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17571 Von Karman Avenue
Irvine, CA 92614 USA

01 September 2020
Irvine, CA USA

TO WHOM IT MAY CONCERN
RE: Independent External Evaluations in the UK

STATEMENT

Biomerica, Inc. is an EN ISO 13485:2016 certified company specializing in the research, development and manufacturing of in vitro diagnostic products for clinical and research applications, located at 17571 Von Karman Avenue, Irvine, CA 92614 USA.

We hereby declare;

The Biomerica COVID-19 IgG/IgM Rapid Test has taken part in the below listed independent external evaluations in the UK. Biomerica has had no influence on the study protocol nor on the outcome of the studies.

NHS Lab, Edinburgh, Scotland

Sensitivity (≥20 days)
Serum samples from hospitalized patients with a positive SARS-CoV2 PCR test and patients with a positive PCR test who did not require hospital admission
83 samples 95.2%

Specificity
A panel of confounder samples was also included to look for cross reactivity. These were from patients who had received a positive PCR for respiratory pathogens including human coronaviruses (hCoV) strains. Patients with elevated Rheumatoid Factor, Cyclic Citrullinated Peptide, anti-Nuclear antigen or positive for CMV IgG, IgM or EBV IgM were also included.
327 samples 99.1%

Imperial College London, UK

Sensitivity (≥21 days)
Serum samples from patients with a positive SARS-CoV-2 PCR Test.
320 samples 94.7%

Specificity
Serum samples through the Airwave Health Monitoring Study.
500 samples 97.8%

In both these external and qualitatively valuable studies, the BIOMERICA COVID-19 IgG/IgM Rapid Test reported excellent Specificity and very good Sensitivity.

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Please refer to the attached document which details why a high specificity is more important than a high sensitivity.

On behalf of Biomerica, Inc.

5.1.2e

Europe & South America
Biomerica, Inc.

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Biomerica Inc.