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MEDICINE

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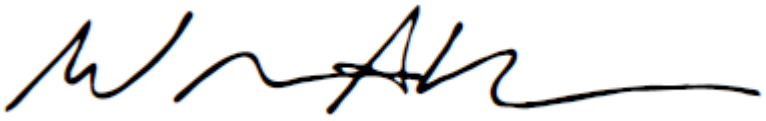
RE: Evaluation of the Premier Biotech COVID-19 IgG/IgM Rapid Test Cassette

We evaluated the sensitivity and specificity of the Premier Biotech COVID-19 IgG/IgM Rapid Test Cassette on samples from individuals residing in Baltimore. The sensitivity was evaluated on 182 samples from 22 hospitalized patients at Johns Hopkins Hospital who were RT-PCR positive for SARS-CoV-2 infection and under observation for 4 to 11 days. Of these subjects, seven were IgM positive at first sample tested, 13 seroconverted during observation and two subjects never seroconverted. Positivity for IgG occurred an average of 1.25 days later than IgM with three individuals being sero-positive on the first day of observation. The sensitivity was 91% (20/22) for the subjects tested. For the two individuals who never seroconverted under observation, their samples were consistently negative for four other COVID-19 serological assays.

The specificity analysis included 120 samples from 120 patients who attended the Johns Hopkins Emergency Department in the winter of 2016. These subjects could not have been exposed to SARS-CoV-2, as the infection was not circulating in the population at that time. Additional specificity testing included the symptomatic and convalescent sera from six individuals known to be infected with other strains of coronavirus, specifically 229E, NL63, OC43 or HKU1. No sample evaluated to date has generated a false positive result by the Premier Biotech COVID-19 IgG/IgM Rapid Test Cassette. The specificity was 100% (95% CI 97, 100) for both the IgG and IgM tests. Additionally, none challenge samples from individuals known to be infected by other coronaviruses was reactive by this assay.

These results are from an independent evaluation. Premier Biotech, the distributer of the assay, was unaware of our evaluation until it was completed and did not have any influence in conduction or evaluation performed.

Signed,



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