TEST RÁPIDOS

COVID19

PREVIENE CONTAGIOS Y MEJORA TU CALIDAD DE VIDA

www.tucuerposiente.cl / contacto@tucuerposiente.cl
+569 9158 82 49 / +569 9079 83 17 / +569 3382 74 10

VENTA DE PRODUCTOS AL POR MAYOR...

HANGZHOU - DEANGEL

TEST RÁPIDO (N°55, MINSAL)

PORCENTAJE EFECTIVIDAD:

El resultado de la detección del anticuerpo IgG: sensibilidad 100.00%, especificidad 98.89%, precisión 99,17%.

El resultado de la detección del anticuerpo IgM: sensibilidad 90.00%, especificidad 97.78%, precisión 95,83%.

Solicita cotización llamando al +569 9079 8317 / leopoldo.ramirez@tucuerposiente.cl

Listado de test rápido para detección de anticuerpos CoVID-19 de la Autoridades Reguladoras Nacionales pertenecientes al Foro Internacional de Reguladores de Dispositivos Médicos

El Instituto de Salud Pública de Chile (ISP) informa el listado de kit de anticuerpos IgG e IgM que se encuentran reportados en los sitios web oficiales de autoridades reguladoras de alta vigilancia sanitaria en dispositivos médicos, como son algunas de las agencias que forman parte del Foro Internacional de Reguladores de Dispositivos Médicos (IMDRF, por sus siglas en inglés), como la FDA de Estados Unidos, TGA de Australia, HSA de Singapur, ANVISA de Brasil, HEALTH CANADA de Canadá, PMDA de Japón y MFDS de Corea del Sur.

Cabe señalar que la aprobación otorgada por las autoridades reguladoras corresponde a una autorización de uso de emergencia de estos test.

	Nombre del Kit	Fabricante	País de fabricación	Técnica Detección	Tiempo de Lectura	Autoridades Reguladoras donde está aprobado	Donde se comercializa
54	SARS-CoV-2 Antibody Test (colloidal gold immunochromatography)	LEPU MEDICAL TECHNOLOGY (BEIJING) CO., LTD.	CHINA	Inmunoensayo IgG/IgM	15 minutos	**ANVISA, Brasil**	Brasil
55	COVID-19 IgG/IgM Rapid Test Device (WB/S/P)	HANGZHOU DEANGEL BIOLOGICAL ENGINEERING CO., LTD	CHINA	Inmunoensayo IgG/IgM	15 minutos	**ANVISA, Brasil**	Brasil
56	COVID-19 IgG/IgM Rapid Test	HUMASIS CO., LTD	COREA DEL SUR	Inmunoensayo IgG/IgM	15 minutos	**ANVISA, Brasil**	Brasil

5 | Página

Actualmente la Organización Mundial de la Salud (OMS) recomienda la implementación del protocolo de detección molecular para 2019-nCoV. RT-PCR en tiempo real y señala una serie de limitaciones del uso de test de detección de anticuerpos IgM e IgG, por lo que no son considerados como un test apropiado para la confirmación o diagnóstico de casos de SARS-CoV-2. La detección de anticuerpos IgM e IgG pueden apoyar en investigaciones epidemiológicas, estudios de brotes o estudios de seroprevalencia.

Hangzhou Deangel Biological Engineering Co.,Ltd

EC Declaration of Conformity

DoC #: QT203

Legal Manufacturer:	Hangzhou Deangel Biological Engineering Co., Ltd
Legal Manufacturer's Address:	Jinxing Cun, Yuhang Community, Yuhang District (Future Sci-Tech City), Hangzhou, Zhejiang P. R. China
EC Representative's Name:	Wellkang Ltd
EC Representative's Address:	16 Castle St, Dover, CT16 1PW, UK

Declares, that the product
Product Name and Model(s):
COVID-19 IgG&IgM Rapid Test Device (WB/S/P) COVID-19-D02

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.

standards, Applied	EN 23640-2015	EN 13640:2002
	EN 980:2016	EN 13641:2002
	EN ISO 14971:2019	EN ISO 18113-1 2011
	EN 13612:2002	EN ISO 18113-4 2011

This self-declaration is according to Annex III (excluding Section 6) of the Directive.

I, the undersigned, hereby declare that the medical devices specified above conform with the Directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements with sole responsibility.

CE

Date Signed: 2020. 4. 15

Ying Yu
Genaral Manager
Hangzhou Deangel Biological Engineering Co.,Ltd

Medicines & Healthcare products Regulatory Agency

MHRA

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Our Ref:IVD000713

Dr Edward Wang
Wellkang Ltd
16 Castle Street
Dover
Kent
CT16 1PW
United Kingdom

28 April 2020

Dear Dr Wang

IN VITRO DIAGNOSTIC MEDICAL DEVICES REGULATIONS 2002: REGULATION 44
Registration of manufacturers of *In-Vitro Diagnostic* Medical Devices and devices for Performance Evaluation

Thank you for informing the Competent Authority of the details of ***Manufacturers* Name:- Hangzhou Deangel Biological Engineering Co., Ltd.** located at **Manufacturers Address:- Jinxing Cun, Yuhang Community, Yuhang District (Future Sci-Tech City), Hangzhou, Zhejiang, China 311121** for whom you are acting as the authorised representative and for supplying the medical device information.

Your registration has been recorded based on your declaration that you have determined that the device(s) fall within the definition of "in vitro diagnostic medical device", and that you have classified it/them correctly considering the intended purpose(s) and mode(s) of action. In accepting your registration, I should make clear that the Competent Authority does not examine each individual notification and therefore cannot and does not necessarily endorse these determinations.

Please note this letter does not represent any form of accreditation, certifcation or approval by the UK Competent Authority.

If you stop placing devices on the market or if you are not complying with the Regulations you should inform us as required by the Regulations. You should be aware that it is an offence to place on the market CE marked devices that do not comply with the Regulations.

The information you provided has been recorded against the reference number shown at the top of this letter, which we ask you to quote in all future correspondence and communications.

Please inform us of any of the following changes;

- the company information
- additional generic groups of devices or, for Annex II or Self-Test devices, additional devices
- discontinuation of a generic group of devices or, for Annex II or Self-Test devices, discontinuation of devices

You should submit your change of registration via DORS with the required statutory fee, which should be accompanied with the information when it is supplied, (the fee is payable for each record notified, and you may place multiple changes on one record).

Thank you for registering the following generic groups of devices

1. ***Part 5: IVDs which are not Annex II and not self-test devices***

中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号: 浙杭食药监械出 20200190 号
Certificate NO.: 浙杭食药监械出 20200190 号

产品名称: 新冠肺炎抗体检测试剂盒（胶体金法），见附件（共 1 页）
Product(s): COVID-19 IgG/IgM Rapid Test Device (WB/S/P), See Attachment (1 Page)

规格型号: 见附件（共 1 页）
Model: See Attachment (1 Page)

产品注册或备案凭证号: /
Registration certificate(s): /

生产企业: 杭州德安奇生物工程有限公司
Manufacturer: Hangzhou Deangel Biological Engineering Co., Ltd.

生产企业住所: 杭州余杭区余杭街道金星村
Address of manufacturer: Jinxing Industry Zone,Yuhang Community,Yuhang District,Hangzhou

生产许可或备案凭证号: 浙食药监械生产许 20120078 号
Manufacturing License(s): 浙食药监械生产许 20120078 号

该证明上述产品未在中国注册，尚未进入中国市场。该产品出口不受限制。
This is to certify that the above product(s) are not registered in China and not distributed on the Chinese market. The exportation of the product(s) is not restricted.

证明有效日期至: 2022 年 01 月 27 日
This certification valid until: 2022/01/27

备注: /
Remark: /

Zhejiang Medical Products Administration
（浙江省药品监督管理局）
2020 年 03 月 19 日
（出具单位盖章）