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New VaxArray Potency Test Kit for Pandemic Flu Vaccines

InDevR launches a new product that could shave weeks off the timeline to deliver flu vaccines in the event of a pandemic

BOULDER (2/20/18) — InDevR, a Boulder-based analytical technology and life science company, today announced that it has expanded its VaxArray® product portfolio with a new reagent kit to address the “need for speed” in combating flu viruses with pandemic potential. The VaxArray Influenza Pandemic Hemagglutinin potency test kit is now available for flu vaccines containing H5, H7, and H9 flu subtypes, which includes new H7 vaccines against the deadly avian H7N9 virus. This new potency assay enables rapid determination of immunogenic hemagglutinin in low-dose and adjuvanted flu vaccines.

The panel of monoclonal antibodies that provide the test with virus subtype specificity were developed by scientists at the Center for Biologics Evaluation and Research (CBER) within the US Food and Drug Administration (FDA) and licensed by InDevR in 2017.

Avian influenza viruses, especially A/H5N1 and A/H7N9 viruses represent the latest threat for a lethal influenza pandemic. According to the December 2017 Risk Assessment Summary by the World Health Organization (WHO), “*Since 2013, a total of 1565 laboratory-confirmed cases of human infection with avian influenza A(H7N9) viruses, including at least 612 deaths, have been reported to WHO.*” In response to concerns over these deadly H7N9 flu viruses, in 2017 the US government issued a call for new vaccines to include in the Strategic National Stockpile for protection of the US population in the event of an outbreak.

To enable a rapid vaccine response during a severe outbreak or pandemic, there is a pressing need for a potency test that is rapid and has sufficient sensitivity to track potency in dose-sparing and adjuvanted vaccines. The current gold standard method for flu vaccine potency determination, single radial immunodiffusion (SRID), falls short on all these counts. Most importantly, it can take months to develop the reference reagents needed to perform the SRID assay, which, as demonstrated in the 2009 H1N1 pandemic can delay the delivery of flu vaccine.

In contrast, the VaxArray® Pandemic Hemagglutinin Potency product is ready for use “off the shelf” and, subject to regulatory approval for lot release testing, could be implemented immediately for dose-sparing and/or adjuvanted vaccines if a new, responsive H5, H7, or H9 flu virus emerges as a threat.

The new test kit complements InDevR’s VaxArray® Seasonal Hemagglutinin potency assay and InDevR’s potency testing service, which includes a potency assay for neuraminidase. More product information is available at: <http://indevr.com/products/vaxarray-influenza/>.

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About InDevR

InDevR has a demonstrated commitment to innovative solutions for the life science industry. With focus on enhancing diagnostics, vaccines and other biotherapeutics, InDevR has emerged as a leader in progressive new analytical technologies that enable accelerated development and manufacturing of these life-saving products. For more information about the company and products, please visit www.indevr.com or call 303-402-9100.

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