



Phone: +(949) 645-2111
Fax: +1(949) 553-1231
Email: info@biomerica.com
Web: www.biomerica.com

CONFIRMATION

17571 Von Karman Avenue
Irvine, CA 92614 USA

Date: 19 July 2022

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 and current mutations to the non-conserved regions of the Nucleocapsid Protein. To ensure that the Biomerica test reacts with known variants of SARS-CoV-2, laboratory studies confirmed reactivity with the following variants that have known and documented Spike Protein and Nucleocapsid Protein mutations:

Alpha (B.1.1.7)
Beta (B.1.351)
Gamma (P.1)
Delta (B.1.617.2)
Epsilon (B.1.427)
Epsilon (B.1.429)
Zeta (P.2),
Eta (B.1.525)
Theta (P.3)
Iota (B.1.526)
Kappa (B.1.617.1)
Lambda (C.37)
Omicron (B.1.1.529)
Omicron (BA.1)
Omicron (BA.2)
Omicron (BA.2.12.1)
Omicron (BA.2.75)
Omicron (BA.3)
Omicron XE
Omicron (BA.4)
Omicron (BA.5)

By and on Behalf of

Hans Boehringer, Ph.D.
SVP, POC Research & Development
Biomerica, Inc.

