IMMUNO-COV™
A NEUTRALIZING ANTIBODY TEST

TECHNICAL NOTE

IMMUNO-COV™ v2.0 Assay Sensitivity and Specificity

BASED ON ASSAY VALIDATION AND VERIFICATION DATA OBTAINED IN OCTOBER 2020

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WHAT IS THE SENSITIVITY AND SPECIFICITY OF IMMUNO-COV™?

IMMUNO-COV™ exhibited 98.4% sensitivity and 100% specificity in validation and verification studies.

SENSITIVITY: 98.4%

SPECIFICITY: 100%

WHAT ARE SENSITIVITY AND SPECIFICITY?

Assay sensitivity and specificity are measures of how accurately an assay discriminates between positive and negative samples. For SARS-CoV-2 neutralizing assays, sensitivity is a test's ability to correctly identify samples with neutralizing antibodies. Specificity is a test's ability to correctly identify samples that do not contain neutralizing antibodies. High sensitivity means fewer false negatives, while high specificity means fewer false positives.

WHAT MATTERS MORE, SENSITIVITY OR SPECIFICITY?

Both are important for determining a test's accuracy. If an assay has poor specificity, some individuals without neutralizing antibodies will receive false positive results and think they have some protection against future infection. In contrast, if an assay has poor sensitivity, false negatives will make some individuals with neutralizing antibodies think they have no protection against future infection*.

**It is not currently known what constitutes a protective response for SARS-CoV-2.*

To evaluate the sensitivity and specificity of IMMUNO-COV™ v2.0, 176 serum samples were tested in a single-blinded approach. Two test cohorts were used: positive and negative. Samples in the negative cohort tested negative for SARS-CoV-2 antibodies by ELISA or plaque reduction neutralization test (PRNT). Samples in the positive cohort tested positive for SARS-CoV-2 antibodies by ELISA and for SARS-CoV-2-neutralizing antibodies by PRNT using a clinical isolate of SARS-CoV-2 (PRNT80% titers were used as the cut-off to discriminate positive and negative samples).