



SUPERINTENDENCIA DE PENSIONES

5/5/2020

## OFERTA ECONÓMICA

Página 1 de 1

NOMBRE DEL OFERENTE: C.E.M CARIBBEAN EQUIPMENT MEDICAL S.R.L

Item No.	Descripción del Bien, Servicio u Obra	Unidad de medida <sup>1</sup>	Cantidad <sup>2</sup>	Precio Unitario	ITBIS	Precio Unitario Final
1	Pruebas Rápidas COVID-19 IgG/IgM Certificadas	1	100	RD\$ 1,435	RD\$ 258.30	RD\$ 1,693.30

**VALOR TOTAL DE LA OFERTA: 169,330 RD\$**

Valor total de la oferta en letras: CIENTO SESENTA Y NUEVE MIL TRESCIENTOS TREINTA 00/100

Emmanuela Navarro en calidad de Gerente debidamente autorizada para actuar en nombre y representación de C.E.M CARIBBEAN EQUIPMENT MEDICAL S.R.L

/UR.02.2011



Firma



5/5/2020

No. EXPEDIENTE

SIPEN-DAF-CM-2020-0009

DISTRIBUCION Y COPIAS  
Original 1 - Expediente de Compras  
Copia 1 - Agregar Destino





## SUPERINTENDENCIA DE PENSIONES

## FORMULARIO DE INFORMACIÓN SOBRE EL OFERENTE

## DIVISION DE COMPRAS Y CONTRATACIONES

Fecha: 5/5/2020

1. Nombre/ Razón Social del Oferente:	C.E.M CARIBBEAN EQUIPMENT MEDICAL S.R.L
2. Si se trata de una asociación temporal o Consorcio, nombre jurídico de cada miembro: <i>[indicar el nombre jurídico de cada miembro del Consorcio]</i>	
3. RNC/ Cédula/ Pasaporte del Oferente:	1-31-08474-5
4. RPE del Oferente:	37738
5. Domicilio legal del Oferente:	Calle Los Javillos, Edificio 5, 102, Los Prados
6. Información del Representante autorizado del Oferente:	<p>Nombre: Emmanuela Navarro</p> <p>Dirección: Calle Los Javillos, Edificio 5, 102, Los Prados</p> <p>Números de teléfono y fax 829-844-4159 / 809-864-4750</p> <p>Dirección de correo electrónico: <a href="mailto:info@caribbeanmedical.com">info@caribbeanmedical.com</a></p>



DISTRIBUCIÓN  
Original 1 – Expediente de Compras





SNCC.F.



No. EXPEDIENTE

SIPEN-DAF-CM-2020-0009

5/5/2020

SUPERINTENDENCIA DE PENSIONES

Página 1 de 2

### PRESENTACIÓN DE OFERTA

Señores

**C.E.M CARIBBEAN EQUIPMENT MEDICAL S.R.L**

Nosotros, los suscritos, declaramos que:

- a) Hemos examinado y no tenemos reservas a los Pliegos de Condiciones para la Licitación de referencia, incluyendo las siguientes enmiendas/ adendas realizadas a los mismos:

ADQUISICION DE PRUEBAS RAPIDAS DE COVID-19 PARA USO EN LA SUPERINTENDENCIA DE PENSIONES (SIPEN).

- b) De conformidad con los Pliegos de Condiciones y según el plan de entrega especificado en el Programa de Suministros/ Cronograma de Ejecución, nos comprometemos a suministrar los siguientes bienes y servicios conexos, o ejecutar los siguientes servicios u Obras:

Pruebas Rapidas COVID-19 IgG/IgM Certificadas.

Si nuestra oferta es aceptada, nos **comprometemos** a obtener una garantía de fiel cumplimiento del Contrato, de conformidad con los Pliegos de Condiciones de la Licitación, por el importe del **CUATRO POR CIENTO (4%)** del monto total de la adjudicación, para asegurar el fiel cumplimiento del Contrato.

- d) Para esta licitación no somos partícipes en calidad de Oferentes en más de una Oferta, excepto en el caso de ofertas alternativas, de conformidad con los Pliegos de Condiciones de la Licitación.
- e) Nuestra firma, sus afiliadas o subsidiarias, incluyendo cualquier subcontratista o **proveedor** de cualquier parte del Contrato, no han sido declarados inelegibles por el Comprador para **presentar ofertas**.



- f) Entendemos que esta Oferta, junto con su aceptación por escrito que se encuentra incluida en la notificación de adjudicación, constituirán una obligación contractual, hasta la preparación y ejecución del Contrato formal.
- g) Entendemos que el Comprador no está obligado a aceptar la Oferta evaluada como la más baja ni ninguna otra de las Ofertas que reciba.

**Emmanuela Navarro** en calidad de Gerente debidamente autorizada para actuar en nombre y representación de **C.E.M CARIBBEAN EQUIPMENT MEDICAL S.R.L**



Firma \_\_\_\_\_

Sello





## Año de la Consolidación de la Seguridad Alimentaria

CERTIFICACION No. 1601946

A QUIEN PUEDA INTERESAR

Por medio de la presente hacemos constar que en los registros de la Tesorería de la Seguridad Social, la empresa **C E M CARIBBEAN EQUIPMENT MEDICAL SRL** con RNC/Cédula 1-31-08474-5, a la fecha no presenta balance con atrasos en los pagos de los aportes a la Seguridad Social.

La presente certificación no significa necesariamente que **C E M CARIBBEAN EQUIPMENT MEDICAL SRL** haya realizado sus pagos en los plazos que establece la Ley 87-01, ni constituye un juicio de valor sobre la veracidad de las declaraciones hechas por este empleador a la Tesorería de la Seguridad Social, ni le exime de cualquier verificación posterior.

Esta certificación tiene una vigencia de 30 días, a partir de la fecha y se expide totalmente gratis sin costo alguno a solicitud de la parte interesada.

Dado en la ciudad de Santo Domingo, Republica Dominicana, a los 5 días del mes de Mayo del año 2020.

  
Sahadía E. Cruz Abreu  
Directora  
Dirección de Asistencia al Empleador

Para verificar la autenticidad de esta certificación diríjase a la siguiente dirección:  
<http://www.tss2.gov.do/sys/VerificarCertificacion.aspx>

E introduzca los siguientes datos:

- Código: 1601946-T1914434-52020
- Pin: 2205



NO HAY NADA ESCRITO DEBAJO DE ESTA LINEA



República Dominicana  
MINISTERIO DE HACIENDA  
**DIRECCIÓN GENERAL DE IMPUESTOS INTERNOS**  
RNC: 4-01-50625-4  
"AÑO DE LA CONSOLIDACIÓN DE LA SEGURIDAD ALIMENTARIA"  
**CERTIFICACIÓN**

No. de Certificación: **C0220951253259**

La Dirección General de Impuestos Internos **CERTIFICA** que el o la contribuyente **C E M CARIBBEAN EQUIPMENT MEDICAL SRL**, RNC No. **131084745**, con su domicilio y asiento fiscal en **SANTO DOMINGO DE GUZMAN**, Administración Local **ADM LOCAL ABRAHAM LINCOLN**, está al día en la declaración y/o pago de los impuestos correspondientes a las obligaciones fiscales siguientes:

Nombre del Impuesto	
• RETENCIONES Y RETRIB. EN RENTA	• ANTICIPO IMPUESTO A LAS RENTAS
• ACTIVOS IMPONIBLES	• IMPUESTO A LA RENTA SOCIEDADES
• ITBIS	• OTRAS RETENCIONES Y RETRIB COM

**Dada en la OFICINA VIRTUAL, a los cuatro (4) días del mes de mayo del año dos mil veinte (2020).**

**NOTAS:**

- La presente certificación tiene una vigencia de treinta (30) días a partir de la fecha y se emite a solicitud del o de la contribuyente o su representante.
- Esta certificación no constituye un juicio de valor sobre la veracidad de las declaraciones presentadas por el o la contribuyente, ni excluye cualquier proceso de verificación posterior.
- Este documento no requiere firma ni sello.



Verifique la legitimidad de la presente certificación en <http://www.dgii.gov.do/verifica> o llamando a los teléfonos 809-689-3444 y 1-809-200-6060 (desde el interior sin cargos).





## Registro de Proveedores del Estado

### Constancia de inscripción

**RPE: 37738**

**Fecha de Registro:** 21/11/2013

**Fecha Actualización:** 13/4/2020

**Razón Social:** CEM Caribbean Equipment Medical, SRL

**No. Documento:** 131084745 - RNC

**Género:** Female

**Provee:** Servicios, Bienes

**Certificación MIPYME:** true

**Registro de Beneficiario:** true

**Clasificación Empresa:** Mediana Empresa

**Estado:** Activo

**Ocupación:**

**Motivo:**

**Domicilio:** Calle Los Javillos, Edificio 5, 102, Los Prados

10132 - REPÚBLICA DOMINICANA

**Persona de Contacto:** Emmanuel De Jesús Navarro Martínez



**Observaciones:**

#### Actividad Comercial

CÓDIGO	DESCRIPCIÓN
12140000	Elementos y gases
23150000	Maquinaria, equipo y suministros de procesos industriales
24100000	Maquinaria y equipo para manejo de materiales
30200000	Estructuras prefabricadas
30220000	Estructuras permanentes
41100000	Equipo de laboratorio y científico
41110000	Instrumentos de medida, observación y ensayo
42120000	Equipos y suministros veterinarios
42130000	Telas y vestidos médicos
42150000	Equipos y suministros dentales
42170000	Productos para los servicios médicos de urgencias y campo
42180000	Productos de examen y control del paciente
42190000	Productos de centro médico
42200000	Productos de hacer imágenes diagnósticas médicas y de medicina nuclear
42220000	Productos para administración intravenosa y arterial



42230000	Nutrición clínica
42240000	Productos medicinales de deportes y ortopédicos y prótesis
42250000	Productos de rehabilitación y terapia ocupacional y física
42260000	Equipo y suministros post mortem y funerarios
42270000	Productos de resucitación, anestesia y respiratorio
42280000	Productos para la esterilización médica
42290000	Productos quirúrgicos
42300000	Suministros para formación y estudios de medicina
42310000	Productos para el cuidado de heridas
47100000	Tratamiento, suministros y eliminación de agua y aguas residuales
51100000	Medicamentos antiinfecciosos
51110000	Agentes antitumorales
51120000	Medicamentos cardiovasculares
51130000	Medicamentos hematólogos
51140000	Medicamentos para el sistema nervioso central
51150000	Medicamentos para el sistema nervioso autónomo
51160000	Medicamentos que afectan al sistema respiratorio
51170000	Medicamentos que afectan al sistema gastrointestinal
51180000	Hormonas y antagonistas hormonales
51190000	Agentes que afectan el agua y los electrolitos
51200000	Medicamentos inmunomoduladores
51210000	Categorías de medicamentos varios
51240000	Fármacos que afectan a los oídos, los ojos, la nariz y la piel
52100000	Revestimientos de suelos
52130000	Tratamientos de ventanas
52140000	Aparatos <b>electrodomésticos</b>
56110000	Muebles comerciales e industriales
72100000	Servicios de mantenimiento y reparaciones de <b>construcciones</b> e instalaciones
76130000	Limpieza de residuos tóxicos y peligrosos
81100000	Servicios <b>profesionales</b> de ingeniería
85110000	Prevención y control de enfermedades
85120000	Práctica médica
85130000	Ciencia médica, investigación y experimentación
86100000	Formación profesional



Portal Transaccional - 21/4/2020 10:51:06 p.m.





República Dominicana

*Ministerio de Salud Pública*

"Año de la Consolidación de la Seguridad Alimentaria"

Santo Domingo, D. N.

29-4-2020

000672

El Ministerio de Salud Pública, en virtud de las atribuciones que le confiere la Ley General de Salud No. 42-01, y a la luz de la Ley No. 21-18 sobre regulación de los estados de excepción contemplados por la Constitución de la República Dominicana y el Decreto No. 134-20, mediante el cual el Presidente de la República declara el estado de emergencia en todo el territorio nacional, como consecuencia de la pandemia de coronavirus (COVID-19) **Certifica que:**

La empresa **C.E.M CARIBBEAN EQUIPMENT MEDICAL S.R.L** debidamente constituida bajo las leyes de la República Dominicana, registrada bajo el número nacional de contribuyente (RNC) **1-31-08474-5** está autorizada a la importación del producto **Kits de pruebas rápida SAFECARE BIO-TECH COVID-19 IgG/IgM**. Esta certificación será válida únicamente mientras perdure el estado de emergencia como consecuencia de la pandemia de coronavirus COVID-19.

  
Dr. Rafael Sánchez Cárdenas  
Ministro de Salud Pública







República Dominicana  
Ministerio de Salud Pública

DIRECCION GENERAL DE MEDICAMENTOS, ALIMENTOS Y PRODUCTOS SANITARIOS

**CERTIFICADO DE REGISTRO  
DISTRIBUIDORA**

Autorización para instalación y funcionamiento a  
**C.E.M. CARIBBEAN EQUIPMENT MEDICAL, SRL**

En virtud de las facultades que nos confiere el Art. No. 103 párrafo I de la Ley General de Salud 42-01 y el Reglamento 246-06 de fecha 19 de junio del año 2006.

**C.E.M. CARIBBEAN EQUIPMENT MEDICAL, SRL**

Propiedad del Sr.(a) \_\_\_\_\_

**CLASIFICACION**

Venta de Producto Terminado



Se le otorga el Número de Habilitación **00101A26946**

Fecha de autorización <b>5 de Marzo de 2018</b>	Fecha de vencimiento <b>5 de Marzo de 2023</b>
Ubicación: <b>C/ PASEO DE LOS RUISEÑORES, APTO. 101, EDF. 12 DEL BLOQUE B, URB. ESTANCIA NUEVA, DISTRITO NACIONAL, SANTO DOMINGO.</b>	Profesional responsable <b>FLAVIA MARIA SANTANA VASQUEZ DE TEJADA</b>  Número de exequátur <b>53-89</b>

Otorgado en Santo Domingo, Capital de la República Dominicana en fecha **12 de Marzo de 2018.**

**Dra. Altigracia Gázmán Marcano**  
Ministra de Salud Pública

**Karina Mena Fdez., M.Sc. /MESM**  
Directora General de Medicamentos,  
Alimentos y Productos Sanitarios

Recibo No. 162853

Fecha de pago 16/01/2018

Valor

6,000.00



# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Safecare Biotech (Hangzhou)  
Co., Ltd.**  
**Building 2/203, No. 18 Haishu Rd.**  
**Cangqian Sub-district, Yuhang District**  
**Hangzhou**  
**311121 Zhejiang**  
**China**

has established and applies a quality management system for medical devices  
for the following scope:

**Design and Development, Manufacture and  
Distribution of In Vitro Diagnosis of  
Rapid Test of Fertility, Drug of Abuse,  
Cardiac Markers, Infectious Diseases**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2016**

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-05-23  
Certificate Registration No.: SX 60129086 0001  
An audit was performed. Report No.: 15096152 002  
This Certificate is valid until: 2020-06-06

Certification Body



Date 2018-05-23



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

Tel. +49 221 806-1371 Fax +49 221 806-3935 e-mail cert-validity@de.tuv.com http://www.tuv.com/safety



# EC Declaration of Conformity



according to the Directive 98/79/EC  
(applicable to IVD Devices of **NOT Annex II** and **NOT self-test**)

**Manufacturer:** Safecare Biotech (Hangzhou) Co., Ltd.

**Address:** Building 2/203, No.18 Haishu Rd.Cangqian Sub-district, Yuhang District, Hangzhou, Zhejiang China 311121

**EC Representative:** Wellkang Ltd,  
16 Castle St,Dover, Kent, CT16 1PW,England,UK

**We, the manufacturer, declare under our sole responsibility that**

<b>the medical device(s)</b>	<b>Product Name</b>	COVID-19 IgG/IgM Rapid Test Kit (Whole Blood/serum/plasma)
	<b>Type/model, identification of product allowing traceability (Where applicable)</b>	Cassette(NCO-4022)
<b>of Category</b>	: <b>Common/Others IVD</b> (Devices of <b>NOT Annex II</b> and <b>NOT self-test</b> )	

**is/are in conformity with the relevant provisions and requirements of Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.**

Applied harmonised standards, national standards or other normative documents	EN ISO23640:2015	EN ISO 18113-1:2011
	EN 13612:2002	ISO 18113-2: 2009
	EN 13641:2002	EN1041- 2008
	EN ISO 14971:2012	EN ISO15223-1:2016
	ISO13485:2016	

**Conformity assessment procedure** **Module A (EC Declaration of Conformity) (Annex III, except point 6)**

**Notified Body (name & number)** **NOT applicable**

**Certificate & number**

**Signed on:** 6 March, 2020. **Place:** Hangzhou, Zhejiang, China

**Signature (on behalf of the manufacturer)** Kevin Qiu 2020.3.6

**Name of authorized signatory:** Kevin, Qiu

**Position held in the company:** General Manager

**Seal/Stamp:**



# SAFECARE BIO-TECH / COVID-19 DIAGNOSTIC TEST KIT

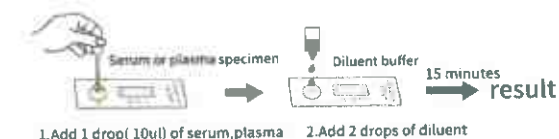


This kit (colloidal gold method) is a rapid in vitro diagnostic reagent developed by many scientific research institutions with colloidal gold as indicator, colloidal gold immunochromatography technology, anti human IgG and anti human IgM as coating materials, artificial expression and purification of 2019-nCoV specific antigen as labeling materials.

A statistical comparison was made between the results yielding a sensitivity of 96.9%, a specificity of 98.89% and **an accuracy of 97.8%.**



## Testing Method of Serum / plasma specimen



## Testing Method of Whole blood Specimen



## The Interpretation of results

### POSITIVE RESULT



**IgG Positive:** \*The colored line in the control line region (C) appears and a colored line appears in test line region G (G). The result is positive for COVID-19 specific-IgG and is probably indicative of secondary COVID-19 infection.



**IgM Positive:** \*The colored line in the control line region (C) appears and a colored line appears in test line region M (M). The result is positive for COVID-19 virus specific-IgM antibodies and is indicative of primary COVID-19 infection.



**IgG and IgM Positive:** \*The colored line in the control line region (C) appears and two colored lines should appear in test line regions G and M (G and M). The color intensities of the lines do not have to match. The result is positive for IgG & IgM antibodies and is indicative of secondary COVID-19 infection.

\*NOTE: The intensity of the color in the test line region(s) (G and M) will vary depending on the concentration of COVID-19 antibodies in the specimen. Therefore, any shade of color in the test line region(s) (G and M) should be considered positive.

### NEGATIVE RESULT



The colored line in the control line region (C) appears. No line appears in test line regions G and M (G and M).

### INVALID RESULT



Control line (C) fails to appear. Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for test of line failure. Review the procedure and repeat the procedure with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



## Ordering Information

Description	UPC	ID #	KITS / BOX	Boxes/Case	Each/Case
COVID-19 DIAGNOSTIC KIT	7832113564 4825	78-0802 -1142-3	25	80	2000



## COVID-19 IgG/IgM Rapid Test Device e Package Insert

### INTENDED USE

The COVID-19 IgG/IgM Rapid Test is a lateral flow immunoassay for the simultaneous detection and differentiation of IgG anti-COVID-19 virus and IgM anti-COVID-19 virus in human whole blood, serum or plasma. It is intended to be used by the professionals as a screening test and as an aid in the diagnosis of infection with COVID-19 viruses. Any reactive specimen with the COVID-19 IgG/IgM Rapid Test must be confirmed with alternative testing method(s).

### INTRODUCTION

Coronaviruses are enveloped RNA viruses that are distributed broadly among humans, other mammals, and birds and that cause respiratory, enteric, hematologic and neurologic diseases.<sup>1,2</sup> Six coronavirus species are known to cause human disease.<sup>3</sup> Four viruses — 229E, OC43, NL63, and HKU1 — are prevalent and typically cause common cold symptoms in immunocompetent individuals.<sup>3</sup> The two other viruses — severe acute respiratory syndrome coronavirus (SARS-CoV) and Middle East respiratory syndrome coronavirus (MERS-CoV) — are zoonotic in origin and have been linked to sometimes fatal illness.<sup>4</sup> Given the high prevalence and wide distribution of coronaviruses, the large genetic diversity and frequent recombination of their genomes, and increasing human-animal interface activities, novel coronaviruses are likely to emerge periodically in humans owing to frequent zoonotic species infections and occasional spillover events.<sup>4,5</sup>

In late December 2019, several local health facilities reported clusters of patients with pneumonia of unknown cause that were epidemiologically linked to a seafood and wet animal wholesale market in Wuhan, Hubei Province, China.<sup>6</sup> On December 31, 2019, the Chinese Center for Disease Control and Prevention (China CDC) dispatched a rapid response team to accompany Hubei provincial and Wuhan city health authorities and to conduct an epidemiologic and etiologic investigation. We report the results of this investigation, identifying the source of the pneumonia clusters, and describe a novel coronavirus detected in patients with pneumonia whose specimens were tested by the China CDC at an early stage of the outbreak. We also describe clinical features of the pneumonia in many of these patients.

The COVID-19 IgG/IgM Rapid Test detects IgG and IgM anti-COVID-19 virus in one test within 15 minutes. The test is easy to use, therefore, without cumbersome laboratory equipment, and requires minimal staff trainings.

### PRINCIPLE

The COVID-19 IgG/IgM Rapid Test Device (Whole Blood/Serum/Plasma) is a qualitative membrane-based immunoassay for the detection of COVID-19 antibodies in whole blood, serum, or plasma. This test consists of two components, an IgG component and an IgM component. In the Test region, anti-human IgM and IgG is coated. During testing, the specimen reacts with COVID-19 antigen-coated particles in the test strip. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgM or IgG in test line region. If the specimen contains IgM or IgG antibodies to COVID-19, a colored line will appear in test line region.

Therefore, if the specimen contains COVID-19 IgM antibodies, a colored line will appear in test line region M. If the specimen contains COVID-19 IgG antibodies, a colored line will appear in test line region G. If the specimen does not contain COVID-19 antibodies, no colored line will appear in either of the test line regions, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

### KEY COMPONENTS

Individually packed test devices

Instructions for use

Material Safety Data Sheet

Reference Value Chart

Test Result Guide

Specimen Absorption Not Provided

Specimen collection containers

Each device contains a strip with colored conjugates and reactive reagents pre-spread at the corresponding regions  
For adding specimens use  
Phosphate buffered saline and preservative  
For operation instruction

Droppers

Package insert

Timer

### WARNINGS AND PRECAUTIONS

For professional in vitro diagnostic use only. Do not use after expiration date.

Do not use outside the area where the specimens or kits are handled.

Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.

Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.

Humidity and temperature can adversely affect results.

### REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 4°C-30°C. The positive and negative controls should be kept at 4°C-8°C. If stored at 4°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

### SPECIMEN COLLECTION AND HANDLING

Obtain any materials of human origin as infectious and handle them using standard biosecurity procedures.

Whole Blood:

Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer) by venipuncture.

Plasma:

Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer) by venipuncture. Separate the plasma by centrifugation. Carefully withdraw the plasma into a new pre-labeled tube.

Serum:

Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer) by venipuncture. Allow the blood to clot. Separate the serum by centrifugation. Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store specimens at 2°C-8°C if not tested immediately.

Store specimens at 2°C-8°C up to 15 days. The specimens should be frozen at -20°C for longer storage.

Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing. Do not use samples demonstrating gross hemolysis, gross hemolysis or turbidity in order to avoid interference on result interpretation.

### ASSAY PROCEDURE

Bring the specimen and test components to room temperature. Mix the specimen well prior to assay once thawed. Place the test device on a clean, flat surface.

For whole blood sample:

Fill the dropper with the specimen then add 2 drops (about 80 µL) of specimen into the sample well. The volume is around 80µL. Making sure that there are no air bubbles. Then add 1 drop (about 40 µL) of Sample Diluent immediately into the sample well.

For Plasma/ Serum sample:

Fill the dropper with the specimen then add 1 drop (about 40 µL) of specimen into the sample well. The volume is around 80µL. Making sure that there are no air bubbles. Then add 1 drop (about 40 µL) of Sample Diluent immediately into the sample well.

### For Plasma/ Serum sample:

Fill the dropper with the specimen then add 1 drop (about 40 µL) of specimen into the sample well. The volume is around 80µL. Making sure that there are no air bubbles. Then add 1 drop (about 40 µL) of Sample Diluent immediately into the sample well.

Set up a timer. Read the result at 15 minutes. Don't read result after 30 minutes. To avoid confusion, discard the test device after interpreting the result.

### INTERPRETATION OF ASSAY RESULT

#### POSITIVE RESULT:



IgG Positive: \* The colored line in the control line region (C) appears and a colored line appears in test line region (G). The result is positive for COVID-19 specific-IgG and is probably indicative of secondary COVID-19 infection.



IgM Positive: \* The colored line in the control line region (C) appears and a colored line appears in test line region (M). The result is positive for COVID-19 virus specific-IgM antibodies and is indicative of primary COVID-19 infection.



IgG and IgM Positive: \* The colored line in the control line region (C) appears and two colored lines also appear in test line regions G and M (G and M). The color intensities of the lines do not have to match. The result is positive for IgG & IgM antibodies and is indicative of secondary COVID-19 infection.

\*NOTE: The intensity of the color in the test line region(s) (G and M) will vary depending on the concentration of COVID-19 antibodies in the specimen. Therefore, any shade of color in the test line region(s) (G and M) should be considered positive.

#### NEGATIVE RESULT:



The colored line in the control line region (C) appears. No line appears in test line regions G and M (G and M).

#### INVALID RESULT:



Control line (C) fails to appear. Insufficient buffer volume or incorrect procedural technique are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

### QUALITY CONTROL

1. Internal Control: This test contains a built-in control feature, the C band. The C line develops after adding specimen and sample diluent. Observe, review the whole procedure and repeat test with a new device.
2. External Control: Good Laboratory Practice recommends using the external controls, positive and negative (provided upon request), to assure the proper performing of the assay.

### PERFORMANCE CHARACTERISTICS

The COVID-19 IgG/IgM Rapid Test has been evaluated with a leading commercial test using clinical specimens. The results show that the accuracy is 90.19 %.













### LIMITATIONS OF TEST

1. The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of antibodies to COVID-19 virus in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The COVID-19 IgG/IgM Rapid Test is limited to the qualitative detection of antibodies to COVID-19 virus in human whole blood, serum or plasma. The intensity of the test band does not have linear correlation with the antibody titer in the specimen.
3. The COVID-19 IgG/IgM Rapid Test can not be used to differentiate if the infection is primary or secondary. No information of COVID-19 serotypes can be provided with this test.
4. A negative or non-reactive result for an individual subject indicates absence of detectable COVID-19 virus antibodies. However, a negative or non-reactive test result does not preclude the possibility of exposure to or infection with COVID-19 virus.
5. A negative or non-reactive result can occur if the quantity of the COVID-19 virus antibodies present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
6. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
7. If the symptom persists, while the result from COVID-19 IgG/IgM Rapid Test is negative or non-reactive result, it is recommended to re-sample the patient few days late or test with an alternative test device.
8. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

### REFERENCES

1. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011;81:85-164.
2. Masters PS, Perlman S. Coronaviridae. In: Knipe DM, Howley PM, eds. Fields virology. 6th ed. Lippincott Williams & Wilkins, 2013:825-58.
3. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. Trends Microbiol 2016;24:490-502.
4. Cui J, Li J, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019;17:181-192.
5. Wong G, Liu W, Liu Y, Zhou B, Bi Y, Gao GF. MERS, SARS, and Ebola: the role of super-spreaders in infectious disease. Cell Host Microbe 2015;18:398-401.
6. Report of clustering pneumonia of unknown etiology in Wuhan City. Wuhan Municipal Health Commission, 2019. (<http://wjw.wuhan.gov.cn/front/web/showDetail/2019122109999>, opens in new tab).

### INDEX OF SYMBOLS

	Do not reuse		For in vitro diagnostic use only
	Stored between 4-30		Consult instruction for use
	Caution		Lot number
	Use by		Contains sufficient for <n> tests
	Keep away from sunlight		Keep dry
	Manufacturer		Do not use if package is damaged

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