Singclean®

CE

COVID-19 Test Kit Antígeno
(Metodo Oro Coloidal)

Preciso Rápido Sensible

- Alta sensibilidad y especificidad
- Para uso masivo a gran escala
- Fácil uso y detección

Hangzhou Singclean Medical Products Co.,Ltd.

Singclean®

COVID-19 Test Kit Antígeno (Colloidal Gold Method)

Uso previsto

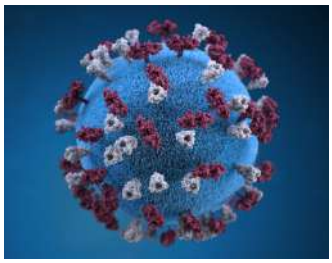
El kit de prueba Antígeno Singclean para COVID -19 con el método de oro coloidal es un ensayo inmunocromatográfico en fase sólida para la detección rápida y cualitativa del antígeno de COVID-19 en una muestra de frotis nasal humano.

Este kit de prueba rápida de antígenos es el segundo kit de prueba desarrollado por Singclean Medical para COVID-19 sobre la base del método del oro coloidal después de su prueba Singclean COVID-19 IgG / IgM Test Kit.

.

Síntomas más comunes de COVID-19

- ☑ Fiebre
- ☑ Fatiga
- ☑ Tos
- ☑ Dificultad respiratoria



Caracteristicas

- Resultados listos en 15 minutos
- Herramienta de diagnóstico precisa para infecciones activas
- Resultados fáciles de administrar y leer
- Económico
- Sin necesidad de instrumentos
- Muy portátil
- Habilita las pruebas a gran escala en forma rápida

Singclean®

COVID-19 Test Kit Antígeno (Colloidal Gold Method)

Comparativa de Diferentes Metodos de testeo para COVID-19

Singclean®	Test PCR	Test Anticuerpo	Test Antigeno
Valor clínico	Diagnóstico	Diagnóstico auxiliar	Diagnóstico auxiliar y screening
¿Cuando hacer la prueba?	Etapa temprana de infección	Etapa tardía o recurrente de la infección	Etapa temprana de la infección
Tiempo de resultado	24 horas	10-15 minutos	10-15 minutos
Requisito de instalaciónes	PCR Laboratorio	No se necesitan instalaciones especiales, fáciles de usar para los profesionales de la salud	No se necesitan instalaciones especiales, fáciles de usar para los profesionales de la salud
Costo	ALTO	ECONÓMICO	ECONÓMICO
Muestra requerida	Saliva, nasal, oral	Sangre, suero o plasma.	Hisopo nasofarígenos
Almacenamiento	Cadena de frío	Temperatura ambiente	Temperatura ambiente
Sensibilidad	Alto; un falso positivo es poco probable, podría ocurrir un falso negativo	Moderado; pueden ocurrir falsos positivos y falsos negativos.	Moderado; Es improbable un falso positivo, podría ocurrir un falso negativo y el resultado negativo se puede confirmar con la prueba de PCR. Las pruebas de antígeno son más baratas y más rápidas de ejecutar.

Singclean®

COVID-19 Test Kit Antígeno (Colloidal Gold Method)

Informa ción del producto

Nombre del producto	Singclean COVID-19 Test Kit
Tipo de test	Test de Antígeno
Principio del test	Colloidal Gold Method
Tipo de muestra	Nasofaríngea
Volumen de muestra	3 gotas (aproximado 100μl)
Qualitativo/Quantitativo	Qualitativo
Tiempo de resultado	15 minutos
Temperatura de operación	15-30°C
Temperatura bodega	4-30°C
Vencimiento	24 meses

Datos clínicos

Nombre del producto	Singclean COVID-19 Test Kit Antígeno
Sensibilidad	88.89%
Especificidad	97.87%
Exactitud	94.17%

Singclean®

COVID-19 Test Kit Antígeno (Colloidal Gold Method)

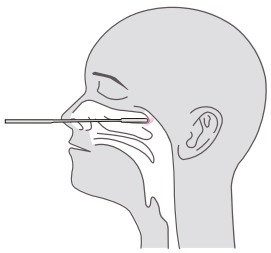
Contenido

Tipo de test	Especificacíon	Contenido 1 caja	Embalaje
Test Antígeno	20 tests/kit	1 Manual 1 Estacion trabajo 20 Test 20 Hisopos 20 Tubos 20 Buffer	30 cajas, 600 test, Largo 650 mm Ancho 270 mm Alto 370 mm

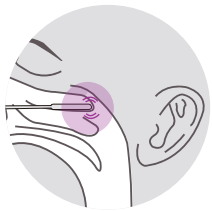
Almacenamiento y estabilidad

El kit puede almacenarse a temperatura ambiente o refrigerado (4-30 ° C). El dispositivo de prueba es estable hasta la fecha de vencimiento impresa en la bolsa sellada. El dispositivo de prueba debe permanecer en la bolsa sellada hasta su uso. No congelar . No lo use después de la fecha de vencimiento.

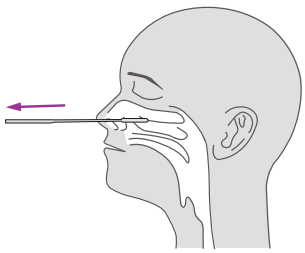
Procedimientos de prueba



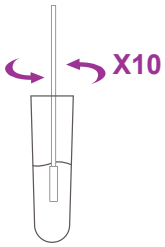
1. Inserte un hisopo estéril en la fosa nasal del paciente , hasta llegar a la superficie de la nasofaringe



2. Frote sobre la superficie de la nasofaringe posterior

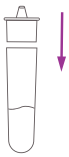


3. Retire el hisopo estéril de la cavidad nasal.

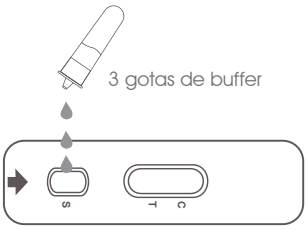


4. Inserte el hisopo en un tubo de extracción con 6 gotas de buffer previamente agregados , gire el hisopo unas 10 veces en el tubo para mezcla

5. Deje el hisopo en el tubo de extracción durante 1 minuto. Retire el hisopo mientras aprieta la punta del hisopo para extraer el líquido del hisopo.



6. Presione la punta del gotero firmemente sobre el tubo.



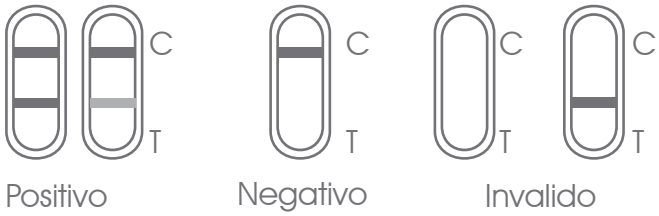
7. Aplique 3 gotas de la solución extraída al lugar señalado S de la tarjeta test

8. Lea el resultado en 15 minutos.

Singclean®

COVID-19 Test Kit Antígeno (Colloidal Gold Method)

Interpretación de resultados



Positivo:

Si aparecen tanto la línea de control (C) como la línea de prueba (T), el resultado indica la presencia de antígeno COVID-19 (SARS-CoV-2) en la muestra.El resultado es COVID-19 positivo.

Negativo:

Si solo aparece la línea de control (C), el resultado indica que no se han detectado antígenos COVID-19 (SARS-CoV-2) en la muestra. El resultado es COVID-19 negativo.

Inválido:

Si la línea de control (C) no aparece después de realizar la prueba, el resultado se considera inválido. Un volumen de muestra insuficiente o técnicas de procedimiento incorrectas son las razones más probables de la falla de la línea de control. Revise el procedimiento y repita la prueba con un nuevo kit de prueba.

Limitaciones

1. Utilice muestras frescas siempre que sea posible.

2. Resultados positivos en raras ocasiones no descartan infecciónes bacteriana o coinfección con otros virus.

3. Puede producirse un resultado negativo si la cantidad de antígeno COVID-19 presente en la muestra está por debajo de los límites de detección del ensayo, o que no se recolecto correctamente el antígeno COVID-19 en la cavidad nasal del paciente.

4. Resultados negativos no descarta la infección por COVID-19 y no debe usarse como la base final o única para el tratamiento o decisiones de manejo del paciente. Los resultados negativos deben considerarse en el contexto de las exposiciones recientes de un paciente, los antecedentes y la presencia de signos y síntomas clínicos

Si requiere un resultado de prueba más preciso, repetir las pruebas o confirmar con otros métodos de prueba y hallazgos clínicos.

Advertencias

1. El rendimiento óptimo del ensayo requiere un estricto cumplimiento al procedimiento de ensayo descrito en la hoja insertada. La recolección, el almacenamiento y el transporte de muestras inadecuados o inapropiados pueden causar resultados falsos de la prueba.

COVID-19 Test Kit Antígeno (Colloidal Gold Method)

Singclean®

Noticias sobre sus usos

El Comercio

Test de antígenos: detección más rápida y menos costosa

La Vanguardia

Los test rápidos de antígenos empezarán la semana próxima

Los test rápidos de antígenos, los que detectan proteínas del virus en el frotis nasal en 15 minutos y sin mediar un laboratorio.

EL INDEPENDIENTE

Test rápidos de antígenos, resultado en 15 minutos y con la misma fiabilidad que una PCR

En ese sentido, los hospitales están comenzando a incorporar a sus servicios las pruebas rápidas de antígenos, una nueva prueba que permite

ABC.es

Oxford trabaja en el test de antígenos que diagnostica el Covid en cinco minutos

Test de antígenos: vía para reabrir economías. Las pruebas rápidas de antígenos se consideran clave para implementar las pruebas masivas

La Voz

Hospitales y centros de salud empiezan a utilizar el test

El test rápido de antígenos ya ha llegado. Esta prueba, que tiene una fiabilidad similar a la de una PCR para diagnosticar el coronavirus,

Heraldo

Los nuevos test de antígenos se usarán en sintomáticos y en residencias y colegios

E. P. B.. Toma de muestras para un test PCR en un centro de salud de ...

LA NACION

Coronavirus: qué son las pruebas rápidas de antígenos por las que apuesta la OPS en América Latina

Coronavirus: qué son las pruebas rápidas de antígenos por las que apuesta la OPS en América Latina.

El Mostrador

Nuevo test rápido permitiría detectar el Covid-19 en 15 minutos

Las pruebas de antígenos SARS-CoV-2 aportan a reducir las ... La prueba de antígeno SARS-CoV-2 permitiría detectar de manera cualitativa ...

RPP Noticias

COVID-19: Los test de antígenos son más eficientes que las pruebas serológicas

Si esta prueba da positivo es que la persona tiene el virus y puede contagiar.

El Confidencial

Madrid realiza 62.232 pruebas de antígenos y 58.198 PCR

Por el momento son pocas las comunidades autónomas que ofrecen cifras de sus test de antígenos

swissinfo.ch

Alto uso de pruebas de antígenos en India

RT-PCR es el test dominante en Estados Unidos, pero las autoridades planean aumentar el uso de pruebas de antígenos. El Ministerio de ...

Redacción Médica

Covid-19: el test de antígenos de BD llega a Europa

Becton Dickinson (BD) ha anunciado que su sistema de realización de test de antígenos para Covid-19,

www.notimerica.com

Coronavirus.- EEUU autoriza los ensayos con la primera prueba de antígenos del coronavirus, que da resultados ...

EEUU autoriza los ensayos con la primera prueba de antígenos del ... de Alimentación y Medicamentos de Estados Unidos (FDA, por sus siglas

Heraldo

Francia hará tests de antígenos en los aeropuertos a los viajeros de negocios

Francia hará tests de antígenos en los aeropuertos a los viajeros de negocios. La medida, que echará a andar en los aeropuertos de Orly y De

Diario

El hospital Quirónsalud incorpora las pruebas rápidas de antígenos covid-19

... se debe realizar test de antígeno o PCR. Para pacientes con síntomas de más de 6 días de inicio se debe realizar PCR y test de anticuerpos ...

Teletrece

Japón aprueba test rápido antígeno para COVID-19

El kit de examen, que toma una muestra nasofaríngea, no necesita de un laboratorio para obtener el diagnóstico, a diferencia del método más ...

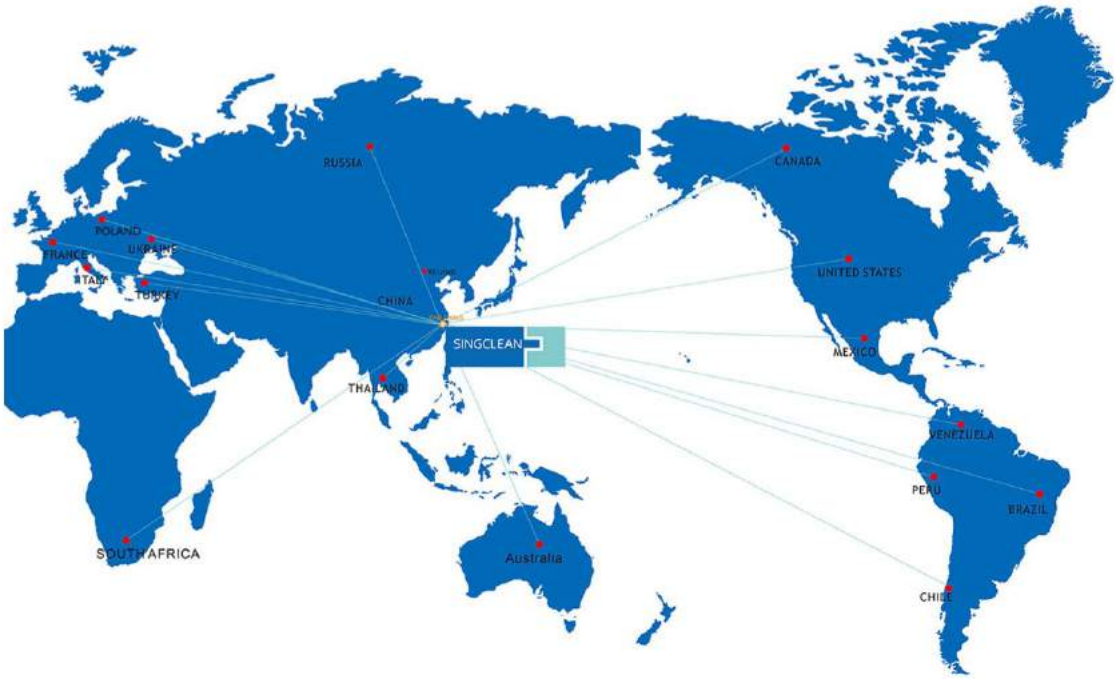
13 may. 2020

PERFIL DE LA COMPAÑÍA

PASO A PASO PARA CONVERTIRSE EN EL LÍDER

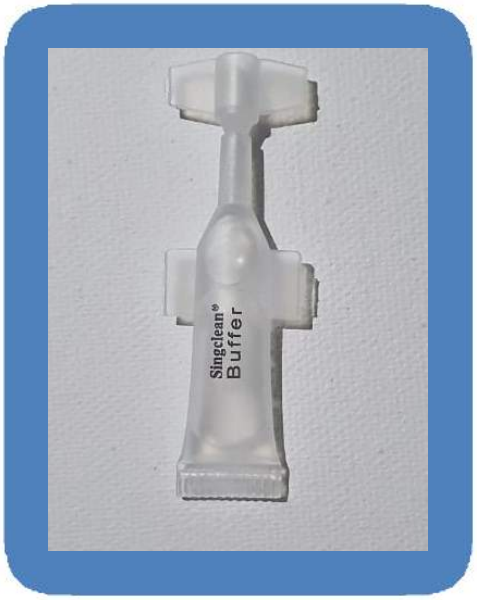
Hangzhou Singclean Medical Products Co., Ltd., establecida en 2002 con un capital social de 80.000.000 RMB, es una empresa de nacional China de alta y nueva tecnología, tiene personal bien calificado, un sistema de gestión de calidad completo e instalaciones de primera clase, la compañía asegura la producción continua de dispositivos médicos y productos de inyección de drogas de Clase III que confirman las leyes y regulaciones de la Administración Estatal de Alimentos y Medicamentos (SFDA) y EU MDD.

La planta de la empresa en Xiasha tiene una superficie de 13.000 m2 con un área de construcción de 17.000 m2 y un área de producción de 13.200 m2 incluyendo salas blancas de 2.300 m2 en las Clase A, Clase B y Clase A. Tiene salas limpias con el estándar GMP, con lo que obtuvo la Licencia de Producción Farmacéutica en 2012.



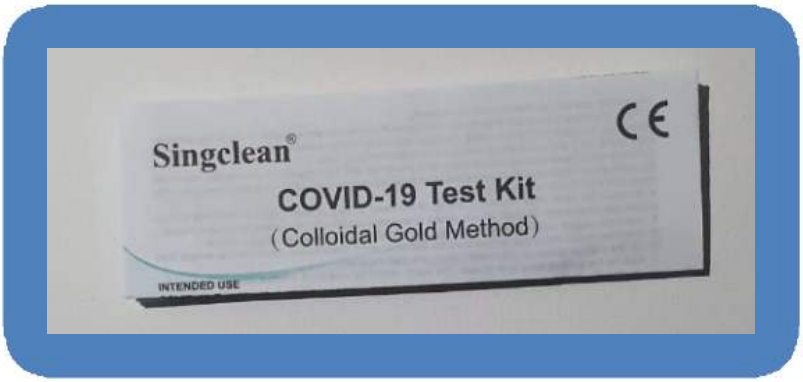
CONTENIDO DEL KIT DE TEST RÁPIDO ANTÍGENO SINGCLEANE

20 TUBOS

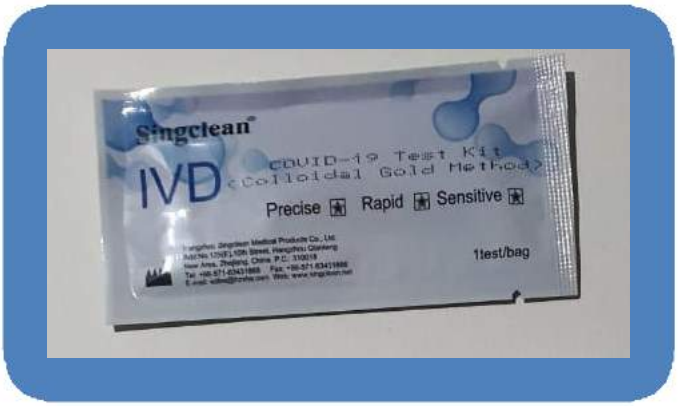


20 BUFFER REACTIVO

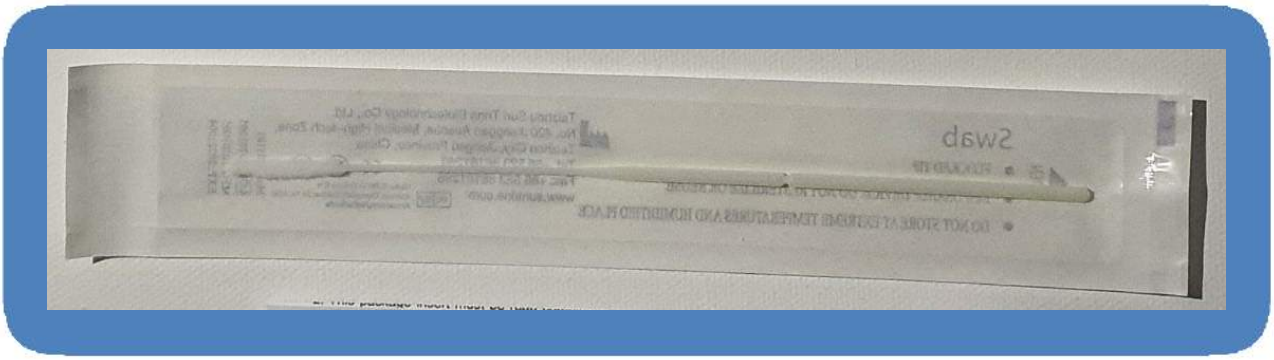
1 ESTACION DE TRABAJO



1 MANUAL DE USO



20 CASSETTE DE PRUEBA



20 HISOPOS NASOFARÍNGEOS

Singclean®
IVD
COVID-19 Test Kit
(Colloidal Gold Method)
Precise Rapid Sensitive

Fold The Paper Workbench
Singclean®
IVD
Precise Rapid Sensitive
Singclean®
CE
COVID-19 Test Kit
(Colloidal Gold Method)
INTENDED USE

Statement

To Whom It May Concern,

Product Name:
COVID-19 Test Kit (Colloidal Gold Method)
Manufacturer:
Hangzhou Singclean Medical Products Co.,ltd.

Hangzhou Singclean Medical Products Co.,ltd. declare that COVID-19 Test Kit (Colloidal Gold Method) is the COMMERCIAL NAME on the EC Declaration of Conformity.
COVID-19 Test Kit (Colloidal Gold Method) is a solid phase immunochromatographic assay for the rapid, qualitative test of antigen to 2019 Novel Coronavirus in human nasal cavity. The product uses an antigen test, so the product name + method is COVID-19 Test Kit (Colloidal Gold Method) Anti-gen.

Hangzhou Singclean Medical Products Co., Ltd.

General Manager:_____ 杭州协合医疗用品有限公司 HANGZHOU SINGCLEAN MEDICAL PRODUCTS CO., LTD.

Date: 2020.10.23

地址：杭州经济技术开发区10号大街（东）125号 邮编：310018
ADD: No. 125(E), 10th Street, Hangzhou Economic and Technological Development Zone, Zhejiang, China 310018
电话(TEL):0571-63431868 传真(FAX):0571-63431886 网站(WEB):www.hzxhe.com/www.singclean.net

CE EC Declaration of Conformity CE

Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer: Hangzhou Singclean Medical Products Co., Ltd.
Address: No. 125 (E), 10th Street, Hangzhou Economic and Technological Development Zone, Zhejiang, China 310018

European Representative: SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product Name:
COVID-19 IgG/IgM Test kit (Colloidal Gold Method)
COVID-19 Test kit (Colloidal Gold Method) (Anti-gen)
COVID-19 IgG Test kit (Colloidal Gold Method)
COVID-19 IgM Test kit (Colloidal Gold Method)

Classification: Others

We confirm our product meet the requirement of In Vitro Diagnostic Medical Devices Directive (98/79/EC) and the following harmonized standards.

EN ISO 14971:2012	EN 15223-1:2016	EN ISO 23640:2015
EN ISO 18113-1:2011	EN 13612:2002/AC:2002	EN 13641:2002
EN ISO 18113-2:2011	EN ISO 13485:2016	

Hangzhou, Oct. 23, 2020
Place and Date

Wei Qing Sun General Manager
Signature and Position
Signed for and on behalf of the Manufacturer

ORIGINAL

1.Exporter's name, address, country:
HANGZHOU SINGCLEAN MEDICAL PRODUCTS CO.,LTD.
NO. 125 (E), 10TH STREET, HANGZHOU ECONOMIC & TECHNOLOGICAL DEVELOPMENT ZONE, ZHEJIANG, CHINA TEL: 0-086-571-63431868 FAX: 0086-571-63431886 P.C.:310018

2.Producer's name and address, country:
AVAILABLE UPON REQUEST

Certificate No.: F207471819110018

CERTIFICATE OF ORIGIN

Form for China-Chile FTA

Issued in THE PEOPLE'S REPUBLIC OF CHINA

(see Instruction overleaf)

3.Consignee's name, address, country
IMPORTADORA DE PRODUCTOS MEDICOS SPA
ADDRESS:ISLUGA 7349 HUECHURABA, REGION MEROPOLITANA, CHILE
TEL : 56 991915025 ATTN:ALEXIS MELLA

For Official Use Only

Verification:origin.customs.gov.cn

4.Means of transport and route (as far as known)

Departure Date OCT. 17, 2020

Vessel /Flight/Train/Vehicle No. ET3779

Port of loading SHANGHAI, CHINA

Port of discharge SANTIAGO, CHILE

5.Remarks
ISSUED RETROACTIVELY

6.Item number	7.Marks and packages No.	8.Number and kind of packages; description of goods	9.HS code (Six digit code)	10.Origin criterion	11.Net weight or quantity, with unit of measurement	12.Number(s) and date(s) of invoice(s)
1	N/M	TEN (10) CTNS OF COVID-19 TEST KIT (COLLOIDAL GOLD METHOD) *** *** *** *** ***	3002.15	"WP"	6000PCS	2020XH-004-1_0S02-1 OCT. 10, 2020

13.Declaration by the exporter or producer

The undersigned hereby declares that the above details and statement are correct, that all the goods were produced in

CHINA
(Country)

0 0 0 0 0 8 6 8 2 1 9 1 0

and that they comply with the origin requirements specified in the China-Chile FTA for the goods exported to

CHILE
(Importing country)

杭州协合医疗用品有限公司
HANGZHOU SINGCLEAN MEDICAL PRODUCTS CO.,LTD

Hangzhou, China, OCT. 21, 2020

Place and date, signature of authorised signatory

14.Certification
On the basis of control carried out, it is hereby certified that the declaration made by the exporter or producer is correct.

HANGZHOU CUSTOMS 中华人民共和国 杭州 ORIGIN 海关 THE PEOPLE'S REPUBLIC OF CHINA

Hangzhou, China, OCT. 21, 2020

Place and date, signature and stamp of authorised body

N° CDA 310393/20

Santiago, 22 de octubre de 2020

N° Ref: CD1478315/20

CERTIFICADO DE DESTINACIÓN ADUANERA

Importador:	Importadora de productos médicos SpA
RUT Importador:	77141126-6
Dirección/Comuna:	ISLUGA , HUECHURABA
Región de Ingreso:	REGIÓN METROPOLITANA
Agente Aduana/Código:	POZO ORTIZ LUIS EDUARDO/F71
N° de Documento de Transporte:	07138579391
País Embarque:	CHINA
Bodega destino:	IMPORTADORA DE PRODUCTOS MEDICOS SPA
Dirección/Comuna:	ISLUGA 7349, HUECHURABA

El Instituto de Salud Pública de Chile en cumplimiento a lo dispuesto en la ley 18.164/82 del Ministerio de Hacienda, el Código Sanitario y sus Reglamentos, Decreto Supremo 825/98; ha recibido la solicitud N° CD1478315, el 22 del octubre de 2020, para que se otorgue el Certificado de Destinación Aduanera a la mercancía detallada en el anexo foliado adjunto, que forma parte del presente documento, ingresada por la Aduana METROPOLITANA, para ser presentado ante el Servicio Nacional de Aduanas.

De acuerdo a lo declarado por Importadora de productos médicos SpA se certifica que las referidas mercancías serán trasladadas a la bodega de destino señalada precedentemente.

Por delegación del Director del Instituto de Salud Pública de Chile.

INSTITUTO DE SALUD PÚBLICA CHILE
Agencia Nacional de Medicamentos
Incorpora Firma Electrónica Avanzada

Q.F. Carlos Bravo Goldsmith
SUBDEPARTAMENTO DE CONTROL Y VIGILANCIA DE MEDICAMENTOS Y COSMÉTICOS
DEPARTAMENTO AGENCIA NACIONAL DE MEDICAMENTOS
Instituto de Salud Pública de Chile

El presente certificado podrá ser validado en www.ispdocel.ispch.cl con el siguiente identificador: C40092B390381FF703258609006449D7

N° CDA 310393/20

N° Ref: CD1478315/20

Santiago, 22 de octubre de 2020

CERTIFICADO DE DESTINACIÓN ADUANERA

"ANEXO DE PROVEEDOR Y PRODUCTOS"

Proveedor	País	Factura/Año
HANGZHOU SINGCLEAN MEDICAL PRODUCTS CO., LTD.	CHINA	2020XH-004-10S02-1/2020

Sección V. Dispositivos Médicos Sin Registro Sanitario

1 - RAPID TEST ANTIGEN COVID-19

Nombre DM ISP:	REACTIVOS/KITS PARA ENSAYOS DE DIV (DIAGNOSTICO IN VITRO)
Nombre Productor:	HANGZHOU SINGCLEAN MEDICAL PRODUCTS CO., LTD.
País Productor:	CHINA
País Procedente:	CHINA
Cantidad:	6000
Unidad:	UNIDADES
Lote(s):	P49200922A1A

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 097027 0002 Rev. 01

Manufacturer: **Hangzhou Singclean Medical Products Co., Ltd.**
No. 125(E), 10th Street
Hangzhou Economic and
Technological Development Zone
310018 Hangzhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: Wellkang Ltd
Suite B, 29 Harley Street, LONDON, W1G 9QR, UNITED KINGDOM

Product Category(ies): In Vitro diagnostic for self testing

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. See also notes overleaf.

Report no.: SH18111503

Valid from: 2018-11-22
Valid until: 2022-01-17

Date, 2018-11-22

Stefan Preiß

TÜV SÜD ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

REGISTRATION NO. 04718Q10000632

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that the quality management system of

Hangzhou Singclean Medical Products Co., Ltd.

Registered Address: No.125 (E), 10th Street, Hangzhou Economic and Technological Development Zone, Zhejiang, China 310018

Manufacturing Address: No.125 (E), 10th Street, Hangzhou Economic and Technological Development Zone, Zhejiang, China 310018

Has been assessed and conformed to the following standard(s)

YY/T 0287-2017 idt ISO 13485:2016

The certificate is valid for the following scope:

The Design, Development, Production and Service of Medical Sodium Hyaluronate Gel, Cross-linked Sodium Hyaluronate Gel for plastic surgery, Prevent Adhesive Rinse Fluid for Surgery, MPH Absorbable Hemostatic Particles, Bacterial Vaginosis Diagnostic Strip Sets (Dry Chemical Enzymatic Detection) Bacterial Sialidase Test Kit (Sialidase Detection), Follicle Stimulating Hormone Test Kit (Colloidal Gold), Luteinizing Hormone Ovulation Test Kit (Colloidal Gold), Alpha-fetoprotein (AFP) Assay Kit (ELISA), Medical Mask.

The Design, Development, Production and Service (Export only) of Absorbable Gauze of Oxidized Regenerated Cellulose, Medical Sodium Hyaluronate Gel for Bone Joint, Medical Sodium Hyaluronate Gel (Viscoelastic Solution for Ophthalmic Surgery), MPH Absorbable Hemostatic Particles Applicator, Modified Sodium Hyaluronate Gel for Injection, Human Chorionic Gonadotropin (Colloidal Gold).

Date of issue: Janurary 08,2019

Date of expiry: Janurary 07,2022

Date of change: Janurary 02,2020

General Manager:

BEIJING HUA GUANG CERTIFICATION OF MEDICAL DEVICES CO., LTD.

Note: This certificate will not be valid until the organization has been approved in the annual audits. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (www.cnca.gov.cn) or the website of CMD (www.cmdc.com.cn). Address: 5th floor of Zhong Lian building, No.jia88, An Ding Men Wai street, Dongcheng district, Beijing,100011, P.R. China Telephone: 010-62351993

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

SUNGO Europe B.V.
T.a.v. de heer Luo
Olympisch Stadion 24
1076 DE Amsterdam

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
T.I. van Langeveld - Baas

medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20200532

Bijlagen
-

Uw aanvraag
7 maart 2020

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 16 maart 2020
Betreft: aanmelding In-vitro diagnostica

Geachte heer Luo,

Op 7 maart 2020 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam Hangzhou Singclean Medical Products Co., Ltd. met Europees gemachtigde SUNGO Europe B.V. onderstaande producten als in-vitro diagnostica op de Europese markt te brengen.

De producten staan geregistreerd als in-vitro diagnostica onder nummer:

COVID-19 IgG Test kit(Colloidal Gold Method)
(geen merknaam) (NL-CA002-2020-49495)
COVID-19 IgG/IgM Test kit(Colloidal Gold Method)
(geen merknaam) (NL-CA002-2020-49493)
COVID-19 IgM Test kit(Colloidal Gold Method)
(geen merknaam) (NL-CA002-2020-49496)
COVID-19 Test kit(Colloidal Gold Method)
(geen merknaam) (NL-CA002-2020-49494)

Hiermee heeft u voldaan aan uw verplichting op grond van artikel 4, BIVD.

In alle verdere correspondentie betreffende bovenvermelde producten verzoek ik u deze nummers te vermelden. Aan deze nummers kunnen geen verdere rechten ontleend worden, ze dienen alleen om de notificatie administratief te vergemakkelijken.

De registratie van in-vitro diagnostica als medisch hulpmiddel op grond van de Classificatiecriteria (Bijlage II) bij Richtlijn 98/79/EG betreffende medische hulpmiddelen voor in-vitro diagnostiek is onderhevig aan mogelijke revisies van Europese regelgeving inzake de classificatie van medische hulpmiddelen en aan voortschrijdend wetenschappelijk inzicht (zie artikel artikel 10, eerste lid van Richtlijn 98/79/EG).

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
T.I. van Langeveld - Baas

medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20200532

Bijlagen
-

Uw aanvraag
7 maart 2020

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, Hangzhou Singclean Medical Products Co., Ltd. de CE-conformiteitsmarkering heeft aangebracht op de desbetreffende producten alvorens deze in een EU-lidstaat in de handel te brengen. Zodoende garandeert SUNGO Europe B.V. dat de in-vitro diagnostica voldoen aan de essentiële eisen zoals opgenomen in bijlage I bij Richtlijn 98/79/EG (en in het daarmee corresponderende onderdeel 1 bij het besluit)

Volledigheidshalve wijzen wij u erop dat een in-vitro diagnosticum moet voldoen aan de eisen uit het BIVD. Het BIVD is gebaseerd op Richtlijn voor in-vitro diagnostiek, 98/79/EG. Met name wijzen wij u op de Nederlandse-taaleis zoals deze in Nederland geldt, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Marketing Surveillance- en vigilantiesysteem.

Tot slot merk ik op dat met uw notificatie - de administratieve notificatie als fabrikant - en deze brief geen sprake is van een oordeel over de status of kwalificatie van uw product: notificering betekent niet dat daadwerkelijk sprake is van een in-vitro diagnosticum in de zin van de onderhavige wet- en regelgeving. In voorkomende gevallen kan de Inspectie Gezondheidszorg en Jeugd (IGJ), belast met het toezicht op de naleving van het bij of krachtens de wet bepaalde, een standpunt innemen over de status van een product, waarbij het volgens vaste jurisprudentie uiteindelijk aan de nationale rechter is om te bepalen of een product onder de definitie van in-vitro diagnosticum valt.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec

Dr. M.J. van de Velde

Dhr. M.J. van de Velde

出口方和进口方共同声明

Joint Declaration of the Exporter and the Importer

产品名称（含规格、型号）Product Name (including specifications and model)	产品数量 Product Quantity	中国质量标准名称或国外质量标准名称 The Name of Quality Standards of China or the Foreign Country	进口国（地区）Importing Country/Region	生产厂商 Producer
新冠状病毒肺炎 IgG IgM 抗体检测试剂盒（胶体金法） 规格: 20 人份、盒 型号:无 COVID-19 IgG/IgM Test Kit (Colloidal Gold Method) specifications 20 test/box Model: None	34060 人份 34060 pieces	CE 欧盟体外诊断试剂指令 IVDD 98/79/EC	智利 Chile	杭州协合医疗用品有限公司 HANGZHOU SINGCLEAN MEDICAL PRODUCTS CO., LTD.

出口方和进口方确认上述产品符合☐中国质量标准/ ☑国外质量标准（请勾选），且符合双方协议确定的产品质量标准。进口方保证协议确定的产品质量标准符合进口国（地区）对该产品的质量标准要求，并确认接受上述产品的质量标准。

The exporter and the importer hereby confirm that the above products are compliant with the ☐quality standards of China/ ☑quality standards of foreign country (please tick the box) and the quality standards stipulated in the agreement between the parties. The importer shall guarantee the product quality standards stipulated by the agreement are compliant with the quality requirements of the importing country/region, and shall confirm it has accepted the quality standards of the above products.

本声明一式两份，双方各执一份。

This declaration is made in duplicate, one original for each party.

特此声明。

杭州协合医疗用品有限公司
HANGZHOU SINGCLEAN MEDICAL PRODUCTS CO., LTD.

付款委托书

Power of Attorney

致：杭州协合医疗用品有限公司

To：Hangzhou Singclean Medical Products Co., Ltd.

我们 Importadora de Productos medicos SPA] ，位于 Isluga Huechuraba, Region Meropolitana, Chile ，致力于进口和分销医疗器械。兹授权 Medina Ramirez Jocelyn Mechellandunate 作为我们在中国的代表，全权负责新型冠状病毒肺炎 IgG/IgM 抗体检测试剂盒（胶体金法） COVID-19 IgG/IgM Test Kit (Colloidal Gold Method) 的付款。

We Importadora de Productos medicos SPA] , a company located in Isluga Huechuraba, Region Meropolitana, Chile , specialized in the import and distribution of medical device. Hereby authorize Medina Ramirez Jocelyn Mechellandunate as our representative in China, take full responsibility in making the payment for COVID-19 IgG/IgM Test Kit (Colloidal Gold Method) to your company.

谢谢！

Thanks and Best regards.

杭州协合医疗用品有限公司
HANGZHOU SINGCLEAN MEDICAL PRODUCTS CO., LTD.

盖章：

Company Stamp:

IMPORTADORA
DE PRODUCTOS MEDICOS SPA
77.141.126 - 6

签字：

Signature:

JOCELYN MICHELL MEDINA RAMIREZ

16.225.608-4

日期：

Date: 06 de mayo de 2020

Singclean®

CE

COVID-19 Test Kit

(Colloidal Gold Method)

INTENDED USE

COVID-19 Test Kit (Colloidal Gold Method) is a solid phase immunochromatographic assay for the rapid, qualitative detection of antigen to 2019 Novel Coronavirus in human nasal cavity. This test provides only a preliminary test result. Therefore, any reactive specimen with the COVID-19 Test Kit (Colloidal Gold Method) must be confirmed with alternative testing method(s) and clinical findings.

PACK FORMATS

20 tests/box

INTRODUCTION

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatically infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

PRINCIPLE

The COVID-19 Test Kit (Colloidal Gold Method) is a colloidal gold immunochromatographic assay. The test uses COVID-19 (SARS-CoV-2) antibody (test line T) and goat anti-mouse IgG (control line C) immobilised on a nitrocellulose strip. The burgundy colored conjugate pad contains colloidal gold conjugated to another COVID-19 (SARS-CoV-2) antibody conjugated with colloid gold and mouse IgG-gold conjugates. When the processed buffer containing the sample is added to the sample well, COVID-19 (SARS-CoV-2) will combine with the COVID-19 antibody conjugate to form an antigen-antibody complex. This complex migrates through nitrocellulose membrane by capillary action. When the complex meets the line of the COVID-19 antibody of test line T, the complex is trapped forming a burgundy colored band which confirm a reactive test result. Absence of a colored band in the test region indicates a non-reactive test result.

The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex goat anti-mouse IgG/mouse IgG-gold conjugate regardless of the color development on any of the test bands. Otherwise, the test result is invalid and the specimen must be retested with another device.

MATERIALS SUPPLIED

Sealed pouches each containing a test cassette, a desiccant
Sampling cotton swabs (for nasal sampling only)
Antigen extract buffer
Antigen extraction tube
Paper workbench
Instruction for use

MATERIAL REQUIRED BUT NOT PROVIDED

1. Specimen collection containers
2. Timer

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (4-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use.
Do not freeze.
Do not use beyond the expiration date.

WARNINGS AND PRECAUTIONS

1. For professional In Vitro diagnostic use only. Do not use after expiration date.
2. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
3. Do not use it if the tube/pouch is damaged or broken.
4. Test is for single use only. Do not re-use under any circumstances.
5. 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.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Humidity and temperature can adversely affect results.
8. Do not perform the test in a room with strong air flow, ie. electric fan or strong air-conditioning.

SPECIMEN COLLECTION

1. COVID-19 Test kit (Colloidal Gold Method) can be performed using nasal sampling.
2. Testing should be performed immediately after specimen collection.
3. Bring specimens to room temperature prior to testing.
4. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

TEST PROCEDURE

Allow test cassette, specimen, and Antigen extract buffer control to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface.

Test procedure:

1. Ask the patient to remove the secretions on the surface of the anterior nasal cavity, keep the head slightly tilted, and gently and slowly insert the swab through the nasal cavity to the nasopharynx, When resistance is encountered, it will reach the posterior nasopharynx, stay for a few seconds to absorb

secretions, and gently rotate to remove the swab.

2. Place the antigen extraction tube on the workbench.Place the antigen extraction buffer bottle vertically downward, squeeze the bottle to make the buffer drip freely into the extraction tube without touching the edge of the tube, and add 6 drops (about 200ul) to the extraction tube.

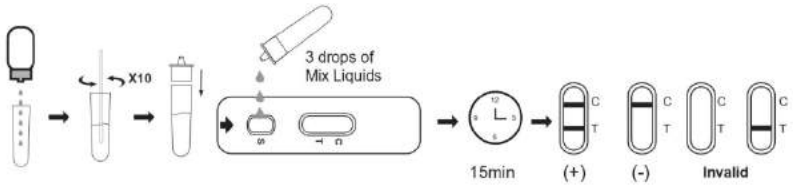
3. Put the swab specimen into the extraction tube pre-added with the antigen extraction buffer, and rotate the swab about 10 times while pressing the swab head against the tube wall to release the antigen in the swab,then let it stand for about 1 minute.

4. Remove the swab while squeezing the tip of the swab so that as much liquid in the swab can be discharged as possible. Dispose of used swabs in accordance with biohazard waste disposal methods.

5. Install the dripper on the extraction tube and cap it tightly, and let it stand for about 1 minute.

6. Open the aluminum foil bag and take out the test card, add 3 drops (about 100ul) into the sample hole of the test card (or use a pipette to add 100ul), and start the timer.

7. Wait for the colored line (T) to appear. The result should be read in 15 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

NEGATIVE: If only the C band is present, the absence of any burgundy color in the T band indicates that no COVID-19 (SARS-CoV-2) antigen are detected in the specimen. The result is negative.

COVID-19 positive:

In addition to the presence of C band, if T band is developed, the test indicates for the presence of COVID-19 (SARS-CoV-2) antigen in the specimen. The result is COVID-19 positive.

INVALID:

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

LIMITATIONS

1. Use fresh samples whenever possible.

2. Optimal assay performance requires strict adherence to the assay procedure described in this insert sheet. Deviations may lead to aberrant results.

3. A negative result for an individual subject indicates absence of detectable COVID-19 (SARS-CoV-2) antigen. However, a negative test result does not preclude the possibility of exposure to or infection with COVID-19.

4. A negative result can occur if the quantity of the COVID-19 (SARS-CoV-2) antigen present in the specimen is below the detection limits of the assay, or failed to collect the COVID-19 (SARS-COV-2) antigen in the nasal cavity of the patient.

5. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

REFERRENCE

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 F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019; 17: 181-192.

SYMBOLS USED ON PACKAGING NOTICE

EC REP	Authorized Representative		Store between 4-30°C	IVD	For in vitro diagnostic use only
	Do not reuse	LOT	Lot Number		Don't use if package is damaged
	Consult instructions for use		Use by		

Hangzhou Singclean Medical Products Co., Ltd.
No. 125(E), 10th street, Hangzhou Economic and Technological Development Zone, Zhejiang, China.P.C.: 310018

SUNGO Europe B.V.
Add: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

EC REP

COVID-19 Test kit（Colloidal Gold Method）

Clinical Performance Study Report

Responsibility	Name	Position	Signature/Date
Drafter	Jin Wang	RA Manager	Qianqian Jia / Sep. 28, 2020
Reviewer	Ming Zheng	Product Manager	Ming Zheng / Sep. 28 2020
Reviewer	Lijiao Meng	Quality Manager (Nanjing Baikang)	Lijiao Meng / sep. 28 2020
Approver	Weiqing Sun	General Manager	Weiqing Sun / Sep. 28, 2020

Change History

Rev.	Change Description	Date Changed
A0	New document	2020.09.19
A1	1."(5)Kappa Analysis "in No.7 revises the calculation error 2. "Kappa consistency test was performed, and k value was 0.8045 with good consistency (k > 0.75). "in No. 8.2 was modified" Kappa consistency test was performed, and k value was 0.7749 with good consistency (k > 0.75)."	2020.09.28

Table of Content

INTRODUCTION 1
ABBREVIATED TERMS 1
1. PRODUCT DESCRIPTION 2
1.1 PRODUCT BACKGROUND 2
1.2 INTENDED PURPOSE 2
1.3 TESTING PRINCIPLE 2
1.4 PRODUCT CHANGE 3
2. OBJECTIVE 3
3. STUDY DESIGN 3
3.1 OVERALL STUDY DESIGN 3
3.2 DETERMINATION OF SAMPLE SIZE 4
3.3 CLINICAL EVALUATION ENDPOINT 5
3.4 PERSONNEL AND RESPONSIBILITIES 5
3.5 SPECIMEN REQUIREMENTS 5
3.6 SAMPLE CHARACTER, COLLECTION AND PRESERVATION 6
3.7 REAGENT INFORMATION 6
3.7.1 TEST REAGENT 6
3.7.2 CONTROL REAGENT 6
4. DATA MANAGEMENT 6
5. STATISTICAL ANALYSIS METHOD 6
6. EVALUATION CRITERIA 8
7. RESULTS OF THE CLINICAL PERFORMANCE STUDY 8
8. CONCLUSION AND DISCUSSION 10
9. MODIFICATION OF CPSP 10
10. DEVIATION FROM CPSP 10
11. ETHICAL REQUIREMENTS AND INFORMED CONSENT 10
12. ADVERSE EVENTS 10
13. REFERENCE STANDARD 11
14. REFERENCE LITERATURE 11

Introduction

The purpose of this study is to confirm the clinical performance of COVID-19 Test kit (Colloidal Gold Method) manufactured by our company by comparison study with similar products approved for marketing.

There were 240 samples collected from human nasal cavity and tested by test reagent and RT-PCR according to their respective Instructions for Use. Record and statistically analyze the test results. Summarize the results and judge the consistency according to the evaluation criteria.

The study results show that the test reagent has good consistency with the control reagent.

Abbreviated Terms

Abbreviation	Full Term
IVD	In Vitro Diagnostic
CPS	Clinical performance study
CPSP	Clinical performance study protocol

1. Product Description

1.1 Product background

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the mair source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifesations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

1.2 Intended purpose

COVID-19 Test Kit（Colloidal Gold Method）is a solid phase immunochromatographic assay for the rapid, qualitative detection of novel Coronavirus 2019 antigen in human nasal cavity.This test provides only a preliminary test result. Therefore, any reactive specimen with the COVID-19 Test Kit（Colloidal Gold Method）must be confirmed with alternative testing method(s) and clinical findings.

1.3 Testing principle

The COVID-19 Test Kit（Colloidal Gold Method） is a colloidal gold immunochromatographic assay. The test uses COVID-19 (SARS-CoV-2) antibody (test line T) and goat anti-mouse IgG (control line C) immobilised on a nitrocellulose strip. The burgundy colored conjugate pad contains colloidal gold conjugated to another COVID-19 (SARS-CoV-2) antibody conjugated with colloid gold and mouse IgG-gold conjugates. When the processed buffer containing the sample is added to the sample well,COVID-19 (SARS-CoV-2) antigen will combine with the COVID-19 antibody conjugate to form an antigen-antibody complex. This complex migrates through nitrocellulose membrane by capillary action. When the complex meets the line of the COVID-19 antibody of test line T, the complex is trapped forming a burgundy colored band which confirm a reactive test result. Absence of a colored band in the test region indicates a non-reactive test result.

The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex goat anti-mouse IgG/mouse IgG-gold conjugate regardless of the color development on

any of the test bands. Otherwise, the test result is invalid and the specimen must be retested with another device.

1.4 Product Change

There are no any changes to COVID-19 Test kit (Colloidal Gold Method) while under investigation during the clinical performance study.

2. Objective

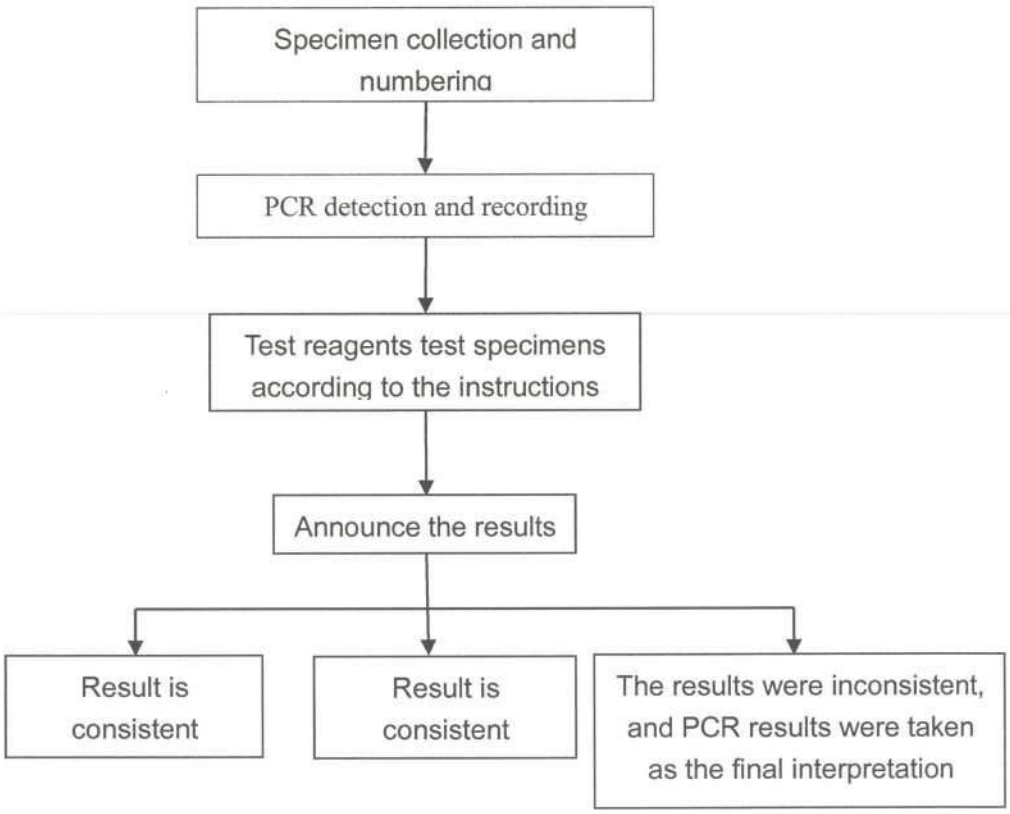
The purpose of this clinical trial is to evaluate the sensitivity and specificity of the COVID-19 Test kit (Colloidal Gold Method) produced by Hangzhou Singclean Medical Products Co., LTD., by comparing a certain number of clinical specimens with PCR nucleic acid detection, and to verify the accuracy of the product in clinical detection, so as to determine whether our product can reach the safety and effectiveness of the marketed product.

3. Study design

3.1 Overall study design

The objective is to conduct clinical comparison test by examining the test reagent and PCR nucleic acid detection, and evaluate the sensitivity and specificity agreement rate and other indicators of the product with the PCR detection results as the criteria, so as to verify the accuracy of the product in clinical detection.

PCR detection and recording were conducted in the sequence of numbersAll the information of the subjects will be hidden and the number and specimens will only be provided. The test operator will test the specimens provided with the test reagent according to the instructions, and record the test results of the test reagent. Compare the results. The test process is as follows:



Note: Specimens from each subject shall be tested in accordance with the instructions for use of the test reagent;

Applicable sample types

This product is applicable to specimens of nose sampling. Samples used in this protocol are collected from the subjects' nasal cavity.

3.2 Determination of sample size

A total of 240 specimens were tested in this study.

- Clinical sensitivity:

  99 positive samples (which was confirmed positive by PCR);

- Clinical specificity:

  141 negative samples (which was confirmed negative by PCR, no history of novel coronavirus exposure);

3.3 Clinical evaluation endpoint

Effectiveness evaluation endpoint: According to the test results, the sensitivity and specificity of the test reagent were calculated respectively, and the evaluation results should be greater than 85%.

Safety evaluation endpoint: The product to be evaluated is in vitro diagnostic reagent and will not have adverse effects on subjects. So do not need the evaluation of safety.

3.4 Personnel and responsibilities

Personnel	Department	Position	Responsibilities
Jixiang Rui	Quality Dept. (Nanjing Baikang)	Quality Specialist	Responsible for specimen collection test operation review and test result analysis
Yi Lv	Quality Dept. (Nanjing Baikang)	Quality Specialist	Responsible for specimen collection test operation review and test result analysis
Haijiao Zheng	R&D Dept. (Nanjing Baikang)	R&D engineer	Responsible for specimen collection test operation review and test result analysis
Lijiao Meng	Quality Dept. (Nanjing Baikang)	Quality Manager	Responsible for the review and confirmation of test results
Ming Zheng	PD	Product Manager	Responsible for the review of test results
Jin Wang	RA Dept.	RA Manager	Responsible for drafting the report
Weiqing Sun	Charge of Company	General Manager	Responsible for the approval of the report

Note: Participants should undergo the unified training, unified recording methods and judgment criteria. The whole clinical trial process should be carried out under strict operation. All observations and findings in clinical trials should be verified to ensure the reliability of the data and to ensure that the conclusions in clinical trials are derived from the original data.

3.5 Specimen requirements

The specimens are from the nasal cavity specimens collected by Nanjing Baikang Biotechnology Co., LTD., and each specimen shall contain the following information:

- The specimen collection date;

- Date of onset of symptoms (if present);
- Date of PCR testing;
- Severity or absence of symptoms;
- Tests used to identify COVID19 patients.

3.6 Sample character, collection and preservation

- Samples are collected with sampling cotton swabs as required for nasal sampling. Label and write the number in the order of inclusion (1, 2, 3.....240).
- After sampling, the samples are immediately processed.

3.7 Reagent information

3.7.1 Test reagent

Manufacturer: Hangzhou Singclean Medical Products Co., Ltd.

Name: COVID-19 Test kit（Colloidal Gold Method）

Packaging specification: 20 tests/box

Storage: Store in a dry place away from light at 4～30℃, avoid frozen. The shelf life is 24 months.

Approved: CE certification

3.7.2 Control reagent

Manufacturer: Huada Biotechnology (Wuhan) Co. LTD.

Name: Covid-19 2019-ncov Nucleic Acid Detection Kit (Fluorescence PCR method)

Packaging specification: 50 test/box

Storage: Store away from light below -18℃. The shelf life is 6 months.

Approved: Medical Device Registration Certificate of China; Japanese PMDA certification; WHO EUL list.

4. Data management

Test all the samples that are waiting to be tested, count the test information of each sample. Subjects' name and other information are not included in this form for reasons of confidentiality.

5. Statistical analysis method

Count the negative and positive specimen of the two reagents respectively and list in a 2×2 contingency table. The final results are summarized in the following table.

Test		Clinical reference standard		Total
		Positive	Negative	
Control reagent	Positive	a	b	a+b
	Negative	c	d	c+d
Total		a+c	b+d	n

(1) Calculate the sensitivity/specificity/accuracy compared with the control reagent.

Sensitivity=a/(a+c)×100% (Calculate a 95% confidence interval)

Specificity=d/(b+d) ×100% (Calculate a 95% confidence interval)

Accuracy=(a+d)/n (Calculate a 95% confidence interval)

(2) Calculate the 95% confidence interval of sensitivity compared with the control reagent

95% confidence interval of agreement rate is [100%(Q1 –Q2)/Q3,100%(Q1 +Q2)/Q3]

$Q1=2a+1.96^2$

$Q2=1.96\sqrt{1.96^2+4ac/(a+c)}$

$Q3=2\ (a+c+1.96^2)$

(3) Calculate the 95% confidence interval of specificity compared with the control reagent

95% confidence interval of agreement rate is [100%(Q1 –Q2)/Q3,100%(Q1 +Q2)/Q3]

$Q1=2d+1.96^2$

$Q2=1.96\sqrt{1.96^2+4bd/(b+d)}$

$Q3=2\ (b+d+1.96^2)$

(4) Calculate the 95% confidence interval of agreement rate compared with the control reagent

95% confidence interval of accuracy is [100%(Q1 –Q2)/Q3,100%(Q1 +Q2)/Q3]

$Q1=2\ (a+d)+1.96^2$

$Q2=1.96\sqrt{1.96^2+4(a+d)(b+c)/n}$

$Q3=2\ (n+1.96^2)$

(5) Kappa analysis

Kappa value is used to evaluate the consistency of the two test methods

The calculation formula is：

$$\text{Kappa}=\frac{P_A-P_e}{1-P_e}$$

$$P_A=\frac{a+d}{n}$$

$$P_e=\frac{(a+b)(a+c)+(c+d)(b+d)}{n^2}$$

6. Evaluation criteria

The judgment of Kappa value (k): k>0.75, have good consistency; 0.40≤k≤0.75, have not so good consistency; k<0.40, have poor consistency.

7. Results of the clinical performance study

- Initiation date：2020.09.04
- Completion date：2020.09.19
- Study site：the laboratory of Nanjing Baikang Biotechnology Co., LTD.
- Sample testing date：2020.09.10~2020.09.16
- Training：All participants completed the training of the product IFU and CPSP before conducting the CPS, understood their responsibilities, operation points and protocol implementation procedures, and were able to perform well in the clinical performance study.
- Disposal of specimens and IVD medical devices under investigation: The used testing materials were discarded in accordance with the requirements in IFU.
- The experimental data are summarized as follows:

Method		RT-PCR		Total
		Positive	Negative	
COVID-19 Test kit	Positive	88	3	91
	Negative	11	138	149
Total		99	141	240
Relative sensitivity		88.89%	confidence interval	81.19%~93.68%
Relative specificity		97.87%	confidence interval	93.93%~99.27%
Accuracy		94.17%	confidence interval	90.45%~96.49%

(1) Calculate the sensitivity/specificity/accuracy compared with the control reagent.

Sensitivity=88/(88+11)×100%=88.89%

Specificity=138/(3+138)×100%=97.87%

Accuracy=(88+138)/240×100%=94.17%

(2) Calculate the 95% confidence interval of sensitivity compared with the control reagent

95% confidence interval of agreement rate is [100%(Q1 –Q2)/Q3,100%(Q1 +Q2)/Q3]

Q1=2a+1.96^2=2*88+1.96^2=179.84

Q2=1.96$\sqrt{1.96^2 + 4ac/(a+c)}$=1.96$\sqrt{1.96^2 + 4*88*11/(88+11)}$=12.85

Q3=2 (a+c+1.96^2)=2*(88+11+1.96^2)=205.68

So the 95% confidence interval of agreement rate is [100%(179.84–12.85)/205.68, 100%(179.84 +12.85)/205.68], [81.19%, 93.68%]

(3) Calculate the 95% confidence interval of specificity compared with the control reagent

95% confidence interval of agreement rate is [100%(Q1 –Q2)/Q3,100%(Q1 +Q2)/Q3]

Q1=2d+1.962=2*138+1.96^2=279.84

Q2=1.96$\sqrt{1.96^2 + 4bd/(b+d)}$=1.96$\sqrt{1.96^2 + 4*138*3/(138+3)}$=7.74

Q3=2 (b+d+1.96^2)=2*(138+3+1.96^2)=289.68

So the 95% confidence interval of agreement rate is [100%(279.84–7.74)/289.68, 100%(279.84+7.74)/289.68], [93.93%, 99.27%]

(4) Calculate the 95% confidence interval of accuracy compared with the control reagent

Q1=2(a+d)+1.962=2(88+138)+1.96^2=455.84

Q2=1.96$\sqrt{1.96^2 + 4(a+d)(b+c)/n}$=1.96$\sqrt{1.96^2 + 4(88+138)(3+11)/240}$=14.74

Q3=2 (n + 1.96^2)=2 (240+ 1.96^2)=487.68

So the 95% confidence interval of agreement rate is [100%(455.84–14.74)/487.68, 100%(455.84+14.74)/487.68], [90.45%, 96.49%]

(5) Kappa analysis

Kappa value is used to evaluate the consistency of the two test methods

The calculation formula is:

PA= $\frac{a+d}{n} = \frac{88+138}{240}$=0.9417

Pe= $\frac{(a+b)(a+c)+(c+d)(b+d)}{n^2} = \frac{(88+3)(88+11)+(88+138)(11+138)}{240^2}$=0.741

Kappa= $\frac{P_A-P_e}{1-P_e} = \frac{0.9417-0.741}{1-0.741}$=0.7749

8. Conclusion and discussion

8.1 The objective of the study has been met. The clinical performance of COVID-19 Test kit (Colloidal Gold Method) manufactured by our company was confirmed by comparison study with similar products approved for marketing.

8.2 A total of 240 samples were tested in this study. The results of test reagent and control reagent both were 141 negative specimens and 99 positive specimens. According to statistical analysis, the sensitivity was 88.89%, the specificity was 97.87% and the accuracy was 94.17%. The 95% confidence interval of sensitivity was [81.19%, 93.68%], specificity was [93.93%, 99.27%], accuracy was [90.45%, 96.49%]. Kappa consistency test was performed, and k value was 0.7749 with good consistency (k > 0.75). Therefore, the test reagent has good consistency with the control reagent.

9. Modification of CPSP

The clinical study was carried out in strict accordance with the CPSP.In the process of clinical study, there is no any modification of CPSP.

10. Deviation from CPSP

The clinical study was carried out in strict accordance with the clinical performance study plan, and no deviation occurred.

11. Ethical requirements and informed consent

This clinical performance evaluation study was conducted in full compliance with the requirements of the Helsinki Declaration. Therefore, this clinical study has no adverse harm or influence on the subjects. And the test results are only for the clinical study, not used as a basis for the clinical diagnosis. On the other hand, the subjects' names have been replaced by numbers, so the subjects' rights and interests, security and privacy are able to fully guarantee, and there are no risks to subjects. For the above reasons, the approval from the ethics committee is not required and the informed consent is also not required.

12. Adverse events

COVID-19 Test kit（Colloidal Gold Method） is an in vitro diagnostic reagent and will not cause adverse effects on subjects.

The test was conducted by personnel with corresponding operational skills in strict accordance with the Instructions for Use, no adverse events such as microbial infection occurred.

13. Reference standard

(1) ISO 20916:2019 In vitro diagnostic medical devices- Clinical performance studies using specimens from human subjects- Good study practice

(2) CLSI. User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline-Second Edition CLSI document EP12-A2, Wayne, PA: Clinical Laboratory Standards Institute; 2008.

14. Reference literature

(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 F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019; 17: 181-192.