

To whom it may concern

Statement of Clinical Correlation for 2019-nCoV IgG/IgM Device (Prestige Diagnostics)

This declaration is to clarify the results of the clinical correlation between the 2019-nCoV IgG/IgM Device and a leading PCR kit and EIA kits available on the market.

Clinical Sensitivity

In comparing the performance of the 2019-nCoV IgG/IgM Device against the predicate PCR kit, which confirmed all samples to be positive for the presence of RNA of SARS-CoV-2 virus, the samples were divided into two groups. One group (n = 48) consisted of samples taken between 1 and 7 days after onset of symptoms and the second group (n = 72) were samples collected between 7 and 14 days after onset of symptoms.

In group 1 the agreement between the 2019-nCoV IgG/IgM Device and the PCR kit was 89.6%. For group 2 the agreement was 95.8%. The increase in coincidence between the testing methods reflects the expected increase in antibody response later into the infective period.

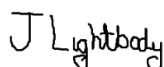
The 2019-nCoV IgG/IgM Device was also compared to predicate EIA kits. The relative sensitivity of the 2019-nCoV IgG/IgM Device was found to be 91.8% for IgG and 95.7% for IgM. The results are consistent with the fact that the samples were collected within 2 weeks of onset of symptoms so IgM would be expected to be the dominant immunoglobulin appearing.

Clinical Specificity

Clinical Specificity was determined using a panel of 250 samples confirmed negative for SARS-CoV-2. Specificity of the 2019-nCoV IgG/IgM Device was compared to predicate EIA kits. The specificity of the device was found to be 96.4% for IgG and 97.3% for IgM.

In conclusion the 2019-nCoV IgG/IgM Device shows good correlation with the gold standard method for testing of samples for evidence of SARS-CoV-2, that is, PCR testing, despite the fact that the two methods test for different analytes. The 2019-nCoV IgG/IgM Device shows excellent specificity and sensitivity compared to alternative test kit methods.

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