



Biomerica files for FDA Emergency Use Authorization (EUA) of its Unique Laboratory Antibody Test for COVID-19

- This high-volume laboratory test will allow for collection of blood samples using a simplified proprietary blood collection device once cleared by the FDA.
- This test adds to the previously announced Biomerica 10-minute finger prick antibody tests already being sold outside of the US.
- Biomerica has filed a provisional patent on technology to allow simplified blood collection.

IRVINE, CA - (June 16, 2020) - Biomerica Inc. (NASDAQ: [BMRA](#)) announced today they have submitted to the FDA an EUA application for an ELISA lab-based serology blood test for the detection of antibodies that identify if a person has been infected with the novel Coronavirus (COVID-19). Antibody testing can be an important next step in opening the economy to tell people if they have been previously infected. This is the third COVID-19 antibody test introduced by the Company. The other two, which are finger-prick rapid tests, are actively being sold outside of the US and have been well received. The Company also intends to obtain a CE mark to market and sell this ELISA laboratory test outside the US.

Biomerica performed testing both internally and at two external labs located in California. The data from this testing that was submitted to the FDA under the EUA application showed 100 percent specificity and zero percent cross reactivity with many common disease states. This test, which uses the ELISA microplate format, can be run on existing open system equipment found in most hospitals and clinical laboratories in the US and outside the US and uses a modified, trimeric spike protein from the SARS-CoV-2 virus. This spike protein is known to be the target of neutralizing antibodies, which can help prevent the virus from entering the cells.¹ Persons who are no longer infectious and have tested positive for the antibodies, can possibly be cleared to return to work as they may have a lower likelihood of reinfection and/or spreading the virus. Antibody tests will also help in better understanding the virus including how long antibodies stay in the body and if they help in immunity as well as how many people have been infected in the population as a whole. Further, this type of testing could be particularly important for the immune surveillance of health care workers, first responders, government workers, and others whose infection risks could be heightened by working with COVID-19 infected individuals.

This ELISA laboratory test was developed by Biomerica and will be manufactured exclusively at Biomerica's manufacturing facility located in Irvine, California, using existing high-throughput, automated equipment. Biomerica has extensive experience manufacturing similar serology ELISA tests for other diseases.

"We are working to provide significant, high specificity and meaningful diagnostic solutions for the novel Coronavirus," said Zack Irani-Cohen, CEO and Chairman of Biomerica. "Our ELISA test will be unique in the market place by simplifying the blood sample collection process in a proprietary way. We have been working with the FDA, who has been very responsive, and we're looking forward to a quick review for this submission. I'm very proud of our team members who are working around the clock to develop, validate and attain regulatory clearance on these COVID-19 diagnostic solutions that benefit patients, healthcare workers and society".

About Serology Tests

Serology tests look for the presence of antibodies, which are specific proteins made in response to infections. The antibodies detected by serology tests indicate that a person has had an immune response to the novel Coronavirus (SARS-CoV-2), whether symptoms developed from infection or the infection was asymptomatic. Antibody test results are important in detecting infections with few or no symptoms.²

1. medRxiv preprint doi: <https://doi.org/10.1101/2020.03.30.20047365>. Accessed 15Jun20

2. Emerging Microbes & Infections 2020, VOL. 9 Molecular and serological investigation of 2019-nCoV infected patients.

About Biomerica (NASDAQ: [BMRA](#))

Biomerica, Inc. (www.biomerica.com) is a global biomedical technology company that develops, patents, manufactures and markets advanced diagnostic and therapeutic products used at the point-of-care (in home and in physicians' offices) and in hospital/clinical laboratories for detection and/or treatment of medical conditions and diseases. The Company's products are designed to enhance the health and well-being of people, while reducing total healthcare costs. Biomerica primarily focus is on Gastrointestinal and inflammatory Diseases where the Company has multiple diagnostic and therapeutic products in development.

About InFoods®

The Biomerica InFoods® IBS product is designed to allow physicians to identify patient specific foods (e.g. eggs, broccoli, wheat, potatoes, corn, etc.), that when removed from the diet, may alleviate or improve an individual's IBS symptoms including, but not limited to, constipation, diarrhea, bloating, pain and indigestion. This patented, diagnostic-guided therapy is designed to allow for a patient specific, guided dietary regimen to improve Irritable Bowel Syndrome (IBS) outcomes. The point-of-care product is being developed to allow physicians to perform the test in-office using a finger stick blood sample while a clinical lab version of the product will be the first for which the company will seek regulatory approval. A billable CPT code that can be used by both clinical labs and physicians' offices is already available for InFoods® diagnostic products. Since the InFoods® product is a diagnostic-guided therapy, and not a drug, it has no drug type side effects. An estimated 45 million people in America currently suffer from IBS making it a leading cause for patient doctor visits.

The Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for forward-looking statements. Certain information included in this press release (as well as information included in oral statements or other written statements made or to be made by Biomerica) contains statements that are forward-looking, such as statements relating to the efficacy of the Company's COVID-19 test, FDA clearance, EUA clearance, the rapidity of testing results, uniqueness of a product, pricing of the Company's test kits, demand for international orders, availability of the Company's COVID-19 test kits, and patent protection on the test technology. Such forward-looking information involves important risks and uncertainties that could significantly affect anticipated results in the future, including, without limitation: results of studies testing the efficacy of the Company's COVID-19 test; regulatory approvals necessary prior to commercialization of the Company's COVID-19 test; availability of the Company's COVID-19 test kits; capacity, resource and other constraints on our

suppliers; dependence on our third party manufacturers; dependence on international shipping carriers; governmental import/export regulations; demand for our COVID-19 test; competition from other similar products and from competitors that have significantly more financial and other resources available to them; governmental virus control regulations that make it difficult or impossible for the company to maintain current operations; regulations and the Company's ability to obtain patent protection on any aspects of its rapid test technology. Accordingly, such results may differ materially from those expressed in any forward-looking statements made by or on behalf of Biomerica. Additionally, potential risks and uncertainties include, among others, fluctuations in the Company's operating results due to its business model and expansion plans, downturns in international and or national economies, the Company's ability to raise additional capital, the competitive environment in which the Company will be competing, and the Company's dependence on strategic relationships. The Company is under no obligation to update any forward-looking statements after the date of this release.

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