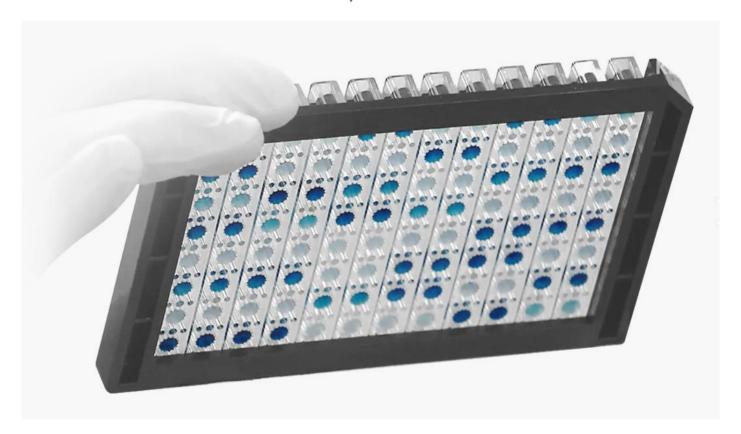
# **ACCEL ELISA®**

# **COVID-19 Total Antibody Kit**

For Detection of Total Antibody to SARS-CoV-2 in Human Serum



## Simple - Fast - Reliable

This test kit is a serology-based SARS-CoV-2 total antibody detection assay which utilizes Plexense's proven and patented ACCEL ELISA® technology for sensitive, rapid and accurate results.

The ACCEL ELISA® can be used as a rapid and reliable tool to assess the immune response of the patient during and after the infection of COVID-19 virus.



# ACCEL ELISA®

# **COVID-19 Total Antibody Kit**

The ACCEL ELISA® COVID-19 assay uses the SARS-CoV-2 nucleocapsid protein (N-protein) develope d by the BioNano Health Guard Research Center (a division of the Ministry of Science and ICT, Kor ea) in collaboration with Korea Research Institute of Bioscience and Biotechnology (KRIBB) for the sole use of COVID-19 antibody detection on ACCEL ELISA® platform.



#### **Plexense Technology Advantage**

ACCEL ELISA® combines a unique, proprietary plate design with adv anced surface chemistry and reag ent formulation to create an inno vative immunoassay platform designed to maximize speed and sensitivity.

### Why choose ACCEL ELISA® over other platforms?

- Quick testing turnaround for the detection of total antibodies (IgA, IgM, IgG) against SARS-Cov-2 antigens
- · Highly improved sensitivity over lateral flow (immunochromatography) method
- · High-throughput testing available up to **94 patient samples** at a single run
- · 96-well strip plate formatted
- · Compatible with standard plate reader (OD read at 650nm)
- $\cdot$  Sample type & volume required per well: 10  $\mu$ L human blood serum
- · 30 minutes Assay time
- · Validation of assay with 341 patient sera samples confirmed high accuracy results —Sensitivity 94.4%, Specificity 100%, Overall Agreement with RT-PCR 98.5%

## **Clinical Evaluation**

#### Validation of 341 patient samples

Cutoff value of OD 650nm is 0.224. Positive and negative results were determined by taking the reaction value at OD 650 nm divided by the cutoff value. Resultant values > 1.1 were positive, while values < 1.1 were negative.

Evaluation Parameters	Evaluation Criteria	Results
Sensitivity	Positive : ≥1.1 (ratio) Negative : < 1.1 (ratio)	94.4%
Specificity	Positive : ≥1.1 (ratio) Negative : < 1.1 (ratio)	100%
Overall percent agreement	Correlation to RT-PCR	98.5%

# **Sensitivity & Specificity**

100% 5 days following infection

Plexense ACCELELISA® COVID-19 Kit	Anti-SARS-CoV-2 ELISA (IgG and IgM)	Anti-SARS-CoV-2 ELISA (IgG and IgM)	
Days following infection	% Positive Agreement to RT-PCR	% Negative Agreement to RT-PCR	
< 5	66.7%		
5-10	100.0%	100.0%	
≥ 11	100.0%		

Plexense data from BNHG testing

# **Experiment Results**

		RT-PCR Test Results		
		Positive	Negative	Total
ACCEL ELISA® COVID-19 Kit	Positive	85	0	85
	Negative	5	251	256
	Total	90	251	341





#### **PLEXENSE LOCATIONS**

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## **About Plexense, Inc.**

Since its foundation in 2012, Plexense, Inc. has specialized in the development and production of rapid and cost-effective immunoassay for clinical, food and biological testing.

Plexense, Inc. has been working as development and collaboration partners with Mayo Clinic, the US Department of Agriculture (USDA) – ARS, the Korea Center for Disease Control (KCDC) and the Korea Research Institute of Bioscience and Biotechnology (KRIBB) to develop advanced early diagnostic kits utilizing its proprietary ACCEL ELISA® technology.

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