

# Total solutions for the diagnosis of **COVID-19**



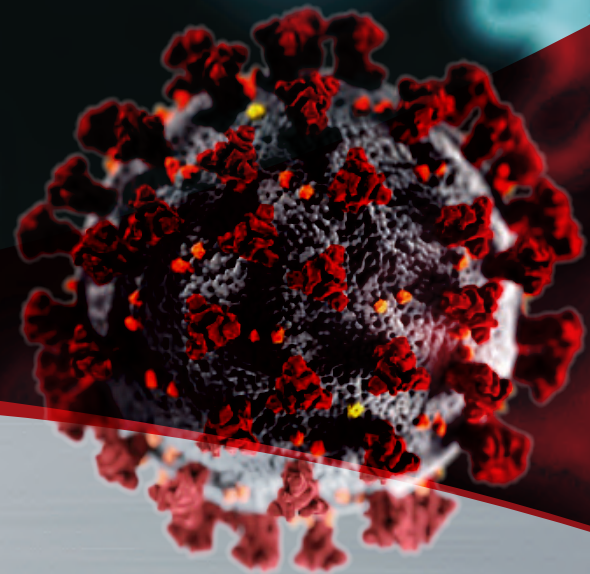
# COVID-19 outbreak

Sars-Cov-2 (COVID19), the newly identified coronavirus 2019-nCoV, causes pneumonia so that prevention and control of the infection has become highly required. So far, tens of millions have been infected and the following huge economic impact shakes global medical and social fundamentals. Since symptoms become rapidly severe without a proper treatment after onset of illness, early diagnosis of the virus infection is quite crucial.

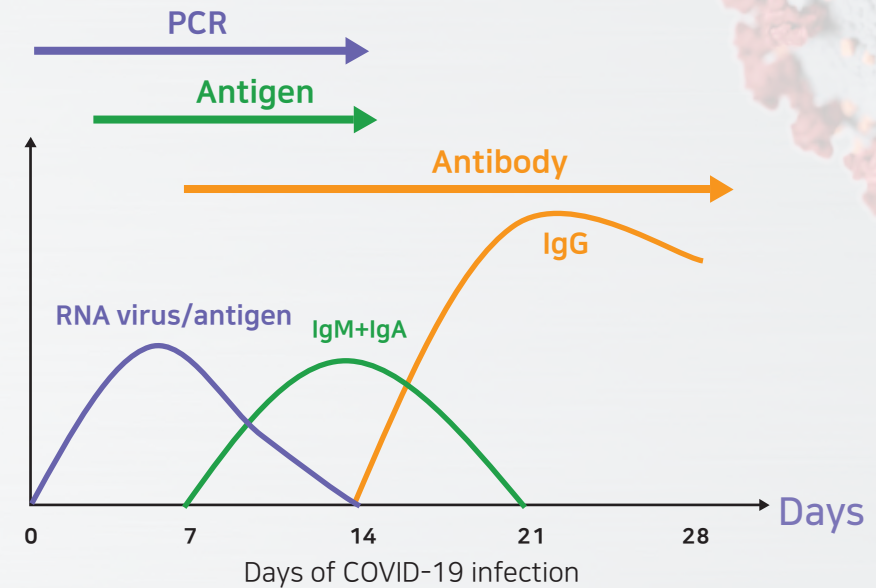
Boditech Med Inc. is a leader in in-vitro diagnostic area and provides total solution of COVID-19 diagnosis that can be used in any environment. Boditech Med manufactures 65 different kinds of diagnostic cartridges and 9 instruments to be used in the field such as cardiac, diabetes, hormones, infection, so on. In addition, we now provide:

- **Quick antigen/antibody kits** optimized for on-site diagnosis with high accuracy
- **Molecular diagnostics** for confirmatory testing
- **Nucleic acid extraction kits** essential for molecular diagnostic pretreatment
- **Interleukin-6 test** for the identification of confirmed COVID-19 patients who could be at high risk.

Boditech Med Inc. will do its best to prevent and diagnose the COVID-19.



# Product selection guide for the diagnosis of COVID-19 infection



## • COVID-19 products list

Category	Product	Description	Catalog No.	Storage
PCR	ExAmplar	ExAmplar PCR machine	FPRR030	2-25 °C
		COVID-19 Real-time PCR kit	UFPK-4	
	NuActor	NuActor extractor machine	FPRR032	15-35 °C
		Viral RNA extraction kit	UFPK-1	
	EasyAmp	Universal COVID-19 PCR kit	UFPK-5	2-25 °C
Antigen	ichroma™	ichroma™ II	FPRR021	4-30 °C
		COVID-19 Antigen test	CFPC-115	
	AFIAS	AFIAS-6	FPRR020	4-30 °C
		AFIAS-1	FPRR019	
		COVID-19 Antigen test	SMFP-71	
Antibody	ichroma™	ichroma™ II	FPRR021	4-30 °C
		COVID-19 Antibody test	CFPC-114	
	AFIAS	AFIAS-6	FPRR020	4-30 °C
		AFIAS-1	FPRR019	
		COVID-19 Antibody test	SMFP-72	
Interleukin-6	ichroma™	ichroma™ IL-6	CFPC-116	4-30 °C
	AFIAS	AFIAS-6 IL-6	SMFP-74	

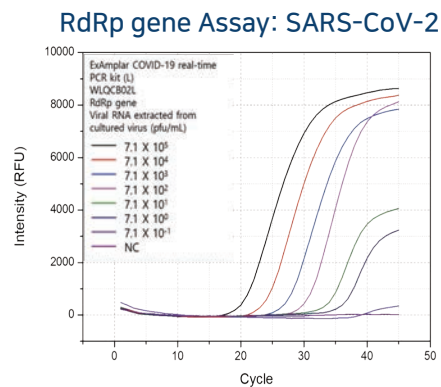
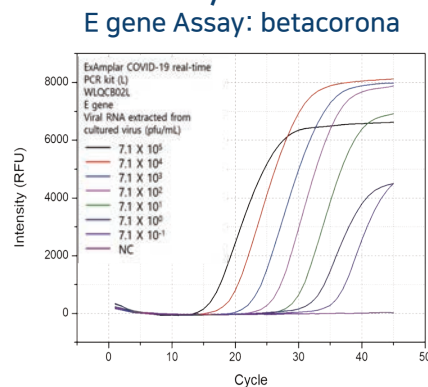
# ExAmplar COVID-19 real-time PCR kit (L)

- Easy shipping & delivery (No dry ice needed)
- Ambient temperature storage (2-25 °C)
- Fast, Small and Cost Effective
- Exclusive Reagent (closed system)
- 8 tests/run (3 controls + 5 samples)
- 30 mins (DNA)/45 mins (RNA)
- Size : 20 cm × 24 cm × 18 cm
- Fully lyophilized, ready-to-use real-time PCR kit
- Open kit: test with ExAmplar or any conventional real-time PCR machines
- Controls included
- Sensitivity to <20 copies/rxn



## • Performance Data

### Analytical Sensitivity



	Limit of Detection	95% confidence interval (CI)
E gene	5.2 copies/μL	4.2 ~ 7.2 copies/μL
RdRp gene	15.1 copies/μL	12.5 ~ 19.6 copies/μL

## • Components

Components	Quantity
Reaction tube (lyophilized)	12 tubes (48 tests/kit)
Resuspension buffer	2 vials (1.5 mL x 2)
Positive control	1 vial
Negative control	1 vial

## • Ordering Information

Product	Cat. No.
ExAmplar	FPRR030
ExAmplar COVID-19 real-time PCR kit (L)	UFPK-4

# NuActor Automatic Extractor

- Extraction Time < 15 mins
- From Sample 200 µL
- Exclusive Cartridge System
- Magnetic bead method
- Full Automated
- UV sterilization
- Size : 24 cm × 24 cm × 26 cm

## NuActor Viral RNA extraction kit



### • Components

Components	Quantity
Extraction cartridges	12 ea
2X lysis buffer (20 mL)	2 bottles
Disposable strip-cap	12 ea

### • Ordering Information

Product	Cat. No.
NuActor	FPRR032
NuActor Viral RNA extraction kit	UFPK-1

# ichroma™ COVID-19 Ag test

ichroma™ COVID-19 Ag is a fluorescence Immunoassay (FIA) for the qualitative detection of novel coronavirus (SARS-CoV-2, 2019-nCoV) in human nasopharyngeal swab. It is helpful as an aid in the screening of early mild, asymptomatic, or acute patients for identification of 'Novel Coronavirus' infection.

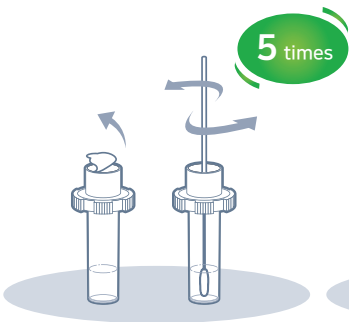
\* For *in vitro* diagnostic use only.



## • Test procedure

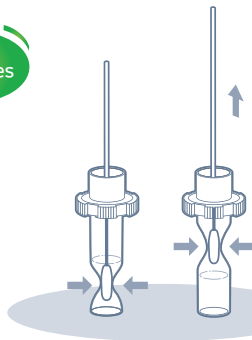
1

Insert the sterile swab used to collect the sample into the extraction tube and swirl 5 times



2

While squeezing the tube, pull the swab out



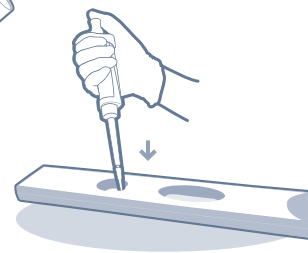
3

Assemble a nozzle and the extraction tube and then add six drops of sample mixture into the detector tube



4

Pipette out 75 µL and load it into the sample well on the cartridge



5

Wait 12 minutes

12 Mins



6

Read the test result



# ichroma™ COVID-19 Ag test

## • Components

- Cartridge
- Detector tube
- Extraction tube
- Nozzle
- ID Chip



## • Ordering Information

Product	Cat. No.
ichroma™ COVID-19 Ag	CFPC-115
ichroma™ II Reader	FPRR021

\* Note. A nylon swab is excluded from the components of the cartridge box.

## • Clinical performance

		RT-PCR		
		Positive	Negative	Total
ichroma™ COVID-19 Ag	Positive	21	2	23
	Negative	3	55	58
	Total	24	57	81

- Clinical sensitivity: 87.5 %

- Clinical specificity: 96.5 %

## • Specification

Product name	ichroma™ COVID-19 Ag
Assay type	TRFLFA*, COVID-19 Antigen
Sample type	Nasopharyngeal swab
Sample prep / extraction	Collecting with nylon swab
Target	COVID-19 Antigen
Platform	ichroma™ II Reader
Unit	25 kit/box

\* TRFLFA: Time-resolved fluorescent lateral flow assay

# AFIAS COVID-19 Ag test

AFIAS COVID-19 Ag is an automatic fluorescence Immuno assay (FIA) for the qualitative detection of novel corona virus (eg, SARS-CoV-2, 2019-nCoV) in human nasopharyngeal swab. It is useful as an aid in management and monitoring of SARS-CoV-2 infection (COVID-19).

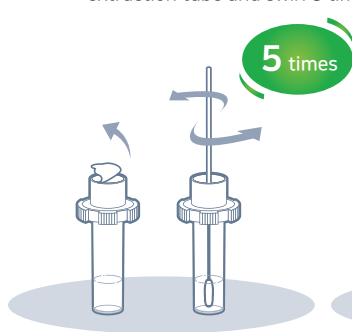
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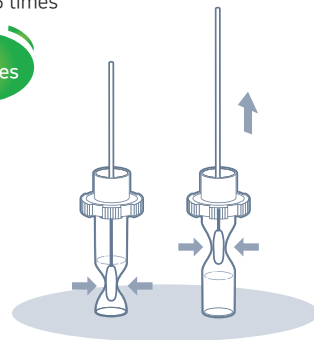
## • Test procedure

### 3 simple steps

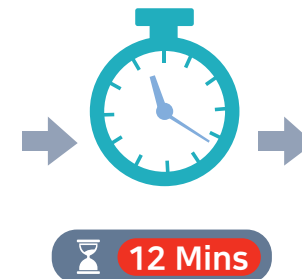
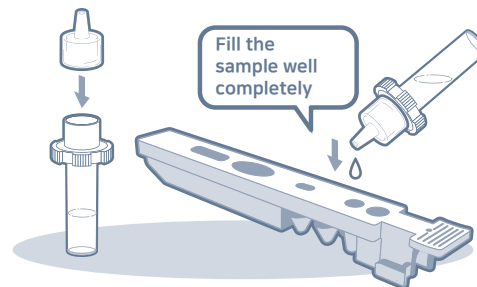
- 1 Insert the sterile swab used to collect the sample into the extraction tube and swirl 5 times



- 2 While squeezing the tube, pull the swab out



- 3 Assemble a nozzle and the extraction tube, and then fill the sample well completely with the sample mixture



# AFIAS COVID-19 Ag test

## • Components

- Cartridge
- Pipette tip for operation
- Extraction tube
- Nozzle
- ID Chip



## • Ordering Information

Product	Cat. No.
AFIAS COVID-19 Ag	SMFP-71
AFIAS-1 Reader	FPRR019
AFIAS-6 Reader	FPRR020

\* Note. A nylon swab is excluded from the components of the cartridge box.

## • Clinical performance

		RT-PCR		
		Positive	Negative	Total
AFIAS COVID-19 Ag	Positive	21	2	23
	Negative	3	55	58
	Total	24	57	81

- Clinical sensitivity: 87.5 %

- Clinical specificity: 96.5 %

## • Specification

Product name	AFIAS COVID-19 Ag
Assay type	TRFLFA*, COVID-19 Antigen
Sample type	Nasopharyngeal swab
Sample prep / extraction	Collecting with nylon swab
Target	COVID-19 Antigen
Platform	AFIAS 1/ 6 (Automated)
Unit	24 kit/box

\* TRFLFA: Time-resolved fluorescent lateral flow assay

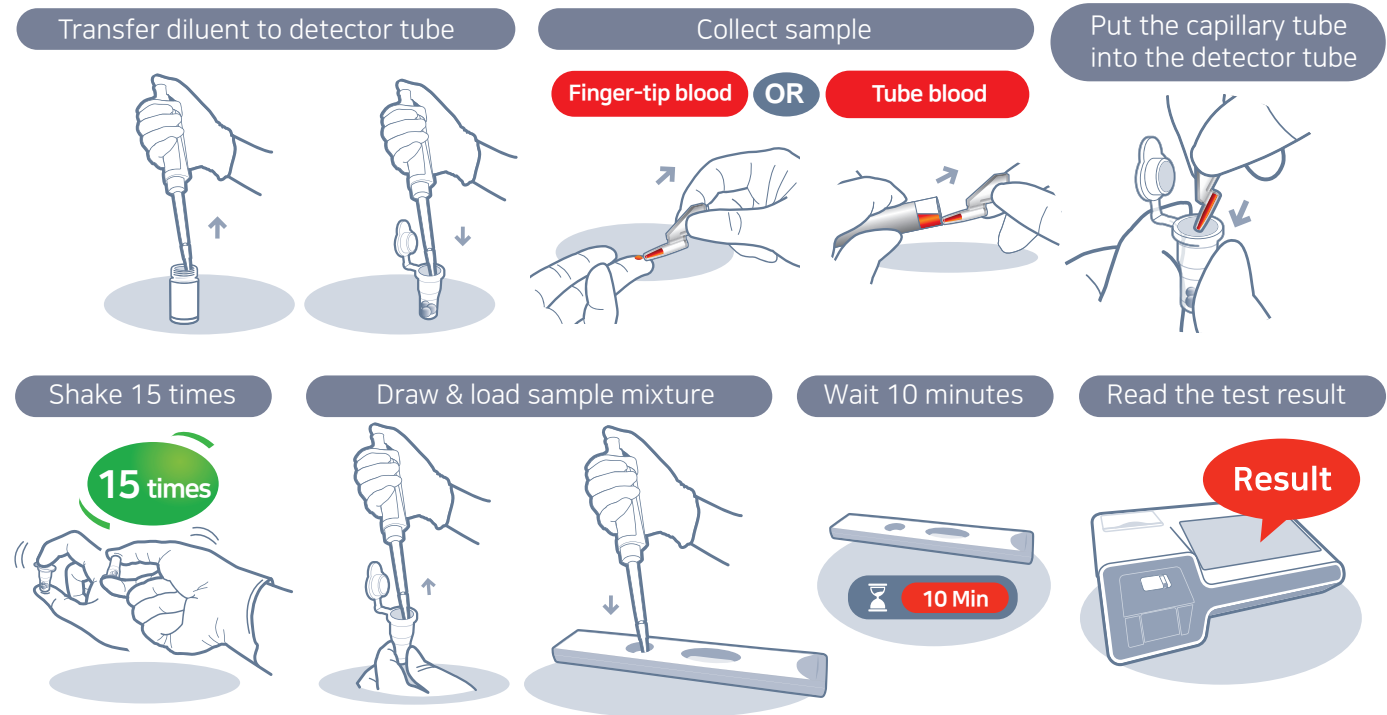
# ichroma™ COVID-19 Ab test

ichroma™ COVID-19 Ab is a fluorescence Immunoassay (FIA) for the qualitative detection of novel coronavirus (SARS-CoV -2, 2019-nCoV) in human whole blood/serum/plasma. It is helpful as an aid in the screening of early mild, asymptomatic, or acute patients for identification of 'Novel Coronavirus' infection.

\* For *in vitro* diagnostic use only.



## • Test procedure



# ichroma™ COVID-19 Ab test

## • Components

- Cartridge
- Detector tube
- Detector diluent
- ID Chip

\* Additional component (Not include in kit box)  
- 10 µL capillary tubes (250 ea/bottle)



## • Ordering Information

Product	Cat. No.
ichroma™ COVID-19 Ab	CFPC-114
ichroma™ II Reader	FPRR021

## • Clinical performance

		RT-PCR		
		Positive	Negative	Total
ichroma™ COVID-19 Ab	Positive	46	0	46
	Negative	0	131	131
	Intermediated	2	4	6
	Total	48	135	183

- Clinical sensitivity: 95.8 %

- Clinical specificity: 97.0 %

## • Specification

Product name	ichroma™ COVID-19 Ab
Assay type	TRFLFA*, IgM/IgG
Sample type	Whole blood/Serum/Plasma
Sample prep / extraction	Finger-prick / Tube blood
Target	Anti-viral IgM/IgG
Platform	ichroma™ II Reader
Unit	25 kit/box

\* TRFLFA: Time-resolved fluorescent lateral flow assay

# AFIAS COVID-19 Ab test

AFIAS COVID-19 Ab is an automatic fluorescence Immunoassay (FIA) for the qualitative determination of IgG/IgM antibodies against 'Novel Coronavirus' in human whole blood/serum/plasma. It is helpful as an aid in the screening of early mild, asymptomatic or acute patients for identification of 'Novel Coronavirus (eg, SARS, 2019-nCoV)' infection with high sensitivity. Finger blood (peripheral blood; whole blood) using the unique 'all-in-one' tube, allows the patient's pain to blood collection to be relatively low and suitable for large-scale screening in the field.

\* For *in vitro* diagnostic use only.



## • Test procedure

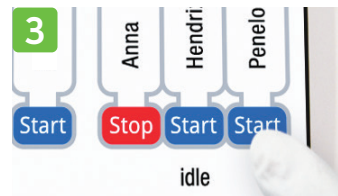
### 3 simple steps



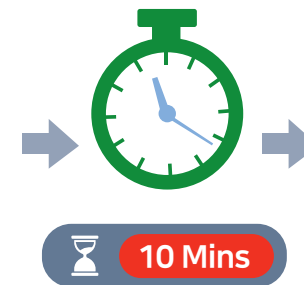
Collect capillary blood



Place the C-tip in the cartridge tip hole and insert the cartridge into the slot



Press START to run the test.



# AFIAS COVID-19 Ab test

- Components

- Cartridge
- Pipette tip for operation
- C-tip for collecting capillary blood
- ID Chip



- Ordering Information

Product	Cat. No.
AFIAS COVID-19 Ab	SMFP-72
AFIAS-1 Reader	FPRR019
AFIAS-6 Reader	FPRR020

- Clinical performance

		RT-PCR		
		Positive	Negative	Total
AFIAS COVID-19 Ab	Positive	46	0	46
	Negative	0	145	145
	Intermediated	2	5	7
	Total	48	150	198

- Clinical sensitivity: 95.8 %
- Clinical specificity: 96.7 %

- Specification

Product name	AFIAS COVID-19 Ab
Assay type	TRFLFA*, IgM/IgG
Sample type	Whole blood/Serum/Plasma
Sample prep/extraction	Finger-prick/Tube blood
Target	Anti-viral IgM/IgG
Platform	AFIAS 1/ 6 (Automated)
Unit	24 kit/box

\* TRFLFA: Time-resolved fluorescent lateral flow assay

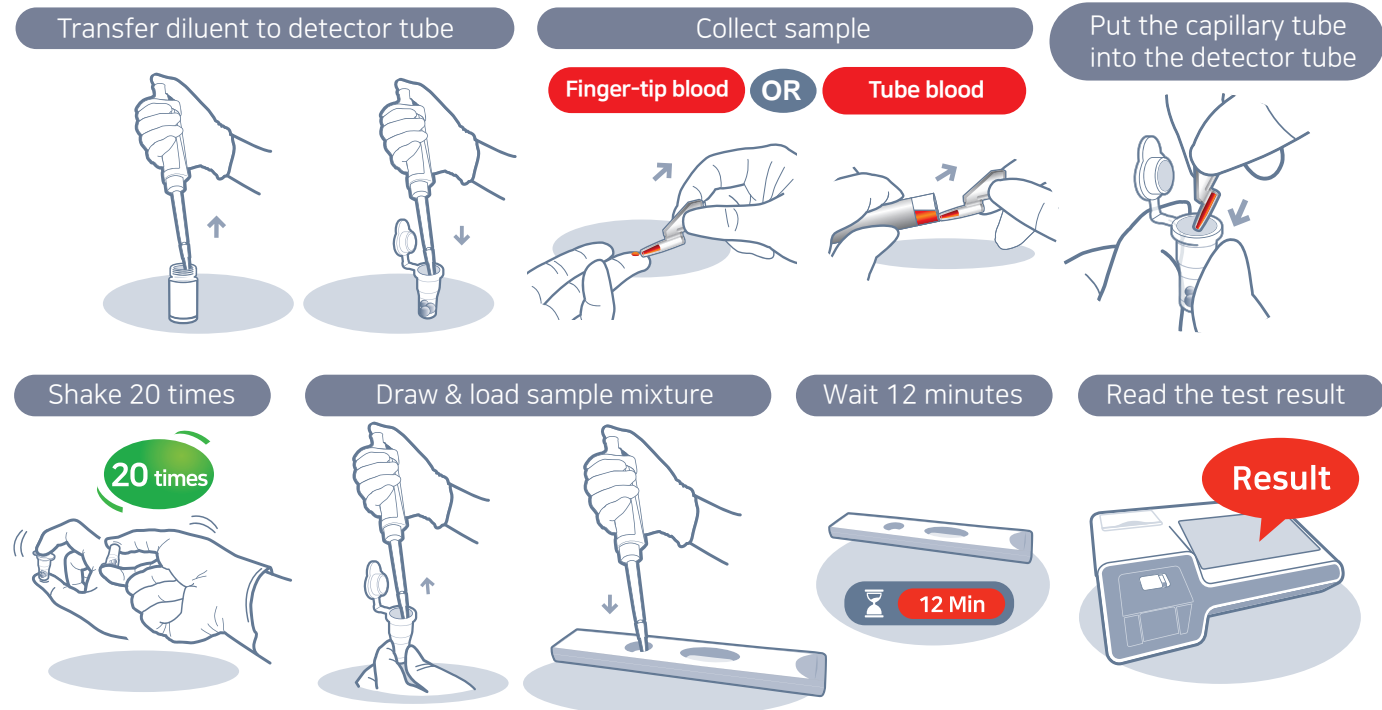
# ichroma™ IL-6 test

- Interleukin-6 (IL-6) is an early biomarker for acute inflammation to assist in the caring of critically ill patients
- Boditech IL-6 test is helpful in identifying severe inflammatory response in patients with confirmed COVID-19.

\* For *in vitro* diagnostic use only.



## • Test procedure



# ichroma™ IL-6 test

## • Components

- Cartridge
- Detector tube
- Detector diluent
- ID Chip



## • Ordering Information

Product	Cat. No.
ichroma™ IL-6	CFPC-116
ichroma™ II Reader	FPRR021

## • Comparison with competitor

	Boditech Med Inc.	Roche
Sample type	WB/Serum/Plasma	Serum/Plasma
Sample volume	30 µL (WB/Serum/Plasma) 35 µL (Capillary blood)	30 µL
TAT	12 min	18 min
Instruments	ichroma™ II Reader	Cobas
Principle	Time-resolved fluorescence	Electro Chemiluminescence
Working range	2- 2,500 pg/mL	1.5- 5,000 pg/mL

## • Specification

Product name	ichroma™ IL-6
Assay type	TRFLFA*, IL-6
Sample type	Whole blood/Serum/Plasma
Sample preparation	Finger or heel prick/Tube blood
Target	IL-6
Platform	ichroma™ II Reader
Unit	25 kit/box

\* TRFLFA: Time-resolved fluorescent lateral flow assay

# AFIAS IL-6 test

- Interleukin-6 (IL-6) is an early biomarker for acute inflammation to assist in the caring of critically ill patients
- Boditech IL-6 test is helpful in identifying severe inflammatory response in patients with confirmed COVID-19.

\* For *in vitro* diagnostic use only.



## • Test procedure

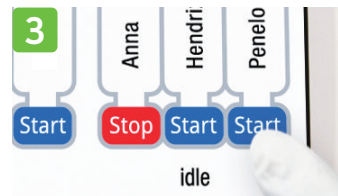
### 3 simple steps



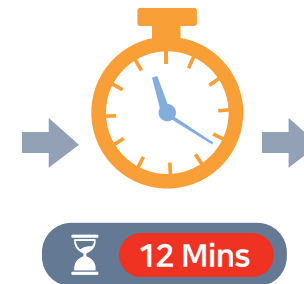
Collect capillary blood



Place the C-tip in the cartridge tip hole and insert the cartridge into the slot



Press START to run the test.



# AFIAS IL-6 test

## • Components

- Cartridge
- Pipette tip for operation
- C-tip for collecting capillary blood
- ID Chip



## • Ordering Information

Product	Cat. No.
AFIAS IL-6	SMFP-74
AFIAS-1 Reader	FPRR019
AFIAS-6 Reader	FPRR020

## • Comparison with competitor

	Boditech Med Inc.	Roche
Sample type	WB/Serum/Plasma	Serum/Plasma
Sample volume	30 µL (WB/Serum/Plasma/Capillary blood)	30 µL
TAT	12 min	18 min
Instruments	AFIAS Reader	Cobas
Principle	Time-resolved fluorescence	Electro Chemiluminescence
Working range	2- 2,500 pg/mL	1.5- 5,000 pg/mL

## • Specification

Product name	AFIAS IL-6
Assay type	TRFLFA*, IL-6
Sample type	Whole blood/Serum/Plasma
Sample preparation	Finger or heel prick/Tube blood
Target	IL-6
Platform	AFIAS 1/6 (Automatic)
Unit	24 kit/box

\* TRFLFA: Time-resolved fluorescent lateral flow assay

# iCHROMA II™

Advanced compact immuno-analyzer

- QC & system check
- Battery & AC operated
- LIS/ HIS connectivity
- Multi-timer function
- USB/ LAN, SD Card

## Specifications

### QC / Calibration

System check cartridge  
COVID-19 controls available

### Interface

7" touch screen  
Built-in thermal printer  
USB port / Ethernet / SD card slot  
WiFi dongle (optional)  
LIS / HIS compatible

### Memory

1,000 patient results  
1,000 QC results  
100 User IDs

### Analyzer

276 x 220 x 91 mm  
1.3 kgs  
100 - 240V AC, 50-60Hz  
Battery (AA×4)



# AFIAS-6

Versatile desktop immuno-analyzer

- Automated desktop analyzer
- 30  $\mu$ L finger prick blood
- 6 different tests on 6 different channels
- Bay random access (2 bays)



## Specifications

### QC / Calibration

COVID-19 controls available

### Interface

7" touch screen

Built-in thermal printer

RS 232 / USB port / Ethernet / SD card slot

LIS / HIS compatible

### Memory

5,000 patient results

5,000 QC results

500 ID chips

100 User IDs

### Throughput

Up to 36 tests / hour

### Analyzer

420 x 336 x 293 mm

15.1 kgs

100 - 240V AC, 50-60Hz

Internal temperature control

# AFIAS-1

Doctor's reliable associate

- Automated desktop analyzer
- LIS / HIS connectivity
- All-in-one cartridge
- 30  $\mu$ L finger prick blood
- Walk away function



## Specifications

### QC / Calibration

COVID-19 controls available

### Interface

5" touch screen

Built-in thermal printer

RS 232 / USB port / Ethernet / SD card slot

LIS / HIS compatible

### Memory

5,000 patient results

5,000 QC results

500 ID chips

100 User IDs

### Throughput

Up to 10 tests / hour

### Analyzer

320 x 204 x 180 mm

3.9 kgs

100 - 240V AC, 50-60Hz

Internal temperature control