SpearBio

Product Data Sheet

NAB-Sure™ SARS-CoV-2 Neutralizing Antibody Test Kit

This data sheet contains key performance data for NAB-Sure SARS-CoV-2 Assay.

Product Description

NAB-Sure SARS-CoV-2 Neutralizing Antibody Test Kit is a neutralizing antibody (NAb) test for immune response to SARS-CoV-2. The assay can be processed using a variety of real-time PCR systems to produce a quantified (titer) result. NAB-Sure SARS-CoV-2 Kit is a surrogate virus neutralization test.

For research use only - not for diagnostic use.

Supported Sample Types

- Dried Blood Spot
- Plasma
- Serum

Kit Contents:

- Spear Probe Dilution Buffer
- Spear Probes A1, A2 & B
- Positive Control Sample
- Reaction Buffer & Enzyme
- qPCR Nucleotide Mix, Enzyme & Positive Control
- Dried Blood Spot Sample Elution Buffer

System Compatibility, Automation & Analysis

Hardware & Instrumentation	Make & Model
qPCR	NAB-Sure SARS-CoV-2 Kit is designed to work under standard 96 and 384 well qPCR operations. The following systems have been used in development. Applied Biosystems real-time PCR systems: • Quantstudio 7 & 12k • 7500 Bio-Rad real-time PCR systems: • CFX Connect 96 • CFX Opus 96, CFX Opus 384
Thermocycler	NAB-Sure SARS-CoV-2 Kit is designed to work for standard thermocycler operations. The following systems have been used in development. • Applied Biosystems ProFlex™ PCR System Base Unit, 96-well head, dual 384-well head • Bio-Rad C-1000 Touch PCR system
Liquid Handling	NAB-Sure SARS-CoV-2 is designed to work for standard 8, 16, 96 and 384 liquid handling systems. The following systems have been used in development. Integra Assist Plus with: • Integra VIAFLO 16 Channel Pipette, 0.5-12.5µl • Integra VIAFLO 16 Channel Pipette, 5-125µl • Integra VOYAGER 8 Channel Pipette, 0.5-12.5µl • Integra VOYAGER 8 Channel Pipette, 5-125µl Integra VIAFLO 96, 12.5µl Integra VIAFLO 384, 12.5µl
Data Analysis	Windows: Excel 365, Excel 2021 Mac OS: Excel 365, Excel 2021

Performance Characteristics

Method Comparison

To evaluate clinical performance, samples were assayed and results compared between NAB-Sure SARS-CoV-2 Assay and Plaque Reduction neutralization test (PRNT). Figs. 1 and 2 show the degree of concordance for 1) PRNT and NAB-Sure SARS-CoV-2 Kit for plasma or serum samples (PS) and 2) PRNT and NAB-Sure SARS-CoV-2 Kit for dried blood samples (DBS).

PRNT PS vs SPEAR PS

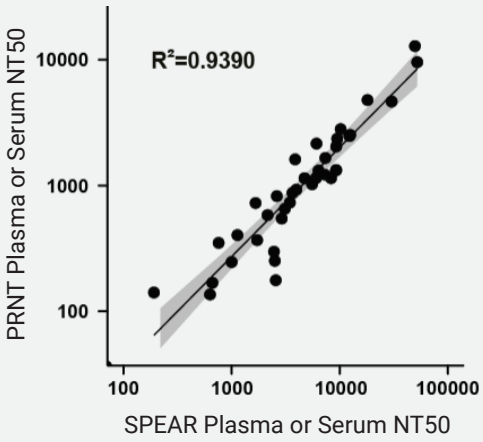

Figure 1

PRNT PS vs SPEAR DBS

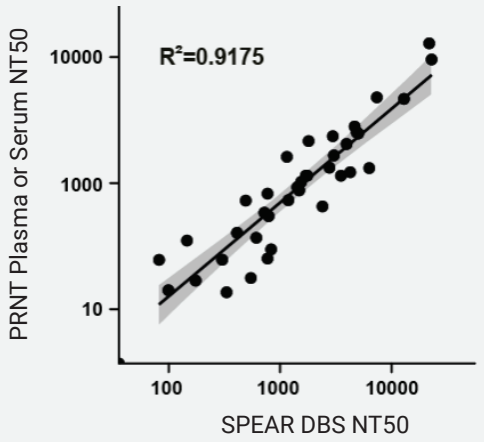

Figure 2

NAB-Sure Result		Positives		Negatives	Total
Positives	True Positive	77	False Positive	0	77
Negatives	False Negative	0	True Negative	19	19

COVID-19 status defined as follows: Positives include subjects who were immunized or have or had COVID-19 confirmed by laboratory testing.

Statistic	Value	95% Confidence Interval
Sensitivity	100.00%	95.35% -100.00%
Specificity	100.00%	82.35% -100.00%
Positive Predictive Value	100.00%	
Negative Predictive Value	100.00%	
Accuracy*	100.00%	96.23% -100.00%

*Based on CDC Estimated prevalence of 92%

Clinical Accuracy

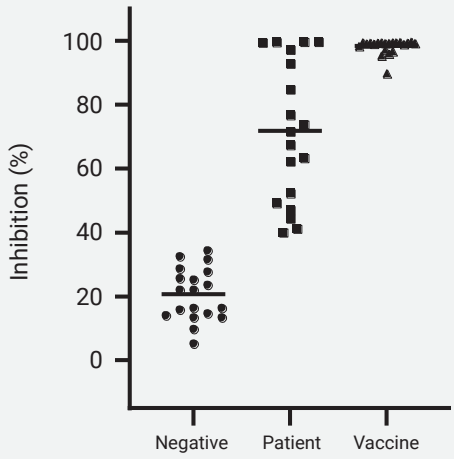

Figure 3

NAB-Sure SARS-CoV-2 assay was used to evaluate samples that were self-reported as no exposure (negative), previous infection (patient) or vaccinated (vaccine). Figure 3 shows NAB-Sure SARS-CoV-2 Assay's ability to differentiate these samples (negative samples <40% inhibition).

Clinical Consistency by Sample Type

To evaluate consistency between sample types, dried blood samples (DBS) and plasma or serum samples (PS) were taken from the same subject. The samples were evaluated using NAB-Sure SARS-CoV-2 Assay and results compared. Fig. 4 illustrates the degree of concordance between the sample types.

PRNT PS vs SPEAR DBS

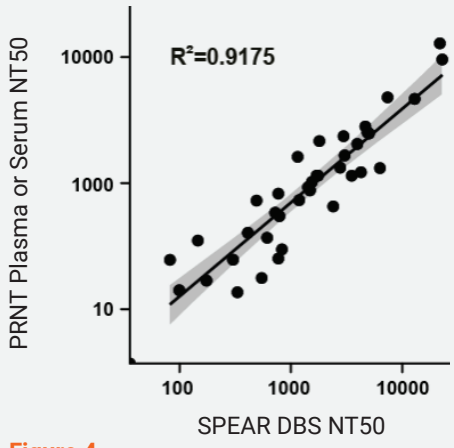

Figure 4

Intraplate CV

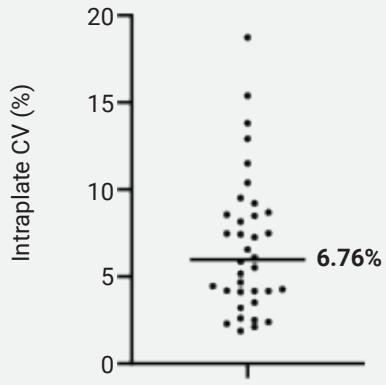

Figure 5

Analytical Precision

15 samples of monoclonal antibody were assayed, once/day for five days. (See Figure 5)

Specimen	Average Intraplate CV	Average Interplate CV
R2B17 Monoclonal antibody	7.28%	6.76%

Interplate CV

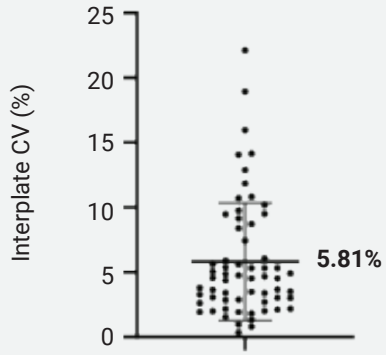

Figure 6

Clinical Precision

Samples from COVID-19 vaccine recipients were assayed to evaluate precision. For Intraplate CV, each assay had 20 DBS samples, duplicated three times. For Interplate CV, 61 DBS samples were evaluated daily for three days. (See Figure 6)

Specimen	Average Intraplate CV	Average Interplate CV
COVID-19 vaccine recipients	6.80%	5.81%

Inter-lab CV

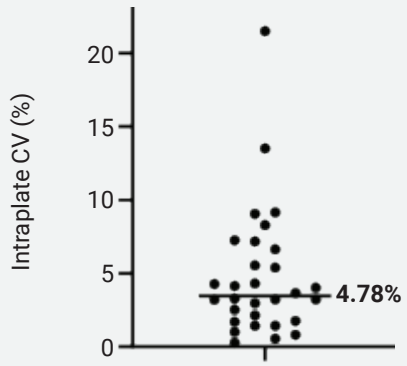

Figure 7

Clinical Reproducibility Between Laboratories

30 DBS samples were eluted at one lab. The eluates were split and tested at two different laboratories. (See Figure 7)

Specimen	Average Intraplate CV	Inter-lab CV
DBS	60	4.78%

Cross-Reactivity

Cross reactivity was evaluated by assaying serum for four different coronavirus species and four other common respiratory viruses diluted at 1:10. They were found to have no cross-reactivity.

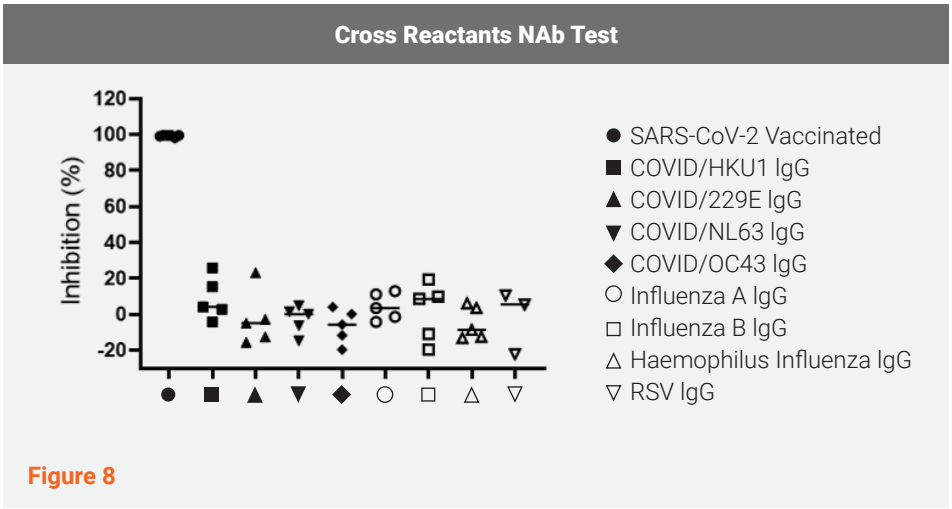

Figure 8

Lot to Lot Reproducibility

Data Summary for Positive Control with different reagent lots

Lot	Lot A	Lot B	Lot C	Cross Lots
Mean	19.80	19.87	20.64	19.95
%CV	3.8%	8.9%	4.1%	5.5%

ANOVA Summary

Source	Degrees of Freedom DF	Sum of Squares SS	Mean Square MS	F-Stat	P-Value
Between Groups	2	1.12	0.56	0.41	0.67
Within Groups	10	13.53	1.35		
Total:	12	13.53	14.65		

P= 0.67 No significant differences between lots.

Additional Notes

- Figure graphs represent the results of testing in our laboratories and are not a guarantee of future performance.
- This product detects the presence of antibodies against SARS-CoV-2 and does not detect the presence of the SARS-CoV-2 virus itself.
- For safety information, please refer to NAB-Sure SARS-CoV-2-Neutralizing Test Kit Safety Data Sheet (SDS).

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