Epitope Diagnostics, Inc.
7110 Carroll Road
San Diego, CA 92121 USA
Tel: (858) 693 7877

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This statement is regarding our products performance in a study conducted by researchers at University of California San Francisco, University of California Berkeley, Chan Zuckerberg Biohub, and Innovative Genomics Institute. The study's findings did not correlate with the results of the Clinical Testing listed on the product instructions for use. While we appreciate the initiative and advocate the nature of the study, the researchers failed to follow requirements and protocol as listed in the instructions for use. These deviations from the instructions for use contributed to the study's results, most critically:

1. **The study failed to follow the instructions for use regarding sample type and sample treatment.** Per the instructions for use: "human serum is required for measurement in duplicate. Samples should only be used on the same day." Samples utilized in the study were either serum or plasma including archived samples. These samples were subject to improper treatment by thawing at 37°C or heat-inactivation. External studies demonstrate that heat inactivation interferes with the immunoanalysis of antibodies to SARS-CoV-2. Therefore, the samples selected would not be valid for testing per the instructions for use and relevant literature.
2. **The researchers determined their own criteria for positive/negative determination and adjusted the background.** Per the instructions for use, the interpretation of results calculates the cutoffs of the test based off of formulas utilizing the average of the negative control absorbance values. The study "background-corrected OD values were divided by the cutoff to generate signal-to-cutoff (S/CO) ratios. Samples with S/CO values greater than 1.0 were considered positive." These calculations, most notably the adjustment of the background, would alter the interpretation of results.

In addition to these deviations to the instructions for use, the study was conducted under inadequate conditions, most notably:

1. **The researchers did not perform each test under fixed conditions.** This is demonstrated through two significant points: "During testing, two plates were transposed 180˚ and assays were run in the opposite order from the wells documented on cartridges" and the Epitope Diagnostics ELISA was manually washed while the in-house ELISA was done using a plate washer. It is standard practice to conduct tests under similar conditions. Issues such as these could greatly contribute to inaccurate results.
2. **Samples that were exhausted were not rejected from the study**. The study claims, "Some tests were not performed on a subset of specimens due exhausted sample material, which may have affected reported percent positivity." The decision to include these samples rather than reject them adds potential bias to the results.

Additionally, the study has a conflict of interest, as a major competitor who is currently manufacturing their own COVID-19 ELISA kits was cited as a proving research support funding. The researchers cannot claim to be an independent review board of COVID-19 assays while accepting support from a manufacturer of these products.

Regardless of the study's flaws, our test still reports higher levels of sensitivity and specificity consistently throughout the study especially when compared to other methods as seen from the study's website titled: Summary by Assay and Days Since Onset. The results for the IgM assay even showed higher levels than reported in the product instructions for use.

Epitope Diagnostics, Inc. strives to provide you with products of the highest quality. We value your business and thank you for your continued support.

Ping Gao, MD.
CEO, Epitope Diagnostics, Inc.