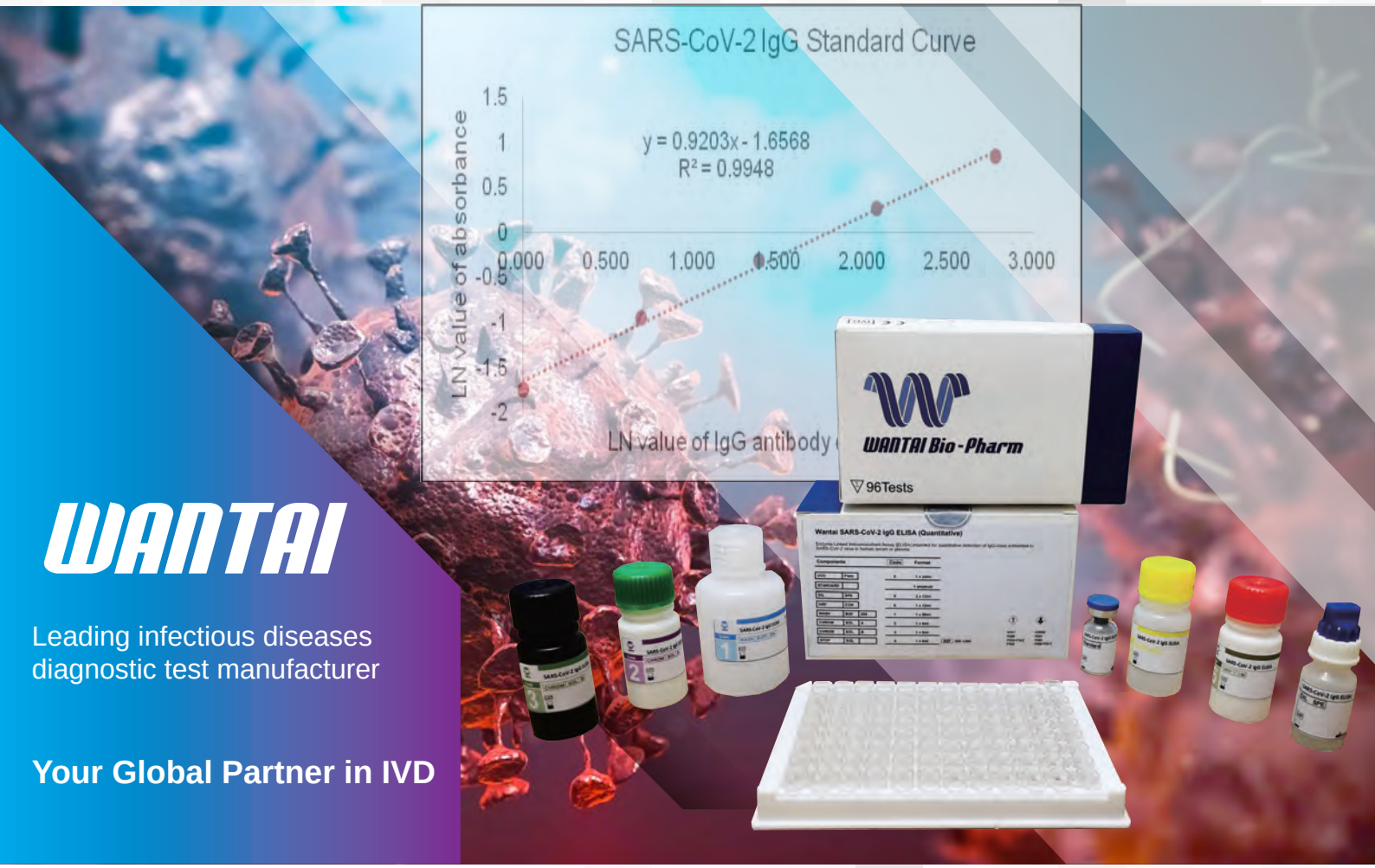
Another InnovativeTest Designed by WANTAI

WANTAI BioPharm

CE

QUANTITATIVE ELISA for IgG Antibody to COVID-19

For monitoring antibody level after vaccination



WANTAI

Leading infectious diseases diagnostic test manufacturer

Your Global Partner in IVD

WANTAI SARS-CoV-2 IgG ELISA is an ELISA intended for **quantitative detection of IgG-class antibodies** to SARS-CoV-2 virus in human **serum** or **plasma**.

It works as an aid in detecting **immune response** levels for individuals infected with SARS-CoV-2, or in individuals who have received **COVID-19 vaccination**.

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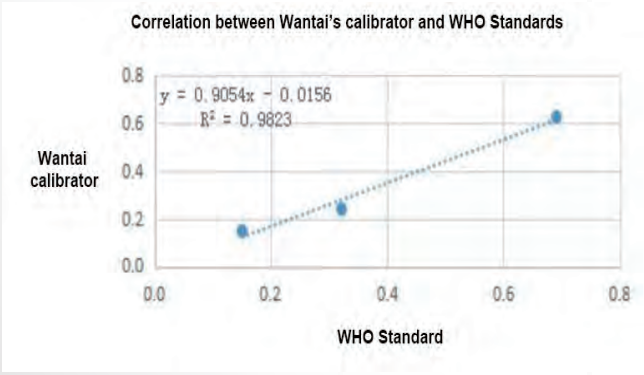
Intended Use

The WANTAI SARS-CoV-2 IgG ELISA (Quantitative) is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection, or as an aid in individual vaccination management decisions. The quantitative result obtained with this kit is as a reference for clinician only, cannot be used as the sole basis for further individual vaccination and treatment.

In June 2020, NIBSC filled and freeze-dried the candidate International Standard, NIBSC code 20/136 and the Reference Panel members (NIBSC codes 20/140, 20/142, 20/144, 20/146, 20/148, 20/150) using documented procedures.
The WHO has now officially approved the first international reference material, the "First WHO International Standard Anti-SARS-CoV-2 Immunoglobulin" (NIBSC code: 20/136). This standard presents a clearly defined antibody activity/concentration against which test systems can be matched and which allows standardising the results.

Wantai 's internal kit standard is calibrated against NIBSC 20/136 standard. As a consequence, the test results can now be issued in standardised units. This optimises the use of the ELISA as a valuable support in the quantification and assessment of antibody concentrations achieved through vaccination.



Sensitivity & Specificity

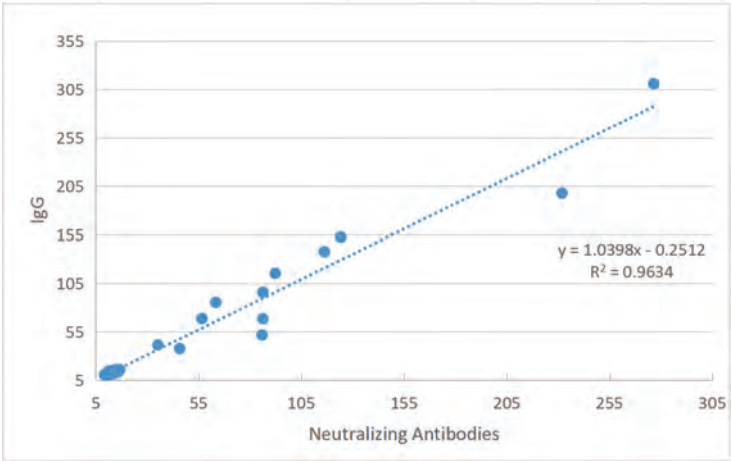
In a clinical study, of the total of 154 positive by PCR samples, 125 were positive on the WANTAI SARS-CoV-2 IgG ELISA (Quantitative), and of the 197 negative samples, 196 were negative. The kit demonstrated the Positive Percent Agreement (PPA) of 81.17% (125/154), the Negative Percent Agreement (NPA) of 99.49% (196/197). The kit demonstrated the PPA of 94.94% (75/79) for ≥ 15 days from onset of symptoms, as indicated in the tables below.

Cases		PCR Comparator		Total
		Positive	Negative	
WANTAI SARS-CoV-2 IgG ELISA	Positive	125	1	126
	Negative	29	196	225
Total		154	197	351
PPA		81.17% (95%CI: 74.26%-86.56%)		
NPA		99.49% (95%CI: 97.18%-99.91%)		

Days from onset of symptoms	Total PCR Positive Samples	Number of Wantai Positive Result	PPA	95% CI
≤ 7	20	8	40.00%	21.88% - 61.34%
8 - 14	55	42	76.36%	63.65% - 85.63%
≥ 15	79	75	94.94%	87.69% - 98.01%
Total Subjects	154			

Other Performance Data

Retrospective analysis of the 75 positive samples (≥ 15 days from onset of symptoms) was conducted to measure the levels of IgG antibodies in the specimens. All specimens had IgG concentration of > 10.0 U/ml. Good correlation between the detected antibody levels with Wantai SARS-CoV-2 IgG (quantitative) ELISA and pseudovirus neutralization test was established.



To evaluate the potential cross-reactivity of the WANTAI SARS-CoV-2 IgG ELISA (Quantitative) to antibodies to other viruses that may be present in the population, the following viruses were assessed.

Specimen	No.	+	-	Specificity
alpha COV 229E	5	0	5	100%
alpha COV NL63	5	0	5	100%
beta COV OC43	7	0	7	100%
beta COV HKU1	4	0	4	100%

Principle and Procedures

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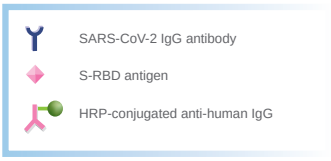
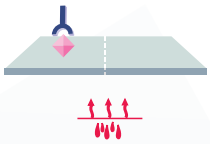
- Microwell strips pre-coated with
  - recombinant, highly immunoreactive SARS-CoV-2 antigens

2 

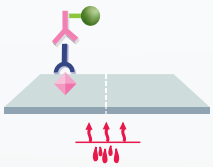
- Add 100μl sample diluent



3 

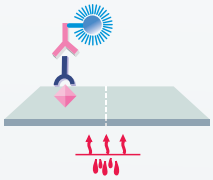
- Add 10μl of Specimens/ Controls
  Incubation at 37℃ for 30 min

4 5 Wash cycles

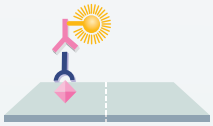
5 

- Add 100μl of HRP-conjugate
  Incubation at 37℃ for 30 min

6 5 Wash cycles

7 

- Add 50μl of Chromogen Solution A and 50μl of Chromogen Solution B
  Incubation at 37℃ for 15 min

8 

- Add 50μl of Stop Solution

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- Read by single wavelength 450nm or dual wavelength 450/600~650nm

Ordering Info

Cat.	Product	Detection	Specimen	Pack size
WS-1396	SARS-CoV-2 IgG ELISA (Quantitative)	IgG Antibody	Serum/Plasma	96T/kit