

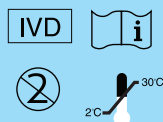
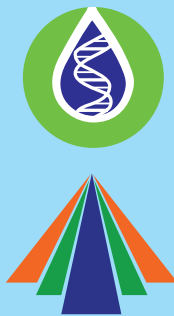
COVID-19 IgM/IgG

AccoRapid Test



DOCUMENTS

FOR CERTIFICATION



AccoRapid 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



ISO 13485:2016 Medical Device Directive (MOD) 93/42/EEC& 98/79/EC IVD
(Standard Applicable EN ISO 13485: 2016, EN ISO 14971: 2012, EN ISO 18113-1: 2011,
EN ISO 18113-2: 2011, EN 13612: 2002, EN 23640: 2015, EN 15223: 2016, EN 13641: 2002)



Ref No. SRAMGDIH/ FDA/ 01/ 2020-2021

13th APRIL 2020

To whom it may concern,

Dear Sir,

RE : ACCO COVID-19 IgM/IgG RAPID TEST KITS BUSINESS PROPOSAL

We, SRAM & MRAM TECHNOLOGIES LIMITED (a 100% subsidiary of SRAM & MRAM TECHNOLOGIES AND RESOURCES LIMITED, UK- a Billion Dollar Enterprise) in association with GDIH FIRST RESPONSE AND SECURITY GROUP (GDIH), located in Lomond Court, Castle Business Park, Stirling, Stirlingshire, FK9 4TU, United Kingdom and United 50 Linen Hall 162 Regency Street London W1B 5TF Kingdom respectively represented by Dr.Sailesh Lachu Hiranandani and Mr.Philip Cabana, hereby confirm under our Full Corporate and Legal responsibility that we are **READY, WILLING** and **ABLE** to distribute Acco COVID-19 IgM/IgG Rapid Test kits upon placement of purchase orders.

Our Product:

Introduction : SRAM MRAM Technologies in association with its group company AccoBiotechSdnBhd (Malaysia) has developed Rapid Diagnostic test kit for novel coronavirus COVID-19 infection. This test detects qualitatively both early marker and late marker, IgM/IgG antibodies of the novel coronavirus in human serum, plasma or whole blood in vitro.

SRAM-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.

Product : **AccoCOVID-19 IgM/IgG Rapid Test Kit**
Accurate Test Results : Within 15 minutes
Sensitivity : 95% or more
Specificity : 99%
Price : **USD 12.00 for Joint Venture Partners**
(F.O.B. Kuala Lumpur) : **USD 14.00 for Distributors / Large Retailers**
: **USD 15.00 for Small Retailers**

Rapid screening of carriers of virus that are symptomatic or asymptomatic

Easy & Efficient : Intuitive visual interpretation, No special equipment needed
Test Purpose : Clinical Diagnostic use, ideally suited for hospitals, clinics, laboratories

SRAM & MRAM Technologies: R & D Facility

First & Only Full Fledge RDT Manufacturing In Malaysia
GMP Status, ISO certified, CE US Patent (No; 9,354,234)
Recognize as BIOTECH company by BIOTECHCORP & MIDA
Ministry of International Trade and Industry: Awarded Manufacturing License for "Diagnostic Test Kits"

Diagnostic Kits : In vitro Diagnosis Test (IVD), Rapid Test Kit (RTK), Point of Care Test (POCT)
Manufacturing Technology : Nano Technology
Production Capacity : **Minimum of 30,000 kits per day**
Technology Innovations : Q-RTK & Microarray Chip etc
Certifications : CE for Company, MOH of Malaysia Registration for Company, CE of Product FDA of Product (Processing), Brazil (CE Approval Processing), India (CE Approval Processing), Kingdom of Saudi Arabia (CE, FDA Processing)

We remain at your disposal should you required any further information in this regard.

Thank you.

Regards,

SRAM & MRAM TECHNOLOGIES LIMITED

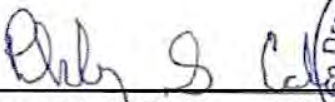




Name: Dr.Sailesh Lachu Hiranandani

Title: Chairman

GDIH FIRST RESPONSE AND SECURITY GROUP





Name: Mr. Phillip Steven Cabana

Title: Chairman

SEAL OF COMPANY

SRAM - ACCO

COVID 19 Igm/IgG

Rapid Diagnostic Test Kit



Manufactured by AccoBiotech Sdn. Bhd. (Business Associate and partner of SRAM & MRAM Group with its office at No 11, Jalan Bukit 27, Bandar Baru Seri Alam, 81750 Masai, Johor, Malaysia) has developed Rapid Diagnostic test kit for coronavirus infection.

This test detects qualitatively both early marker and late marker, IgM/IgG antibodies of the novel coronavirus in human serum, plasma or whole blood in vitro

- Test results within 15 minutes
- Accuracy: 99%
- Ideally suited for hospitals, clinics, laboratories.
- Accurate results
- Test Purpose: Clinical Diagnostic use
- Intuitive visual interpretation
- Sensitivity: 95% or more
- Rapid screening of carriers of virus that are symptomatic or asymptomatic.
- No special equipment needed

COVID -19 diagnosis in 10-15 minutes:

It is widely accepted that IgM provides the first line of defense during viral infections, followed by the generation of adaptive, high affinity IgG responses for long term immunity and immunological memory. Therefore, testing of COVID-19 IgM and IgG antibodies is an effective method for the rapid diagnosis of COVID-19 infection.

Furthermore, detection of COVID-19 IgM antibodies tends to indicate a recent exposure to COVID-19, whereas detection of COVID-19 IgG antibodies indicates a later stage of infection. Thus, this combined antibody test could also provide information on the stage of infection

A product brochure & detailed presentation explaining the technology with images attached for your kind perusal.

Clinical Trials : Done

Certifications (applied) : MOH Malaysia Certification available, CE Certification in process, FDA & WHO application in process

These approvals are part of a continuous process, takes time, but this is an emergency situation so things can move in fast track.

Please let us know if you need more information

SRAM & MRAM TECHNOLOGIES LIMITED

Lomond Court, Castle Business Park,
Stirling, Stirlingshire, FK9 4TU,
United Kingdom.

Tel : +44-74529 26055

SRAM & MRAM RESOURCES BHD

Suite 9, Block B, Level 3A, Megan Avenue
II, 12, Jalan Yap Kwan Seng, 50450 WP
Kuala Lumpur, Malaysia.

Tel : +60 3-2775 7326



CERTIFICATE

*This is to Certify that the
Medical Devices – Quality Management System
of*

JINTEX INTERNATIONAL DMCC

**Unit No: 4285, DMCC Business Centre, Level No-1,
Jewellery & Gemplex-3, DUBAI (UAE)**

**has been independently assessed and is compliant
with the requirements of**

ISO 13485:2016

**This Certificate is applicable to the following product or service ranges:
Importers, Exporters & Retailers of: - ACCO COVID 19 IgM/ IgG Rapid Test Kit,
ACCO Dengue NSI Ag, ACCO Dengue IgG/ IgM Ab, ACCO Dengue IgG/ IgM- NSI Combo,
ACCO Malaria Pf/Pan, ACCO Syphilis, ACCO Zika IgG/IgM, ACCO Zika NSI Ag,
ACCO hCG & Other Surgical, Diagnostic Products, Devices & Hospital Equipment.**

Certificate No.: AE88362H

Date of initial registration	11 April 2020
Date of this Certificate	11 April 2020
Surveillance audit on or before	10 April 2021
Recertification Due/ Certificate Expiry	10 April 2023

This Certificate is property of LMS Certification and remains valid
subject to satisfactory surveillance audits.

Director

For conditions and updated information concerning the present certificate visit to www.lmscertification.com

This Certificate is the property of LMS Certification Limited and shall be returned immediately when demanded.



ACCREDITED
Management System
Certification Body
MSC8132

LMS Certification Limited
35 Park Hill, Huddersfield, HD2 1QG, West Yorkshire, United Kingdom.
Phone : +44 2089355094
Visit : www.lmscert.com
E-mail : info@lmscert.com



LMS/IAS/13485/1798 V02



Certificate

*This is to Certify that the Product
as per Annexure I
Marketed By*

JINTEX INTERNATIONAL DMCC

**Unit No: 4285, DMCC Business Centre, Level No-1,
Jewellery & Gemplex-3, DUBAI (UAE)**

**has been independently assessed and is compliant
with the requirements of**

**Medical Device Directive (MDD) 93/42/EEC & 98/79/EC IVD
(Standard Applicable EN ISO 13485: 2016, EN ISO 14971: 2012, EN ISO 18113-1: 2011,
EN ISO 18113-2: 2011, EN 13612: 2002, EN 23640: 2015, EN 15223: 2016, EN 13641: 2002)
The CE Marking may be used if all relevant & effective EN Standard & EC Directive are complied with.**

:: Certificate No :: AE11112U



Date of initial registration	14 April 2020
Date of this certificate	14 April 2020
Surveillance audit on or before	13 April 2021
Recertification Due / Certificate expiry	13 April 2023

This Certificate is property of Certiva Limited Certifications and remains valid
subject to satisfactory surveillance audits.

Certiva Limited
3rd Floor, 207 Regent Street
London, W1B 3HH.
Tel : + 44 203 5143425
Phone : +44 7042042076
Fax: +44 8458741820
Email: enquiry@certiva.co.uk
Web: www.certiva.co.uk
Company Number : 9799171



For precise and updated information concerning the present certificate visit at www.certiva.co.uk



Certificate

Annexure 1

Product Manufactured By

ACCOBIOTECH SDN BHD

**NO. 11, JALAN BUKIT 27, MASAI INDUSTRIAL PARK,
BANDAR SERI ALAM, 81750 MASAI JOHOR, MALAYSIA**

List of Product Covered Under Certification

Serial No	Product Details
1	ACCO COVID 19 IgM/ IgG Rapid Test Kit
2	ACCO Dengue NS1 Ag
3	ACCO Dengue IgG/ IgM Ab,
4	ACCO Dengue IgG/ IgM- NS1 Combo,
5	ACCO Malaria Pf/Pan,
6	ACCO Syphilis,
7	ACCO Zika IgG/IgM,
8	ACCO Zika NS1 Ag,
9	ACCO hCG

CE

:: Certificate No :: AE11112U

This Certificate is property of Certiva Limited Certifications and remains valid
subject to satisfactory surveillance audits.

Certiva Limited
3rd Floor, 207 Regent Street
London, W1B 3HH.
Tel : + 44 203 5143425
Phone : +44 7042042076
Fax: +44 8458741820
Email: enquiry@certiva.co.uk
Web: www.certiva.co.uk
Company Number : 9799171



For precise and updated information concerning the present certificate visit at www.certiva.co.uk



Sram & Mram

Acco Biotech Sdn Bhd

Malaysia



AccoBIOTECH

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-coronavirus>

SYMPTOMS

Common Symptoms



FEVER



SHORTNESS OF BREATH



DRY COUGH

Some patients may have:



ACHES AND PAINS



NASAL CONGESTION



RUNNY NOSE



SORE THROAT



DIARRHEA



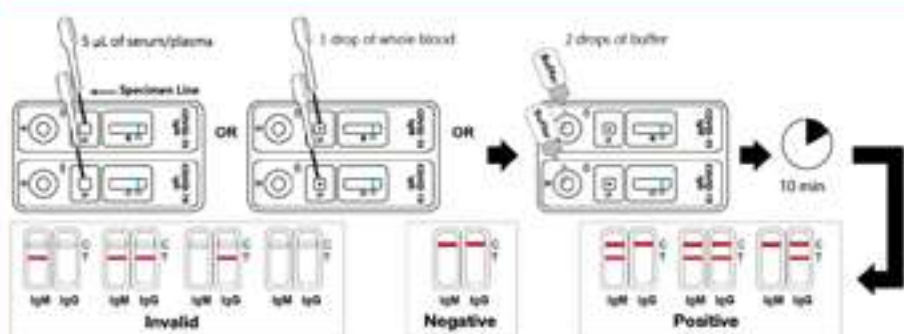
Rapid Differential Detection Kit
 (IgM and IgG against COVID-19)

ADVANTAGES

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

FAST • RELIABLE • ACCURATE

PROCEDURE & INTERPRETATION



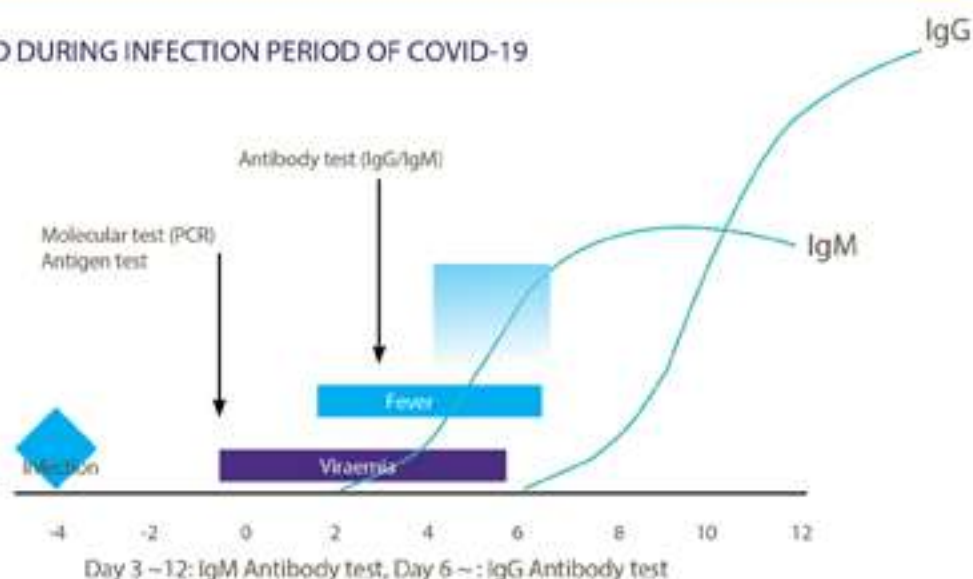
PRECAUTIONS

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 handling specimens.
7. Decontaminate and dispose of all specimens in a biohazard container.

SCREEN EARLY WITH ACCO COVID-19

Your Results in 10 Minutes!!!

TEST METHOD DURING INFECTION PERIOD OF COVID-19



COMPARISON WITH MOLECULAR TESTING

	MOLECULAR TESTING (RT-PCR)	ACCO COVID-19 IgM/IgG RAPID TEST
Principle	Nucleic acid test of COVID-19	Antibody (IgM & IgG) detection in the blood
Accuracy in the fields	- China: 30 ~ 50% (Junganglibo,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- 30%, IgG- 0% After Day 7 from symptom: IgM- 80%, IgG- >95%	w. limited cases
Specificity	IgM 98% (118/120), IgG: 99% (119/120)	

ORDERING INFORMATION

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



PIONEER IN MALAYSIA RAPID TEST KITS SINCE 2013



Company Profile



- Medical Diagnostic Development and Manufacturing Company.
- Facility - Build up area 38,000sqf on One Build up area 38,000sqf on One Acres land.

Our Vision

- To be the leading Rapid Diagnostic Test Kit Manufacturer in theWorld.

Our Vision

- To Design Develop and Market new Patented Technologies

Market -Customers

- Currently the Government of Malaysia and Malaysian Clinics..
- Overseas Customersincluding countries like Laos, Cambodia, PNG, etc.,
- It is expected to have 500 channels partners





Global Presence In 2020

- Expected to be represented globally – 1 Billion Tests
- Appointing reputable representative / agents globally – 10% of the Market
- Over 100 countries worldwide to be represented
- New target market are Vietnam, Kazakhstan, Indonesia, India, Philippines, Thailand, Middle East and Africa



Management Strength

- 500 Employees



Manufacturing

- Full Scale Manufacturing Company Including R&D in Malaysia.
- Nano Technology
- Production capacity Min 1 Million kits per day

Research & Development

- COVID-19 Test Kit has been Developed
- Continue to Develop Test Kit for Tropical Diseases
- Tie up with R&D organizations
- Technology Innovation – Q-RTK & Microarray chip



RESEARCH & DEVELOPMENT

Research & Development

R&D Title	University	Logo	Researchers
Identification, evaluation and alleviation of the threat of Vector- borne rickettsial agents to human health in Malaysia.	Liverpool University, UK and University Malaya, M'sia		Prof Dr Benjamin & Prof Sazali
Rapid measurement of important multiple biomarkers using microcapillary film (MCF), a portable low cost rapid test kit.	Reading University , UK		Prof Alexander
Development of a novel rapid point-of-care in Vitro Diagnostic Device for detection of HPV and cervical cancer prevention- DNA-based lateral flow assay.	Nazarbayev University School of Medicine, Kazakhstan		Prof Aziliyati
Clinical diagnosis of early dengue infection by novel one-novel one time RT-PCR targeting NS1 gene.	ChungBuk National University, Korea		As Prof Dr Chong
IT-POC convergence in cardiac care and to evaluate the efficacy of Rapid test kit in chest pain evaluations in developing countries.	National University of Singapore Hospital		Prof Dr Chester Drum

R&D Collaborators

- Prof Dr Sazaly Sazaly b Abu Bakar
- Prof Dr.Alexander D. Edwards Reading University, UK
- Prof Chester Drum M.D PhD
- Prof Azliyati Azizan
- Ass Prof Dr.Chom KyuKyu Chong
- Dr Murali Sukumaran





- First & Only Full Fledge Rdt Manufacturing In Malaysia
- GMP Status, ISO certify, CE certificate
- US Paten Patetn (No ;9,354 ,234)
- Recognize as BIOTECH company by BIOTECHCORP & MIDA



THE TEST KITS ARE MANUFACTURED & DESIGNED TO

- PRODUCE RAPID & FAST ASSAY TIME (WITHIN 15 MINUTES)**
- HIGH SPECIFICITY (95-100%)**
- HIGH SENSITIVITY (95-100%)**
- STABILITY (SHELF LIFE OF 2 YEARS)**
- COST EFFECTIVE & MANY MORE**



- In vitro Diagnosis Test (IVD)
- Rapid Test Kit (RTK)
- Point of Care Test (POCT)

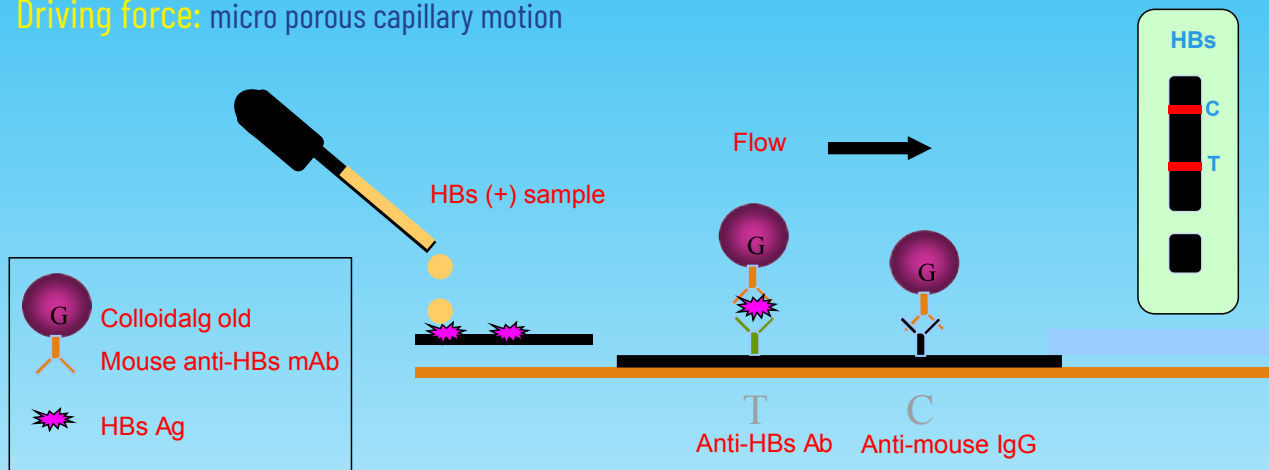
Assay principals of Rapid Test

Main principle : immunochromatographic assay.(interactions of capture and conjugate)

Capture: immobilized antigens or antibodies onto N/C membrane.

Conjugate: antigen -or antibody-coupled colloidal gold

Driving force: micro porous capillary motion

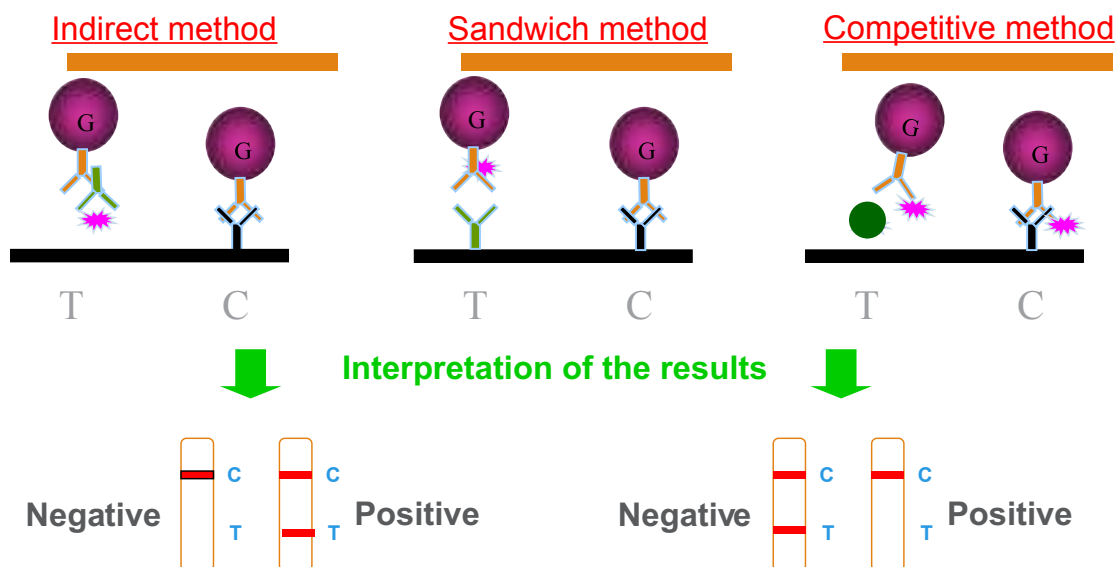


Assay types of Rapid test

Indirect method: using gold conjugate coupled 2nd antibodies and protein A (or G)

Sandwich method: Ab(C)-target-Ab(G), Ag(C)-target-Ag(G)

Competitive method: using molecular competition



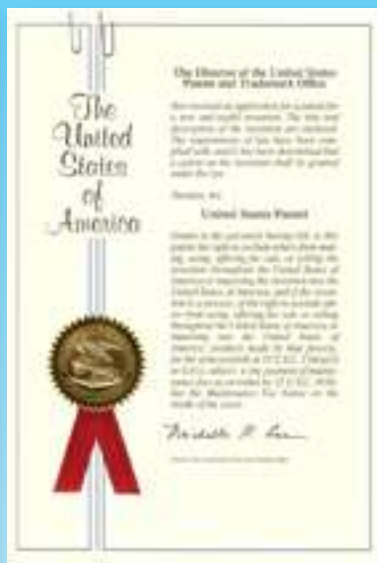
Approvals & Certificates

ISSUED BY

Medical Device Authority of Malaysia
 Obelis European Authorized Representative Center
 Care Certification International (M) Sdn Bhd
 The Director of the United State Patent & Trademark Office
 MOSTI
 MIDA
 Ministry of International Trade and Industry

PURPOSE

Manufacturer Status
 CE Certificate (European Union)
 ISO 13485-2005
 Patent / Trademark
 Bio-economy Transformation Programme
 'PioneerStatus' in Malaysia
 'Manufacturing License
 "Diagnostic Test Kits"





AccoBiotech



SRAM & MRAM
GROUP



An SRAM & MRAM N SITI Initiative



ASAL
ORIGINAL

PIHAK BERKUASA
PERANTI PERUBATAN



MEDICAL DEVICE
AUTHORITY

PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY
AKTA PERANTI PERUBATAN 2012 (AKTA 737)
MEDICAL DEVICE ACT 2012 (ACT 737)
LESEN ESTABLISHMEN
ESTABLISHMENT LICENCE
Seksyen 15(1) Akta 737
Section 15(1) of Act 737

No. Lesen:
License No.:

KP9709296516

Tarikh Sah Lesen:
License Validity Date:

18/12/2017
17/12/2020

Lesen adalah dengan ini diberi kepada:
Licence is hereby granted to:

ACCOBIOTECH SDN BHD

yang beralamat di:
of

**NO.11, JALAN BUKIT 27,
MASAI INDUSTRIAL PARK,
BANDAR SERI ALAM, MASAI
81750 JOHOR**

Sebagai:
as

**PEMBUAT
MANUFACTURER**

Orang yang bertanggungjawab: **SIVALINGAM A/L RAJAGOPAL (I/C: 680616-01-5449)**
Person Responsible:

Lesen ini diberikan tertakluk kepada peruntukan-peruntukan di bawah Akta 737 dan peraturan-peraturan dibawahnya serta syarat-syarat seperti di Lampiran 1.
This licence is granted subject to the provisions under Act 737 and its subsidiary legislations and the conditions as in Attachment 1.



ZAMANE BIN ABDUL RAHMAN
Ketua Eksekutif
Chief Executive
PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY

CERTIFICATE OF CE (IVD) NOTIFICATION

Ref. No.: DT 5433-2017

BELGIUM

Date: 19/04/2017

Order No.: DT 5191-2016

THIS IS TO CERTIFY THAT, ACCORDING TO THE COUNCIL DIRECTIVE 98/79/EC, OBELIS S.A. (O.E.A.R.C.) PERFORMED ALL NOTIFICATION DUTIES AND RESPONSIBILITIES AS THE EUROPEAN AUTHORIZED REPRESENTATIVE (EC REP) OF:

NAME: ACCOBIOTECH SDN BHD

ADDRESS: NO. 11, JALAN BUKIT 27, BANDAR SERI ALAM,
81750 MASAI. JOHOR,
MALAYSIA

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED DIRECTIVE.

The Manufacturer declares that the IVD devices comply with the Directive including all essential requirements.

The Manufacturer has provided Obelis s.a. (O.E.A.R.C.) with all the appropriate declarations according to the 98/79/EC Directive – article 10 requirements including the EC Declaration of Conformity confirming that his In-Vitro Diagnostics medical devices, as stipulated here above, are fulfilling the applicable requirements of the European Council Directive 98/79/EC


The notification of the following In-Vitro Diagnostic medical devices has been completed by Obelis s.a. (O.E.A.R.C.) on the 13/04/2017 in compliance with the European Council Directive 98/79/EC - article 10 requirements.

IN-VITRO DIAGNOSTIC MEDICAL DEVICES: PLEASE SEE ANNEX A - LIST OF DEVICES (1PAGE, 8 DEVICES)

As of the 14/04/2017, and as long as the manufacturer will continue complying with the hereabove mentioned requirements* he therefore:

- Is required to affix the CE marking on these devices;

- Place these devices in the Territory of Belgium and the other EEA Member States (excluding territories not in alignment with Decision 2010/227/EU).

P.O.

Mr. G. Elkayam CEO
Obelis sa
date & stamp

Obelis s.a.
Registered Address :
Bld Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

S. FERRETTI
C.C.O.



Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001:2008 and ISO 13485:2003 certified in accordance to the profession of a European Authorized Representative.

*and provided that the product classification will not be rejected by the Competent Authorities.

Registered Address: Bd. Général Wahis 53- 1030 Brussels | Registered Office Address: Av. de Tervueren 34 B44 - 1040 Brussels - Belgium
T: + 32 (0) 2 732 5954 | F: + 32 (0) 2 732 6003 | Email: mail@obelis.net | Website: www.obelis.net



Annex A* - List of Devices

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

No.	Catalogue reference number	Commercial name	Generic Device Term	Short description and intended use	GMDN/EDMS code	Class**
1	DVAG10	Acco Dengue NS1 Ag	Dengue NS1 Ag Rapid Test	Detection of dengue virus NS1 Antigen	0	Others
2	DVAB10	Acco Dengue IgG/IgM Ab	Dengue IgG/IgM Ab Rapid Test	Detection of IgG and IgM against dengue virus type I, II, III, and IV	0	Others
3	DVC010	Acco Dengue IgG/IgM-NS1 Combo	Dengue IgG/IgM-NS1 Combo Rapid Test	Detection of both Dengue Antigen & primary / secondary infection	0	Others
4	MAAG10	Acco Malaria Pf/Pan	Malaria Pf/Pan Ag Rapid Test	Detection of histidine-rich protein 2 (HRP2) antigen and plasmodium lactate dehydrogenase (pLDH)	0	Others
5	SYP010	Acco Syphilis	Treponema pallidum Antibody Rapid Test	Detection of anti-TP antibody	30828	Others
6	ZIKA011	Acco Zika IgG/IgM	Zika IgG/IgM Rapid Test	Detection of immunoglobulin G (IgG) and immunoglobulin M (IgM) against zikavirus.	0	Others
7	ZIKA010	Acco Zika NS1 Ag	Zika NS1 Ag Rapid Test	Detection of zikavirus NS1 antigen	0	Others
8	HCG010	Acco hCG	Pregnancy, hCG Rapid test over the counter	Detection of pregnancy	40155	Others

* Annex A is part of the Agreement

** The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (IVD 98/79/EC).

Manufacturer's Name
ACCOBIOTECH SDN BHD

Obelis S.A.

Name: SIVALINGAM A/L RAJAGOPAL
CHIEF EXECUTIVE OFFICER

Position: _____

Signature: 



Signature: _____

Date: 18/09/2017

Stamp: 

Obelis s.a.
Registered Address:
Bld Général Wahis 53
1030 Bruxelles
Tel: +32 2 732 59 54 - Fax: +32 2 712 60 03
S. FERRETTI
C.C.O.

E.A.R.-CERTIFICATE

(RECITAL 29 OF THE DIRECTIVE 98/79/EC ON IN VITRO DIAGNOSTIC MEDICAL DEVICES)

REF. NO. : DT 5432-2017

ORDER NO. : DT 5191-2016

DATE: 19/04/2017

MANUFACTURER: Accobiotech SDN BHD
No. 11, Jalan Bukit 27,
Bandar Seri Alam,
81750 Masai. Johor,
Malaysia

FACILITIES: Accobiotech SDN BHD
No. 11, Jalan Bukit 27,
Bandar Seri Alam,
81750 Masai. Johor,
Malaysia

PRODUCT CATEGORIES: Please See Annex A - List of Devices (8 Devices, 1 Page)

MODELS: Please See Annex A - List of Devices (8 Devices, 1 Page)

The European Authorized Representative Center Obelis s.a. declares that the aforementioned manufacturer has fulfilled the essential requirement of appointing a European Authorized Representative in accordance with IVD 98/79/EC and to the terms and conditions set out in the agreement entered into force on 1st November 2016.

P.O. 

Mr. G. Elkayam CEO
Obelis sa
date & stamp

Obelis s.a.
Registered Address :
Bld Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

S. FERRETTI
C.C.O.



Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001:2008 and ISO 13485:2003 certified in accordance to the profession of a European Authorized Representative.



Annex A* - List of Devices

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

No.	Catalogue reference number	Commercial name	Generic Device Term	Short description and intended use	GMDN/EDMS code	Class**
1	DVAG10	Acco Dengue NS1 Ag	Dengue NS1 Ag Rapid Test	Detection of dengue virus NS1 Antigen	0	Others
2	DVAB10	Acco Dengue IgG/IgM Ab	Dengue IgG/IgM Ab Rapid Test	Detection of IgG and IgM against dengue virus type I, II, III, and IV	0	Others
3	DVC010	Acco Dengue IgG/IgM-NS1 Combo	Dengue IgG/IgM-NS1 Combo Rapid Test	Detection of both Dengue Antigen & primary / secondary infection	0	Others
4	MAAG10	Acco Malaria Pf/Pan	Malaria Pf/Pan Ag Rapid Test	Detection of histidine-rich protein 2 (HRP2) antigen and plasmodium lactate dehydrogenase (pLDH)	0	Others
5	SYP010	Acco Syphilis	Treponema pallidum Antibody Rapid Test	Detection of anti-TP antibody	30828	Others
6	ZIKA011	Acco Zika IgG/IgM	Zika IgG/IgM Rapid Test	Detection of immunoglobulin G (IgG) and immunoglobulin M (IgM) against zikavirus.	0	Others
7	ZIKA010	Acco Zika NS1 Ag	Zika NS1 Ag Rapid Test	Detection of zikavirus NS1 antigen	0	Others
8	HCG010	Acco hCG	Pregnancy, hCG Rapid test over the counter	Detection of pregnancy	40155	Others

* Annex A is part of the Agreement

** The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (IVD 98/79/EC).

Manufacturer's Name
ACCOBIOTECH SDN BHD

Obelis S.A.

Name: SIVALINGAM A/L RAJAGOPAL
CHIEF EXECUTIVE OFFICER

Position: _____

Signature: 



Signature: _____

Date: 18/09/2017

Stamp: 

Obelis s.a.
Registered Address:
Bld Général Wahis 53
1050 Bruxelles
Tel: +32 2 732 59 54 - Fax: +32 2 712 60 03
S. FERRETTI
C.C.O.

ACCOBIOTECH SDN. BHD.

TECHNICAL DOCUMENTATION

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No. 11 Jalan Bukit 27, Masai Industrial Park,
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Tel: +607-382 1077, Fax :+607-3821717



Doc. No. Acco-TCF-100-01/ Rev. No.O

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.

PLANT MASTER FILE

Sr. No.	Requirements	Information
A	GENERAL INFORMATION	
I	<p>Brief information on the site (including name and address), relation to other sites</p>	<p>1) Manufacturer Information</p> <p>AccoBiotech is the innovative & research-orientated diagnostic company in Malaysia. The institute for AccoBiotech Sdn Bhd was established at 2006 and then, the company was established at October 2012 having lots of R&D strength. For these reasons, AccoBiotech Sdn Bhd is very strong activities on the R&D, production, and quality control. AccoBiotech Sdn Bhd. is very famous and one of well-known biotechnology company. Now, AccoBiotech Sdn Bhd is the leading manufacturer of various in vitro diagnostic products, especially various rapid diagnostic tests known as Acco brand name.</p> <p>Our products such as raw materials and unfinished ones, AccoBiotech, have been popularly sold in the domestic market and also it is exported to various countries due to its high accuracy and innovative technologies for end users. AccoBiotech Sdn Bhd. have aggressively developed many special devices and produced those IVD kits under Good Manufacturing Practices (GMP) system. Thus, AccoBiotech Sdn Bhd. is very confident on that its quality and user-oriented service.</p> <p>2) Main Locations/ Address</p> <p>No 11, Jalan bukit 27, Masai Industrial Park, Bandar Seri Alam, 81750 Masai, Johor</p>

	<p>Manufacturing activities as licensed by the Competent Authorities.</p>	<p>1. Foreign Approval</p> <ul style="list-style-type: none"> ☐ Certificate of CE (IVD) Notification – by Obelis European Authorized Representative Center ☐ E.A.R Certificate - by Obelis European Authorized Representative Center <p>2. Local Approval</p> <ul style="list-style-type: none"> ☐ Establishment License – by MDA ☐ Manufacturing License – by Ministry of International Trade and Industry of Malaysia ☐ ISO 13485: 2003 – by CARE Certification International (M) Sdn. Bhd.
<p>III</p>	<p>Any other operations carried out on the site</p>	<p style="text-align: center;">NOT APPLICABLE</p>
<p>IV</p>	<p>Name and exact address of the site, including telephone, fax numbers, web site URL and e-mail address</p>	<p style="text-align: center;">1. AccoBiotech Sdn Bhd</p> <p>(No 11, Jalan bukit 27, Masai Industrial Park, Bandar Seri Alam, 81750 Masai, Johor)</p> <p>2. TEL : 07-3821077/1771</p> <p>FAX : 07-3821717</p> <p>E-mail : info@acobiotech.com</p>

V	Type of medical devices handled on the site and information about specifically toxic or hazardous substances handled, mentioning the way they are handled and precautions taken	In-Vitro diagnosis <input type="checkbox"/> Rapid test kit <input type="checkbox"/> Rapid diagnosis test <input type="checkbox"/> Point – of – care
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<p>VI</p>	<p>Short description of the site (size, location and immediate environment and other activities on the site)</p>	<p>PRIVATE & CONFIDENTIAL</p>		
<p>VII</p>	<p>Number of employees engaged in Production, Quality Control, warehousing, and distribution.</p>	<p>Area of Operation</p>	<p>No. Of Permanent / Regular Employee</p>	<p>No. of Contractual employee</p>
		<p>1. Production</p>	<p>10</p>	<p>35</p>
		<p>2. Quality Control</p>	<p>3</p>	<p>-</p>
		<p>3. Warehousing</p>	<p>2</p>	<p>-</p>
		<p>4. Storage</p>	<p>2</p>	<p>-</p>
		<p>5. Distribution</p>	<p>2</p>	<p>-</p>
		<p>6. Technical & Engineering Support Services</p>	<p>2</p>	<p>-</p>
		<p>Total of the above</p>	<p>21</p>	<p>35</p>
<p>VIII</p>	<p>Use of outside scientific, analytical or other technical assistance in relation to the design, manufacture and testing.</p>	<p>NOT APPLICABLE</p>		

IX	Short description of the quality management system of the company	1. Quality Policy Accobiotech Sdn Bhd is committed to comply with ISO 13485 & applicable regulatory requirements, and maintain the effectiveness of the quality management system.
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		<p>☐ We strive to deliver quality & safe products to our customer. Excellent customer service and customer satisfactory is our mission.</p> <p>☐ The policy will be communicated and reviewed for continuing suitability.</p> <p>2. Quality Assurance function</p> <p>☐ To ensure the monitoring and measurement are carried out and are carried out in a manner that is consistent with the monitoring and measuring requirements</p> <p>*ISO 13485: 2003 – by CARE Certification International (M) Sdn. Bhd.</p>
X	Devices details registered with foreign countries	NOT APPLICABLE
XI	Brief description of testing laboratory	NOT APPLICABLE
B	PERSONNEL	
I	Organisation chart showing the arrangements for key personnel	*Attached in the end of the Master File
II	Qualifications, experience and responsibilities of key personnel	<p><u>CEO</u></p> <p><u>Qualification / Experience</u></p> <ol style="list-style-type: none"> 1. Degree in any discipline 2. Minimum 10 years working experience in the same industry

		<p><u>Job Description</u></p> <ol style="list-style-type: none">1. Decision making for company2. Sign cheque and authorize official documents.3. Setting directions, policy and guidelines <p style="text-align: center;"><u>MEDICAL ADVISOR</u></p> <p><u>Qualification / Experience</u></p> <ol style="list-style-type: none">1. Educational : minimum MD, PhD or PharmD2. Experience : Minimum five (5) year in similar capacity/field. <p style="text-align: center;"><u>Job Description</u></p> <ol style="list-style-type: none">1. To assemble and manage key opinion leader advisory groups for each product.2. To represent the company via teaching skills and presentations of groups of experts, societies, regulatory bodies, public events and at international meetings in a professional manner.3. To establish ongoing liaison with key opinion leaders, government officials, senior staff, and health care organizations to ensure that significant developments in the field are identified and monitored. <p style="text-align: center;"><u>ADMINISTRATION MANAGER</u></p> <p><u>Qualification / Experience</u></p> <ol style="list-style-type: none">1. Minimum degree2. Minimum three (3) years in similar capacity/field. <p style="text-align: center;"><u>Job Description</u></p> <ol style="list-style-type: none">1. Reporting to CEO.2. Responsible for total human resources spectrum of the company.3. Supporting management to achieve company's goal and targets.4. Drive, train and profile cases such as labor office case, court case, workers union matter, audits, etc. where subordinates are incapable to deal with.5. To assist CEO on his task to manage the company
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		<p style="text-align: center;"><u>SALES DIRECTOR</u></p> <p><u>Qualification / Experience</u></p> <ol style="list-style-type: none"> 1. Minimum Degree 2. Five (5) years of related experience with progressive management experience. <p><u>Job Description</u></p> <ol style="list-style-type: none"> 1. Developing strategy, tactics, sales plans and profit targets 2. Developing relationships with clients 3. Identifying and reporting on business opportunities in target markets <p style="text-align: center;"><u>OPERATION MANAGER</u></p> <p><u>Qualification / Experience</u></p> <ol style="list-style-type: none"> 1. Educational : Minimum Degree. 2. Experience : Minimum three (3) year in similar capacity/field. <p><u>Job Description</u></p> <ol style="list-style-type: none"> 1. Reporting to CEO. 2. Responsible for production operation matters. 3. To overview operation of respective production requirements such as line productivity, efficiency, quality, yield and machines utilization. 4. To responsible for performance such as quality system, products quality, delivery performance, technical competency of the team, etc. 5. To initiate improvement plan based on customers' feedback, internal quality audits, line performances, etc.
<p style="text-align: center;">III</p>	<p>Outline of arrangements for basic and in-service training and how records are maintained</p>	<p>Accobiotech regularly organizes education of the employees through different seminars and training courses and different experiences are constantly exchanged and implemented in the area of production with other companies that have achieved progress in the selected area. The training and the education is conducted by selected person responsible for education, who has qualifications and knowledge of the education area. The education is obligation for each employee and depends from the degree of development of the company in the area of GMP and GLP standards.</p>

IV	Health requirements for personnel engaged in production	Each employee is obligated, prior to getting employed, to undergo medical checkup determining his/her health capability to perform the assigned job in pharmaceutical industry. Further on, all employees are obliged to undergo medical check-ups every three years. Each employee coming in direct contact with product during the job performance is obliged to undergo the sanitary inspection, prior to getting employed. Consequent regular sanitary inspections are carried out according to the plan and program related to current year, and in compliance with Plan and Program of Work Safety in Quality Management and Environmental Management Sector.
V	Personnel hygiene requirements, including clothing.	Personnel working in the manufacturing plant should wear the clean working clothes, trousers, blouses, gloves, caps, masks, clogs, in accordance with procedure. Working clothes and their quality should be appropriate for the work process and working environment to enable product's safety from contamination. Use and changing frequency are proscribed in the procedures. All personnel is well acquainted with hygienic standards required in pharmaceutical production in individual hygienic zones. Every person is expected to come to work clean, tidy and healthy. In manufacturing and laboratory spaces, consumption and keeping of food and drinks as well as smoking are prohibited. Direct contact between operator's hands and starting materials, intermediaries, parts of equipment coming in direct contact with product, is not allowed.
C	PREMISES AND FACILITIES	
I	Layout of premises with indication of scale	<p>Work Environment</p> <ul style="list-style-type: none"> ☐ The room is a controlled room with controlled temperature between 2°C - 3°C and monitored by using thermometer.

		<p>☐ The cabinet is a controlled environment with controlled humidity between 20% - 25% RH and monitored by using hygrometer.</p>
II	<p>Nature of construction, finishes/fixtures and fittings.</p>	<p>Accobiotech produces rapid test kits. Our production line is implemented in the first floor of the factory. All standards are obtained. The used materials meet the requirements of GMP standards, with which the required quality of the product is obtained. The walls are made from special materials (multi layer laminates) and the finishes are treated with temperature-resistant and chemical-resistant material, which allow quality maintenance of the purity of the area. The finishes of the angles and the edges are made from rubber silicone materials, with which is formed unity of the area. The floors are molded with PVC material with thickness from 10 mm. The air is treated through HVAC unit where is heated or cooled, humidified or dehumidified, filtered and let into the manufacturing areas through absolute filters. When passing through the exhaust units, the air is filtered and exhausted in the environment. The number of changes of the air is appropriate for the area of the production. Each HVAC unit is conducted with control of the system and with regular change of the filter. The air of the manufacturing area is removed with extracting AHU systems and is released in the atmosphere, without mixing with the fresh air. The temperature is maintained on 2°C -32°C and the humidity on 20% RH ± 25% RH.</p>



<p>III</p>	<p>Brief description of ventilation systems. More details should be given for critical areas with potential risks of airborne contamination (including schematic drawings of the systems). Classification of the rooms used for the manufacture of sterile products should be mentioned</p>	<p>Accobiotech produces rapid test kits. Our production line is implemented in the first floor of the factory. All standards are obtained. The used materials meet the requirements of GMP standards, with which the required quality of the product is obtained. The walls are made from special materials (multi layer laminates) and the finishes are treated with temperature-resistant and chemical-resistant material, which allow quality maintenance of the purity of the area. The finishes of the angles and the edges are made from rubber silicone materials, with which is formed unity of the area. The floors are molded with PVC material with thickness from 10 mm. The air is treated through HVAC unit where is heated or cooled, humidified or dehumidified, filtered and let into the manufacturing areas through absolute filters. When passing through the exhaust units, the air is filtered and exhausted in the environment. The number of changes of the air is appropriate for the area of the production. Each HVAC unit is conducted with control of the system and with regular change of the filter. The air of the manufacturing area is removed with extracting AHU systems and is released in the atmosphere, without mixing with the fresh air. The temperature is maintained on 2°C -32°C and the humidity on 20% RH ± 25% RH.</p>
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IV	Special areas for the handling of highly toxic, hazardous and sensitizing materials	NOT APPLICABLE
V	Brief description of water systems (schematic drawings of the systems are desirable) including sanitation	The system is designed and executed according to GMP requirements enabling the produced purified water quality to meet the requirements.
VI	Maintenance (description of planned preventive maintenance programmes for premises and recording system)	<ul style="list-style-type: none"> ☐ All equipment are monitored in daily, weekly and monthly basis. ☐ The findings are reported and noted accordingly
D	EQUIPMENT	

I	<p>Brief description of major production and quality control laboratories equipment (a list of the equipment is required)</p>	<ul style="list-style-type: none"> ☐ Cutter ☐ Sealer ☐ Assembly ☐ Printing ☐ Weighing
II	<p>Maintenance (description of planned preventive maintenance programmes and recording system).</p>	<ul style="list-style-type: none"> ☐ All equipment are monitored in daily, weekly and monthly basis. ☐ The findings are reported and noted accordingly
III	<p>Qualification and calibration, including the recording system. Arrangements for computerized systems validation.</p>	<p>Review the calibration results for the following criteria :</p> <ul style="list-style-type: none"> a. Calibration Due date b. Calibration standard – must be traceable to international / national standard, if no standard exist based on manufacturer recommendation
E	<p>SANITATION</p>	
I	<p>Availability of written specifications and procedures for cleaning the manufacturing areas and equipments.</p>	<p>Cleaning procedures for manufacturing areas and equipment are defined in SOPs. Preparing of cleaning material and cleaning techniques are précised within the SOP. Kinds of cleaning agents and their preparation (specific concentration), as well as cleaning frequency are defined in SOPs.</p>

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F	PRODUCTION

	Brief description of production operations using, wherever possible, flow sheets and charts specifying important parameters	Production is performed in compliance with approved technological procedure. Detailed description of manufacturing procedure together with critical points of process are given in master formula. Production is carried out and headed by competent personnel. During production, the batch production and batch packaging records are filled in. Individual phases, including key parameters, are controlled and documented by in- process control. Separate appropriate procedures are followed for handling of the raw materials, packaging materials and finished products, from taking samples and their final storage.
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II	<p>Arrangements for the handling of starting materials, packaging materials, bulk and finished products, including sampling, quarantine, release and storage.</p>	<p>Receipt, storage and approving of raw materials are carried out in accordance with Good Storing Practice (GSP) and Good Manufacturing Practice (GMP) and in accordance with SOPs.</p> <p>Receipt of raw materials is carried out by competent personnel in compliance with written procedures in Raw Materials Warehouse.</p> <p>The procedure's requirements are as follows:</p> <ul style="list-style-type: none"> ▣ checking of compliance for shipment, delivery note (for domestic supplies), invoice (for international supplies), certificate and purchase order; these checks are carried out in area intended for receipt ▣ labeling of raw materials and moving into the quarantine area ▣ request for analysis to the appropriate personnel <p>Sampling is performed following the written instruction in the SOP.</p> <p>Report on raw materials quality (approval or refusal to use the raw materials) after analysis of samples made in accordance with specifications is issued.</p>
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		<p>Approved materials are labeled and transferred to intermediate storage within raw materials warehouse.</p> <p>Raw materials can be handed out on material requisition slip only and it refers to one batch of raw materials only.</p>
III	Arrangements for reprocessing or rework	<p>Mode of handling the product which is not meeting the specified quality and nevertheless found in the market and thus must be withdrawn from the market, is described in details in respective procedure. The procedure involves persons responsible for decisions on recall, reports and coordination of the recall. Recall is done when quality of products (for example, damaged device, result appearance, packaging, expiry date, etc.) does not comply with defined requirements according to information obtained on the basis of: postproduction inspection of device, claim of buyer, or any other external client. Decision on recall is taken by The CEO.</p>
IV	Arrangements for the handling of rejected materials and products	<p>Products withdrawn from the market are stored in separate dedicated area marked with RECALLED PRODUCTS and recall. Recalled products in all recalling phases must be handled in such a way not allowing for repeated distribution. Recalled products must be destroyed (transferred into Pharmaceutical waste storage). The documentation regarding decisions and execution of recall is kept. The period for keeping of documentation in recall is one year after expiry date of product being subject of the recall.</p>
V	Brief description of general policy for process validation	<p>Process validation is precised within the SOP.</p>
VI	Brief description of sterilization facility	<p>Sterilization Process validation is precised within the SOP.</p>

G	QUALITY ASSURANCE	
I	Description of the Quality assurance system and of the activities of the Quality assurance Department. Procedures for the release of finished products.	Quality Control is a part of GMP in handling sampling, specifications and testing, as well as organizing, documenting and approving of procedures providing that necessary and appropriate tests are carried out and that materials are not released for usage or products for sales or supplies until their quality is ascertained to be satisfactory.
H	STORAGE	
I	Policy on the storage of medical device	Storing conditions for our device are as follows: <ul style="list-style-type: none"> ▣ 2°C to 30°C (38-86°F).
I	DOCUMENTATION	
I	Arrangements for the preparation, revision and distribution of necessary documentation, including storage of master documents	Documentation system in AccoBiotech is in compliance with GMP requirements of ISO 13485 : 2003 and it represents a significant element of quality management and environmental management. <ul style="list-style-type: none"> ▣ Quality Manual & Procedure (Flowchart) ▣ SOP / WI /Spec / Drawing / Quality Plan ▣ Forms Master List <p>In AccoBioetch there is an established and documented system of documentation control, covering systemic, process and external documentation.</p>



		<p>Internal and external documentation is recorded in the Master Documentation List with the employee in charge of documentation. All activities related to issuing, approving, revising and filling of documentation and data are defined in documented procedure and instructions.</p> <p>Documents are stored in various places, depending on nature of document.</p>
J	MEDICAL DEVICE COMPLAINTS AND FIELD SAFETY CORRECTIVE ACTION	
I	Arrangements for the handling of the complaints	*Attached in the end of the Master File
II	Arrangements for the handling of field safety corrective action.	*Attached in the end of the Master File
K		
	INTERNAL AUDIT	



I	<p>Short Description of the internal audit system</p>	<p>Internal inspection covers all activities inside and outside AccoBiotech that can have impact on quality of product and level of fulfillment of GMP requirements, legal and other regulations related to drug manufacturers. Inspection areas are the areas foreseen in GMP, i.e.: personnel, areas, equipment, documentation, production, quality control, distribution of products, claims and recalls settlement, as well as inspection with raw materials suppliers and in-bulk product suppliers.</p> <p>Internal inspection is carried out according to annual plan of internal inspection and exceptionally, it can be made upon request of Manager. Results of internal inspection are given in internal inspection reports. Reports on inspection including proposed corrective actions, terms and persons in charge, verified by internal inspector, are delivered to the company's Manager.</p>
L	<p>CONTRACT ACTIVITIES</p>	
I	<p>Description of the way in which the compliance of the contract acceptor is assessed</p>	<p>NOT APPLICABLE</p>

ACCOBIOTECH SDN. BHD.

I2: Procedure

CORRECTIVE & PREVENTIVE ACTION, CUSTOMER AND MEDICAL DEVICE COMPLAINT

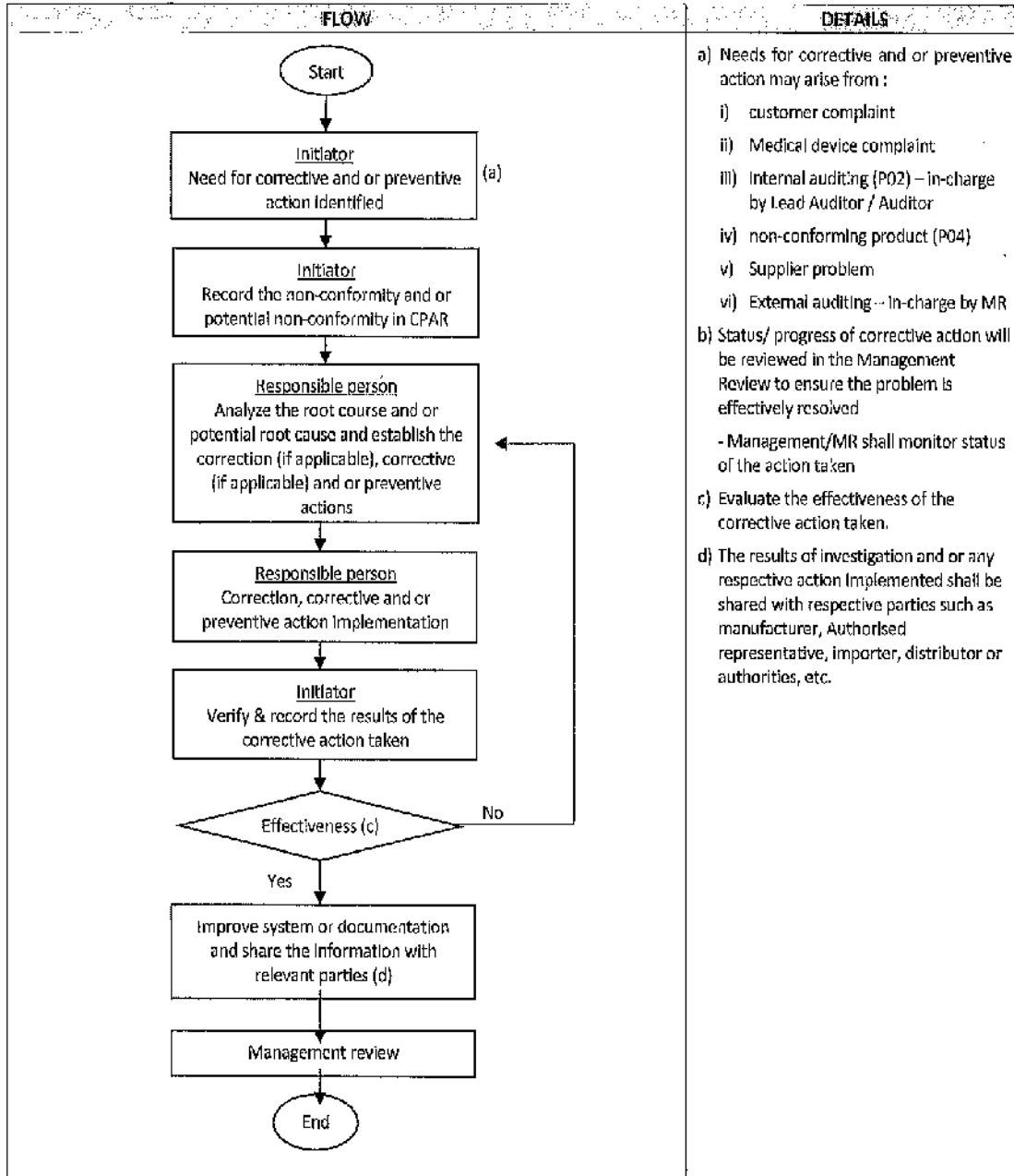
Doc. No.: P04

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PURPOSE: To eliminate the cause and or potential cause of non-conformities and or potential non-conformities in order to prevent recurrence and or occurrence.

SCOPE: This shall be applicable to product, process and quality system non-conformity.



GENERAL DESCRIPTION OF THE DEVICE

0.1. The name of the device

Acco COVID-19 IgM/IgG

0.2. The variants

Product Name	Contents	Number
Acco COVID-19 IgM/IgG - Cat.No.ACOV2015	Acco COVID-19 IgM/IgG test device	10 ea
	Assay buffer in dropping bottle	1 ea
	Capillary tube for sample loading	10 ea
	Instructions for use	1 sheet

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

0.3. 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)

0.4. Additional special equipment

N/A

0.5. The microbiological state if appropriate

N/A

INTENDED USE

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

0.6. 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.

0.7. History of the product

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), previously known by 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 evidence of community transmission of the disease.

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.

PROTOCOL

0.8. Materials provided

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

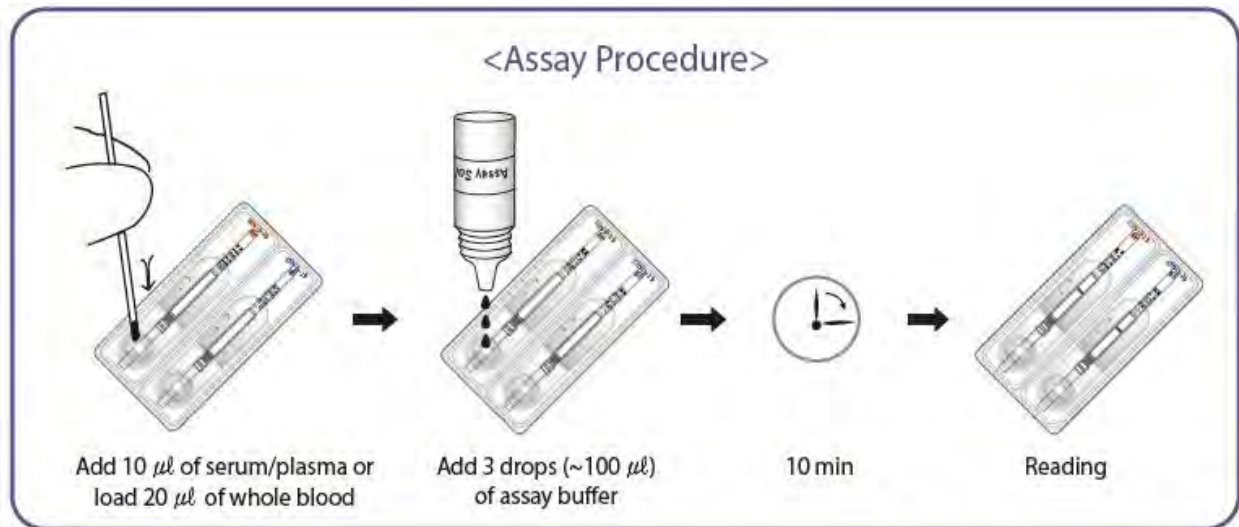
Contents	No of N
Acco COVID-19 IgM/IgG test device	10 ea
Assay buffer in dropping bottle	1 ea
Capillary tube for sample loading	10 ea
Instructions for use	1 sheet

0.9. 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.

0.10. Test procedure

- (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.



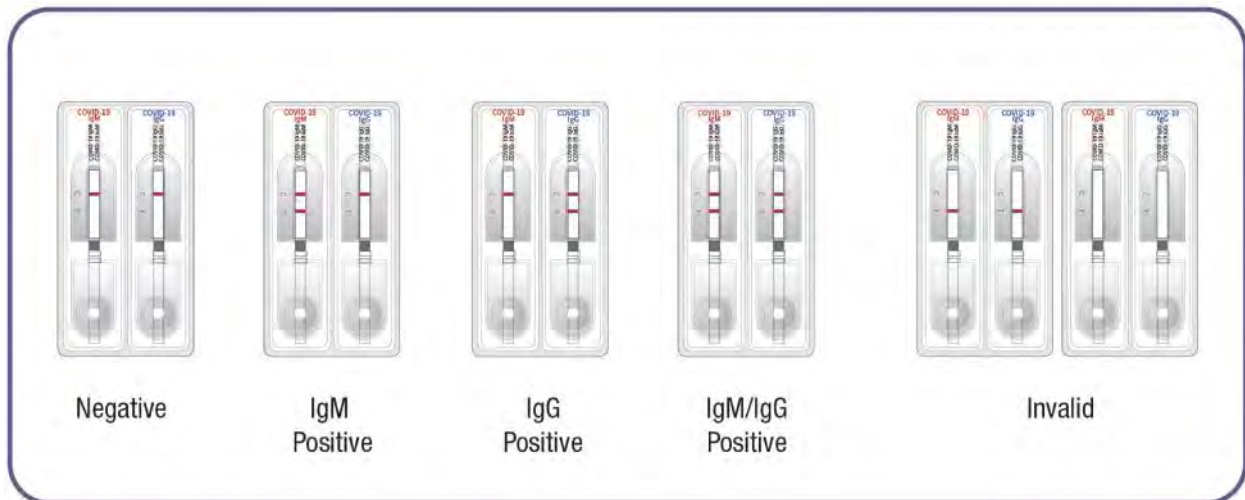
0.11. Reading and interpretation of results

[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.
- (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.



0.12. 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.

0.13. 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.

0.14. Precautions

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

Performance Evaluation

(Test Results)

Product:	Acco COVID-19 IgM/IgG
Date:	2020-03-02

Prepared by / date	Reviewed by / date	Approved by / date
Researcher	R&D Director	QMR
Lee Jihoo	C.K.Chong	Jung Young Choi

Revision history

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

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. : [요약]
- Batch No : 3 Lots (ACOV2015)

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

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

ANALYTICAL PERFORMANCE EVALUATION

1.1 Analytical Sensitivity / Reference Material

1.1.1 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
- Result analysis

Lot	Smample	type	ELISA (s/CO)	FJ001
		Serial dliution		
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: positive result, Neg: negative result

1.1.2 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**.

1.2 Analytical Specificity

1.3 Analytical Specificity(Interfering substances testing)

1.3.1 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

1.3.2 Results

Sample name	Compound	Concentration(mg/dL)	Only positive	Positive sample	Negative sample
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			sample		+ Material		+ 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			+	+	+	+	+	+

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

1.3.3 Conclusion

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

1.4 Cross-reactivity

1.4.1 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.

1.4.2 Result

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

1.4.3 Conclusion

Other pathogens cell should not be affected to its reactions.

1.5 Whole System Failure

1.5.1 Protocols

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

1.5.2 Results

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

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

1.5.3 Conclusion

100 sample were detected at Whole system Failure test

1.6 Precision assay

1.6.1 Protocols

- Test purpose: To determine the variation for multiple results of samples (same concentration)

- Material: each sample spiked in matrix. Samples concentration below 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.: ACOV2015)
- 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

1.6.2 Results

- Precision : Results was determined within intensity

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

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

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

Positive signal: + Negative signal: -

1.7 Reproducibility / Inter-Operator

1.7.1 Protocols

- Test purpose: Experiment was performed by different operators within one laboratory)
- Material: each sample spiked in matrix. Sample concentration below 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. : [범주])
- Protocol: Followed by Acco COVID-19 IgM/IgG manual
- of Quantitative Measurement Method ; Approved Guideline-Second Edition, EP05-A3, NCCLS

1.7.2 Test Result

- Results was determined within intensity

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

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: -

1.8 Reproducibility / Inter-site

1.8.1 Protocols

- Test purpose: Experiment was performed by different sites within two laboratory
- Material: each materials spiked in matrix. Material concentration below 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. : [범주])
- 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

1.8.2 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	+	+	+	+

Day 3				
-------	--	--	--	--

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

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

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

Positive Signal: + Negative signal: -

1.9 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

CLINICAL EVALUATION/DIAGNOSTIC SENSITIVITY & SPECIFICITY

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.

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 overall diagnostic performance was the below;

- **Sensitivity= 100% (25/30 for IgM + 30/30 for IgG)**
- **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 overall sensitivity and specificity of Acco COVID-19 IgM/IgG was 100% and 99.5%, respectively, comparing with molecular testing (RT-PCR).

[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
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
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
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.

SPECIFICATION OF MATERIALS

Product:	Acco COVID-19 IgM/IgG
Date:	2020-03-02

Prepared by / date	Reviewed by / date	Approved by / date
Researcher	R&D Director	QMR
Lee Jihoo	C.K.Chong	Jung Young Choi

Revision history



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

Specify:

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1. **Materials used (characterize all starting material, e.g. chemical name)**
2. **Biological Safety**

2.1. MSDS

1. Product and Company Information			
Product Name: Acco COVID-19 IgM/IgG			
Product Number: ACOV2015			
Company: Accobiotech.			
Address: Accobiotech.			
No. 11 Jalan Bukit 27, Masai Industrial Park, Bandar Seri Alam 81750, Masai, Johor, MALAYSIA			
2. Composition/Information on Ingredient			
Hazardous/Non-hazardous Components			
Chemical Name	CAS No.	EEC No.	Weight %
Sodium azide	26628-22-8	247-852-1	≤ 0.1 %
3. Hazards Identification.			
The product is classified and labeled in accordance with Directive 1272/2008/EC.			
Classification			
Indication of danger			
Warning			
 			
Hazard Statement			
H300: Fatal if swallowed			
H410: Very toxic to aquatic life with long lasting effects			
EUH032: Contact with acids liberates very toxic gas			
Precautionary Statement			
P273: Avoid release to the environment			
P308+P310: IF exposed or concerned: immediately call a POISON CENTER or doctor/physician			
4. First Aid Measures.			
Inhalation	: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.		
Ingestion	: Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything mouth to an unconscious person. If large quantities of		

	<p>this material are swallowed, call a physician immediately. Loosen tight clothing such as a collar, tie, belt or waistband.</p> <p>Skin Contact : In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Cold water may be used. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention.</p> <p>Eye Contact : Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water at least 15 minutes. Cold water may be used. Get medical attention.</p>
5. Fire Fighting Measures.	
Extinguishing Media	
Suitable	: Not applicable. Use an extinguishing agent suitable for surrounding fires.
Flammability of the Product	: Non-flammable.
Autoignition Temperature	: Not applicable.
Flash Points	: Not applicable.
Flammable Limits	: Not applicable.
Fire Hazards in Presence of Various Substances	: Not applicable.
Explosion Hazards in Presence of Various Substances	: Not considered as a product presenting risks of explosion.
Special Remarks on Fire Hazards	: Not available.
6. Accidental Release Measures	
Environmental and Clean-up Methods	Precautions : Absorb with an inert material and put the spilled material in an appropriate waste disposal. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.
Small Spill and Leak	: Dilute with water and mop up, or absorb with an inert dry material and place in an appropriate waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.
7. Handling / Storage	
Handling	: Avoid breathing vapors or spray mists.
Storage	: Keep container tightly closed. Keep container in a cool, well-ventilated area.

8. Exposure Controls / Personal Protection

Engineering measures : Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective occupational exposure limits.

Personal protective equipment

Skin and Body : Lab coat.
Hands : Gloves.
Eyes : Safety glasses.
Feet : Not applicable

Personal Protection in Case of a Large Spill : Splash goggles. Full suit. Boots. Gloves. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Consult local authorities for acceptable exposure limits.

9. Physical / Chemical Properties

Physical state : Liquid.
Color : Colorless.
Odor : Not available.
Odor Threshold : Not available.
Taste : Not available.
Molecular Weight : Not applicable.
Molecular Formula : Not applicable.
pH :: Neutral
Boiling Point : The lowest known values is 100°C (212°F)(water)
Melting Point : May start to solidify at 0°C (32°F) based on data for: water.
Critical Temperature : The lowest known value is 374.3°C(705.7°F)(water).
Vapor Pressure : The highest known value is 3.2 kPa (23.8 mmHg) (at 20°C)
Volatility : 0%(w/w). (water). Weighted average: 0%(w/w).
VOC : -90°C(%).
Evaporation rate : 0.36 (water) compared to (n-butyl acetate= 1).
Specific Gravity : Not available.
Solubility : Easily soluble in cold water, hot water, methanol, acetone.
Ionicity (in Water) : Amphoteric. (water).
Dispersion Properties : See solubility in water, methanol, acetone.
Physical Chemical : Not available.

Comments

10. Stability / Reactivity

Stability : The product is stable.
Hazardous Decomposition Products : Not applicable.
Hazardous Polymerization : Will not occur.
Explosion Hazards in Presence of Various Substances : Not considered as a product presenting risks of explosion.

11. Toxicological Information

Acute toxicity

Chemical Name	LD50(oral, rat/mouse)	LD50(dermal, rat/rabbit)	LC50(inhalation, rat/mouse)
Sodium azide	No data available	Rabbit: 20 mg/kg	Rat: 37 mg/m ³
Water, Distilled	No data available	No data available	No data available

Principle Routes of Exposure/

Potential Health effects

Eyes: May cause eye irritation with susceptible persons.

Skin: May cause skin irritation in susceptible persons.

Inhalation: see the table

Ingestion: No information available

Specific effects

Carcinogenic effects: No information available

Mutagenic effects: No information available

Reproductive toxicity: No information available

Sensitization: No information available

Target Organ Effects: Eyes. Skin.

12. Ecological Information

Ecotoxicity effects: No information available.

Mobility: No information available.

Biodegradation: No information available.

Bioaccumulation: No information available.

13. Disposal Considerations

Methods of disposal; Waste of residues; Contaminated packaging : Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Waste Stream : Not available.

Consult your local or regional authorities.

14. Transport Information

IATA

Proper shipping name: Not classified as dangerous in the meaning of transport regulations

Hazard Class: No information available

Subsidiary Class: No information available

Packing group: No information available

UN-No: No information available

15. Regulatory Information

Chemicals known to cause cancer:

None of the ingredients is listed.

Chemicals known to cause reproductive toxicity:

None of the ingredients is listed

Carcinogen categories

EPA (Environmental Protection Agency):

None of the ingredients is listed

IARC (International Agency for Research on Cancer):

None of the ingredients is listed

NTP (National Toxicology Program) :

None of the ingredients is listed

TLV(Threshold Limit Value established by ACGIH) :

None of the ingredients is listed

MAK(German Maximum Workplace Concentration) :

None of the ingredients is listed

NIOSH-Ca(National Institute for Occupational Safety and Health) :

None of the ingredients is listed

OSHA-Ca(Occupational Safety & Health Administration) :

None of the ingredients is listed

Hazard-determining components of labelling :

sodiumazide

Risk phrases:

Harmful if swallowed

safety phrases:

This material and its container must be disposed of in a safe way.
Wear suitable protective clothing.
If swallowed, seek medical advice immediately and show this container or label.
National regulations:
Water hazard class: Generally not hazardous for water.

16. Other Information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guideline of ACCO. shall not be held liable for any damage resulting from handling or from contact with above product. Final determination of suitability of any material is the sole responsibility of user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that are the only hazards that exist.

3. Information on the conditions in which it was collected

N/A

4. Information on possible risks

N/A



NO 11 Jalan Bukit 27, Masai Industrial Park, Bandar Seri Alam, 81750 Masai, Johor.
Tel No : +607 -3821077 Fax No : +607-3821717, info@accobiotech.com

MATERIAL SAFETY DATA SHEET

Printing data: 12/05/2019 Reviewed on : : 12/05/2019

1. Product and Company Identification

Product name :

DIAGNOSTIC TEST KIT

Application of the Product: Clinical Laboratory Application

Manufacturer/Supplier : AccoBiotech Sdn Bhd

No. 11, Jalan Bukit 27, Masai Industrial Park, Bandar Seri Alam,
81750 Masai, Johor Darul Takzim, Malaysia.

TEL: +607-3821077

FAX: +607-3821717

2. Composition/Information on Ingredients

Name	CAS#	% by weight	Exposure Limits
Sodium azide	26628-22-8	<1.00%	-

3. Hazards Identification

Physical State and Appearance	: Liquid.
Emergency	: No specific hazard.
Routes of Entry	: Absorbed through skin. Inhalation. Ingestion.
Skin Contact	: Irritation of the product in case of skin contact: Not available. Sensitization of the product: Not available.
Aggravating conditions	: Repeated or prolonged exposure is not known to aggravate medical condition.
Potential Chronic Health Effects	: <u>Carcinogenic effects:</u> Classified None. by OSHA, None. by NIOSH [Bovine Serum Albumin]. Classified None. by NIOSH [Sodium Phosphate (dibasic)]. Classified None. by NIOSH [Magnesium Nitrate]. Classified None. by NIOSH [Sodium Chloride]. Classified None. by NIOSH [Sodium Phosphate (monobasic)]. <u>Mutagenic effects:</u> Not available. <u>Teratogenic effects:</u> Not available.



NO 11 Jalan Bukit 27, Masai Industrial Park, Bandar Seri Alam, 81750 Masai, Johor.

Tel No : +607 -3821077 Fax No : +607-3821717, info@accobiotech.com

Overexposure : Not available

/Signs/Symptoms

See Toxicological Information (section 11)

4. First Aid Measures

Inhalation : If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Ingestion : Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately. Loosen tight clothing such as a collar, tie, belt or waistband.

Skin Contact : In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Cold water may be used. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention.

Eye Contact : Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water at least 15 minutes. Cold water may be used. Get medical attention.

5. Fire-Fighting Measures

Extinguishing Media

Suitable : Not applicable. Use an extinguishing agent suitable for surrounding fires.

Flammability of the Product : Non-flammable.

Autoignition Temperature : Not applicable.

Flash Points : Not applicable.

Flammable Limits : Not applicable.

Fire Hazards in Presence of Various Substances : Not applicable.

Explosion Hazards in Presence of Various Substances : Not considered as a product presenting risks of explosion.

Special Remarks on Fire Hazards : Not available.

6. Accidental Release Measures

Environmental Precautions and Clean-up Methods

Absorb with an inert material and put the spilled material in an appropriate waste disposal. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

Small Spill and Leak

: Dilute with water and mop up, or absorb with an inert dry material and place in an appropriate waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

7. Handling and Storage

Handling : Avoid breathing vapors or spray mists.

Storage : Keep container tightly closed. Keep container in a cool, well-ventilated area.

8. Exposure controls and Personal protection

Engineering measures : Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective occupational exposure limits.

Personal protective equipment

Skin and Body : Lab coat.

Hands : Gloves.

Eyes : Safety glasses.

Feet : Not applicable

Personal Protection in Case of a Large Spill : Splash goggles. Full suit. Boots. Gloves. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Consult local authorities for acceptable exposure limits.

9. Physical and Chemical Properties

Physical state : Liquid.

Color : Colorless.

Odor : Not available.

Odor Threshold : Not available.

Taste : Not available.

Molecular Weight	: Not applicable.
Molecular Formula	: Not applicable.
pH	:: Neutral
Boiling Point	: The lowest known values is 100°C (212°F)(water)
Melting Point	: May start to solidify at 0°C (32°F) based on data for: water.
Critical Temperature	: The lowest known value is 374.3°C(705.7°F)(water).
Vapor Pressure	: The highest known value is 3.2 kPa (23.8 mmHg) (at 20°C)
Volatility	: 0%(w/w). (water). Weighted average: 0%(w/w).
VOC	: -90°C(%).
Evaporation rate	: 0.36 (water) compared to (n-butyl acetate= 1).
Specific Gravity	: Not available.
Solubility	: Easily soluble in cold water, hot water, methanol, acetone.
Ionicity (in Water)	: Amphoteric. (water).
Dispersion Properties	: See solubility in water, methanol, acetone.
Physical Chemical Comments	: Not available.

10. Stability and Reactivity

Stability	: The product is stable.
Hazardous Decomposition Products	: Not applicable.
Hazardous Polymerization	: Will not occur.
Explosion Hazards in Presence of Various Substances	: Not considered as a product presenting risks of explosion.

11. Toxicological information

Chronic Effects on Humans	: <u>Carcinogenic effects</u> : Classified None. by OSHA, None. by NIOSH [Bovine Serum Albumin]. Classified None. by NIOSH [Sodium Phosphate (dibasic)]. Classified None. by NIOSH [Magnesium Nitrate]. Classified None. by NIOSH [Sodium Chloride]. Classified None. by NIOSH [Sodium Phosphate (monobasic)].
Other Toxic Effects on Human	: No specific information is available in our database regarding the other toxic effects of this material for humans.
Special Remarks on Toxicity to Animals	: Not available.
special Remarks on Chronic Effects on Humans	: Not available.

Special Remarks on Other Toxic Effects on Humans : Not available.

12. Ecological information

BOD and COD : Not available.
Biodegradable/OECD : Not available.
Mobility : Not available.
Products of Degradation : Not available.
Toxicity of the products of Biodegradation : Not available.
Special Remarks on the Products of Biodegradation : Not available.

13. Disposal considerations

Methods of disposal; Waste of residues; Contaminated packaging : Waste must be disposed of in accordance with federal, state and local environmental control regulations.
Waste Stream : Not available.
Consult your local or regional authorities.

14. Transport information

DOT regulations :
Hazard class : - None hazard
Land Transport ADR/RID (cross-border)
ADR. RID class : -
Maritime transport IMDG :
IMDG Class : - None hazard
Marine pollutant : No
Air transport ICAO-TI and IATA-DGR : None hazard
ICAO/IATA Class : - None hazard

15. Regulations

Chemicals known to cause cancer:
None of the ingredients is listed.
Chemicals known to cause reproductive toxicity:
None of the ingredients is listed



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Tel No : +607 -3821077 Fax No : +607-3821717, info@accobiotech.com

Carcinogenicity categories

EPA (Environmental Protection Agency):

None of the ingredients is listed

IARC (International Agency for Research on Cancer):

None of the ingredients is listed

NTP (National Toxicology Program) :

None of the ingredients is listed

TLV(Threshold Limit Value established by ACGIH) :

None of the ingredients is listed

MAK(German Maximum Workplace Concentration) :

None of the ingredients is listed

NIOSH-Ca(National Institute for Occupational Safety and Health) :

None of the ingredients is listed

OSHA-Ca(Occupational Safety & Health Administration) :

None of the ingredients is listed

Hazard-determining components of labelling :

sodium azide

Risk phrases:

Harmful if swallowed

safety phrases:

This material and its container must be disposed of in a safe way.

Wear suitable protective clothing.

If swallowed, seek medical advice immediately and show this container or label.

National regulations:

Water hazard class: Generally not hazardous for water.

16. Other information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guideline of AccoBiotech Sdn Bhd. shall not be held liable for any damage resulting from handling or from contact with above product. Final determination of suitability of any material is the sole responsibility of user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that are the only hazards that exist.

ACCO COVID-19 IgM/IgG

IVD

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

2020.02.24 (Rev.0)

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.

EXPLANATION OF THE TEST

The recombinant COVID-19 antigen was coated on the membrane and anti-human IgM and IgG monoclonal antibody was conjugated to 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. ACCO COVID-19 IgM/IgG can detect the antibodies against COVID-19, so that the device is suitable for the diagnosis of COVID-19 infections.

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

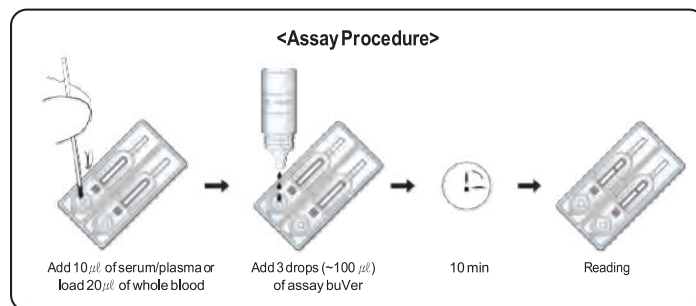
1. The presence of humidity may decrease the stability of the reagents. Thus, please carry out the test immediately after removing the device from the foil pouch.
2. Do not use the kit after the expiration date. Do not freeze the kit.
3. For in vitro diagnostic use only. Do not re-use the test device.
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 handling specimens.
7. Decontaminate and dispose of all specimens, in a biohazard container.

SPECIMEN COLLECTION AND STORAGE

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.

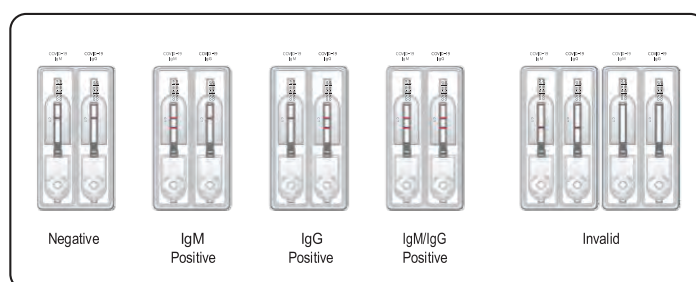
TEST PROCEDURE

1. Place all specimens, test devices, and assay solution at room temperature prior to testing (15-30min).
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.



INTERPRETATION OF THE 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.



[Use quantitative analyzer]

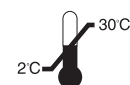
- Using Confiscope G20 is optional.
- Please refer to instructions for Use in the analyzer package.



Confiscope G20

STORAGE & EXPIRATION

1. ACCO COVID-19 IgM/IgG kit 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.



LIMITATIONS OF THE TEST

ACCO COVID-19 IgM/IgG is designed for the primary 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.

Manufactured & Sold By:



No. 11, Jalan Bukit 27, Masai Industrial Park,
Bandar Seri Alam, 81750, Masai, Johor, Malaysia
www.accobiotech.com

In Association with:



Malaysia Office:
B-3A-09, Megan Avenue II, No.12, Jalan Yap Kwan
Seng, 50450 Kuala Lumpur, Malaysia.
Head Quarters:
Lomond Court, Castle Business Park, Stirling,
Stirlingshire, FK9 4TU, United Kingdom.
www.srammram.com

Imported By

REF ACOV2015