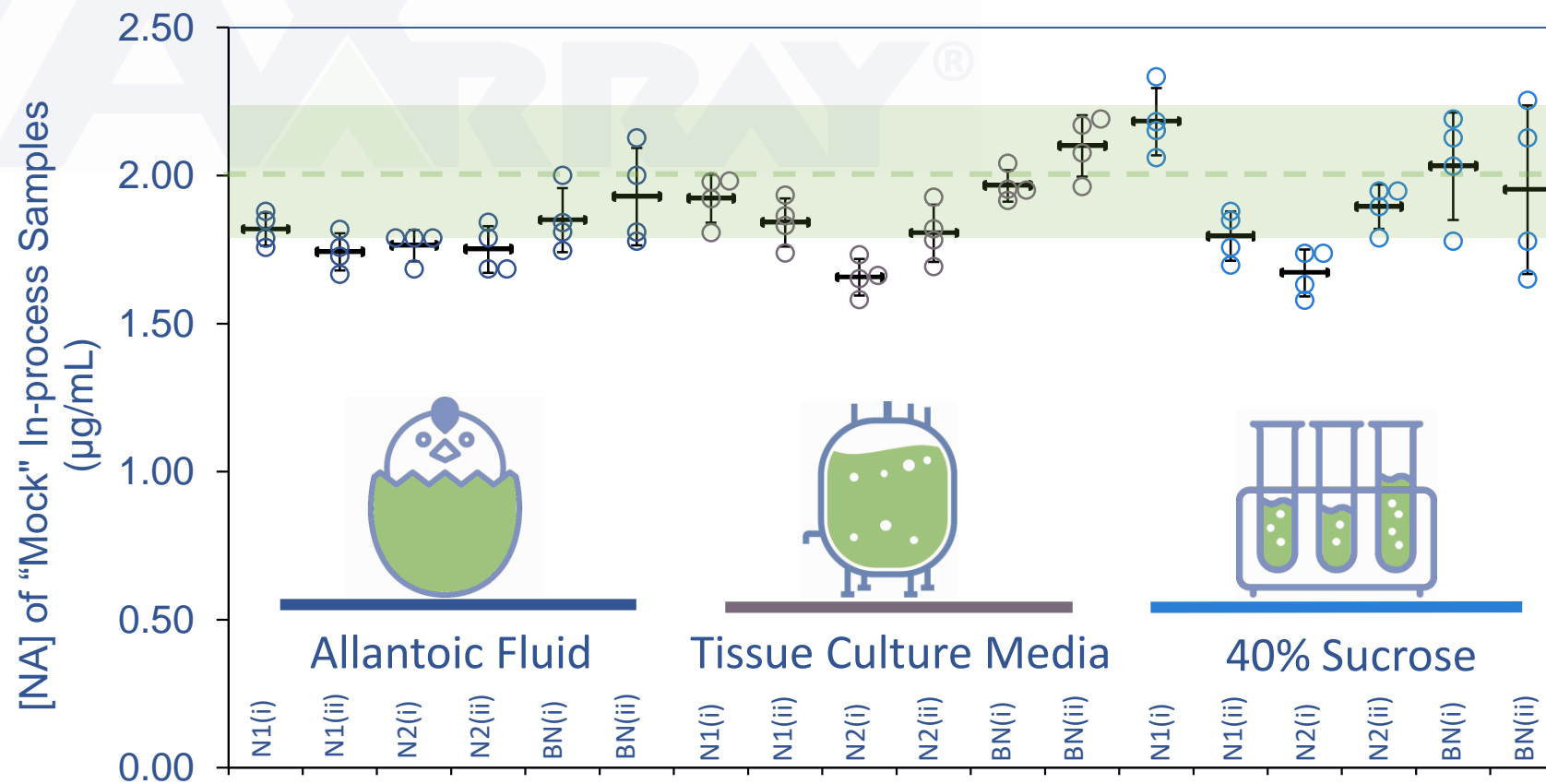
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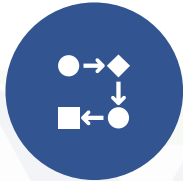


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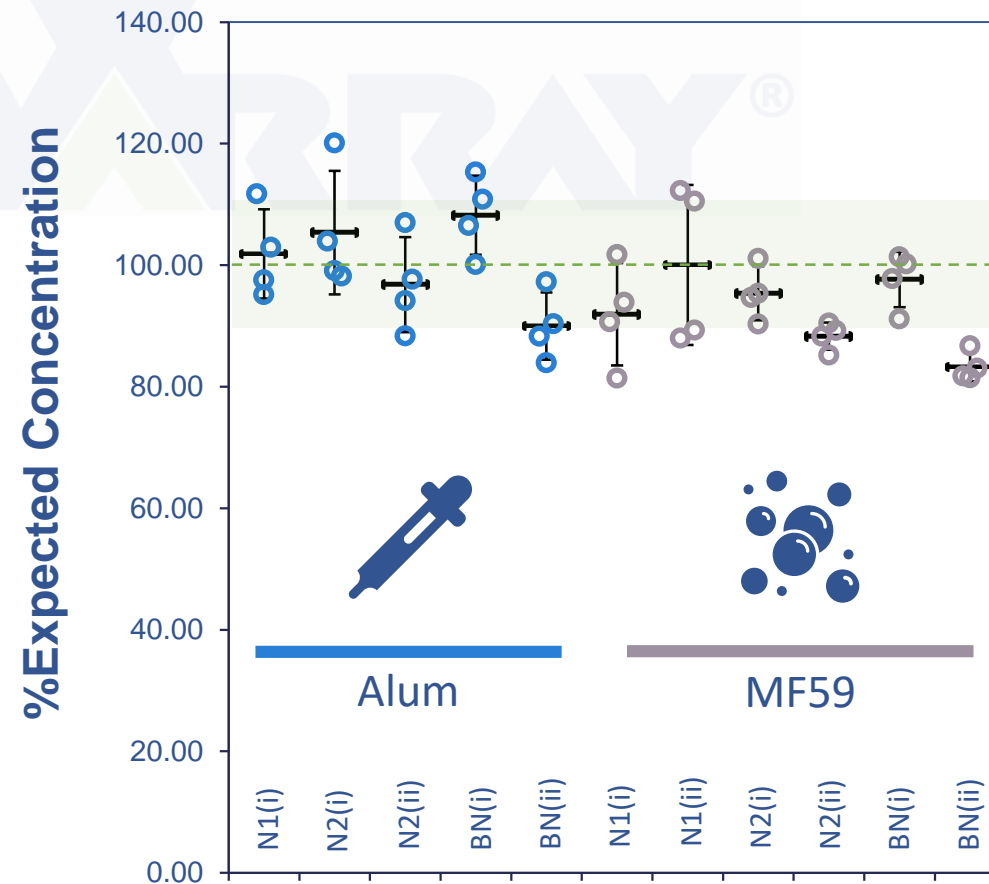


COMPATIBLE THROUGHOUT PROCESS





COMPATIBLE THROUGHOUT PROCESS





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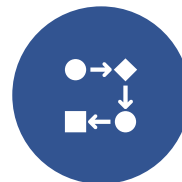
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EASE OF
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OFF THE SHELF

Manufactured under
ISO:13485 quality standards

No need for customization
or lengthy reagent
preparation

Standardize across sites





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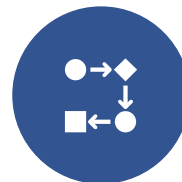
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EASE OF VALIDATION

21 CFR Part 11 – Annex 11
Compatible Software

Compatible with QbD

Rigorously validated
according to ICH guidelines
with Influenza Vaccines





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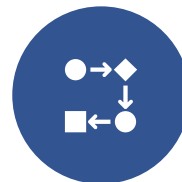
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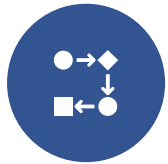
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EASE OF
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Biological methods 

Chromatography 

Molecular methods 

Immunoassays 

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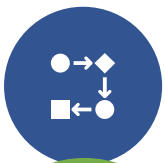
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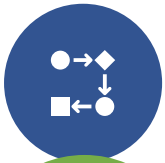
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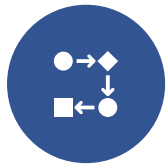
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THANK YOU

And thanks again to DCVMN for hosting this webinar