



Phone: (949) 645-2111  
Fax: (949) 553-1231  
Email: [bmra@biomerica.com](mailto:bmra@biomerica.com)  
[www.biomerica.com](http://www.biomerica.com)

17571 Von Karman Avenue  
Irvine, CA 92614 USA

## CONFIRMATION

Date: 8<sup>th</sup> February 2021

To Whom It May Concern:

We, Biomerica, Inc., an EN ISO 13485:2016 certified company specializing in the research, development and manufacturing of in vitro diagnostic products for clinical and research application, located at 17571 Von Karman Avenue, Irvine, CA 92614 USA, hereby confirm that the Biomerica COVID-19 Antigen Rapid Test Nasopharyngeal is based on the Nucleocapsid Protein (N), hence reliably detecting the N Protein in patients' samples while the currently reported genetic variations mostly affect the Spike Protein (S). Since our test detects a highly conserved portion of the Nucleocapsid Protein, it will not be affected by any mutations to the Spike Protein.

**For this reason, the German Paul Ehrlich Institut requires additional testing for all antigen tests based on the S Protein for reliable detection of the genetic variants, but not for those tests based on the N Protein.**

By and on behalf of

5.1.2e

5.1.2e

Europe & South America  
Biomerica, Inc.

