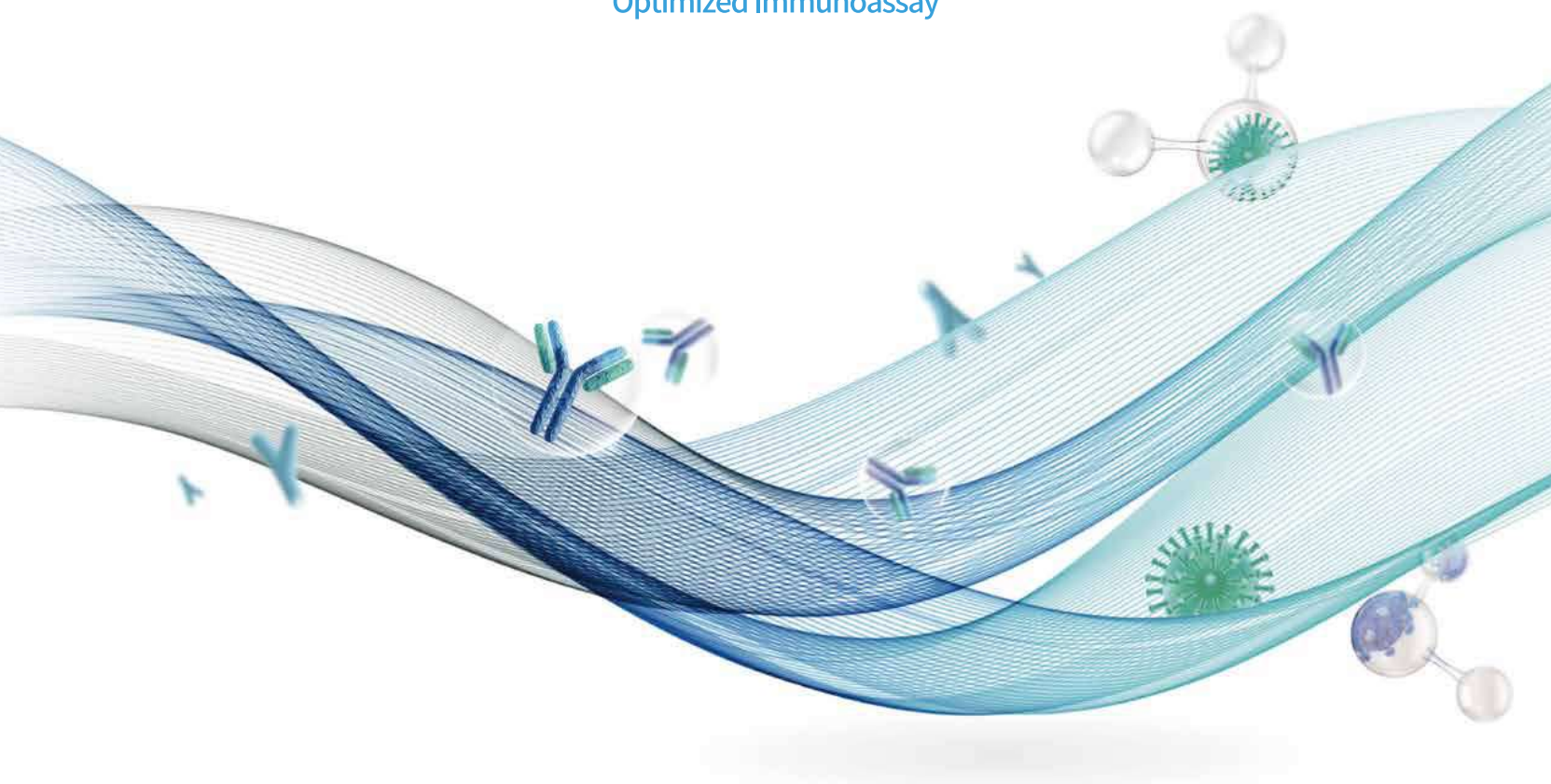




# OPTICALQ

PRODUCT CATALOG

Optimized Immunoassay



Committed to promoting health through technology

## About Us

OptiBio Co., Ltd. is a South Korean in-vitro diagnostics (IVD) company focused in researching, developing, and manufacturing cutting edge **fluorescence immunoassay (FIA)** solutions to enhance and progress quality healthcare access globally. In 2020, OptiBio was selected by a research fund sponsored by the **Bill & Melinda Gates foundation** for its unique and dedicated approach to immunoassay. OptiBio's fundamental approach of integrating in-house capabilities allows us to constantly improve product performance, customize solutions based on client feedback, develop new test parameters, and respond to changing market needs.

OptiBio will continue to create, improve, and innovate world class diagnostic solutions in the field of fluorescence immunoassay and **point-of-care testing (POCT)**, aiming to ultimately transform **medical diagnosis into a universally available right**.

### 2019. 10

- Factory registration
- Medical device manufacturing license



### 2020. 04

- ISO13485



### 2020. 07

- GMP (Devices for Clinical Immunology)



### 2020. 12

- GMP (Devices for Clinical Chemistry)



### 2019. 11

- Company affiliated research institute certificate



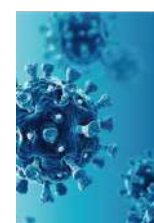
### 2019. 12

- EMC / EC / RoHS certificate
- Approved by Korea (MFDS)



### 2020. 08

- CE IVD
- Selected by Right Fund, (sponsored by Bill & Melinda Gates Foundation)



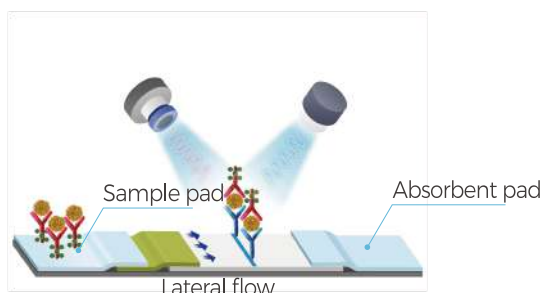
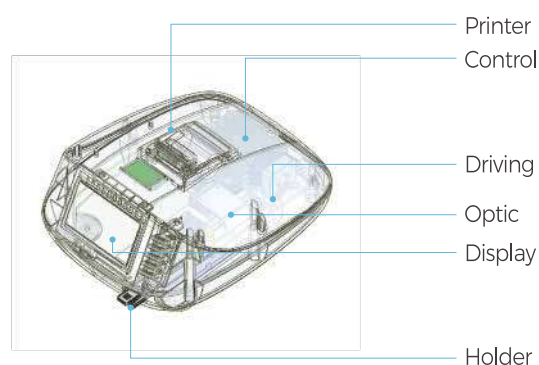
### 2021. 10

- COVID-19 Neutralizing Antibody FDA EUA application

## Technical Advantage

# 1 Analyzer Development

Our analyzer development team specializes in optical engineering and machine configuration, incorporating fluorescence microscopy and differential interference to develop, modify, and optimize powerful and low-cost fluorescence immunoassay analyzers.

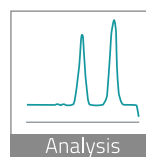


# 2 Test Kit Development

Our test kit development team is formed with a core foundation in bioscience. Our team delves into bio-core raw material development and bio raw material synthesis to develop complex biomarkers, innovate new test parameters, and create high performing test kits.

# 3 Optimal combination

Our unique ability to develop our analyzers, kits, and markers in-house allows for constant honing of our test kits for maximized performance. This combination – the optimization of our machines and kits based on the diagnostic markers we develop – has enabled us to constantly optimize, modify, and innovate our diagnostic solutions.



• Quantitative Analysis : ng / mL / mIU / mL

Manual Type System for IVD  
Fluorescence Immunoassay Analyzer

# OPTICALQ

## Optimized Immunoassay



Barcode

Internal  
Printer

RFID

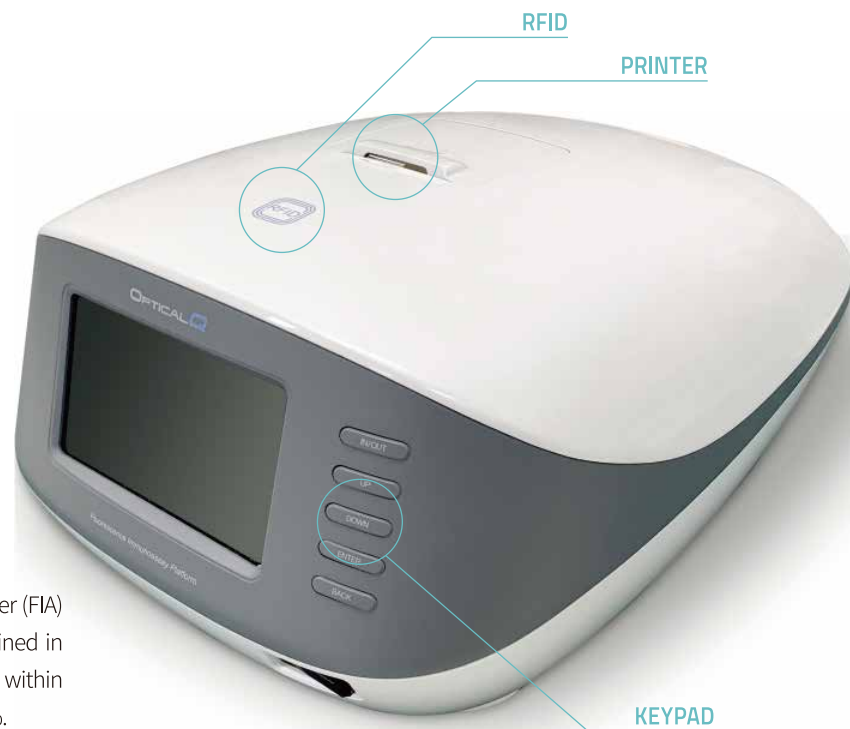


Portable

*Top Performance.*  
*Wide Test Options.*  
*Modifiable.*

Optical Q™ is a cutting edge fluorescence immunoassay analyzer (FIA) that accurately measures the concentration of analytes contained in blood, serum, plasma, and other samples. Results are generated within a prompt 15-minute time frame with CV's ranging from 5%~10%.

Optical Q™ utilizes advanced fluorescence chemistry and incorporates world class lens technology to accurately quantify the concentration - or severity - of each analyte. Optical Q™ also features up to 27 diagnostic markers that cover health categories such as inflammation, diabetes, and thyroids. OptiBio's capacity to develop analyzers and antibodies in-house enables optimized performance against competitors, continued expansion of our test menu, and modification of tests based on client needs. Optical Q™ is truly a rapid one-stop diagnostic solution.



## Technical Highlights



### Easy and simple

3 steps: dilution, drop, analysis



### Top performance

<10% CV across all test parameters



### Instantaneous results

3~15 minutes per diagnostic marker



### Expanding Test Menu

27 test parameters and expanding



## Specification

Test method	Quantitative Fluorescence Immunoassay
Dimensions	357 mm (L) x 284 mm (W) x 156 mm (H)
Weight	1.5 kg
Power supply	DC 12V/5A, AC/DC Adaptor
Data output	LCD / Internal printer
Memory	99 Patient results
Interface	RS422 (RJ45) / mini 5pin / USB
Display LCD	5" Mono LCD
Working condition	Temperature: 15 ~ 30°C / Humidity: 10 ~ 70%

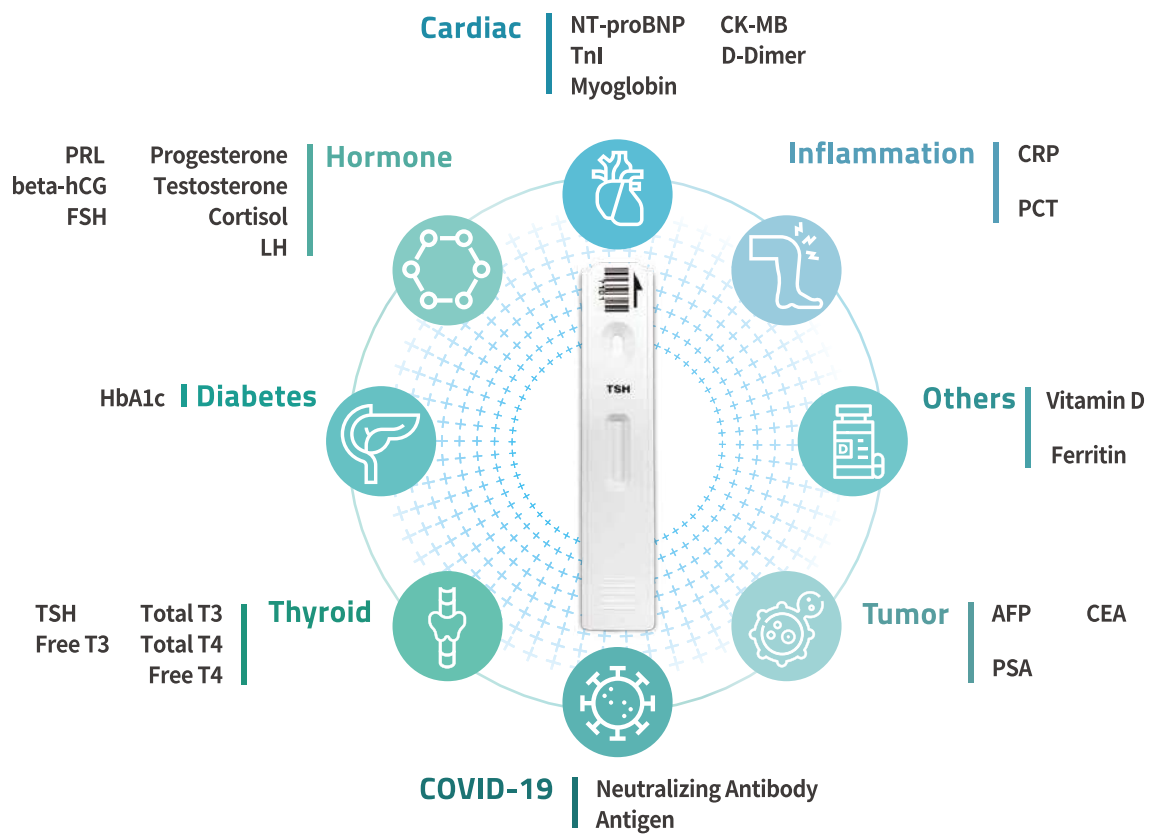


Optimized Immunoassay

# VARIOUS CATEGORIES

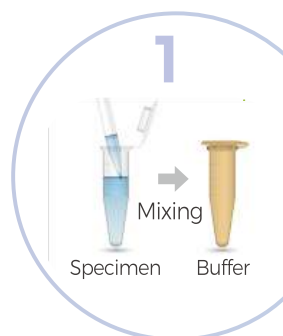


BARCODE



## Test Procedure

Only  
3  
steps



Dilution



Loading



Analyzing

# CRP

CRP--C-reactive protein--is an acute reaction substance produced by the liver and is secreted into the bloodstream within a few hours after the onset of infection or inflammation. As CRP increases in severe cases of inflammation, tests are done based on the patient's clinical symptoms or for patients at risk of acute inflammation post surgery. CRP is also tested to assist with conditions such as rheumatoid arthritis and lupus, and is often repeated to determine the efficacy of a treatment. When the inflammation subsides, the CRP concentration drops, so it is a particularly useful test index for inflammatory reactions, and can also be used for early detection of potential infections in wound healing and surgical resection, organ transplantation, and burn patients. Rapid diagnosis and treatment is essential in acute inflammatory reactions.

The Optical Q™ CRP test quantitatively measures the amount of CRP within a 3-minute timeframe, rendering our test imperative in accurately monitoring inflammation status in urgent situations.



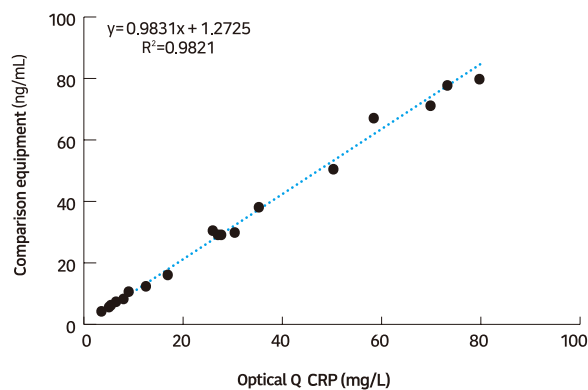
## Specification

### Optical Q™ CRP

Working range	0.1 – 200.0 mg/L
Reference range	< 10 mg/L
Performance	CV<10%
Sample type	Whole blood / Serum / Plasma
Sample volume	10µL
Loading volume	100µL
Assay time	3mins
Storage condition	Cartridge : 2 - 30°C / Detection buffer : 2 - 8°C
Shelf life	24 months



## Performance



## Ordering Information

Cat #	OB111-25
Test / Kit	25

# Vitamin D

There are two types of vitamin D measured in blood: 25-hydroxyvitamin D [25(OH)D] and 1,25-dihydroxyvitamin D [1,25(OH)(2)D]. 25(OH)D is the main form of vitamin D hormones found in the blood and is an inactive precursor to become the active hormone 1,25(OH)(2)D. Because of its long half-life and high concentration, 25(OH)D is primarily used to assess and monitor vitamin D status. Vitamin D helps regulate the absorption of calcium, phosphorus and magnesium and is essential for bone growth and health. Vitamin D deficiency causes bone deterioration which can lead to diseases such as rickets in children and osteomalacia in adults. Interestingly, Vitamin D is also involved in the regulation of autoimmunity, metabolic function, and cancer prevention.

The Optical Q™ Vitamin D test quantitatively measures the amount of Vitamin D in a 25 minute timeframe to accurately assess and detect Vitamin D deficiency in patients.



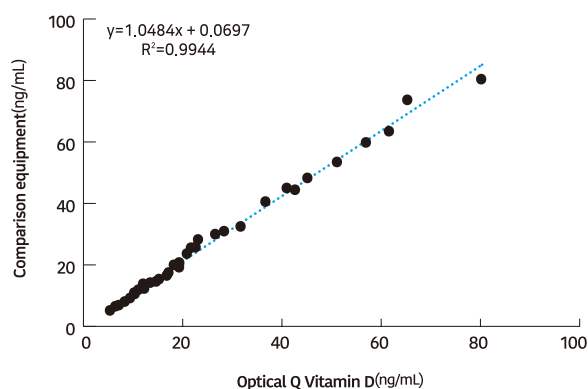
## Specification

### Optical Q™ Vitamin D

Working range	5.00 - 80.00 ng/mL
Reference range	* Deficiency : 10 ng/mL    * Insufficiency : 10-29 ng/mL
Performance	CV <10%
Sample type	Serum / Plasma
Sample volume	100μL
Loading volume	100μL
Assay time	Step A : 10 mins, Step B : 15 mins
Storage condition	Cartridge : 2 - 30°C / Detection buffer : 2 - 8°C
Shelf life	24 months



## Performance



## Ordering Information

Cat #	OB131-25
Test / Box	25

# HbA1c

The glycated hemoglobin test measures the concentration of glycated A1c hemoglobin by evaluating the average level of glucose in the blood over the past 2 to 3 months. Hemoglobin is an oxygen-carrying protein found inside red blood cells. Although several normal and variant hemoglobins are known, the most common form, accounting for 95-98%, is hemoglobin A. When glucose circulates in the blood, some of it naturally binds to hemoglobin A. A molecule that combines glucose and hemoglobin is said to be glycated. The higher the blood glucose level, the more glycated hemoglobin is produced. Once glucose binds to the hemoglobin, it remains bound until the end of the lifespan of red blood cells, which is normally 120 days. The combination of glucose and hemoglobin A is called HbA1c or A1c. A1c is produced daily and is slowly eliminated as mature red blood cells die and young (with non-glycosylated hemoglobin) red blood cells take over.

The Optical Q HbA1c test quantitatively measures the amount of HbA1c within a 15 minute timeframe to accurately detect diabetes in patients and also effectively monitor treatment of diabetes by assessing glucose levels over a period of time.



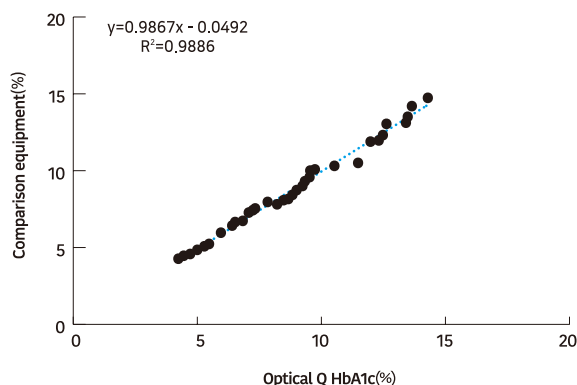
## Specification

### Optical Q HbA1c

Working range	4.0 - 15.0%
Reference range	< 6.5%
Performance	CV < 10%
Sample type	Whole blood
Sample volume	5 µL
Loading volume	100 µL
Assay time	15 mins
Storage condition	Cartridge: 2 - 30°C / Detection buffer: 2 - 8°C
Shelf life	24 months



## Performance



## Ordering Information

Cat #	OB121-25
Test / Kit	25



# TSH

Thyroid stimulating hormone (TSH) is a pituitary hormone that stimulates the thyroid gland to produce thyroxine and triiodothyronine which stimulates metabolism of almost every tissue in the body. The levels of TSH and TRH are inversely related to the level of thyroid hormone. When there is a high level of thyroid hormone in the blood, less TSH is secreted by the pituitary. The opposite action will occur when there are decreased levels of thyroid hormones in the blood. This process, known as a negative feedback mechanism, is responsible for maintaining the proper blood levels of these hormones.

The Optical Q™ TSH test quantitatively measures TSH within a 15 minute time-frame, allowing for instant on-field diagnosis and monitoring of thyroid complications.



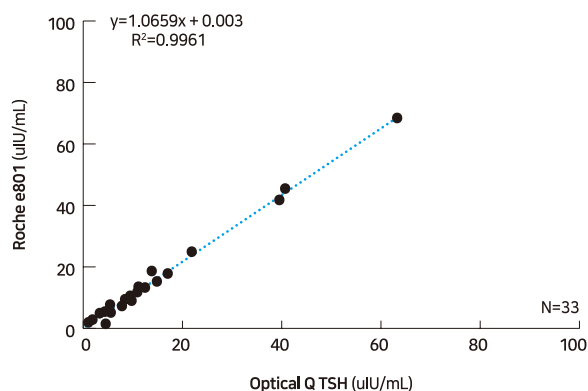
## Specification

### Optical Q™ TSH

Working range	0.10 - 100.00 uIU/mL
Reference range	0.4 - 5.0 uIU/mL
Performance	<10%
Sample type	Serum / Plasma
Sample volume	100µL
Loading volume	100µL
Assay time	15 mins
Storage condition	Cartridge : 2 - 30°C / Detection buffer : 2 - 8°C
Shelf life	24 months



## Performance



## Ordering Information

Cat #	OB171-25
Test / Box	25

# CoV-19 Neutralizing Antibody

CoV-19 neutralizing antibodies (nAbs) are special antibodies that function to prevent CoV-19 from binding to the ACE2 receptor of human cells. High levels of nAbs indicate immunity against COVID-19. Standard IGM/IGG antibody tests – which are universally available – do not detect for nAbs and can only provide an indirect indication for immunity.

A CoV-19 nAb test can be used to monitor immunization against COVID-19, evaluate vaccine efficacy across vaccinated patients, and assess recovering patients.



## Specification

### Optical Q™ CoV-19 nAb

Working range	30 - 100%
Reference range	<30% Negative / ≥30% Positive
Performance	CV<10%
Sample type	Serum / Plasma
Sample volume	100 µL
Loading volume	100 µL
Assay time	15 mins
Storage condition	Cartridge : 2 - 30°C / Detection buffer : 2 - 8°C
Shelf life	24 months



## Performance

### Clinical Performance

Clinical Agreement using Cancecrp's Q-Sens® as the comparator method

		RT-PCR test (Q-Sens®)	
		Positive ( n = 60 )	Negative ( n = 30 )
Optical Q™ CoV-19 nAb	Positive	60	0
	Negative	0	30
	Positive Percent Agreement	100%	
	Negative Percent Agreement	100%	

## Ordering Information

Cat #	OB193-25
Test / Kit	25

The Optical Q™ tests up to 27 different parameters across 8 major diagnostic categories.

Category	Item	Sample type	Sample volume (μL)	Loading volume (μL)	Detection range	Reaction time (mins)	Certifications	
							FSC (Free Sales Certificate)	CE-IVD
Analyzer	Analyzer	-	-	-	-	-	O	O
Inflammation	CRP	WB/S/P	10	100	0.1 - 200.0 mg/L	3	O	O
	PCT	S/P	100	100	0.1 - 100.0 ng/mL	15	O	O
Tumor	AFP	S/P	100	100	1.0 - 400.0 ng/mL	15	O	O
	CEA	S/P	100	100	1.0 - 200.0 ng/mL	15	O	O
	PSA	S/P	100	100	0.1 - 100.0 ng/mL	15	O	TBD
Hormone	beta-hCG	S/P	100	100	1.0 - 30,000.0 mIU/mL	15	O	O
	LH	S/P	100	100	1.0 - 100.0 mIU/mL	15	O	O
	FSH	S/P	100	100	1.0 - 100.0 mIU/mL	15	O	O
	PRL	S/P	100	100	1.0 - 100.0 ng/mL	15	O	O
	Cortisol	S/P	100	100	1.0 - 25.0 ug/dL	15	O	O
	Testosterone	S/P	100	100	1.0 - 10.0 ng/mL	15	O	O
	Progesterone	S/P	100	100	1.0 - 60.0 ng/mL	15	O	O
Thyroid	TSH	S/P	100	100	0.1 - 100.0 uIU/mL	15	O	O
	Total T3	S/P	100	100	0.1 - 6.0 ng/mL	23	O	O
	Free T3	S/P	100	100	1.0 - 20.0 pg/mL	15	O	O
	Total T4	S/P	100	100	0.5 - 25.0 ug/dL	23	O	O
	Free T4	S/P	100	100	0.1 - 8.0 ng/dL	15	O	O
Cardiac	*TnI	S/P	100	100	0.1 - 50.0 ng/mL	15	TBD	O
	Myoglobin	S/P	100	100	5.0 - 500.0 ng/mL	15	O	O
	CK-MB	S/P	100	100	3.0 - 100.0 ng/mL	15	O	O
	D-Dimer	P	100	100	50.0 - 10,000.0 ng/mL	15	O	O
	NT-proBNP	S/P	100	100	1.0 - 30,000.0 pg/mL	15	O	O
Diabetes	HbA1c	WB	5	100	4.0 - 15.0%	15	O	O
Others	* Vitamin D	S/P	100	100	5.0 - 80.0 ng/mL	25	O	O
	Ferritin	WB	10	100	1.0 - 1,000.0 ng/mL	15	O	O
Covid-19	Neutralizing Antibody	S/P	100	100	30.0 - 100.0 %	15	TBD	O
	*Antigen	-	-	-	-	-	-	-

\*Under development

## Optimized Immunoassay



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MFDS  
KOREA