U.S. FOOD & DRUG ADMINISTRATION

Acknowledgment Letter

6/5/2020

Will Graham
ACCOBIOTECH SDN. BHD.
No. 11 Jalan Bukit 27, Masai Industrial Park
Masai, Johor 81750
MALAYSIA

Dear Will Graham:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: EUA201638
Received: 6/4/2020
Applicant: ACCOBIOTECH SDN. BHD.
Device: ACCO COVID-19 IgM/IgG

We will notify you when the review of this document has been completed or if any additional information is required. If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

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ATTACHMENT #1

Product Description

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ACCOBIOTECH SDN. BHD (925954-V)
No. 11 Jalan Bukit 27, Masai Industrial Park,
Bandar Seri Alam, 81750, Masai, Johor, MALAYSIA
Tel: +607-382 1077, Fax :+607-3821717

Technical File

Product description

Product: **Acco COVID-19 IgM/IgG**

Date: **2020-03-02**

Prepared by	Reviewed by	Approved by
Researcher	**R&D Director**	**Quality Manager**

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0. Revision history

Revision History		
Rev.O	2020. 03. 02	Release of the product description for Acco COVID-19 IgM/IgG

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1. COMPANY PROFILE

We are an established IVD (In-Vitro Diagnostics) development and manufacturing company in Malaysia . Our company has been granted pioneer status by the Malaysian Government. Our company was formed in 2010 and its management team consists of highly experienced personnel in wide ranging field like manufacturing, marketing, finance and R&D . Our company's core is to promote health and well being of mankind via fast and accurate diagnostic of disease, with this competency patients can be given detailed test, early treatment and medical care.
We engaged in R&D based on NanoTechnology.

2. General description of the device

2.1. The name of the device

Acco COVID-19 IgM/IgG

2.2. The variants

Product Name	Contents	Number
Acco COVID-19 IgM/IgG - Cat.No.ACOV2015	Acco COVID-19 IgM/IgG test device	20 ea
	Assay buffer in dropping bottle	1 ea
	Capillary tube for sample loading	20 ea
	Instructions for use	1 sheet

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2.3. Components

Cat.No. ACOV2015

Name	Composition	Quantity	CAS number
Test Strip	Mouse-gold conjugate	QS	N/A
	Anti-human IgM-gold conjugate	QS	N/A
	Anti-human IgG-gold conjugate	QS	N/A
	Anti-mouse IgG	QS	N/A
	Recombinant COVID-19 NP	QS	N/A
	Absorbance pad	QS	N/A
	Conjugation pad	QS	N/A
	Nitrocellulose membrane	QS	N/A
Test Device	Poly Ethylene	N/A	N/A
Others	Silica gel	N/A	N/A

2.4. Classification of the product

EDMA code: 15 04 80 90 00 Other Viral Antigen/Antibody Detection
IVDD Classification: Others
(Neither Listed in Annex II of IVDD, nor self-testing device)

2.5. Additional special equipment

N/A

2.6. The microbiological state if appropriate

N/A

3. A Short description of the intended use and operation of the device, containing;

3.1. Intended use

Acco COVID-19 IgM/IgG device is a chromatographic immunoassay kit for the rapid and differential detection of immunoglobulin M (IgM) and immunoglobulin G (IgG) against COVID-19 using serum, plasma and whole blood.

3.2. History of the product

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), previously known by

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the provisional name 2019 novel coronavirus (2019-nCoV), is a positive-sense single-stranded RNA virus. It is contagious in humans and is the cause of the ongoing 2019–20 coronavirus outbreak, an epidemic of coronavirus disease 2019 (COVID-19) that has been designated a Public Health Emergency of International Concern by the World Health Organization (WHO).

SARS-CoV-2 has close genetic similarity to bat coronaviruses, from which it likely originated. An intermediate reservoir such as a pangolin is also thought to be involved in its introduction to humans. From a taxonomic perspective SARS-CoV-2 is classified as a strain of the species severe acute respiratory syndrome-related coronavirus (SARSr-CoV). To avoid confusion with the disease SARS, the WHO sometimes refers to the virus as "the virus responsible for COVID-19" in public health communications.

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS coronavirus 2 or SARS-CoV-2), a virus closely related to the SARS virus. The disease was discovered and named during the 2019–20 coronavirus outbreak. Those affected may develop a fever, dry cough, fatigue, and shortness of breath. A sore throat, runny nose or sneezing is less common. Cases can progress to pneumonia and multi-organ failure.

The infection is spread from one person to others via respiratory droplets produced from the airways, often during coughing or sneezing. Time from exposure to onset of symptoms is generally between 2 and 14 days, with an average of 5 days. The standard method of diagnosis is by reverse transcription polymerase chain reaction (rRT-PCR) from a nasopharyngeal swab or sputum sample, with results within a few hours to 2 days. Antibody assays can also be used, using a blood serum sample, with results within a few days. The infection can also be diagnosed from a combination of symptoms, risk factors, and a chest CT scan showing features of pneumonia.

Hand washing, maintaining distance from people who are coughing and not touching one's face with unwashed hands are measures recommended to prevent the disease.[26] It is recommended to cover one's nose and mouth with a tissue or a bent elbow when coughing. Those who suspect they carry the virus are recommended to wear a surgical face mask and seek medical advice by calling a doctor rather than visiting a clinic in person. Masks are also recommended for those who are taking care of someone with a suspected infection but not for the general public. There is no vaccine or specific antiviral treatment, with management involving treatment of symptoms, supportive care, and experimental measures. The case fatality rate is estimated at between 1% and 3%.

The WHO has declared the 2019–20 coronavirus outbreak to be a Public Health Emergency of International Concern (PHEIC). As of 29 February 2020, China, Hong Kong, Iran, Italy, Japan, Singapore, South Korea and the United States are areas having

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evidence of community transmission of the disease.

4. Measures to protect personnel

- Wear disposable powder-free gloves and lab coats
- No drinks or foods in working place
- Trained personnel use only
- Other general precautions are listed in the user's manual.

5. Protocol

5.1. Materials provided

Acco COVID-19 IgM/IgG contains the following items:

Contents	No of N
Acco COVID-19 IgM/IgG test device	20 ea
Assay buffer in dropping bottle	1 ea
Capillary tube for sample loading	20 ea
Instructions for use	1 sheet

5.2. Specimen collection, storage and precaution

(1) Specimen to be tested should be obtained and handled by standard methods for their collections.

(2) Serum: Allow the blood to clot, then centrifuge to separate the serum.

(3) Plasma: Collect the whole blood into the tube containing anticoagulants such as heparin, citrate, or EDTA. Centrifuge the blood and separate the plasma.

(4) Whole blood: whole blood should be collected over heparin, citrate, or EDTA. Mix the blood by inversion and use it to the test. If fingertip blood is used to the test, prick the finger and collect the blood by a capillary tube. And then, load the blood onto the sample well (S) of the test device.

(5) All specimens should be tested as soon as early they are prepared. If necessary, they may be stored at 2-8°C for up to 24 hours or at -20°C for longer periods.

5.3. Test procedure

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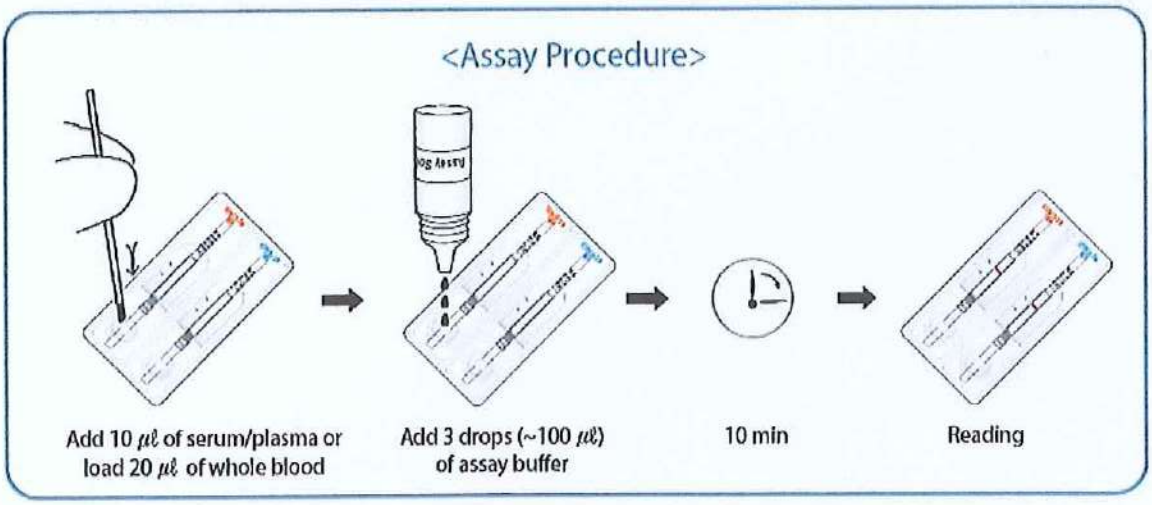
(1) Place all specimens, test devices, and assay solution at room temperature prior to testing (15min).

(2) [Capillary tube use] Using a capillary tube, add 10 µl of serum/plasma or load 20 µl of whole blood up to black line into the sample well (S).

[Micropipette use] Add 10 µl of serum/plasma or load 20 µl of whole blood into the sample well (S) directly. Add 3 drops (approx. 100 µl) of assay solution into the buffer well (S) in the device.

(3) After 10 minutes, interpret the test results.

Please do not read the results after 10 minutes of this testing.



5.4. Reading and interpretation of results

[Qualitative reading]

(1) Negative: ONLY one band in the control line (C). No COVID-19-specific IgM and IgG were detected. Re-test in 3-5 days if COVID-19 is suspected.

(2) IgM Positive: two bands appear in the test line (T) and control line (C) in the left side of device.

(3) IgG Positive: two bands appear in the test line (T) and control line (C) in the right side of device.

(4) IgG and IgM Positive: each two bands appear in the test line (T) and control line (C) in both side of device.

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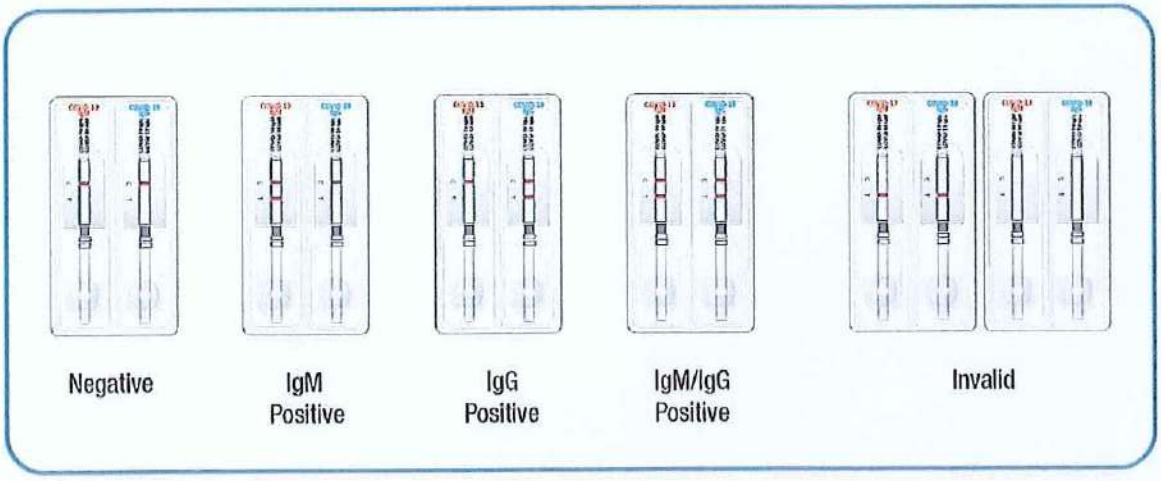
(5) 5. Invalid result: If at 20 minutes, the red band does not appear in the control line (C), the result is considered invalid. If the test is invalid, a new test should be performed with a new patient specimen and a new test device.

[Use quantitative Analyzer]

(1) Using Confiscope G20 is optional.

(2) Please refer to the instructions for use in analyzer package.



5.5. Storage and expiration

(1) Acco COVID-19 IgM/IgG should be stored between 2 to 30°C (35.6 to 86°F).

(2) Expiration date of this kit is 24 months after its manufacture date.

5.6. Limitations of the method

Acco COVID-19 IgM/IgG is designed for primary the screening of IgM and IgG antibodies against COVID-19. This kit can provide a fast and simple results but, do not completely exclude the possibilities of false positive or false negative results caused by various factors. For confirmation, please make a final decision with clinical symptoms, other testing results, and doctor's assessment, collectively.

5.7. Precautions

1. For *in vitro* diagnostic use only. Do not use after expiry date.

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2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Do not use test if pouch is damaged.
4. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
5. The used test should be discarded according to local regulations.
6. Keep out of the reach of children.

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ATTACHMENT #2

Previous Performance Evaluation

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Technical File

Performance Evaluation

Product: **Acco COVID-19 IgM/IgG**

Date: **2020-03-02**

Prepared by	Reviewed by	Approved by
Researcher	**R&D Director**	**Quality Manager**

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0. Revision history

Revision History		
Rev. O	2020. 03. 02	Release of the product description for the Acco COVID-19 IgM/IgG

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Technical File

1 Performance Evaluation Plan

1.1 Purpose

To confirm the performance and effectiveness of Acco COVID-19 IgM/IgG through the performance evaluation test and clinical trial designed with reference to the CLSI guideline

1.2 Responsibility

- Test specialist name : Lee Jihoo at the Acco Biotech Institute
- Team leader/first reviewer : Jeidi Moon at the Acco Biotech Institute.

1.3 Test guidance / regulation documents

- Acco Inc.'s performance evaluation test guide document for diagnostic kit
- European harmonised standard EN13612:2002 and EN23640:2015,
- NCCLS (EP17-A2, EP06-A, EP07-A2, MM17-A, EP05-A3, EP12-A2, EP10-A3, EP09-A2)

1.4 Information of the test diagnostic kit

- Kit name : Acco COVID-19 IgM/IgG
- Catalog No. : COVI025
- Batch No : 3 Lots (FJ001, FJ002, FJ003)

1.5 Intended use

Acco COVID-19 IgM/IgG device is a chromatographic immunoassay kit for the rapid and differential detection of immunoglobulin M (IgM) and immunoglobulin G (IgG) against COVID-19 using serum, plasma and whole blood.

1.6 Information of instruments

Not applicable

1.7 Information of specimen

Human serum, plasma and whole blood

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1.8 Test Design

Test Item		Reference for Test Method
Analytical Sensitivity	Limit of Detection	EP17-A2
Analytical Specificity	Cross Reactivity	EP07-A2
	Substance	MM17-A
Interfering substance		EP07-A2
Whole system failure rate		EP05-A3
Precision assay		EP05-A3
Reproducibility assay	Inter-Operator	EP05-A3
	Intra-Instrument	EP05-A3
	Inter-batch	EP05-A3
Clinical evaluation	Diagnostic sensitivity	EP12-A2
	Diagnostic specificity	EP12-A2

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2 Anlytical performance evaluation

2.1 Anlytical Sensitivity / Reference Material

2.1.1 Protocols

- Material:

No	Serial dilution
M1	1x IgM
M2	1/2x IgM
M3	1/4x IgM
M4	1/8x IgM
M5	1/16x IgM
M6	1/32x IgM
M7	1/64x IgM
M8	1/128x IgM
M9	1/256x IgM
G1	1x IgG
G2	1/2x IgG
G3	1/4x IgG
G4	1/8x IgG
G5	1/16x IgG
G6	1/32x IgG
G7	1/64x IgG
G8	1/128x IgG
G9	1/256x IgG

- Method: Material spiked in matrix
- No. of tests: single per sample
- Test Kit: Acco COVID-19 IgM/IgG (Lot No.:FJ001)
- Protocol: Followed by Acco COVID-19 IgM/IgG manual
- Test guidance : Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline - Second Edition EP17-A2

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- Result analysis

Lot	Smaple	type / Serial dliution	ELISA (s/CO)	FJ001
Lot 1	M1	1x IgM	9.23	Pos
	M2	1/2x IgM	8.08	Pos
	M3	1/4x IgM	7.48	Pos
	M4	1/8x IgM	5.77	Pos
	M5	1/16x IgM	4.31	Pos
	M6	1/32x IgM	3.00	Pos
	M7	1/64x IgM	1.84	Pos
	M8	1/128x IgM	1.66	Neg
	M9	1/256x IgM	0.79	Neg
	G1	1x IgG	9.62	Pos
	G2	1/2x IgG	8.11	Pos
	G3	1/4x IgG	7.25	Pos
	G4	1/8x IgG	5.85	Pos
	G5	1/16x IgG	4.44	Pos
	G6	1/32x IgG	2.68	Pos
	G7	1/64x IgG	1.67	Pos
	G8	1/128x IgG	1.57	Pos
	G9	1/256x IgG	0.85	Neg

s/co: signal per cut-off, Pos: positivie result, Neg: negative result

2.1.2 Conclusion

- As shown in the result tables, Acco COVID-19 IgM/IgG' LoD was **1.84 s/CO for IgM** and **1.57 s/CO for IgG.**

2.2 Analytical Specificity

2.3 Analytical Specificity(Interfering substances testing)

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2.3.1 Protocols

- Material:

Sample name	Titer, s/CO
NC(Negative control)	< 1.0
Low titer of PM(LPM)	1.84~2.0
Low titer of PG(LPG)	1.60~2.0

- Method: Material spiked in matrix
- No. of tests: single per sample
- Test Kit: Acco COVID-19 IgM/IgG (Lot No.:FJ001)
- Protocol: Followed by Acco COVID-19 IgM/IgG manual
- Test guidance : Interference Testing in Clinical Chemistry ; Approved Guideline-Second Edition, EP07-A2, NCCLS

2.3.2 Results

Sample name	Compound	Concentration(mg/dL)	Only positive sample		Positive sample + Material		Negative sample + Material	
			S	P	S	P	S	P
NC	K_2 EDTA	540 mg/dL	-	-	-	-	-	-
LPM			+	+	+	+	+	+
LPG			+	+	+	+	+	+
NC	Citrate	327 M/㎖	-	-	-	-	-	-
LPM			+	+	+	+	+	+
LPG			+	+	+	+	+	+
NC	Heparin	3 KU/dL	-	-	-	-	-	-
LPM			+	+	+	+	+	+
LPG			+	+	+	+	+	+
NC	Hemoglobin	200 mg/dL	-	-	-	-	-	-
LPM			+	+	+	+	+	+
LPG			+	+	+	+	+	+
NC	Cholesterol	500 mg/dL	-	-	-	-	-	-
LPM			+	+	+	+	+	+
LPG			+	+	+	+	+	+
NC	Albumin	14.7 g/dL	-	-	-	-	-	-
LPM			+	+	+	+	+	+
LPG			+	+	+	+	+	+
NC	Bilirubin	25 mg/dL	-	-	-	-	-	-
LPM			+	+	+	+	+	+
LPG			+	+	+	+	+	+

S: serum P: Plasma +: Positive signal -: Negative siganl

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2.3.3 Conclusion

No positive, smearing and/or negative interference due to each material test **was not observed**.

2.4 Cross-reactivity

2.4.1 Protocols

- Material: The following table list
- No. of tests: single per sample
- Test Kit: Acco COVID-19 IgM/IgG (Lot No.:FJ001)
- Protocol: Followed by Acco COVID-19 IgM/IgG manual
- Test result: No cross reactivity was observed for any of virus tested etc.

2.4.2 Result

Organism	Conc.(pfu/ml)	Results
229E (alpha coronavirus)	$2.5x10^5$	-
OC43 (beta coronavirus)	$2.2x10^5$	-

2.4.3 Conclusion

Other pathogens cell should not be affected to its reactions.

2.5 Whole System Failure

2.5.1 Protocols

- Test purpose: To determine the variation for multiple results of samples (same concentration)
- Material: each sample spiked in matrix. Samples concentration belew under table.

Sample name	Titer , s/CO
NC(Negative control)	< 1.0
Low titer of PM(LPM)	1.84~2.0
Low titer of PG(LPG)	1.60~2.0

- No. of Tests: singal per run, 100 tests
- Test Kit: Acco COVID-19 IgM/IgG (Lot No.:FJ001)

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- Protocol: Followed by Acco COVID-19 IgM/IgG manual
- Test guidance: Evaluation of Precision Performance of Quantitative Measurement Method ; Approved Guideline-Second Edition, EP05-A3, NCCLS

2.5.2 Results

- Whole System Failure : Results was determined within intensity
- Whole system Faliure rate= 0%(False nagative detection number 0/100 tests)

Sample name	Sepcimen	Tests(n)	False nagative (n)
NC	Serum	0	0
	Plasma	0	0
LPM	Serum	100	0
	Plasma	100	0

2.5.3 Conclusion

100 sample were detected at Whole system Failure test

2.6 Precision assay

2.6.1 Protocols

- Test purpose: To determine the variation for multiple results of samples (same concentration)
- Material: each sample spiked in matrix. Samples concentration belew under table.

Sample name	Titer, s/CO
NC(Negative control)	< 1.0
Low titer of PM(LPM)	1.84~2.0
High titer of PM(HPM)	> 2.0
Low titer of PG(LPG)	1.60~2.0
High titer of PG(HPG)	> 2.0

- No. of Tests: Triplicates per run, 2 run a day; 5 days
- Test Kit: Acco COVID-19 IgM/IgG (Lot No.: FJ001, FJ002, FJ003)
- Protocol: Followed by Acco COVID-19 IgM/IgG manual

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- Test guidance: Evaluation of Precision Performance of Quantitative Measurement Method ; Approved Guideline-Second Edition, EP05-A3, NCCLS

2.6.2 Results

- Precision : Results was determined within intensity

Lot No. FJ001										
Sample name	Day1		Day2		Day3		Day4		Day5	
Repeat	1	2	1	2	1	2	1	2	1	2
NC	-	-	-	-	-	-	-	-	-	-
LPM	+	+	+	+	+	+	+	+	+	+
HPM	+	+	+	+	+	+	+	+	+	+
LPG	+	+	+	+	+	+	+	+	+	+
HPG	+	+	+	+	+	+	+	+	+	+

Lot No. FJ002										
Sample name	Day1		Day2		Day3		Day4		Day5	
Repeat	1	2	1	2	1	2	1	2	1	2
NC	-	-	-	-	-	-	-	-	-	-
LPM	+	+	+	+	+	+	+	+	+	+
HPM	+	+	+	+	+	+	+	+	+	+
LPG	+	+	+	+	+	+	+	+	+	+
HPG	+	+	+	+	+	+	+	+	+	+

Lot No. FJ003										
Sample name	Day1		Day2		Day3		Day4		Day5	
Repeat	1	2	1	2	1	2	1	2	1	2
NC	-	-	-	-	-	-	-	-	-	-
LPM	+	+	+	+	+	+	+	+	+	+
HPM	+	+	+	+	+	+	+	+	+	+

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LPG	+	+	+	+	+	+	+	+	+	+
HPG	+	+	+	+	+	+	+	+	+	+

Positive signal: + Negative signal: -

2.7 Reproducibility / Inter-Operator

2.7.1 Protocols

- Test purpose: Experiment was performed by different operators within one laboratory)
- Material: each sample spiked in matrix. Sample concentration belew under table.

Sample name	Titer, s/CO
NC(Negative control)	< 1.0
Low titer of PM(LPM)	1.84~2.0
High titer of PM(HPM)	> 2.0
Low titer of PG(LPG)	1.60~2.0
High titer of PG(HPG)	> 2.0

- No. of Tests: Duplicates per run, 2 run a day; 5 days
- Test Kit: Acco COVID-19 IgM/IgG (Lot No. : FJ001)
- Protocol: Followed by Acco COVID-19 IgM/IgG manual
- of Quantitative Measurement Method ; Approved Guideline-Second Edition, EP05-A3, NCCLS

2.7.2 Test Result

- Results was determined within intensity

Day 1				
Sample name	Operator 1		Operator 2	
Repeat	1	2	1	2
NC	-	-	-	-
LPM	+	+	+	+
HPM	+	+	+	+
LPG	+	+	+	+
HPG	+	+	+	+

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Day 2				
Sample name	Operator 1		Operator 2	
Repeat	1	2	1	2
NC	-	-	-	-
LPM	+	+	+	+
HPM	+	+	+	+
LPG	+	+	+	+
HPG	+	+	+	+

Day 3				
Sample name	Operator 1		Operator 2	
Repeat	1	2	1	2
NC	-	-	-	-
LPM	+	+	+	+
HPM	+	+	+	+
LPG	+	+	+	+
HPG	+	+	+	+

Day 4				
Sample name	Operator 1		Operator 2	
Repeat	1	2	1	2
NC	-	-	-	-
LPM	+	+	+	+
HPM	+	+	+	+
LPG	+	+	+	+
HPG	+	+	+	+

Day 5				
Sample name	Operator 1		Operator 2	
Repeat	1	2	1	2
NC	-	-	-	-
LPM	+	+	+	+
HPM	+	+	+	+
LPG	+	+	+	+
HPG	+	+	+	+

Positive Signal: + Negative signal: -

2.8 Reproducibility / Inter-site

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2.8.1 Protocols

- Test purpose: Experiment was performed by different sites within two laboratory
- Material: each materials spiked in matrix. Material concentration belew under table.

Sample name	Titer, s/CO
NC(Negative control)	< 1.0
Low titer of PM(LPM)	1.84~2.0
High titer of PM(HPM)	> 2.0
Low titer of PG(LPG)	1.60~2.0
High titer of PG(HPG)	> 2.0

- No. of Tests: Duplicates per run, 2 run a day; 5 days
- Test Kit: Acco COVID-19 IgM/IgG (Lot No. : FJ001)
- Protocol: Followed by Acco COVID-19 IgM/IgG manual
- Test guidance: Evaluation of Precision Performance of Quantitative Measurement Method ; Approved Guideline-Second Edition, EP05-A3, NCCLS

2.8.2 Test Result

- Results was determined within intensity

Day 1				
Sample name	Site 1		Site 2	
Repeat	1	2	1	2
NC	-	-	-	-
LPM	+	+	+	+
HPM	+	+	+	+
LPG	+	+	+	+
HPG	+	+	+	+

Day 2				
Sample name	Site 1		Site 2	
Repeat	1	2	1	2
NC	-	-	-	-
LPM	+	+	+	+
HPM	+	+	+	+
LPG	+	+	+	+
HPG	+	+	+	+

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Day 3				
Sample name	Site 1		Site 2	
Repeat	1	2	1	2
NC	-	-	-	-
LPM	+	+	+	+
HPM	+	+	+	+
LPG	+	+	+	+
HPG	+	+	+	+

Day 4				
Sample name	Site 1		Site 2	
Repeat	1	2	1	2
NC	-	-	-	-
LPM	+	+	+	+
HPM	+	+	+	+
LPG	+	+	+	+
HPG	+	+	+	+

Day 5				
Sample name	Site 1		Site 2	
Repeat	1	2	1	2
NC	-	-	-	-
LPM	+	+	+	+
HPM	+	+	+	+
LPG	+	+	+	+
HPG	+	+	+	+

Positive Signal: + Negative signal: -

2.9 Reproducibility / Total analysis

Item	Results
With-in run	Confirmed
With-in day	Confirmed
Between run	Confirmed
Inter-Operator	Confirmed
Inter-batch	Confirmed
Inter-site	Confirmed

3 Clinical Evaluation/Diagnostic sensitivity & specificity

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1. **Study purpose**

   To evaluate the clinical performance of Acco COVID-19 IgM/IgG Rapid Test

2. **Study design**

   1) One lot of device
   2) Origin of clinical samples: Dankook University Hospital (Korea, IRB-20200311) and DonAccoang Hospital Shanghai (China)
   3) One time per sample
   4) Instrument: N/A
   5) One operator
   6) Sample type: serum, plasma, whole blood
   7) Study site: Dankook University Hospital (Korea, IRB-20200311) and DonAccoang Hospital Shanghai (China)
   8) Study period: Feb. 15 2020 ~ Mar. 05, 2020.

3. **Acceptance criteria & Standards**

   Positive: +

   Negative: -

4. **Methods of statistical analysis**

   4.1 Instrument

   N/A

   4.2 Reagent & Material

   ① Test device: Acco COVID-19 IgM/IgG

   ② Reference method: RT-PCR (Seegene Inc.)

   4.3 Sample preparation

   A study was performed by skilled clinicians using total 159 sera (39 positives and 120 negatives) that were collected by Dankook University Hospital (under IRB approval) and DonAccoang Hospital Shanghai.

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4.4 Test procedure

1) All specimens and test devices should be prepared with warm condition, that is, for 15~30 min at room temperature before testing.
2) All testing were followed by the kit manual.

5. Results

5.1 For IgM

For IgM N= 159		RT-PCR			
		Before Day 3 from symptom		After Day 7 from symptom	
		Positive	Negative	Positive	Negative
Acco COVID-19 IgM/IgG	Positive	3	1	25	1
	Negative	6	119	5	119
Total		9	120	30	120
Sensitivity (Before Day 3/After Day 7)= 30% (3/9) / 80% (25/30) Specificity= 99%					

5.2 For IgG

For IgG N= 159		RT-PCR			
		Before Day 3 from symptom		After Day 7 from symptom	
		Positive	Negative	Positive	Negative
Acco COVID-19 IgM/IgG	Positive	0	0	30	0
	Negative	9	120	0	120
Total		9	120	30	120
Sensitivity (Before Day 3/After Day 7)= 0% (0/9) / 100% (30/30) Specificity= 100%					

5.3 Summary of results

Acco COVID-19 IgM/IgG Rapid test showed the excellent sensitivity and specificity after Day 7 from symptom. Its overal diagnostic performance was the below;

- **Sensitivity= 100% (25/30 for IgM + 30/30 for IgG)**

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- **Specificity= 99.5% (99% for IgM + 100% for IgG)**

However, before Day 3 after symptom, its diagnostic accuracy was low because there was not enough time to generate the antibodies after infections (30% of sensitivity and 99.5% of specificity).

6. Conclusion

The overal sensitivity and specificity of Acco COVID-19 IgM/IgG was 100% and 99.5%, respectively, comparing with molecular testing (RT-PCR).

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Technical File

[Dataset] Clinical study raw data (Positive: 39, Negative: 120)

(+, Positive; N, Negative)

No	Specimen	Sample collection time	RT-PCR	Acco COVID-19 IgM/IgG	
				IgM	IgG
1	DK011020	Before Day 3 from symptom	+	N	N
2	DK021020	Before Day 3 from symptom	+	N	N
3	DK111020	Before Day 3 from symptom	+	N	N
4	DK011023	Before Day 3 from symptom	+	P	N
5	DK011024	Before Day 3 from symptom	+	P	N
6	DK021021	Before Day 3 from symptom	+	N	N
7	DK021022	Before Day 3 from symptom	+	N	N
8	DB021020	Before Day 3 from symptom	+	P	N
9	DB021024	Before Day 3 from symptom	+	N	N
10	DK121020	After Day 7 from symptom	+	+	+
11	DK121120	After Day 7 from symptom	+	+	+
12	DK121121	After Day 7 from symptom	+	+	+
13	DK121122	After Day 7 from symptom	+	+	+
14	DK121123	After Day 7 from symptom	+	N	+
15	DK121124	After Day 7 from symptom	+	+	+
16	DK121125	After Day 7 from symptom	+	+	+
17	DK121126	After Day 7 from symptom	+	+	+
18	DK121127	After Day 7 from symptom	+	+	+
19	DK121128	After Day 7 from symptom	+	N	+
20	DK121129	After Day 7 from symptom	+	+	+
21	DK122101	After Day 7 from symptom	+	N	+
22	DK122102	After Day 7 from symptom	+	+	+
23	DK122103	After Day 7 from symptom	+	+	+
24	DK122104	After Day 7 from symptom	+	+	+
25	DK122105	After Day 7 from symptom	+	+	+
26	DK122106	After Day 7 from symptom	+	+	+
27	DK122107	After Day 7 from symptom	+	+	+
28	DB122001	After Day 7 from symptom	+	+	+
29	DB122002	After Day 7 from symptom	+	+	+
30	DB122003	After Day 7 from symptom	+	+	+
31	DB122004	After Day 7 from symptom	+	+	+
32	DB122005	After Day 7 from symptom	+	+	+
33	DB122006	After Day 7 from symptom	+	+	+
34	DB122007	After Day 7 from symptom	+	N	+
35	DB122008	After Day 7 from symptom	+	N	+
36	DB122009	After Day 7 from symptom	+	+	+
37	DB122010	After Day 7 from symptom	+	+	+
38	DB122011	After Day 7 from symptom	+	+	+
39	DB122012	After Day 7 from symptom	+	+	+
40	DK100201	No History	N	N	N

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41	DK100202	No History	N	N	N
42	DK100203	No History	N	N	N
43	DK100204	No History	N	N	N
44	DK100205	No History	N	N	N
45	DK100206	No History	N	N	N
46	DK100207	No History	N	N	N
47	DK100208	No History	N	N	N
48	DK100209	No History	N	N	N
49	DK100210	No History	N	N	N
50	DK100211	No History	N	N	N
51	DK100212	No History	N	N	N
52	DK100213	No History	N	N	N
53	DK100214	No History	N	N	N
54	DK100215	No History	N	N	N
55	DK100216	No History	N	N	N
56	DK100217	No History	N	N	N
57	DK100218	No History	N	N	N
58	DK100219	No History	N	N	N
59	DK100220	No History	N	N	N
60	DK100221	No History	N	N	N
61	DK100222	No History	N	N	N
62	DK100223	No History	N	+	N
63	DK100224	No History	N	N	N
64	DK100225	No History	N	N	N
65	DK100226	No History	N	N	N
66	DK100227	No History	N	N	N
67	DK100228	No History	N	N	N
68	DK100229	No History	N	N	N
69	DK100230	No History	N	N	N
70	DK100231	No History	N	N	N
71	DK100232	No History	N	N	N
72	DK100233	No History	N	N	N
73	DK100234	No History	N	N	N
74	DK100235	No History	N	N	N
75	DK100236	No History	N	N	N
76	DK100237	No History	N	N	N
77	DK100238	No History	N	N	N
78	DK100239	No History	N	N	N
79	DK100240	No History	N	N	N
80	DK100241	No History	N	N	N
81	DK100242	No History	N	N	N
82	DK100243	No History	N	N	N
83	DK100244	No History	N	N	N
84	DK100245	No History	N	N	N
85	DK100246	No History	N	N	N
86	DK100247	No History	N	N	N

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87	DK100248	No History	N	N	N
88	DK100249	No History	N	N	N
89	DK100250	No History	N	N	N
90	DK100251	No History	N	N	N
91	DK100252	No History	N	N	N
92	DK100253	No History	N	N	N
93	DK100254	No History	N	N	N
94	DK100255	No History	N	N	N
95	DK100256	No History	N	N	N
96	DK100257	No History	N	N	N
97	DK100258	No History	N	N	N
98	DK100259	No History	N	N	N
99	DK100260	No History	N	N	N
100	DK100261	No History	N	N	N
101	DK100262	No History	N	N	N
102	DK100263	No History	N	N	N
103	DK100264	No History	N	N	N
104	DK100265	No History	N	N	N
105	DK100266	No History	N	N	N
106	DK100267	No History	N	N	N
107	DK100268	No History	N	N	N
108	DK100269	No History	N	N	N
109	DK100270	No History	N	N	N
110	DK100271	No History	N	N	N
111	DK100272	No History	N	N	N
112	DK100273	No History	N	N	N
113	DK100274	No History	N	N	N
114	DK100275	No History	N	N	N
115	DK100276	No History	N	N	N
116	DK100277	No History	N	N	N
117	DK100278	No History	N	N	N
118	DK100279	No History	N	N	N
119	DK100280	No History	N	N	N
120	DK100281	No History	N	N	N
121	DK100282	No History	N	N	N
122	DK100283	No History	N	N	N
123	DK100284	No History	N	N	N
124	DK100285	No History	N	N	N
125	DK100286	No History	N	N	N
126	DK100287	No History	N	N	N
127	DK100288	No History	N	N	N
128	DK100289	No History	N	N	N
129	DK100290	No History	N	N	N
130	DK100291	No History	N	N	N
131	DK100292	No History	N	N	N
132	DK100293	No History	N	N	N

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133	DK100294	No History	N	N	N
134	DK100295	No History	N	N	N
135	DK100296	No History	N	N	N
136	DK100297	No History	N	N	N
137	DK100298	No History	N	N	N
138	DK100299	No History	N	N	N
139	DK100300	No History	N	N	N
140	DK100301	No History	N	N	N
141	DK100302	No History	N	N	N
142	DK100303	No History	N	N	N
143	DK100304	No History	N	N	N
144	DK100305	No History	N	N	N
145	DK100306	No History	N	N	N
146	DK100307	No History	N	N	N
147	DK100308	No History	N	N	N
148	DK100309	No History	N	N	N
149	DK100310	No History	N	N	N
150	DK100311	No History	N	N	N
151	DK100312	No History	N	N	N
152	DK100313	No History	N	N	N
153	DK100314	No History	N	N	N
154	DK100315	No History	N	N	N
155	DK100316	No History	N	N	N
156	DK100317	No History	N	N	N
157	DK100318	No History	N	N	N
158	DK100319	No History	N	N	N
159	DK100320	No History	N	N	N

-END.

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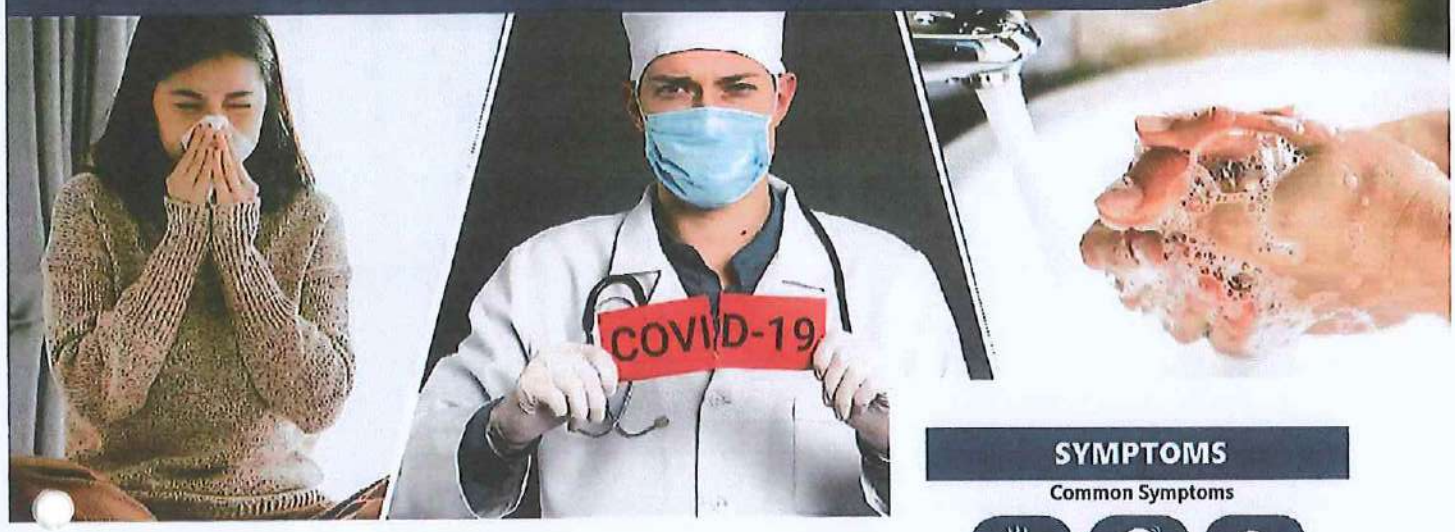
ATTACHMENT #3

Acco Rapid Test COVID-19 Brochure

ACCO COVID-19 IgM/IgG TEST

Rapid Immunoassay for COVID-19 Infection



ABOUT COVID-19

Coronaviruses are a large family of viruses which may cause illness in animals or humans. In humans, several coronaviruses are known to cause respiratory infections ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS).

COVID-19 is an infectious disease caused by the most recently discovered coronavirus. This new virus and disease were unknown before the outbreak began in Wuhan, China, in December 2019.

Source: World Health Organization (https://www.who.int/news-room/q-a-detail/q-a-coronaviruses)

SYMPTOMS

Common Symptoms

FEVER | SHORTNESS OF BREATH | DRY COUGH

Some patients may have:

ACHES AND PAINS | NASAL CONGESTION | RUNNY NOSE

SORE THROAT | DIARRHEA

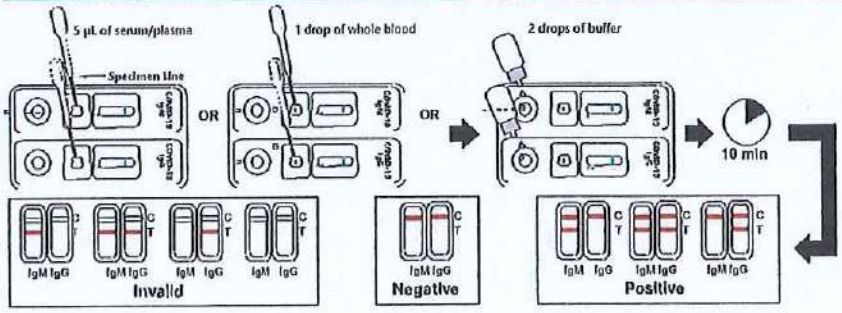
Rapid Differential Detection Kit (IgM and IgG against COVID-19)

ADVANTAGES

- IgG and IgM in human serum and plasma
- Quick & Immediate Results
- High Sensivity
- High Specificty
- Only needs 1 drop of blood

FAST • RELIABLE • ACCURATE

PROCEDURE & INTERPRETATION



PRECAUTIONS

1. The presence of humidity may decrease the stability of the reagents. Thus, please carry out the test immediately after removing the device from the foil pouch.
2. Do not use the kit after the expiration date. Do not freeze the kit.
3. For in vitro diagnostic use only. Do not re-use the test device.
4. Wear protective gloves while handling samples and wash hands thoroughly after the test.
5. Dispose gloves, swabs, test tubes, and the used strips properly after the test, in accordance with Good Laboratory Practice (GLP).
6. Do not eat or smoke while handing specimens.
7. Decontaminate and dispose of all specimens in a biohazard container.

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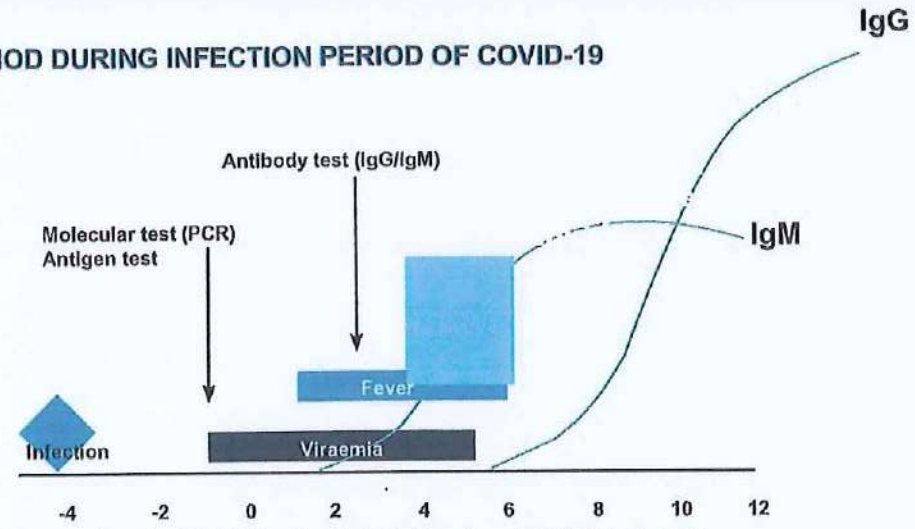
SCREEN EARLY WITH ACCO COVID-19

Your Results in 10 Minutes!!!

TEST METHOD DURING INFECTION PERIOD OF COVID-19



Day 3 ~12: IgM Antibody test, Day 6 ~ : IgG Antibody test

COMPARISON WITH MOLECULAR TESTING

	MOLECULAR TESTING (RT-PCR)	ACCO COVID-19 IgG/IgM RAPID TEST
Principle	Nucleic acid test of COVID-19	Antibody (IgM & IgG) detection in the blood
Accuracy in the fields	- China: 30 ~ 50% (Jungangilbo.2020.02.13) - Depending on the swab positioning of specimen and yield of gene extraction	- Before Day 5: very low - After Day 5: 81-99% for IgM, 81-99% for IgG
Test time	>6 hours	10 minutes
Test cost	Very expensive	Highly economical
Users	Skilled & trained	Normal
Specimen	Throat, anal, nasopharyngeal, sputum	Whole blood, serum, plasma
Test capacity	Limited	Possible to bulk testing
Adv/disadvantages	• Good accurate at early stage. • Difficult to detect at latent or asymptomatic period. • Appropriate for early stage with limited cases of patients up to 100 patient load	• Possible to detect at latent or asymptomatic period. • Appropriate for 5th Day-After testing on mass populations

DIAGNOSTIC ACCURACY OF ACCO COVID-19 IgM/IgG

PARAMETERS	PERFORMANCE (ONGOING)	COMMENTS
Analytical sensitivity	1.84 s/CO for IgM 1.57 s/CO for IgG	w. ELISA
Sensitivity	Day 3 after symptom: IgM- 33%, IgG- 0% After Day 7 from symptom: IgM- 83%, IgG- 100%	w. limited cases
Specificity	IgM 99% (119/120), IgG: 99% (120/120)	

ORDERING INFORMATION

CAT NO.	PRODUCT NAME	PACKAGE	BOX SIZE (MM)	CARTON SIZE(MM)
ACOV2015	Acco COVID-19 IgM/IgG	20 Tests/Box	226x125x75	650x455x405

www.accobiotech.com

Accobiotech Sdn Bhd (Co. Reg. No. 925954-V)

No 11, Jalan Bukit 27, Masai Industrial Park, Bandar Seri Alam, 81750 Masai, Johor, Malaysia Tel :

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ATTACHMENT #4

Acco Rapid Test COVID-19 Patient Fact Sheet

FACT SHEET FOR PATIENTS

ACCO COVID-19 IgM/IgG

Accobiotech Sdn Bhd

May 2, 2020

Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using the ACCO COVID-19 Igm/IgG System.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

- For the most up to date information on COVID-19 please visit the CDC General webpage:
- https://www.cdc.gov/COVID19

What is COVID-19?
COVID-19 is caused by the SARS-CoV-2 virus. The virus, which can cause mild to severe respiratory illness, was first identified in Wuhan, China, and has now spread globally, including the United States. There is limited information available to characterize the spectrum of clinical illness associated with COVID-19 but it likely spreads to others when a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.).

What is the ACCO COVID-19 Igm/IgG System?
The test is designed to detect antibodies against the virus that causes COVID-19 in blood specimens, for example venous whole blood, serum or plasma specimens.

Why was my sample tested?
You were tested because your healthcare provider believes you may have been exposed to the virus that causes COVID-19 based on your signs and symptoms (e.g., fever, cough, difficulty breathing), and/or because:

- You live in or have recently traveled to a place where transmission of COVID-19 is known to occur, and/or
- You have been in close contact with an individual suspected of or confirmed to have COVID-19.

Testing of the samples will help find out if you may have COVID-19.

What are the known and potential risks and benefits of the test?

Potential risks include:

- Possible discomfort or other complications that can happen during sample collection.
- Possible incorrect test result (see below for more information).

Potential benefits include:

- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 to your family and others in your community.

What does it mean if I have a positive test result?
The test has several possible results. Depending on the result, it may be more likely that you have COVID-19 and that you may need isolation to avoid spreading the

- Where can I go for updates and more information? The most up-to-date information on COVID-19 is available at the CDC General webpage: https://www.cdc.gov/COVID19. In addition, please also contact your healthcare provider with any questions/concerns.

virus to others. Other results may indicate you were infected previously. Your healthcare provider will work with you to determine how best to care for you based on the test results along with other factors of your medical history, and your symptoms, possible exposures, and geographic location of places you have recently traveled. There is also the small chance that this test can give a positive result that is wrong (a false positive result).

What does it mean if I have a negative test result? A negative test result means that the antibodies to the virus that causes COVID-19 was not found in your sample. However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. A negative result may occur if you are tested early in your illness and your body hasn't had time to produce antibodies to infection. This means that you could possibly still have COVID-19 even though the test is negative. If this is the case, your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical
location of places you have recently traveled) in deciding how to care for you.

It is important that you work with your healthcare provider to help you understand the next steps you should take.

Is this test FDA-approved or cleared?
No. This test is not yet approved or cleared by the United States FDA. When there are no FDA-approved or cleared tests available, and other criteria are met, FDA may make tests available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA for this test is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics for the detection and/or diagnosis of the virus that causes COVID-19. This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying emergency of IVDs, unless it is terminated or revoked by FDA (after which the test may no longer be used).

- Where can I go for updates and more information? The most up-to-date information on COVID-19 is available at the CDC General webpage: https://www.cdc.gov/COVID19. In addition, please also contact your healthcare provider with any questions/concerns.

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ATTACHMENT #5

Acco Rapid Test COVID-19 Health Care Provider Fact Sheet

FACT SHEET FOR HEALTHCARE PROVIDERS

ACCO COVID-19 IgM/IgG

May 2, 2020

Accobiotech Sdn Bhd

Coronavirus Disease 2019 (COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the ACCO COVID-19 IgM/IgG immunoassay.

The ACCO COVID-19 IgM/IgG immunoassay is authorized for on the detection of antibodies to SARS-CoV-2 in human serum or plasma.

All individuals whose specimens are tested with this assay will receive the Fact Sheet for Patients: ACCO COVID-19 IgM/IgG.

What are the symptoms of COVID-19?
Most individuals with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus. Based on preliminary data, the median incubation period is approximately 4-5 days, but may range 2-14 days.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which poses risks for public health. Please check the CDC webpage for the most up to date information.

What do I need to know about COVID-19 testing?
Current information on COVID-19 for healthcare providers, including case definitions and infection control, is available at CDC's webpage, Information for Healthcare Professionals (see links provided in "Where can I go for updates and more information" section).

- The ACCO COVID-19 IgM/IgG immunoassay can be used to test human serum or plasma (Heparin, EDTA).
- The ACCO COVID-19 IgM/IgG immunoassay should be ordered by a healthcare provider to detect if there has been an adaptive immune response to COVID-19, indicating a recent or prior infection.

This test measures human SARS-CoV-2 antibodies that are generated as part of the adaptive human immune response to the virus and is to be performed only using serum or plasma specimens.

- The ACCO COVID-19 IgM/IgG immunoassay is only authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) 42 U.S.C. §263a, to perform moderate or high complexity tests.
- The ACCO COVID-19 IgM/IgG immunoassay should not be used to diagnose or exclude acute infection and should not be used as the sole basis for treatment or patient management decisions. Direct testing for SARS-CoV-2 should be performed if acute infection is suspected.

Specimens should be collected with appropriate infection control precautions following CDC Interim Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Healthcare Settings.

Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of having COVID-19 as outlined in the CDC Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19). These specimens are only shipped for analysis to laboratories designated by CDC as qualified for analysis. For additional information, refer to CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19) (see links provided in "Where can I go for updates and more information" section).

What does it mean if the specimen tests positive for antibodies against the virus that causes COVID-19?
A positive test result for this test indicates that antibodies against SARS-CoV-2 were detected, and the individual has potentially been exposed to SARS-CoV-2.

Antibodies are generally detectable several days following infection. A positive result can indicate recent or past infection but does not exclude recently infected individuals who are still contagious. It is unknown how long antibodies to SARS-CoV-2 will remain present in the body after infection and if they confer immunity to infection.

A positive antibody result may not mean that an individual's current symptoms are due to COVID-19 infection. Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making patient management decisions.

The ACCO COVID-19 IgM/IgG immunoassay has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks to patients could include the following: a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may increase contact with other potentially COVID-19 patients, limits in the ability to work, the delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects

All laboratories using this test must follow the standard confirmatory testing and reporting guidelines according to their appropriate public health authorities.

What does it mean if the specimen tests negative for antibodies against the virus that causes COVID-19? A negative test result for this test means that anti-SARS-CoV-2 specific antibodies were not present in the specimen above the limit of detection of the assay. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions. A negative result does not exclude the possibility of COVID-19 .

Individuals tested early after infection may not have detectable antibody response despite active infection; in addition, not all patients will develop a detectable antibody response to SARS-CoV-2 infection. The absolute sensitivity of the ACCO COVID-19 IgM/IgG immunoassay is unknown.

When testing is negative, the possibility of a false negative result should be considered in the context of an individual's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19. This is especially important if the individual has had recent exposure to COVID-19, or clinical presentation suggestive of COVID-19, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. Direct testing for virus (e.g., PCR testing) should always be performed in any patient suspected of COVID-19 regardless of ACCO COVID-19 IgM/IgG Immunoassay results.

Risks to a patient resulting from a false negative result include: delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events.

What is an EUA?
The United States FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19.

An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in the detection of the virus that causes COVID-19.

The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs,

unless terminated or revoked (after which the test may no longer be used).

Where can I go for updates and more information?

CDC webpages:
General: https://www.cdc.gov/COVID19
Healthcare Professionals: https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html
Information for Laboratories: https://www.cdc.gov/coronavirus/2019-nCoV/guidance-laboratories.html
Laboratory Biosafety: https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html
Isolation Precautions in Healthcare Settings: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html
Specimen Collection: https://www.cdc.gov/coronavirus/2019-nCoV/guidelines-clinical-specimens.html
Infection Control: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html

FDA webpages:
General: www.fda.gov/novelcoronavirus
EUAs:(includes links to patient fact sheet and manufacturer's instructions) https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

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ATTACHMENT #6

Acco Rapid Test COVID-19 IFU

ACCO COVID-19 IgM/IgG

Rapid differential detection kit for IgM and IgG against COVID-19 in human serum, plasma and whole blood

IVD

2020.06.03 (Rev.2.7)

INTENDED USE

ACCO COVID-19 IgM/IgG device is a chromatographic immunoassay kit for the rapid and differential detection of immunoglobulin M (IgM) and immunoglobulin G (IgG) against COVID-19 using whole blood, serum or plasma. The device can be used to detect the presence of antibodies against COVID-19 and may indicate a previous exposure to the virus. Negative results do not preclude acute COVID-19 infection. If acute infection is suspected, direct testing for COVID-19 is necessary.

EXPLANATION OF THE TEST

The recombinant COVID-19 antigen was coated on the membrane and anti-human IgM and IgG monoclonal antibody was conjugated the gold particles, respectively. When the specimen existing anti-COVID-19 antibodies is loaded into a sample well (S), the antibodies are complexed with anti- human IgM (or IgG) gold conjugate. And this complex migrates and captured by the immobilized recombinant COVID-19 antigens to make a visible band in the test line regions, M and G. The solution continues to migrate to the control line (C) region that binds a control conjugate, thereby producing another red line.

MATERIALS PROVIDED

ACCO COVID-19 IgM/IgG kit contains the following components:

1. Test device individually foil-pouched with a desiccant
2. Assay solution in dropping bottle
3. Capillary tube for sample loading
4. Instructions for Use

MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection container
2. Micropipette
3. Disposable pipette tips
4. Lancets (for finger prick whole blood only)
5. Centrifuge (for plasma only)
6. Watch or timer

PRECAUTIONS

1. The presence of humidity may decrease the stability of the reagents. Thus, please carry out the test immediately after removing the device from the foil pouch.
2. Do not use the kit after the expiration date. Do not freeze the kit.
3. For in vitro diagnostic use only. Do not re-use the test device.
4. Wear protective gloves while handling samples and wash hands thoroughly after the test.
5. Dispose gloves, swabs, test tubes, and the used strips properly after the test, in accordance with GLP.
6. Do not eat or smoke while handing specimens.
7. Decontaminate and dispose of all specimens in a biohazard container.

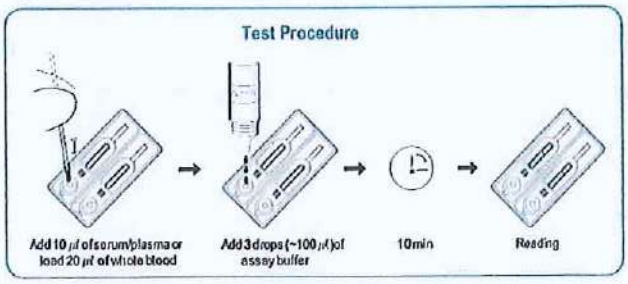
SPECIMEN COLLECTION AND STORAGE

1. Specimens to be tested should be obtained and handled by standard methods for their collections.
2. Whole blood: whole blood should be collected over heparin, citrate, or EDTA. Mix the blood by inversion and use it for the test.
3. Serum: Allow the blood to clot, then centrifuge to separate the serum.
4. Plasma: Collect the whole blood into the tube containing anticoagulants such as heparin, citrate, or EDTA. Centrifuge the blood and separate the plasma.
5. All specimens should be tested as soon as they are prepared. If necessary, serum or plasma may be stored at 2-8°C for up to 24 hours or at -20°C for up to 1 year. Whole blood may be stored at 2-8°C for up to 24 hours. Do not freeze whole blood.

TEST PROCEDURE

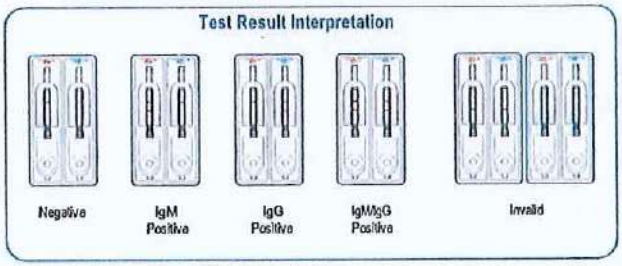
1. Place all specimens, test devices, and assay solution at room temperature prior to testing (15~30min). Note that thawed samples should not be left out at room temperature for longer than 3 hours.
2. [Capillary tube use] Using a capillary tube, add 10 µl of serum/plasma or load 20 µl of whole blood up to black line into the sample well (S).
   [Micropipette use] Add 10 µl of serum/plasma or load 20 µl of whole blood into the sample well (S) directly. Add 3 drops (approx. 100 µl) of assay solution into the buffer well (S) in the device.
3. After 10 minutes, interpret the test results.
   Please do not read the results after 20 minutes.

Σ 20



INTERPRETATION OF RESULTS

1. Negative: ONLY one band in the control line (C). No COVID-19-specific IgM and IgG were detected. Re-test in 3-5 days if COVID-19 is suspected.
2. IgM Positive: two bands appear in the test line (T) and control line (C) in the left side of device.+
3. IgG Positive: two bands appear in the test line (T) and control line (C) in the right side of device.
4. IgG and IgM Positive: each two bands appear in the test line (T) and control line (C) in both side of device.
5. Invalid result: If at 10 minutes, the red band does not appear in the control line (C), the result is considered invalid. If the test is invalid, a new test should be performed with a new patient specimen and a new test device.



STORAGE & EXPIRATION

1. ACCO COVID-19 IgM/IgG kit should be stored between 2 to 30 °C (35.6 to 86 °F).
2. The expiration date of this kit is 24 months after its manufacture date

LIMITATIONS OF THE TEST

ACCO COVID-19 IgM/IgG is designed as an aid in identifying IgM and IgG antibodies against COVID-19. This kit can provide fast and simple results but, does not completely exclude the possibilities of false positive or false negative results caused by various factors. For confirmation, please make a final decision with clinical symptoms, other testing results, and doctor's assessment, collectively.

- This test has not been reviewed by the FDA.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
- Not for the screening of donated blood.

REF ACOV2015

AccoBiotech

ACCOBIOTECH SDN. BHD.
www.accobiotech.com

US Manufacturer Representative:
GQSI, LLC
3777 Winchester Rd,
Memphis TN 38118

PERFORMANCE CHARACTERISTICS

SENSITIVITY AND SPECIFICITY

In an IRB regulated study, 159 patient samples were collected, comprising 30 positive and 129 were confirmed to be COVID-19 positive. The method of confirmation was RT-PCR (Kogene Biotech Inc., Korea). All the tests were performed in the Dankook University Hospital (Cheonan, Korea).

The below summary of test results shows the sensitivity and specificity of the ACCO COVID-19 IgM/IgG in this clinical study

For IgM N=159		RT-PCR			
		Before day 3 from symptom onset		After Day 7 from symptom onset	
		Positive	Negative	Positive	Negative
Acco COVID-19 IgM/IgG	Positive	3	1	25	1
	Negative	6	119	5	119
Total		9	120	30	120
Sensitivity (Before Day 3)= 33%; Sensitivity (After day 7) = 83%					
Specificity = 99%					

Table 2. Calculated sensitivity and specificity for IgM

For IgG N=159		RT-PCR			
		Before day 3 from symptom onset		After Day 7 from symptom onset	
		Positive	Negative	Positive	Negative
Acco COVID-19 IgM/IgG	Positive	0	0	30	0
	Negative	9	120	0	120
Total		9	120	30	120
Sensitivity (Before Day 3)= 0%; Sensitivity (After day 7) = 100%					
Specificity = 100%					

Table 3. Calculated sensitivity and specificity for IgG

CROSS REACTIVITY

A cross-reactivity study was performed using sera containing antibodies (spiked) to the pathogens below and found non-reactive in each case

Antibody	Samples tested	Number reactive	Conclusions
Anti-West Nile virus	3	0	Non-reactive
Anti-Yellow Fever virus	3	0	Non-reactive
Anti-Dengue Fever virus	3	0	Non-reactive
Anti-Zika virus	3	0	Non-reactive
Anti-Chikungunya virus	3	0	Non-reactive
Anti-HCV	3	0	Non-reactive
Anti-HIV	3	0	Non-reactive
Anti-Influenza A, H1pdm09	3	0	Non-reactive
Anti-respiratory syncytial virus	3	0	Non-reactive
229E (alpha coronavirus)	5	1	Reactive in IgM
Anti-NL63 (alpha coronavirus)	3	1	Non-reactive
Anti-OC43 (beta coronavirus)	5	1	Non-reactive

Table 4. Antibody Cross Reactivity Results

Cross-reactivity in IgM was observed for Anti-NL63 in 1 sample out of 5. This should be taken into consideration when interpreting results of test subjects believed to have had past exposure to this virus, and confirmation using another test may be prudent.

INTERFERING SUBSTANCES

The ACCO COVID-19 IgM/IgG was tested to determine potential interference by a several substances. Using a material in spiked matrix methodology, an interference study was performed to explore the effect of potentially endogenous interfering substances. Table 5 indicates that there is no positive or negative reactivity with any of the listed common substances

Sample name	Compound	Conc. (mg/dL)	Only positive sample		Positive sample + Material		Negative sample + Material	
			S	P	S	P	S	P
NC	K_2 EDTA	540 mg/dL	-	-	-	-	-	-
LPM			+	+	+	+	+	+
LPG			+	+	+	+	+	+
NC	Citrate	327 M/mℓ	-	-	-	-	-	-
LPM			+	+	+	+	+	+
LPG			+	+	+	+	+	+
NC	Heparin	3 KU/dL	-	-	-	-	-	-
LPM			+	+	+	+	+	+
LPG			+	+	+	+	+	+
NC	Hemoglobin	200 mg/dL	-	-	-	-	-	-
LPM			+	+	+	+	+	+
LPG			+	+	+	+	+	+
NC	Cholesterol	500 mg/dL	-	-	-	-	-	-
LPM			+	+	+	+	+	+
LPG			+	+	+	+	+	+
NC	Albumin	14.7 g/dL	-	-	-	-	-	-
LPM			+	+	+	+	+	+
LPG			+	+	+	+	+	+
NC	Bilirubin	25 mg/dL	-	-	-	-	-	-
LPM			+	+	+	+	+	+
LPG			+	+	+	+	+	+

Table 5. Results of Interfering Substances study

CONDITIONS OF LABORATORY AUTHORIZATION

Authorized laboratories using the ACCO COVID-19 IgM/IgG, must adhere to the Conditions of Authorization indication as listed below:

1. Authorized laboratories* using your product will include with result reports of your product, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media

2. Authorized laboratories using your product will use your product as outlined in the Instructions for Use. Deviations from the authorized procedures, including the authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

3. Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.

4. Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate. IFU-000765 [A] Page 7 of 13

5. Authorized laboratories will collect information on the performance of your product and report to DMD/OHT7- OIR/OPEQ/ CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and ACCOBIOTECH / Global Quality Solutions International, LLC (https://www.gqsi.net/contact/) any suspected occurrence of false reactive or false nonreactive results and significant deviations from the established performance characteristics of your product of which they become aware.

6. All laboratory personnel using your product must be appropriately trained in immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit and use your product in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the product

7. Authorized distributors, and authorized laboratories using your product will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

*The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate or high complexity tests" as "authorized laboratories."

ACCO COVID-19 IgM/IgG

Rapid differential detection kit for IgM and IgG against COVID-19 in human serum, plasma and whole blood

IVD

2020.06.03 (Rev.2.7)

REFERENCES

1. Clinical and Laboratory Standards Institute (CLSI). Protection of Laboratory Workers From Occupationally Acquired Infections: approved Guideline-Third Edition. CLSI Document M29-A3
2. FDA's Guidance, Emergency Use Authorization of Medical Products and Related Authorities, available at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#coronavirus2019

SYMBOLS LEGEND AND LABEL EXAMPLE

AccoBiotech

Manufactured by:
AccoBiotech SDN.BHD (925954-V)
No. 11 Jalan Bukit 27, Massi Industrial Park,
Bandar Seri Alam, 81750, Masai, Johor, Malaysia
www.accobiotech.com

ACCO RAPID TEST

DESCRIPTION: ACCO COVID-19 IgM/IgG Test. For Investigational Use Only. The performance characteristics of this product have not been established

US Manufacturer Representative:
Global Quality Solutions International, LLC (GQSI)
3777 Winchester Road
Memphis, TN 38118

REF catalog number

LOT batch number

contains sufficient for <n> tests

IVD in vitro diagnostic medical device

SINGLE USE ONLY

CONSULT INTRUCTIONS FOR USE

STORE AT 2 ~ 30°C

LDL-0001 REV A

AccoBiotech

GQSI
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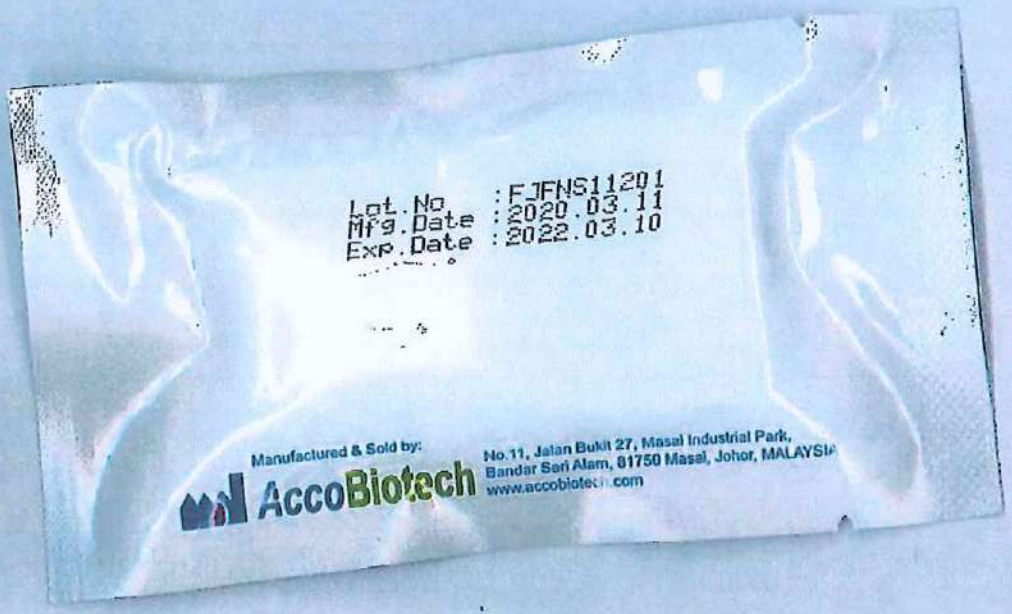
ATTACHMENT #7

Acco Rapid Test COVID-19

1. Test Kit Box Design and Labeling
2. Test Foil Packaging and Labeling (Front and Back)
3. Proposed US Shipping Outside Box Labeling
4. Proposed Test Kit Labeling

75mm
125mm
225mm
Acco Rapid Test
COVID-19 IgM/IgG
FAST • RELIABLE • ACCURATE
• For in vitro diagnostic use only
• Store at 2-30°C
• One step rapid detection kit
20 tests
QTY
LOT / Lot No :
/ Exp. Date :
(YYYY/MM/Day)
Manufactured by:
AccoBiotech
Made in:
GOSI


REF
LOT
IVD
Acco Rapid Test
QTY
1 Test
COVID-19 IgM/IgG
FAST • RELIABLE • ACCURATE
• For in vitro diagnostic use only
• Store at 2-30°C
• One step rapid detection kit


Lot.No : FJFNS11201
Mfg.Date : 2020.03.11
Exp.Date : 2022.03.10
Manufactured & Sold by:
AccoBiotech
No.11, Jalan Bukit 27, Masai Industrial Park,
Bandar Seri Alam, 81750 Masai, Johor, MALAYSIA
www.accobiotech.com

AccoBiotech

Manufactured by:
AccoBiotech SDN.BHD (925954-V)
No. 11 Jalan Bukit 27, Masai Industrial Park,
Bander Seri Alam, 81750, Masai, Johor, Maylasia
www.accobiotech.com

ACCO RAPID TEST

DESCRIPTION: ACCO COVID-19 IgM/IgG Test

REF ACO2015
LOT FJFB24201
Σ 20
IVD in vitro diagnostic medical device

US Manufacturer Representative:
Global Quality Solutions International, LLC (GQSI)
3777 Winchester Road
Memphis, TN 38118

SINGLE USE ONLY

CONSULT INTRUCTIONS FOR USE

2°C–30°C STORE AT 2 ~ 30°C

LBL-0001 REV A

AccoBiotech

Manufactured by:
AccoBiotech SDN.BHD (925954-V)
No. 11 Jalan Bukit 27, Masai Industrial Park,
Bander Seri Alam, 81750, Masai, Johor, Maylasia
www.accobiotech.com

ACCO RAPID TEST

DESCRIPTION: ACCO COVID-19 IgM/IgG Test

REF ACO2015
LOT FJFB24201
Σ 1000
IVD in vitro diagnostic medical device

US Manufacturer Representative:
Global Quality Solutions International, LLC (GQSI)
3777 Winchester Road
Memphis, TN 38118

SINGLE USE ONLY

CONSULT INTRUCTIONS FOR USE

2°C–30°C STORE AT 2 ~ 30°C

LBL-0001 REV A

AccoBiotech

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ATTACHMENT #8

PRODUCT DESIGN SPECIFICATIONS

1. AG-91100 COVID-19 NP
2. AB-70200 anti-human IgM n4G7 and anti-human IgG (anti-hIgG)
3. AB-70100 Anti-human IgG 4G6B5
4. AB-80100 Anti-Nus 5C4
5. AG-80200 Nus Ag

Monoclonal antibody and the Nucleic Protein

1. AG-91100 COVID-19 NP
2. AB-CO200 – Anti-COVID19 NP antibody 2F4
3. AB-CO100 – Anti-COVID19 NP antibody 3C3

• DETAILED SPECIFICATION

PRODUCT NUMBER: AG-91100
PRODUCT : Rec. COVID-19 NP
[*Recombinant SARS-CoV 2 nucleoprotein*]

PRODUCT DESCRIPTION AND PREPARATION:
The recombinant SARS-CoV 2 nucleoprotein (rec. COVID-19 NP) was expressed in *E. coli* and purified by metal-affinity chromatography to homogeneity using 6xHis tag. The purified recombinant protein was concentrated and dialyzed with phosphate-buffered saline.

LOT NUMBER:	Y011201
EXPRESSED IN:	E. coli
TAGGING:	6xHis
PRESERVATIVES:	None
BUFFER:	phophate-buffered saline, without any components.
PROTEIN CONCENTRATION:	>2.0 mg/mL, determinded from spectrophotometric measurement.
TOTAL VOLUME	-- ml
BIOHAZARD	Use normal laboratory precautions and procedures when handling raw materials.
APPLICATIONS:	RDT, FIA, ELISA

(Exp. Date) This product is stable when stored at 2-8°C for 5 months and at -20°C for > 1 year.
(Analysis) SDS-PAGE and immunoassay. SDS-PAGE was carried out 11% polyacrylamide gel and identified its purity and correct molecular weight (47.04 kDa). For checking immuno-reactivity of recombinant protein, immunoassays (ELISA and RDT) with anti-COVID-19-positive sera were performed and identified its reactivity.

Q.C. Approved:

For Research Use Only

Anti-human IgG Monoclonal Antibody n4G7

- For providing the specific detection of human immunoglobulin M
- For research use only
- Suitable for wide ranges of immunological applications including RDT and ELISA

PRODUCT NUMBER: AB-70200
PRODUCT NAME: Anti-human IgM n4G7

PRODUCT DESCRIPTION

The hybridoma n4G7 (IgG_{2a}) producing the specific monoclonal antibody against human immunoglobulin M (IgM) was used to the production of mouse ascitic flood. The ascetic flood was subjected to lipid removing step and followed by protein G-affinity chromatography to purify the monoclonal antibody n4G7. The purified antibody was carried out to concentrate and to dialysis with PBS (phosphate-buffered saline) without any preservatives.

PROPERTY

Monoclonal antibody n4G7 is designed for the specific reaction human IgM. This antibody has been widely used to RDT which diagnose human IgG/IgM, paired with anti-human IgG monoclonal antibody 4G6B5 (Product number: AB-70100).

LOT NUMBER:	O281302
APPLICATION	EPITOPE
1. Diagnostic kit for human IgM	human IgM
2. Various immunological applications	
CONCENTRATION	STORAGE BUFFER
3.75 mg/ml	1X PBS (phosphate-buffered saline)
TOTAL AMOUNT	PRESERVATIVES
2 mg/vial	None
BIOHAZARD	
Use normal laboratory precautions and procedures	
EXP. DATE AND STORAGE	PURITY ANALYSIS
Stored at 2 – 8 ℃ for 1 month and at –20 ℃ for 1 year	>95% in SDS-PAGE (10% PAAG)

QUALITY CONTROL

The product was passed its quality control tests using ELISA (rec. NS1-coated plate).

For Research Use Only

Anti-human IgG Monoclonal Antibody 4G6B5

- For providing the specific detection of human immunoglobulin G
- For research use only
- Suitable for wide ranges of immunological applications including RDT and ELISA

PRODUCT NUMBER: AB-70100
PRODUCT NAME: Anti-human IgG 4G6B5

PRODUCT DESCRIPTION

The hybridoma 4G6B5 (IgG_1) producing the specific monoclonal antibody against human immunoglobulin G (IgG) was used to the production of mouse ascitic flood. The ascetic flood was subjected to lipid removing step and followed by protein G-affinity chromatography to purify the monoclonal antibody 4G6B5. The purified antibody was carried out to concentrate and to dialysis with PBS (phosphate-buffered saline) without any preservatives.

PROPERTY

Monoclonal antibody 4G6B5 is designed for the specific reaction human IgG. This antibody has been widely used to RDT which diagnose human IgG/IgM, paired with anti-human IgM monoclonal antibody n4G7 (Product number: AB-70200).

LOT NUMBER:	O281301
APPLICATION	EPITOPE
1. Diagnostic kit for human IgG	human IgG
2. Various immunological applications	
CONCENTRATION	STORAGE BUFFER
2.2 mg/ml	1X PBS (phosphate-buffered saline)
TOTAL AMOUNT	PRESERVATIVES
5.0 mg	None
BIOHAZARD	
Use normal laboratory precautions and procedures	
EXP. DATE AND STORAGE	PURITY ANALYSIS
Stored at 2 – 8 ℃ for 1 month and at –20 ℃ for 1 year	>95% in SDS-PAGE (10% PAAG)

QUALITY CONTROL

The product was passed its quality control tests using ELISA (rec. NS1-coated plate).

For Research Use Only

Anti-Nus Monoclonal Antibody 5C4

- For research use only
- Suitable for wide ranges of immunological applications including RDT and ELISA

PRODUCT NUMBER: AB-80100
PRODUCT NAME: Anti-Nus 5C4

PRODUCT DESCRIPTION
The hybridoma 5C4 (IgG_1) producing the specific monoclonal antibody against *Nus tag protein* (anti-Nus) was used to the production of mouse ascitic flood. The ascetic flood was subjected to lipid removing step and followed by protein G-affinity chromatography to purify the monoclonal antibody 5C4. The purified antibody was carried out to concentrate and to dialysis with PBS (phosphate-buffered saline) without any preservatives.

PROPERTY
Monoclonal antibody 5C4 is designed for the control line combined with Nus tag protein.

LOT NUMBER:	O291301
APPLICATION	EPITOPE
1. Diagnostic kit	Nus tag protein
2. Various immunological applications	
CONCENTRATION	STORAGE BUFFER
3.39 mg/ml	1X PBS (phosphate-buffered saline)
TOTAL VOLUME	PRESERVATIVES
10.0 mg	None
BIOHAZARD	
Use normal laboratory precautions and procedures	
EXP. DATE AND STORAGE	PURITY ANALYSIS
Stored at 2 – 8 ℃ for 1 month and at –20 ℃ for 1 year	>95% in SDS-PAGE (10% PAAG)

QUALITY CONTROL
The product was passed its quality control tests using ELISA (Nus-coated plate).

For Research Use Only

• DETAILED SPECIFICATION

PRODUCT NUMBER: AG-80200
PRODUCT : Nus Ag

PRODUCT DESCRIPTION AND PREPARATION:
The recombinant Nus antigen was expressed in *E. coli* and purified by metal-affinity chromatography to homogeneity using 6xHis tag. The purified recombinant protein was concentrated and dialyzed with phosphate-buffered saline.

LOT NUMBER:	O301301
EXPRESSED IN:	E. coli
TAGGING:	6xHis
PRESERVATIVES:	None
BUFFER:	phophate-buffered saline, without any components.
PROTEIN CONCENTRATION:	2.8 mg/mL, determinded from spectrophotometric measurement.
TOTAL AMOUNT	5.0 mg
BIOHAZARD	Use normal laboratory precautions and procedures when handling raw materials.
APPLICATIONS:	Control line for any testing kits (ex. rapid diagnostic tests)

(Exp. Date) This product is stable when stored at 2-8℃ for 1 months and at -20℃ for > 1 year.
(Analysis) SDS-PAGE and immunoassay. SDS-PAGE was carried out 11% polyacrylamide gel and identified its purity and correct molecular weight. For checking immuno-reactivity of recombinant protein, ELISA was performed and identified its reactivity.

Q.C. Approved:

For Research Use Only

• DETAILED SPECIFICATION

PRODUCT NUMBER: AG-91100
PRODUCT : Rec. COVID-19 NP
[*Recombinant SARS-CoV 2 nucleoprotein*]

PRODUCT DESCRIPTION AND PREPARATION:
The recombinant SARS-CoV 2 nucleoprotein (rec. COVID-19 NP) was expressed in *E. coli* and purified by metal-affinity chromatography to homogeneity using 6xHis tag. The purified recombinant protein was concentrated and dialyzed with phosphate-buffered saline.

LOT NUMBER:	Y011201
EXPRESSED IN:	E. coli
TAGGING:	6xHis
PRESERVATIVES:	None
BUFFER:	phophate-buffered saline, without any components.
PROTEIN CONCENTRATION:	>2.0 mg/mL, determinded from spectrophotometric measurement.
TOTAL VOLUME	– ml
BIOHAZARD	Use normal laboratory precautions and procedures when handling raw materials.
APPLICATIONS:	RDT, FIA, ELISA

(Exp. Date) This product is stable when stored at 2-8°C for 5 months and at -20°C for > 1 year.
(Analysis) SDS-PAGE and immunoassay. SDS-PAGE was carried out 11% polyacrylamide gel and identified its purity and correct molecular weight (47.04 kDa). For checking immuno-reactivity of recombinant protein, immunoassays (ELISA and RDT) with anti-COVID-19-positive sera were performed and identified its reactivity.

Q.C. Approved:

For Research Use Only

Anti-COVID-19 NP antibody 2F4

- Monoclonal antibody specific to COVID-19 nucleoprotein

PRODUCT NUMBER: AB-CO200
PRODUCT NAME: Anti-COVID-19 NP antibody 2F4

PRODUCT DESCRIPTION

The anti-COVID-19 NP antibody 2F4 was derived from a hybridoma 2F4 (fusion of mouse myeloma cell and the cells after mouse immunization with the nucleoprotein of COVID-19 as immunogen). The antibodies were highly purified by protein G-affinity chromatography from the ascitic fluid of Balb/c mouse. This antibody does not cross-react with other coronavirus except MERS-CoV.

APPLICATION

Immunological diagnostic application for detecting SARS CoV-2 virus

LOT NUMBER	---
IMMUNOGEN	COVID-19 nucleoprotein
CONCENTRATION	STORAGE BUFFER
>2.0 mg/ml (customized)	PBS, pH 7.4
TOTAL AMOUNT	PRESERVATIVES
- mg	Sodium azide

BIOHAZARD

Use normal laboratory precautions and procedures

EXP. DATE AND STORAGE	APPLICATIONS*
Stored at 2 – 8 °C for 1 month and at –20 °C for 1 year	LF,
EIA after its manufacture date	

QUALITY CONTROL

The product was PASSED its quality control tests using ELISA and SDS-PAGE.

For Research Use Only

* LF, lateral flow; IB, immunoblot; EIA, enzyme immunoassay; IFA, immunofluorescence assay; LTIA, latex turbidimetric assay

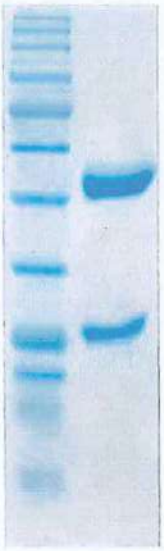
CERTIFICATE OF ANALYSIS

Product:	**Anti-COVID-19 NP antibody 3C3**
Description:	**The anti-COVID-19 NP antibody 3C3 was derived from a hybridoma 3C3 (fusion of mouse myeloma cell and the cells after mouse immunization with the nucleoprotein of COVID-19 as immunogen). The antibodies were highly purified by protein G-affinity chromatography from the ascitic fluid of Balb/c mouse. This antibody does not cross-react with other coronavirus except SARS-CoV.**
Cat Number:	**AB-CO100**
Isoytpe	**IgG_1**
Purity:	**>95% (SDS-PAGE))**
Specificity:	**This antibody does not cross-react with other coronavirus except SARS-CoV.**
Immunogen:	**Recombinant SARS-CoV 2 nucleoprotein**
Buffer:	**PBS pH 7.4**
Preservative:	**0.1% Sodium Azide**
Format:	**Purified Liquid**
Application:	**For *h vitro* diagnostic use only**
Shipping Condition:	**2~8°C**
Storage:	**Short-term store(<2 months) at 2~8°C Long term store(<12 months) at -80°C** **Avoid multiple freeze/thaw cycles**
Caution:	**For research and manufacturing use only.** **Product degradation will result from multiple freeze/thaw cycles.**
Note:	**The replacement of goods should be done within 2 months after the date of dispatch.** **The user assumes all responsibility for storage, care, custody and control of the material.**

C. K. Chong

Chom-Kyu Chong, Ph.D.

SDS-PAGE



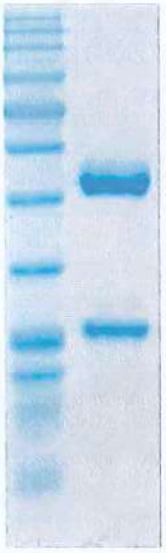
CERTIFICATE OF ANALYSIS

Product:	**Anti-COVID-19 NP antibody 2F4**
Description:	**The anti-COVID-19 NP antibody 2F4 was derived from a hybridoma 2F4 (fusion of mouse myeloma cell and the cells after mouse immunization with the nucleoprotein of COVID-19 as immunogen). The antibodies were highly purified by protein G-affinity chromatography from the ascitic fluid of Balb/c mouse. This antibody does not cross-react with other coronavirus except SARS-CoV.**
Cat Number:	**AB-CO200**
Isoytpe	**IgG_1**
Purity:	**>95% (SDS-PAGE))**
Specificity:	**This antibody does not cross-react with other coronavirus except SARS-CoV.**
Immunogen:	**Recombinant SARS-CoV 2 nucleoprotein**
Buffer:	**PBS pH 7.4**
Preservative:	**0.1% Sodium Azide**
Format:	**Purified Liquid**
Application:	**For *in vitro* diagnostic use only**
Shipping Condition:	**2~8℃**
Storage:	**Short-term store(<2 months) at 2~8℃ Long term store(<12 months) at -80℃** **Avoid multiple freeze/thaw cycles**
Caution:	**For research and manufacturing use only.** **Product degradation will result from multiple freeze/thaw cycles.**
Note:	**The replacement of goods should be done within 2 months after the date of dispatch.** **The user assumes all responsibility for storage, care, custody and control of the material.**

C.K. Chong

Chom-Kyu Chong, Ph.D.

SDS-PAGE



Anti-COVID-19 NP antibody 3C3

- Monoclonal antibody specific to COVID-19 nucleoprotein

PRODUCT NUMBER: AB-CO100
PRODUCT NAME: Anti-COVID-19 NP antibody 3C3

PRODUCT DESCRIPTION

The anti-COVID-19 NP antibody 3C3 was derived from a hybridoma 3C3 (fusion of mouse myeloma cell and the cells after mouse immunization with the nucleoprotein of COVID-19 as immunogen). The antibodies were highly purified by protein G-affinity chromatography from the ascitic fluid of Balb/c mouse. This antibody does not cross- react with other coronavirus except MERS-CoV.

APPLICATION

Immunological diagnostic application for detecting SARS CoV-2 virus

LOT NUMBER	—
IMMUNOGEN	COVID-19 nucleoprotein
CONCENTRATION	STORAGE BUFFER
>2.0 mg/ml (customized)	PBS, pH 7.4
TOTAL AMOUNT	PRESERVATIVES
- mg	Sodium azide

BIOHAZARD

Use normal laboratory precautions and procedures

EXP. DATE AND STORAGE	APPLICATIONS*
Stored at 2 – 8 °C for 1 month and at –20 °C for 1 year	LF,
EIA after its manufacture date	

QUALITY CONTROL

The product was PASSED its quality control tests using ELISA and SDS-PAGE.

For Research Use Only

* LF, lateral flow; IB, immunoblot; EIA, enzyme immunoassay; IFA, immunofluorescence assay; LTIA, latex turbidimetric assay

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ATTACHMENT #9

Cross Reactivity Study and Trina Invoice

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Test for performance of

COVID-19 IgM/IgG RDT

Product: **COVID-19 IgM/IgG**

Date: **2020-05-12**

1. Investigator

Name	Institution	Position	Role in the study
Younhee Park	Dept. Of Laboratory Medicine, Yonsei University Collage of Medicine	Professor (M.D.)	Principal Investigator

2. General Information

Objective	Test for performance evaluation of COVID-19 IgM/IgG Test.
Investigational Device	COVID-19 IgM/IgG (COVI040), Confiscope G20 (Optional)
Study method	Test were performed according to instruction for use COVID-19 IgM/IgG Test' with residual serum from 34 patients confirmed by real-time PCR method. All of the test were repeated twice.
Specimen Information	Residual serum specimen collected. 34 patients confirmed by respiratory related real-time PCR method.
Acceptance Criteria	1) Control line (C) should be appeard. 2) COVID-19 IgM/IgG result.

Signal/Cut Off (S/CO)	Result
≤ 1.0	Negative
> 1.0, < 1.2	Indeterminate
≥ 1.2	Positive

Prepared By / Date	Reviewd by / Date	Approved By / Date
Researcher	Research Director	QMR
2020-05-12	2020-05-12	2020-05-12

3. Result analysis

1) Information of samples to be used in this study and test results.

		COVID-19 IgG/IgM			
No.	Confirmed by Real-time PCR	Visual result*		Confiscope G20 result*	
		IgM	IgG	IgM	IgG
1	Rhinovirus A,B,C	Negative	Negative	Negative	Negative
2	Rhinovirus A,B,C	Negative	Negative	Negative	Negative
3	Rhinovirus A,B,C	Negative	Negative	Negative	Negative
4	Rhinovirus A,B,C	Negative	Negative	Negative	Negative
5	Rhinovirus A,B,C	Negative	Negative	Negative	Negative
6	Influenza A, H1pdm09	Negative	Negative	Negative	Negative
7	Influenza A, H1pdm09	Negative	Negative	Negative	Negative
8	Influenza A, H1pdm09	Negative	Negative	Negative	Negative
9	Influenza A, H3 & Human coronavirus OC43	Negative	Negative	Negative	Negative
10	Parainfluenza 1&2	Negative	Negative	Negative	Negative
11	Parainfluenza 1	Negative	Negative	Negative	Negative
12	Parainfluenza 1	Negative	Negative	Negative	Negative
13	Parainfluenza 1	Negative	Negative	Negative	Negative
14	Parainfluenza 1	Negative	Negative	Negative	Negative
15	Parainfluenza 1	Negative	Negative	Negative	Negative
16	Parainfluenza 3	Negative	Negative	Negative	Negative
17	Parainfluenza 3	Negative	Negative	Negative	Negative
18	Metapneumovirus	Negative	Negative	Negative	Negative
19	Metapneumovirus	Negative	Negative	Negative	Negative
20	Metapneumovirus	Negative	Negative	Negative	Negative
21	Metapneumovirus	Negative	Negative	Negative	Negative
22	Metapneumovirus	Negative	Negative	Negative	Negative
23	Influenza A, H1pdm09 & Human coronavirus Nl63	Negative	Negative	Negative	Negative
24	Human coronavirus Nl63	Negative	Negative	Negative	Negative
25	Human coronavirus Nl63	Negative	Negative	Negative	Negative
26	Human coronavirus OC43	Negative	Negative	Negative	Negative
27	Human coronavirus OC43	Negative	Negative	Negative	Negative
28	Human coronavirus OC43	Negative	Negative	Negative	Negative
29	Human coronavirus OC43	Negative	Negative	Negative	Negative
30	Human coronavirus 229E	Negative	Negative	Negative	Negative
31	Human coronavirus 229E	Negative	Negative	Negative	Negative

32	Human coronavirus 229E	Negative	Negative	Negative	Negative
33	Human coronavirus 229E	Negative	Negative	Negative	Negative
34	Human coronavirus 229E	Positive	Negative	Positive	Negative

*All the test were performed duplicate.

2) Cross reactivity of ·19 IgM/IgG in this performance evaluation study.

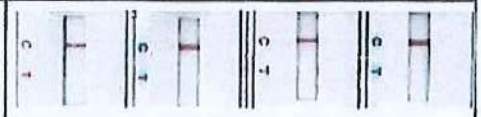
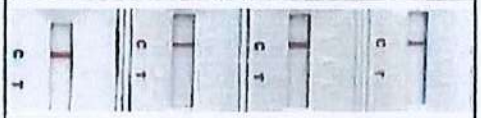
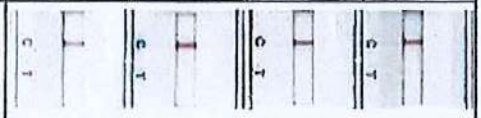
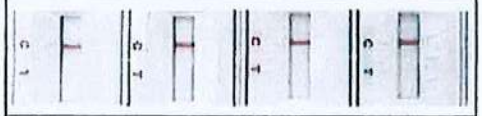
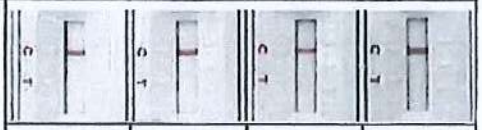
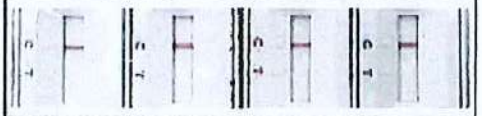
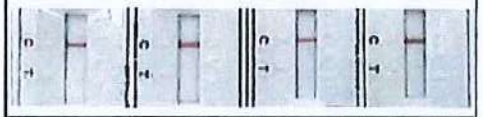
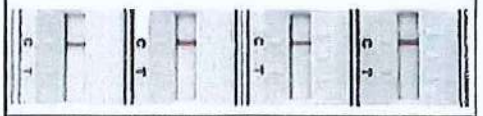
Virus/Bacteria/Parasite Antibody positive	Source/ Sample type	Results
Rhinovirus A,B,C	Residual specimen / Serum	0/5 (0%)
parainfluenza virus 1&2	Residual specimen / Serum	0/1 (0%)
Parainfluenza virus 1	Residual specimen / Serum	0/5,(0%)
Parainfluenza virus 3	Residual specimen / Serum	0/2 (0%)
Influenza A, H3	Residual specimen / Serum	0/1 (0%)
Influenza A, H1pdm09	Residual specimen / Serum	0/3 (0%)
Metapneumovirus	Residual specimen / Serum	0/5 (0%)
Human coronavirus NI63	Residual specimen / Serum	0/3 (0%)
Human coronavirus OC43	Residual specimen / Serum	0/5 (0%)
Human coronavirus 229E	Residual specimen / Serum	1/5 (20%)

3) Summary of the results.

All of the specimens does not react with Covid-19 IgM/IgG except one of five human coronavirus 229E positive serum. The cross react was observed only in anti-COVID 19 IgM test line.

4. Appendix

1) Interpretaion results without using Confiscope G20.

COVID-19 IgG/IgM (visual result)						
List of test specimens		Complete image	Test #1		Test #2	
No.	Confirmed		IgM	IgG	IgM	IgG
1	Rhinovirus A,B,C					
			Negative	Negative	Negative	Negative
2	Rhinovirus A,B,C					
			Negative	Negative	Negative	Negative
3	Rhinovirus A,B,C					
			Negative	Negative	Negative	Negative
4	Rhinovirus A,B,C					
			Negative	Negative	Negative	Negative
5	Rhinovirus A,B,C					
			Negative	Negative	Negative	Negative
6	Influenza A, H1pdm09					
			Negative	Negative	Negative	Negative
7	Influenza A, H1pdm09					
			Negative	Negative	Negative	Negative
8	Influenza A, H1pdm09					
			Negative	Negative	Negative	Negative

9	Influenza A, H3 & Hunam coronavirus OC43		Negative	Negative	Negative	Negative
10	Parainfluenza 1&2		Negative	Negative	Negative	Negative
11	Parainfluenza 1		Negative	Negative	Negative	Negative
12	Parainfluenza 1		Negative	Negative	Negative	Negative
13	Parainfluenza 1		Negative	Negative	Negative	Negative
14	Parainfluenza 1		Negative	Negative	Negative	Negative
15	Parainfluenza 1		Negative	Negative	Negative	Negative
16	Parainfluenza 3		Negative	Negative	Negative	Negative
17	Parainfluenza 3		Negative	Negative	Negative	Negative

18	Metapneumovirus		Negative	Negative	Negative	Negative
19	Metapneumovirus		Negative	Negative	Negative	Negative
20	Metapneumovirus		Negative	Negative	Negative	Negative
21	Metapneumovirus		Negative	Negative	Negative	Negative
22	Metapneumovirus		Negative	Negative	Negative	Negative
23	Influenza A, H1pdm09 & Human coronavirus NL63		Negative	Negative	Negative	Negative
24	Human coronavirus Nl63		Negative	Negative	Negative	Negative
25	Human coronavirus Nl63		Negative	Negative	Negative	Negative
26	Human coronavirus OC43		Negative	Negative	Negative	Negative

27	Human coronavirus OC43		Negative	Negative	Negative	Negative
28	Human coronavirus OC43		Negative	Negative	Negative	Negative
29	Human coronavirus OC43		Negative	Negative	Negative	Negative
30	Human coronavirus 229E		Negative	Negative	Negative	Negative
31	Human coronavirus 229E		Negative	Negative	Negative	Negative
32	Human coronavirus 229E		Negative	Negative	Negative	Negative
33	Human coronavirus 229E		Negative	Negative	Negative	Negative
34	Human coronavirus 229E		Positive	Negative	Positive	Negative

2) Interpretation results by using Confiscope G20.

COVID-19 IgG/IgM (Confiscope G20 result)								
No.	Confirmed	Test Date	Number of test	Item Code	Lot No.	Value	Unit (s/CO)	Result
1	Rhinovirus A,B,C	2020.05.08	Test #1	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.31	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.46	Negative
		2020.05.08	Test #2	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.37	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.57	Negative
2	Rhinovirus A,B,C	2020.05.08	Test #1	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.35	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.31	Negative
		2020.05.08	Test #2	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.37	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.39	Negative
3	Rhinovirus A,B,C	2020.05.08	Test #1	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.23	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.47	Negative
		2020.05.08	Test #2	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.47	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.24	Negative
4	Rhinovirus A,B,C	2020.05.08	Test #1	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.32	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.37	Negative
		2020.05.08	Test #2	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.4	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.37	Negative
5	Rhinovirus A,B,C	2020.05.08	Test #1	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.31	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.33	Negative
		2020.05.08	Test #2	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.41	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.10	Negative
6	Influenza A, H1pdm09	2020.05.08	Test #1	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.41	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.52	Negative
		2020.05.08	Test #2	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.45	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.22	Negative
7	Influenza A, H1pdm09	2020.05.08	Test #1	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.26	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.41	Negative
		2020.05.08	Test #2	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.27	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.47	Negative
8	Influenza A, H1pdm09	2020.05.08	Test #1	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.48	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.28	Negative
		2020.05.08	Test #2	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.2	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.34	Negative
9	Influenza A, H3 &	2020.05.08	Test #1	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.48	Negative

	Human coronavirus OC43	2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.43	Negative
		2020.05.08	Test #2	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.29	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.3	Negative
10	Parainfluenza 1&2	2020.05.08	Test #1	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.24	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.32	Negative
		2020.05.08	Test #2	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.42	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.36	Negative
11	Parainfluenza 1	2020.05.08	Test #1	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.16	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.74	Negative
		2020.05.08	Test #2	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.43	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.77	Negative
12	Parainfluenza 1	2020.05.08	Test #1	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.5	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.46	Negative
		2020.05.08	Test #2	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.32	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.4	Negative
13	Parainfluenza 1	2020.05.08	Test #1	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.2	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.35	Negative
		2020.05.08	Test #2	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.2	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.34	Negative
14	Parainfluenza 1	2020.05.08	Test #1	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.36	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.34	Negative
		2020.05.08	Test #2	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.24	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.43	Negative
15	Parainfluenza 1	2020.05.08	Test #1	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.36	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.27	Negative
		2020.05.08	Test #2	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.26	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.26	Negative
16	Parainfluenza 3	2020.05.08	Test #1	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.24	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.43	Negative
		2020.05.08	Test #2	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.47	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.23	Negative
17	Parainfluenza 3	2020.05.08	Test #1	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.31	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.44	Negative
		2020.05.08	Test #2	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.45	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.62	Negative
18	Metapneumovirus	2020.05.08	Test #1	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.39	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.76	Negative
		2020.05.08	Test #2	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.36	Negative

		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.48	Negative
19	Metapneumovirus	2020.05.08	Test #1	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.3	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.36	Negative
		2020.05.08	Test #2	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.43	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.49	Negative
20	Metapneumovirus	2020.05.08	Test #1	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.37	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.43	Negative
		2020.05.08	Test #2	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.39	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.4	Negative
21	Metapneumovirus	2020.05.08	Test #1	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.43	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.33	Negative
		2020.05.08	Test #2	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.41	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.49	Negative
22	Metapneumovirus	2020.05.08	Test #1	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.29	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.21	Negative
		2020.05.08	Test #2	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.42	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.4	Negative
23	Influenza A, H1pdm09 & Human coronavirus NL63	2020.05.08	Test #1	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.48	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.47	Negative
		2020.05.08	Test #2	COVID-19 IgM/IgG	COVI040.	COVID-19 IgG	0.31	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.55	Negative
24	Human coronavirus NL63	2020.05.08	Test #1	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.42	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.25	Negative
		2020.05.08	Test #2	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.36	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.42	Negative
25	Human coronavirus NL63	2020.05.08	Test #1	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.24	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.2	Negative
		2020.05.08	Test #2	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.45	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.15	Negative
26	Human coronavirus OC43	2020.05.08	Test #1	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.32	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.93	Negative
		2020.05.08	Test #2	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.28	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.37	Negative
27	Human coronavirus OC43	2020.05.08	Test #1	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.47	Negative
		2020.05.08.		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.59	Negative
		2020.05.08	Test #2	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.35	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.97	Negative
28	Human coronavirus OC43	2020.05.08	Test #1	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.3	Negative

		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.73	Negative
		2020.05.08	Test #2	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.48	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.16	Negative
29	Human coronavirus OC43	2020.05.08	Test #1	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.47	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.29	Negative
		2020.05.08	Test #2	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.46	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.26	Negative
30	Human coronavirus 229E	2020.05.08	Test #1	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.28	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.28	Negative
		2020.05.08	Test #2	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.31	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.48	Negative
31	Human coronavirus 229E	2020.05.08	Test #1	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.6	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.35	Negative
		2020.05.08	Test #2	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.5	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.40	Negative
32	Human coronavirus 229E	2020.05.08	Test #1	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.38	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.31	Negative
		2020.05.08	Test #2	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.58	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.33	Negative
33	Human coronavirus 229E	2020.05.08	Test #1	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.44	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.28	Negative
		2020.05.08	Test #2	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.44	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	0.21	Negative
34	Human coronavirus 229E	2020.05.08	Test #1	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.48	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	2.69	Positive
		2020.05.08	Test #2	COVID-19 IgM/IgG	COVI040	COVID-19 IgG	0.44	Negative
		2020.05.08		COVID-19 IgM/IgG	COVI040	COVID-19 IgM	3.1	Positive

5. Conclusion

All tests were performed using serum collected after 4 weeks or more of patients with respiratory virus detected in nasopharyngeal swab. Based on the results of, it was found that COVID-19 IgM/IgG Test showed a high specificity in the test with serum specimens related to respiratory disease.