CARES Act Project

PROVIDING VIRUS PROTEINS TO IMPROVE TESTING CAPABILITIES

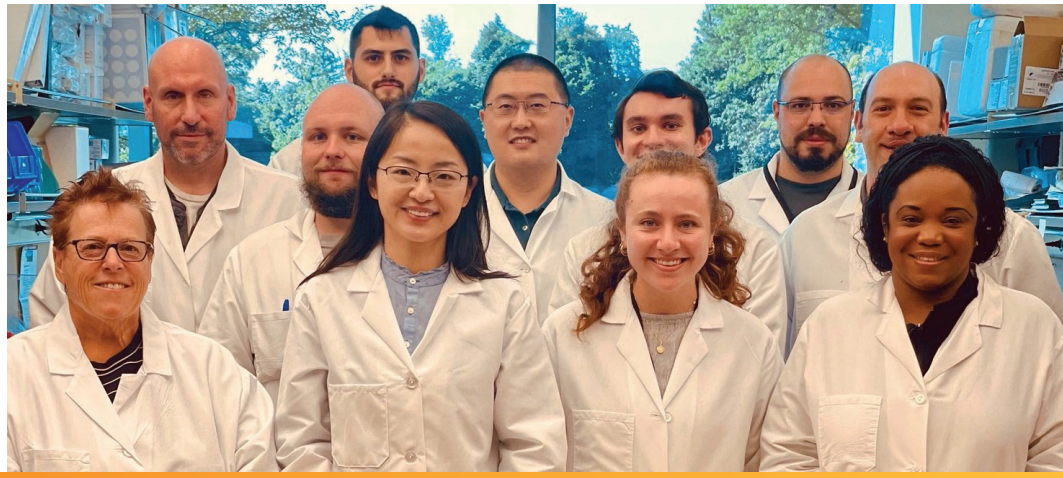
DEVELOPMENT OF A SARS-COV-2 POLYVALENT MICROBEAD IMMUNOASSAY (MIA)

NIIMBL® The National Institute for Innovation in Manufacturing Biopharmaceuticals

New York State Department of Health (Wadsworth Center), Albany, NY

Type:
Non-profit Research Organization

Participating Organizations:
MassBiologics of UMass Chan Medical School



» ***Yang Wang***, *MassBiologics of UMass Chan Medical School*

INDUSTRY NEED

The healthcare industry needed high-throughput and accurate diagnostic tests to screen for SARS-CoV-2 virus-neutralizing antibodies in human blood. When the COVID-19 pandemic began in March 2020, healthcare workers used live virus to measure antibodies, increasing their risk of exposure. Developing a safer and faster method of antibody testing could help to screen quarantined workers before returning to work, identify convalescent patients for potential antibody therapy research, and serve as a benchmark to test the efficacy of future vaccines.

SOLUTION

This collaboration between MassBiologics and the Wadsworth Center aimed to produce high-quality proteins to facilitate the development of a Polyvalent Microbead Immunoassay (MIA) that can measure SARS-CoV-2–specific neutralizing antibodies. This polyvalent assay can detect more than one type of antibody by using microbead technology to capture the antibodies for screening. This high-throughput assay would serve as a surrogate to live virus tests, providing flexibility to patients in a safer laboratory environment.

OUTCOME

The team developed a validated, multiplexed assay for SARS-CoV-2 antibody-based diagnostics. With its high correlation to live virus tests, the assay can serve as a safer, high-throughput surrogate. The assay has the capacity to screen nearly 100 samples within four hours versus the five-day screening time for a live virus assay—a 97% reduction. Furthermore, since the MIA eliminates live virus tests, it reduces the exposure risk for healthcare workers. This MIA can be adapted for new antibodies and viruses in approximately 50% less time than live virus assays, enabling the healthcare industry to meet the challenges of future health emergencies more quickly. The MIA can be adapted for new antibodies in about two weeks and new antigens of virus variants in approximately two months, whereas adaptation of the live virus assay would take nearly a month for new antibodies and up to four months for new viruses and variants.

> *"NIIMBL enabled us to explore multiple different ways to express the protein and qualify the assay to industry standard. Without NIIMBL, a lot of that work is not possible."*

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