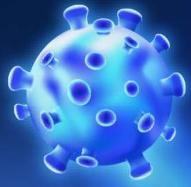


iONE Neutralized Antibody Detection Kit

iONEBIO, Inc.

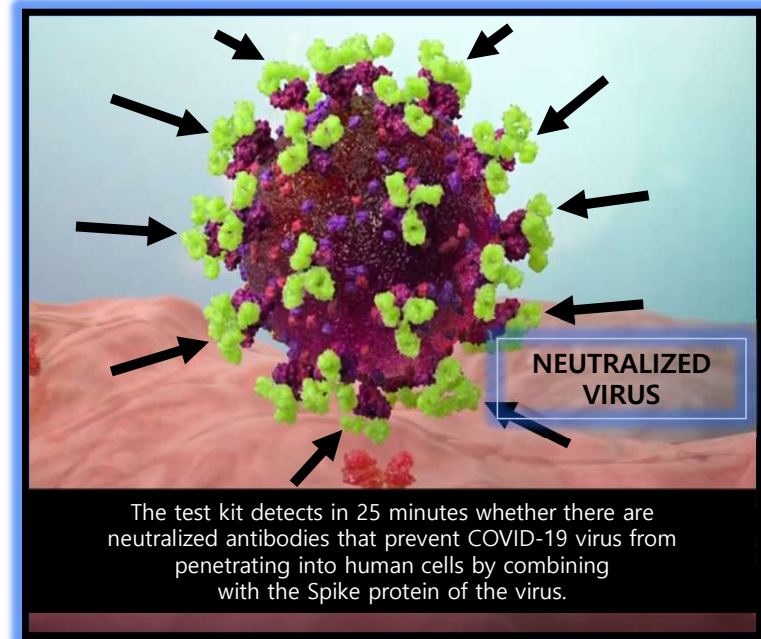
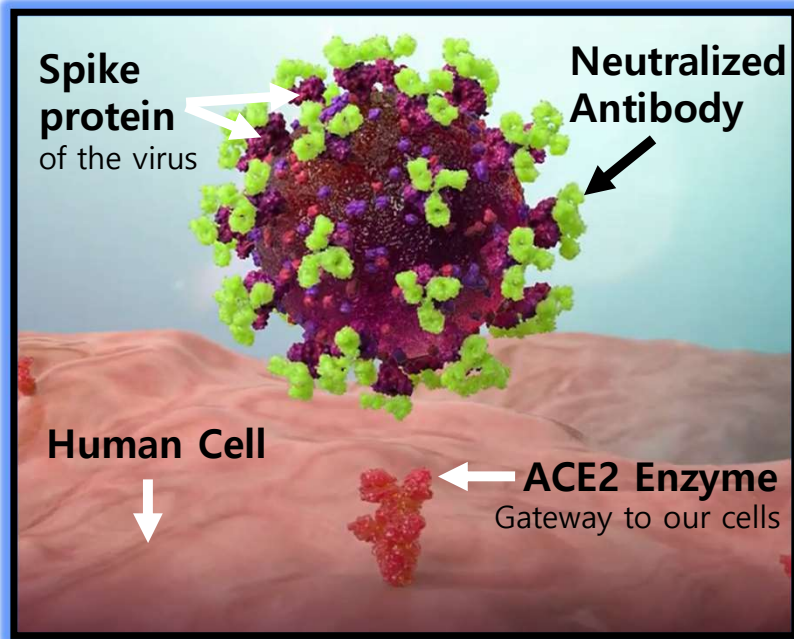
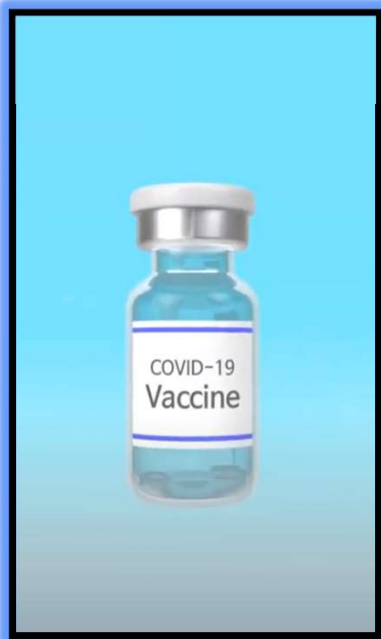
▶ Video Introduction on
iONE Neutralized Antibody Detection Kit

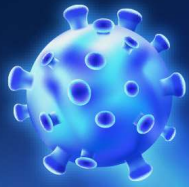




YouTube Video

 **CLICK HERE**





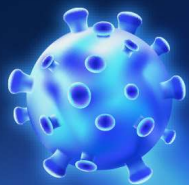
1. Product Overview

iONE Neutralized Antibody Detection Kit



Specification

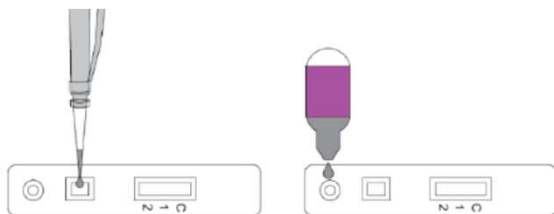
- Antibody Test Kit
- 25 tests per kit/box, sample diluent 1 bottle
- Simple Protocol
- Result analysis in 25~30 min
- Store at 2~35°C in the sealed pouch



2. Test Method

Simple Test Step

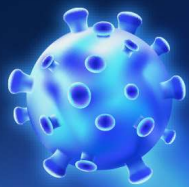
1. Add specimen into sample well.
2. Add diluent(100uL/3drops) into sample well



Result determination time: The result should be judged within **25~30 minutes** after the sample is added into the sample loading well, and the result displayed after **30 minutes** is invalid.

Result Analysis

1	<p>IgG Positive and Neutralizing antibody Negative: Three lines appear. One colored line should be in the control line region (C), a colored line appears in IgG test line (1) region , and a colored line appears in Neutralizing antibody test line (2) region which is darker or equal than C line.</p>	
2	<p>IgG Positive and Neutralizing antibody Positive: Two or three lines appear. One colored line should be in the control line region (C), a colored line appears in IgG test line (1) region , and a colored or no line appears in Neutralizing antibody test line (2) region which is lighter than C line.</p>	
3	<p>NEGATIVE: Two lines appear. One colored line should be in the control line region (C), and a colored line appears in Neutralizing antibody test line (2) region which is darker or equal than C line.</p>	
4	<p>INVALID: Control line fails to appear. Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.</p>	



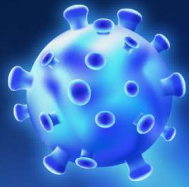
3. Test Benefit

Why Gold type kit is best for Neutralized antibody test

	Gold type	Fluorescent type	ELISA type
Time	20'	20'	2 hour
LoD(Limit of Detection)	10 ⁴	10 ³	10 ²
Accuracy	Medium (qualitative)	Medium (qualitative)	High (quantitative)
Convenience	Good (No need for equipment)	Medium (Need an equipment)	Bad (Need an equipment)
Application	Best	Medium	bad

- It's important to verify above **10⁴ copies of antibodies for neutralized antibody test kit.**
=> Fluorescent type not necessary.
- For neutralized antibody test kit, **“rapidity”** is more important than accuracy.
=> ELISA type is good for research purpose but not appropriate for point of care settings due to its long analysis time.

“Gold type” test kit is the most optimal because of the speed and convenience



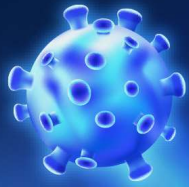
4. Product Features

iONE Neutralized Antibody Detection Kit

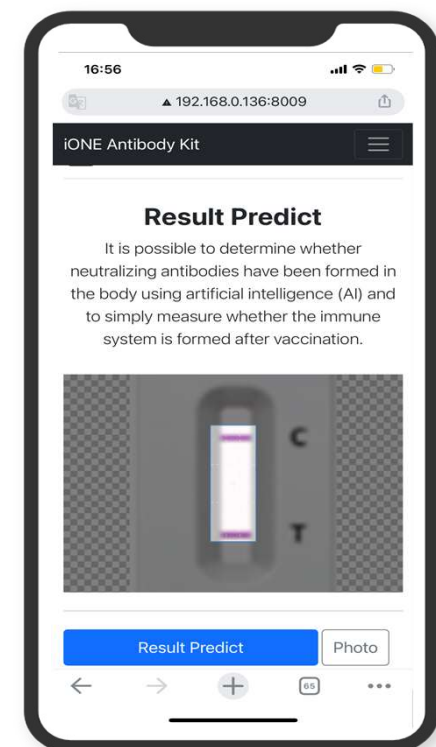
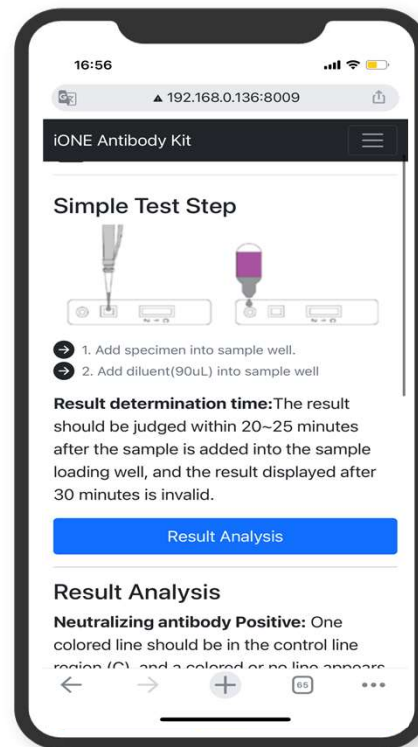
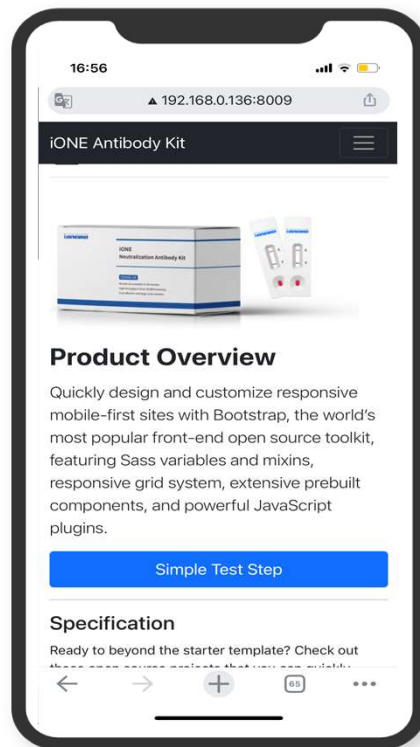


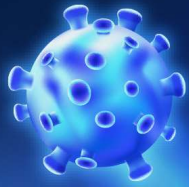
Product Features

-  Results are available in **25~30 minutes**
-  High Throughput (**Over 10,000 tests/day**)
-  **Cost-effective** and **large-scale** solution

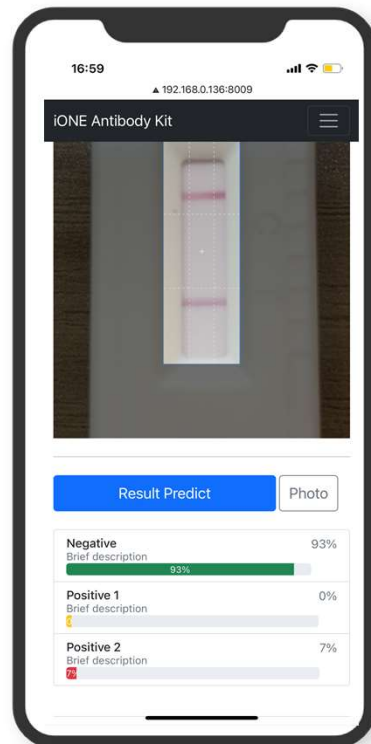
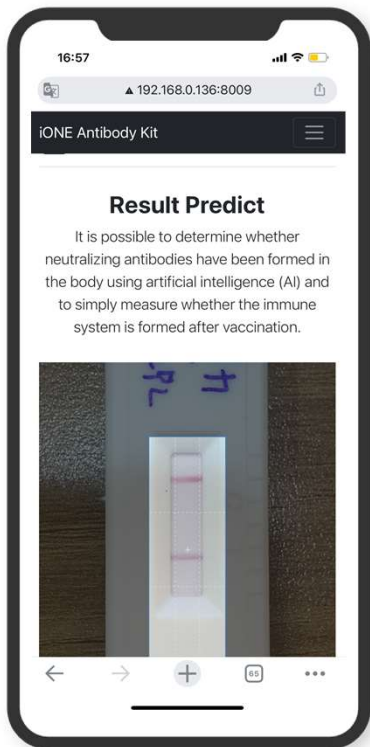


5. AI Deep Learning





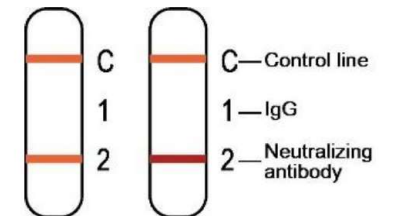
5. AI Deep Learning

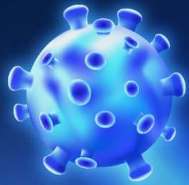


NEGATIVE: Two lines appear. One colored line should be in the control line region (C), and a colored line appears in Neutralizing antibody test line (2) region which is **darker or equal than C line**.



Negative	93%
Brief description	<div style="width: 93%; background-color: green;">93%</div>
Positive 1	0%
Brief description	<div style="width: 0%; background-color: yellow;">0%</div>
Positive 2	7%
Brief description	<div style="width: 7%; background-color: red;">7%</div>





6. KNU Clinical Results



임상시험 결과 보고서

iONE Neutralized Antibody Detection Kit의 평가
Evaluation of iONE Neutralized Antibody Detection Kit

2021.05.06

강원대학교병원 진단검사의학과

서인범 (인)

- 1 -

Sample No.	RT-PCR Data		Result	RT-PCR Test & confirmation data	Serum collection data	PRNT50 Data		이이환바이러스 키트	
	E gene	RdRp gene				Titre	Result	IgG	중립화 실험
4-2	32.35	32.99	POS	2020-06-09	2020-06-29 (+20 days)	20	Pos	Pos	Pos
6-1	21.68	21.03	POS	2020-07-03	2020-08-10 (+38 days)	40	Pos	Pos	Pos
7-1	26.84	26.05	POS	2020-04-07	2020-05-19 (+42 days)	>320	Pos	Pos	Pos
8-1	21.69	20.63	POS	2020-03-05	2020-05-11 (+42 days)	>320	Pos	Pos	Pos
8-4	21.79	20.86	POS	2020-03-05	2020-04-09 (+35 days)	>320	Pos	Pos	Pos
8-5	19.4	20.6	POS	2020-08-10	2020-09-12 (+33 days)	>320	Pos	Pos	Pos
8-6	22.22	21.25	POS	2020-03-05	2020-05-04 (+60 days)	>320	Pos	Pos	Pos
8-7	30.19	28.94	POS	2020-04-07	2020-04-28 (+21 days)	>320	Pos	Pos	Pos
14-10	26.81	29.08	POS	2020-03-20	2020-04-03 (+14 days)	80	Pos	Pos	Pos
16-1	26.4	25.97	POS	2020-02-28	2020-03-14 (+15 days)	160	Pos	Pos	Pos
17-1	27.98	27.14	POS	2020-07-10	2020-07-27 (+17 days)	80	Pos	Pos	Pos
21-5	22.44	25.39	POS	2020-04-20	2020-05-01 (+11 days)	80	Pos	Pos	Pos
21-6	31.93	31.47	POS	2020-08-22	2020-08-31 (+9 days)	160	Pos	Pos	Pos
21-7	32.66	32.5	POS	2020-07-15	2020-07-27 (+12 days)	160	Pos	Pos	Pos
21-10	29.46	28.97	POS	2020-03-20	2020-04-01 (+12 days)	160	Pos	Pos	Pos
21-11	26.68	28.15	POS	2020-09-01	2020-10-09 (+38 days)	>320	Pos	Pos	Pos
21-13	25.89	26.79	POS	2020-08-24	2020-09-23 (+30 days)	>320	Pos	Pos	Pos
21-15	32.85	33.13	POS	2020-09-02	2020-09-23 (+21 days)	>320	Pos	Pos	Pos
27-5	28.23	28.01	POS	2020-09-12	2020-10-12 (+30 days)	>320	Pos	Pos	Pos
30-3	28.63	30.33	POS	2020-02-22	2020-04-14 (+52 days)	20	Pos	Pos	Pos
30-5	32.53	32.24	POS	2020-06-05	2020-06-29 (+24 days)	40	Pos	Pos	Pos
32-3	33.99	34.48	POS	2020-06-05	2020-06-15 (+10 days)	20			
33-2	22.39	25.39	POS	2020-04-20	2020-04-28 (+8 days)	40			
34-2	26.99	26.76	POS	2020-08-21	2020-08-30 (+9 days)	80			
35-4	21.91	20.79	POS	2020-09-10	2020-10-12 (+32 days)	160			
39-8	29.75	31.17	POS	2020-03-02	2020-05-04 (+63 days)	80			

IgG

Positive Percent Agreement (PPA)= 37/39 (94.87%)

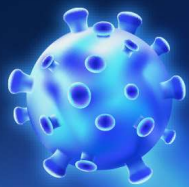
Negative Percent Agreement (NPA)= 15/15 (100%)

nAb

Positive Percent Agreement (PPA)= 37/39 (94.87%)

Negative Percent Agreement (NPA)= 15/15 (100%)





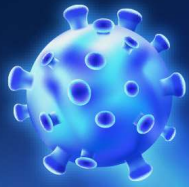
7. Who We Are



iONEBIO is a developer & manufacturer of **iLAMP Novel-CoV19 Detection Kit**, the 25 min test kit. As a K-bio company, we have been gaining expertise on molecular diagnosis, genetic analysis and other medical devices. The iLAMP Novel-CoV19 Detection Kit has secured a strong competitiveness edge having advantages in speed and accuracy.

- 2018** Genetic Analysis Certification (DNA Testing Lab & Platform)
Urine Analyzer Research & Development
Oral Cancer Detection Biomarker
- 2019** **Oral Cancer Test Kit assigned for national task project** (Cooperation with Seoul National University)
3D Intra Oral Scanner Development – Prototype Finished
- 2020** **iLAMP Novel-CoV19 Detection Kit – CE marked**
iLAMP High-Speed Test Kit – CE marked
FICS Platform in Paraguay
iONE-MASK face mask Manufacture
- 2021** Other Virus & Influenza Test Kit Research & Development
Exporting COVID-19 and other Influenza test kits to 50 countries
Oral Cancer Test Kit Launching





8. Products of iONEBIO



Swab Kit



RNA Extraction Machine



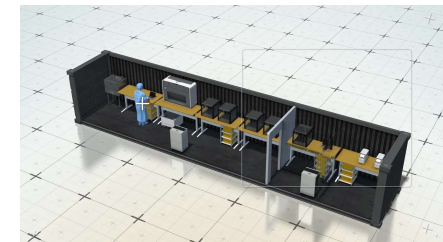
COVID-19 Test Kit



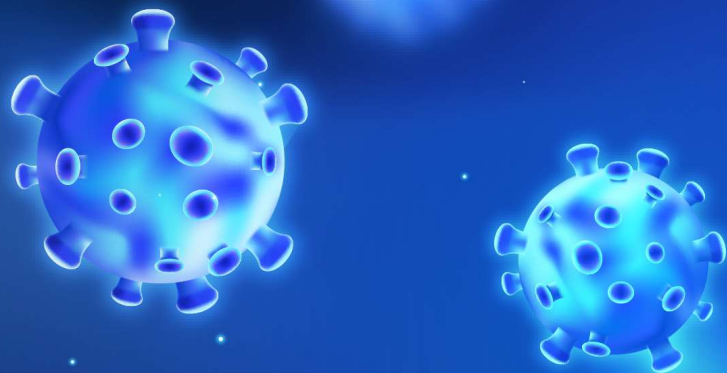
PCR Instrument



COV-19 Analysis Vehicle



Container Analysis Lab



Thank You

Contact Information

EMEA Agent & Distributor

C.D. PRODUCTS S.A. : WWW.CDPSA.EU

Website

www.ionebio.com