INNOVITA

No test too small, No matter too big.

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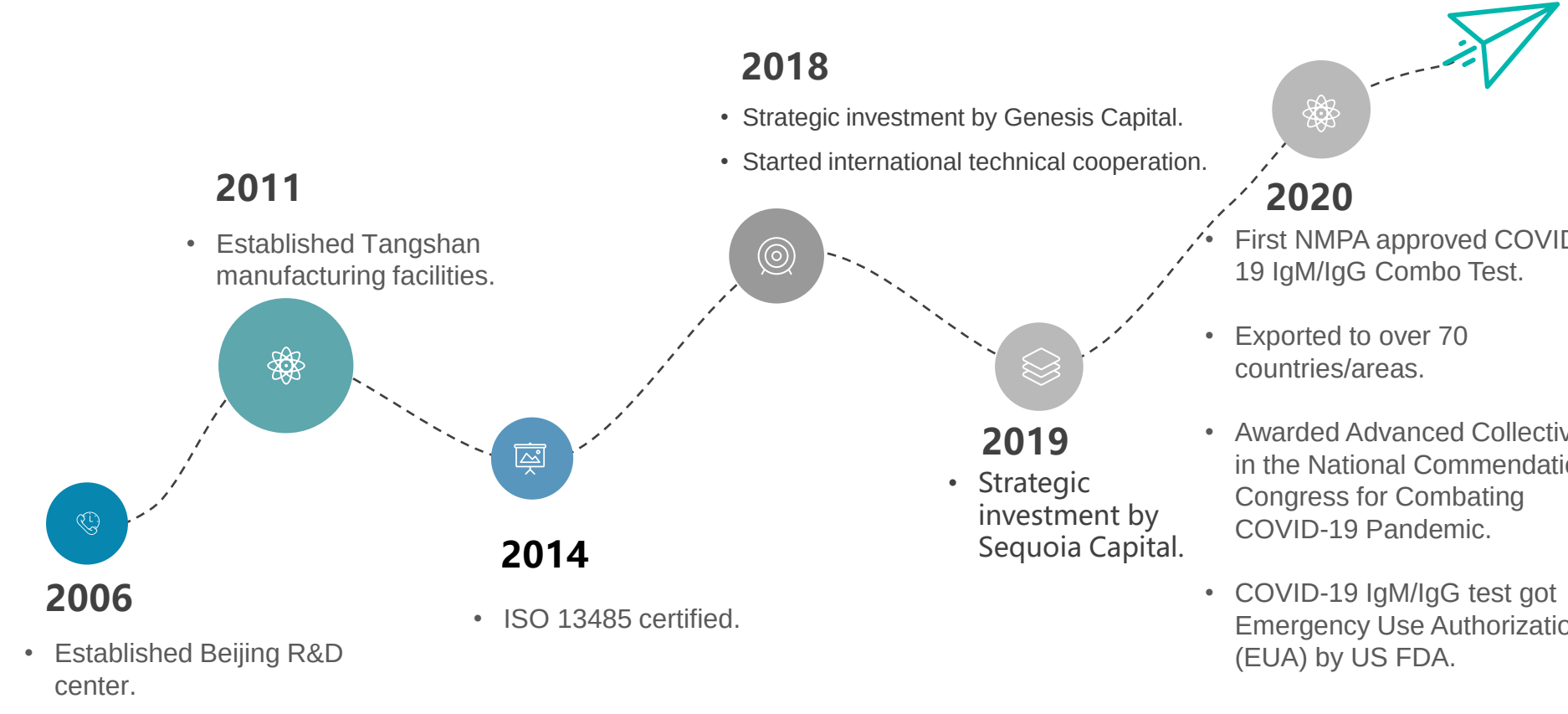
Company Profile

Innovita Biological Technology Co., Ltd. (together with its subsidiaries, collectively known as “INNOVITA",) is a biotechnology company focusing on the research, development, production and sales of in vitro diagnostic POCT products. It consists of Innovita (Tangshan) , Innovita (Beijing) and Innovita (Guangzhou).

- Founded in 2006
- Set up R&D centers in Beijing and Guangzhou, and production base in Qian'an, Hebei

Development Process



2006

- Established Beijing R&D center.

2011

- Established Tangshan manufacturing facilities.

2014

- ISO 13485 certified.

2018

- Strategic investment by Genesis Capital.
- Started international technical cooperation.

2019

- Strategic investment by Sequoia Capital.

2020

- First NMPA approved COVID-19 IgM/IgG Combo Test.
- Exported to over 70 countries/areas.
- Awarded Advanced Collective in the National Commendation Congress for Combating COVID-19 Pandemic.
- COVID-19 IgM/IgG test got Emergency Use Authorization (EUA) by US FDA.

Branches

Beijing R&D & Marketing Center

Establishement: 2006

Focus: R&D, manufacturing, marketing of in-vitro diagnostic product, including platforms such as immunodiagnosis, molecular diagnosis, and gene chips.

Qian'an Manufacturing & Logistic Center

Establishement: 2011

Facility: around 5,000 ㎡ floor area, equipped with multiple production lines of colloidal gold, ELISA, PCR.

Certification: ISO 13485, CE, FDA, NMPA, etc.

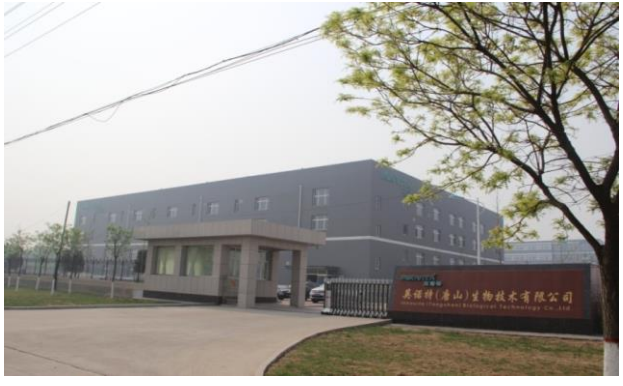
Guangzhou R&D Center

Establishement: 2020

Focus: R&D of IVD technologies

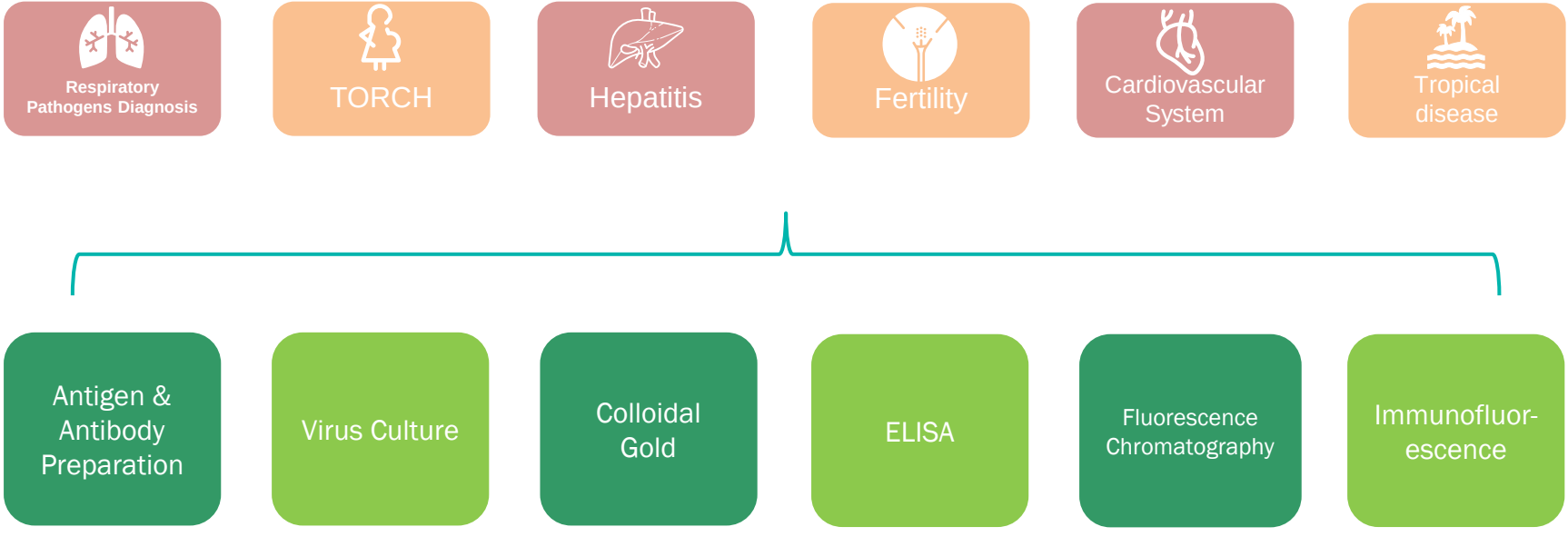
Manufacturing Facilities

Manufacturing Facilities



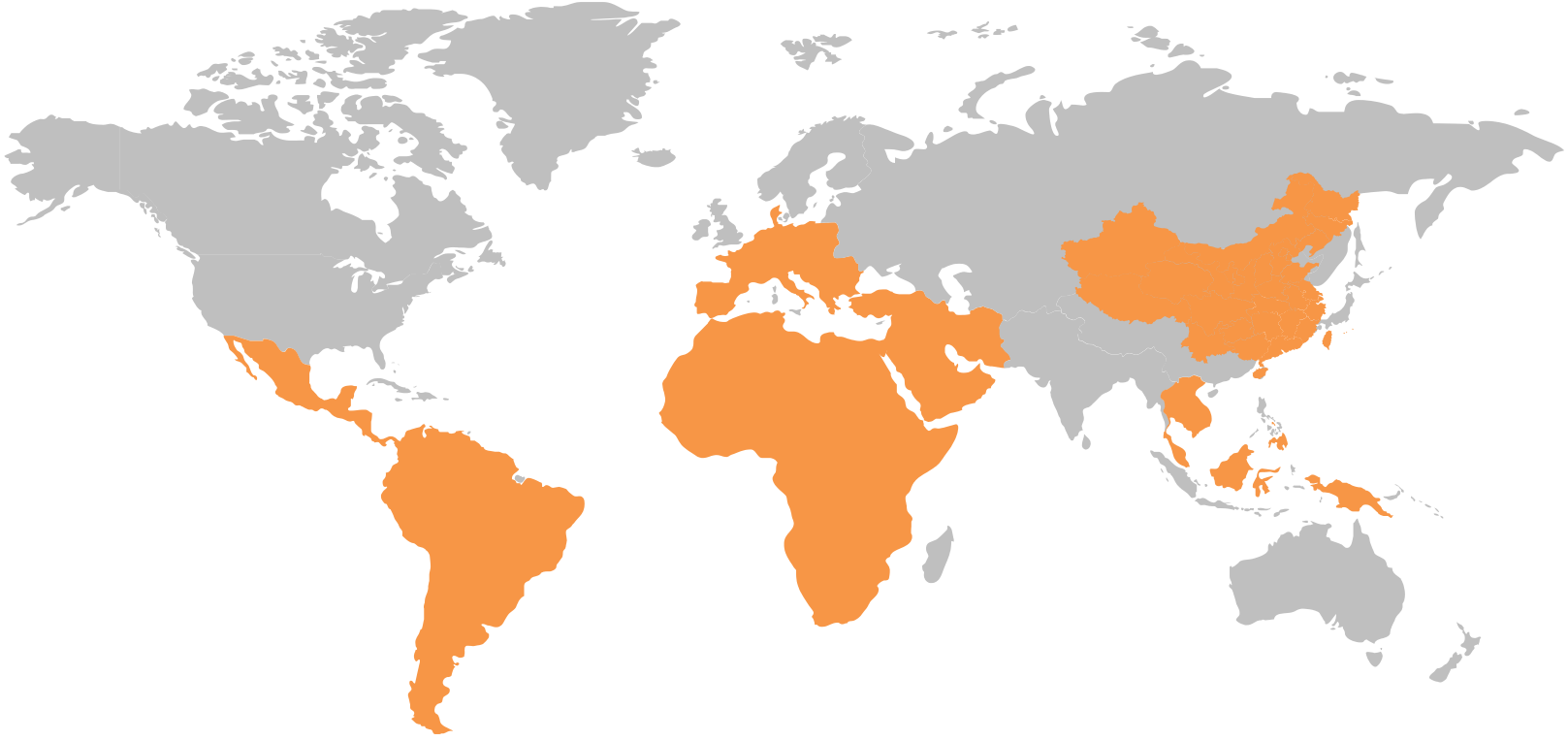
Automatic Production Lines

Products & Platforms



Marketing Network

After years of development, Innovita already has a complete sales and service network, with sales channels covering 32 provinces and regions across China, and have exported to global markets such as Southeast Asia, Middle East, Africa, Latin America, Europe, etc.

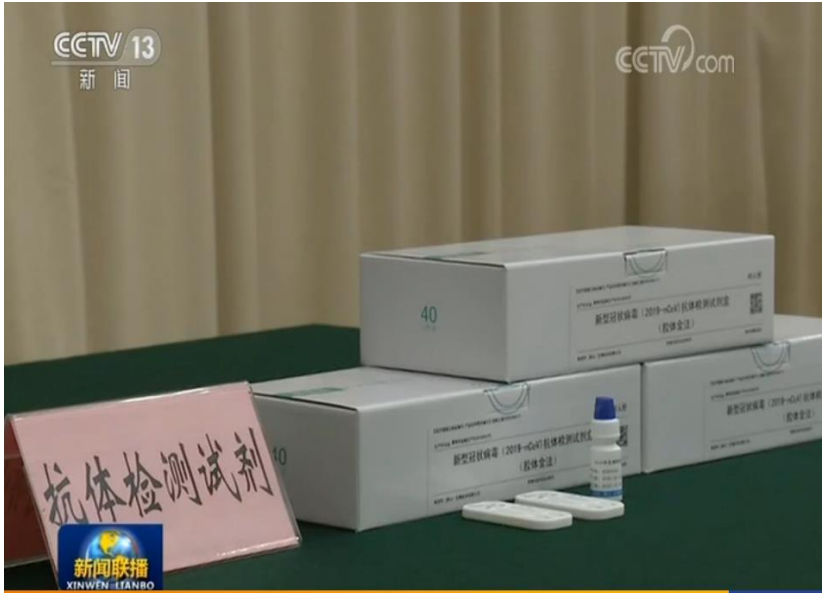


Qualification

High-tech enterprises	Over 60 medical device registration certificates	Over 10 national invention patents	Annual output: 20,000,000 IVD tests	Exported to over 70 countries/areas

Innovita 2019-nCoV Ab Test displayed on the national emergency platform for medicines and medical devices

- On February 28, 2020, Premier Li Keqiang inspected the national emergency platform for medicines and medical devices of COVID-19. Innovita 2019-nCoV Ab Test was displayed as the first NMPA approved IgM/IgG combo antibody test, which was reported on CCTV.



Innovita 2019-nCoV Ab Test named by Academician Zhong Nanshan

- On the afternoon of February 23, 2020, Academician Zhong Nanshan disclosed during a remote consultation in Guangzhou with the Guangdong medical team rushing to help Jingzhou that the National Medical Products Administration has approved two new test kits for 2019-nCoV, one of which is produced by Innovita (Tangshan) Biological Technology Co., Ltd.

- The kit uses the colloidal gold method, which can detect the lgM antibody in the patient's body. The lgM antibody can be detected on the 7th day of the patient's infection or the 3rd day of the onset, which is very helpful for the patient's further diagnosis. Zhong Nanshan said: "Patients can quickly be identifed for a good diagnosis. This can help us quickly separate normal people from infected ones."

Advanced Collective Award

National Commendation Congress for Combating COVID-19 Pandemic

10:00 am Sept. 8 2020 at the Great Hall of the People

Innovita awarded Advanced Collective

Combating Pandemic

International Certification-2019-nCoV Ab Test

FDA EUA

Acknowledgment Letter

3/3/2021

Young Wang, M.D.
Wanda Henry Co.
4426 Prancing Deer Drive
Ellicott City, MD 21043
UNITED STATES

Dear Young Wang, M.D.:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please contact the Office of Product Evaluation and Quality (OPEQ) submission support at (301) 796-5640 or OPEQSubmissionSupport@fda.hhs.gov.

Submission Number: EUA210191
Received: 3/3/2021
Applicant: Innovita (Tangshan) Biological Technology Co., LTD
Device: Innovita 2019-nCoV Ag Test (Latex Chromatography Assay)

We will notify you when the review of this document has been completed or if any additional information is required. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

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

CIBG Netherlands

Salute Italy

Ogyei Hungary

HSA Singapore

FDA Philippines

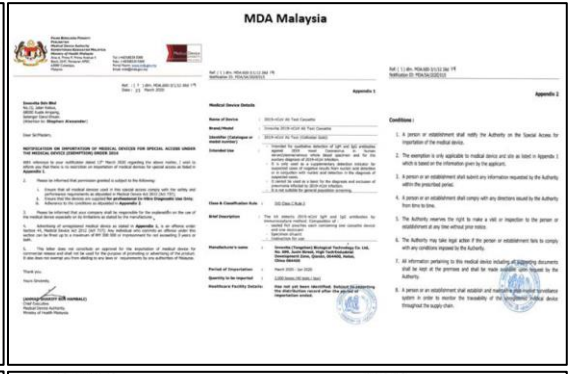
FDA Thailand

AEMPS Spain

RZN Russia

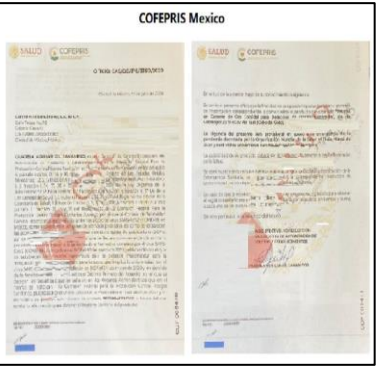
TGA Australia

MDA Malaysia



ARCSA Ecuador

COFEPRIS Mexico

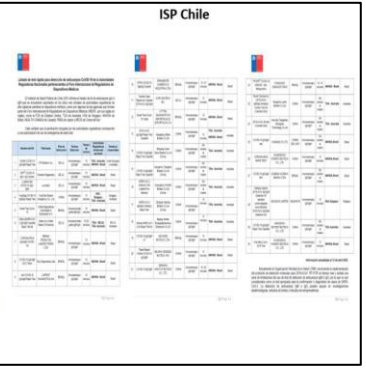


ANVISA Brazil

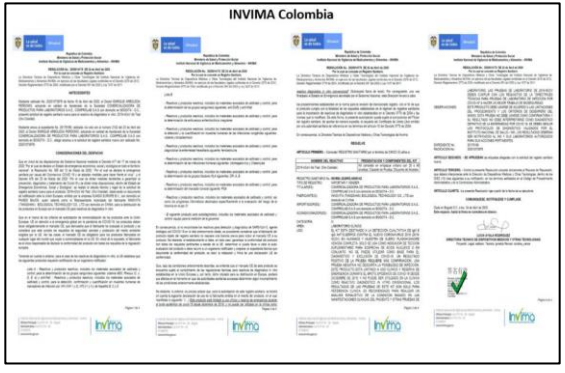
ANMAT Argentina

DIGEMID Peru

ISP Chile



INVIMA Colombia



International Certification-2019-nCoV Ag Test

INNOVITA

BASG Austria

https://www.basg.gv.at/fileadmin/redakteure/Medizinprodukte/Covid/Übersicht_Selbstverpflichtung_Inverkehrbringen_SARS-CoV-2_Schnelltests_202...

Inverkehrbringer Firma	Inverkehrbringer Anschrift	Bezeichnung des Medizinprodukts	Name und Anschrift des Herstellers	Name und Anschrift des Bevollmächtigten
INNOVITA (TANGSHAN) BIOLOGICAL TECHNOLOGY CO., LTD.	No. 699 Juxin Street, High-tech Industrial Development Zone, Qian'an, 064400, Hebei, China.	2019-nCoV Ag-Test (Latex-Chromatografie-Testsatz) - Nasenabstrich	INNOVITA (TANGSHAN) BIOLOGICAL TECHNOLOGY CO., LTD. No. 699 Juxin Street, High-tech Industrial Development Zone, Qian'an, 064400, Hebei, China.	OSMUNDA Medical Technology Service GmbH Von Oppen-Weg 15, 14476 Potsdam
INNOVITA (TANGSHAN) BIOLOGICAL TECHNOLOGY CO., LTD.	No. 699 Juxin Street, High-tech Industrial Development Zone, Qian'an, 064400, Hebei, China.	2019-nCoV Ag-Test (Latex-Chromatografie-Testsatz) - Speichel	INNOVITA (TANGSHAN) BIOLOGICAL TECHNOLOGY CO., LTD. No. 699 Juxin Street, High-tech Industrial Development Zone, Qian'an, 064400, Hebei, China.	OSMUNDA Medical Technology Service GmbH Von Oppen-Weg 15, 14476 Potsdam

CIBG Netherlands

INFARMED Portugal

Detalhes

CDM	Referência	Designação/Nome Comercial
70478678	Innivita Naso Cov Ag Test	Innovita Naso 2019-nCoV Ag Test

Tipo de Dispositivo	Marca	Modelo
DM Diagnóstico In Vitro (DIV)	INNOVITA	Teste Rápido Nasofaringeo

Classe	Família	Estado de Comercialização
Outros (DIV não listado no anexo II da Direc	Não Aplicável	Comercializado

Código NPDM	Fabricante
Testes rápidos para virologia - outros (W010	INNOVITA (TANGSHAN) BIOLOGICAL TEC

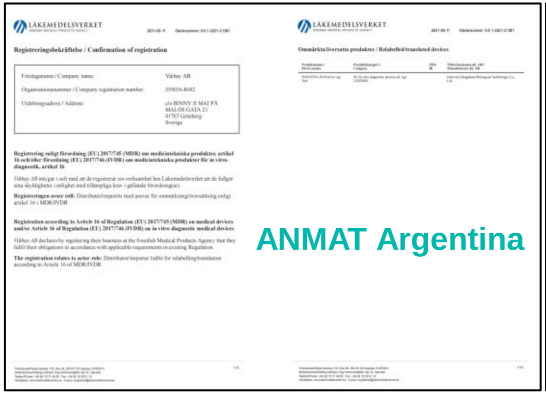
Declaração	Certificado
	Não disponível

Entidades

Papel	Nome Entidade	Estado de Comercialização	Rotulagem	Folheto Informativo
Distribuidor	Prodigy Falcon	Comercializado		

MPA Sweden

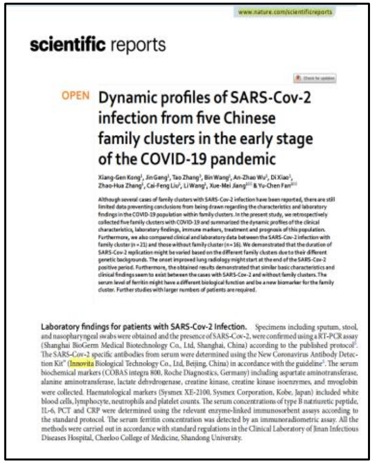
ANMAT Argentina



FDA Philippines

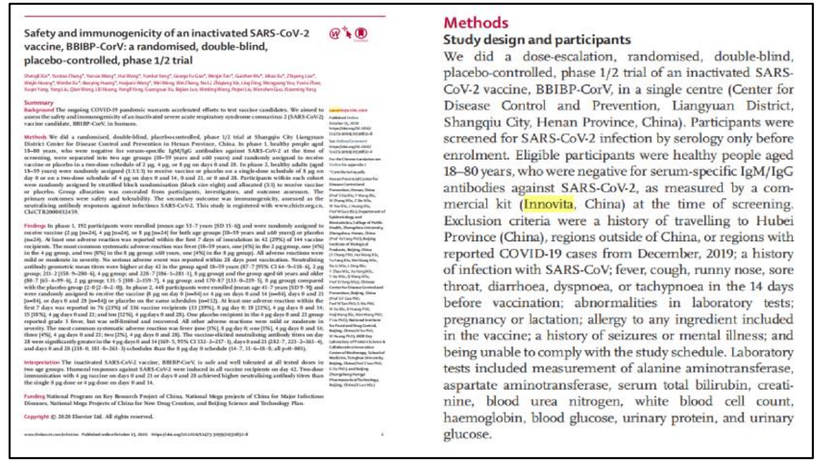
International Studies

Innovita 2019-nCoV Ab Test in NATURE Study


scientific reports

OPEN Dynamic profiles of SARS-Cov-2 infection from five Chinese family clusters in the early stage of the COVID-19 pandemic

Innovita 2019-nCoV Ab Test in LANCET Study


Safety and immunogenicity of an inactivated SARS-CoV-2 vaccine, BBIBP-CorV: a randomised, double-blind, placebo-controlled, phase 1/2 trial

Methods

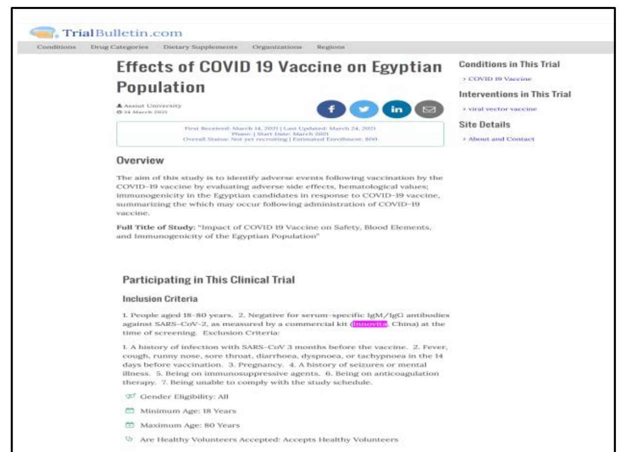
Study design and participants

We did a dose-escalation, randomised, double-blind, placebo-controlled, phase 1/2 trial of an inactivated SARS-CoV-2 vaccine, BBIBP-CorV, in a single centre (Center for Disease Control and Prevention, Liangyuan District, Shangqiu City, Henan Province, China). Participants were screened for SARS-CoV-2 infection by serology only before enrolment. Eligible participants were healthy people aged 18–80 years, who were negative for serum-specific IgM/IgG antibodies against SARS-CoV-2, as measured by a commercial kit (Innovita, China) at the time of screening. Exclusion criteria were a history of travelling to Hubei Province (China), regions outside of China, or regions with reported COVID-19 cases from December, 2019; a history of infection with SARS-CoV; fever, cough, runny nose, sore throat, diarrhoea, dyspnoea, or tachypnoea in the 14 days before vaccination; abnormalities in laboratory tests; pregnancy or lactation; allergy to any ingredient included in the vaccine; a history of seizures or mental illness; and being unable to comply with the study schedule. Laboratory tests included measurement of alanine aminotransferase, aspartate aminotransferase, serum total bilirubin, creatinine, blood urea nitrogen, white blood cell count, haemoglobin, blood glucose, urinary protein, and urinary glucose.

Innovita 2019-nCoV Ab Test in MDPI Study


SARS-CoV-2 Seroprevalence among Healthcare Workers in General Hospitals and Clinics in Japan

Innovita 2019-nCoV Ab Test in Assiut University Study


TrialBulletin.com

Effects of COVID 19 Vaccine on Egyptian Population

Overview

The aim of this study is to identify adverse events following vaccination by the COVID-19 vaccine by evaluating adverse side effects, hematological values; immunogenicity in the Egyptian candidates in response to COVID-19 vaccine, summarizing the which may occur following administration of COVID-19 vaccine.

Participating in This Clinical Trial

Inclusion Criteria

1. People aged 18-80 years. 2. Negative for serum-specific IgM/IgG antibodies against SARS-CoV-2, as measured by a commercial kit (Innovita, China) at the time of screening.

THANK YOU!

CONTACT INFO

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