Ritter®

Eine Marke der Biamed GmbH, 48432 Rheine

DER COVID-19 ANTIGEN SPUCKTEST

Die neue Art zu testen.

- SICHER
- BEQUEM
- SCHMERZFREI
- SCHNELL

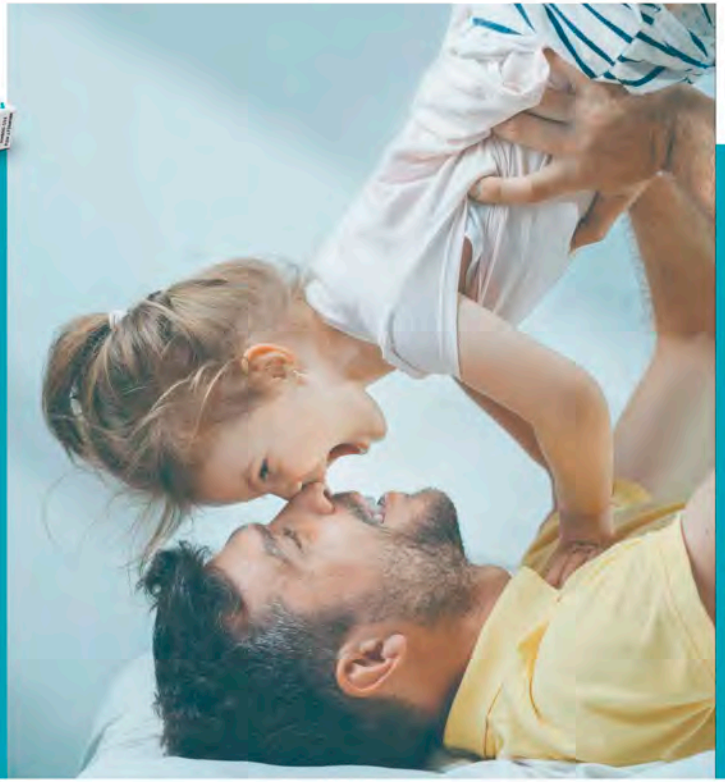
PZN 17204563

PZN 17204586

95,00% Sensitivität

98,78% Spezifität

97,54% Genauigkeit



Der **EASY CHECK** von Ritter auf einen Blick:

- Zum Nachweis von SARS-CoV-2 in Speichel
- Patientenfreundlich durch nicht-invasive Proben-Entnahme
- Ideal für Kinder, ältere Menschen und Menschen mit Behinderungen
- Schnelle Testergebnisse bereits ab 4 Minuten (je nach Raumtemperatur)
- BfArM-gelistet und der Produzent hat eine „Prequalification“ bei der WHO

Bundesinstitut für Arzneimittel und Medizinprodukte

World Health Organization

EASY CHECK LIEFERUMFANG

Eine Packung **EASY CHECK** enthält:

- 20 Testkassetten
- 20 Pipetten
- 20 Probenentnahmeröhrchen
- 20 Einweg-Tüten zum Auffangen von Probenmaterial (Speichel)
- Packungsbeilage

(Wie jeder Test vom Rückgaberecht ausgeschlossen)

Auszug aus der **EASY CHECK** Gebrauchsanweisung:

Der EASY CHECK COVID-19 Antigen-Schnelltest kann mit hinteren oropharyngealen Speichelproben durchgeführt werden.

Für hintere oropharyngeale Speichelproben: waschen Sie Ihre Hände mit Seife und wasser- oder alkoholbasierten Lösungen. Öffnen Sie den Behälter.

1. Räuspern Sie sich, lösen Sie den Speichel aus dem Rachen und spucken Sie ihn in den Behälter (ungefähr 2ml). Vermeiden Sie eine Kontamination an der äußeren Oberfläche des Behälters durch den Speichel.
   Die beste Zeit um die Probe zu sammeln ist nach dem Aufstehen, bevor der Patient die Zähne geputzt, gegessen oder getrunken hat.

2. Nehmen Sie die Speichelprobe mit der Pipette auf.

3. Öffnen Sie das Probenröhrchen, geben die Probe hinein und schütteln Sie es um alles gut zu vermischen.

4. Nehmen Sie die Testkassette aus dem Beutel, legen Sie sie auf einen Tisch und schneiden Sie den vorstehenden Teil vom Deckel des Probenröhrchens ab. Geben Sie dann 3 Tropfen der Probe in die Probenvertiefung und lesen Sie das Resultat, je nach Raumtemperatur, nach 4-15 Minuten ab. Schnellste Ergebnisse bei Raumtemperatur zwischen 18-30°C.

(Testdurchführung nur durch medizinisches Fachpersonal)

ÜBER DEN HERSTELLER

Weltweit führender Hersteller von Lateral Flow Testkits in China. Das Unternehmen ist ein auf Forschung und Entwicklung fokussiertes chinesisches Biotechnologie-Unternehmen, das qualitativ hochwertige medizinische In-vitro-Diagnostik (IVD)-Schnelltestkits sowie revolutionäre kundenspezifische Reagenzienkits entwickelt, herstellt und in alle Teile der Welt liefert.

Das Unternehmen wurde von einem Team von Fachleuten mit langjähriger kombinierter Erfahrung in den Bereichen Technik, Marketing/Vertrieb, Betrieb und Herstellung in dieser Branche gegründet. Ihre in-vitro-diagnostischen Lateral-Flow-Kits screenen auf eine breite Palette von Targets, darunter Infektionskrankheiten, Tumore, Herzanomalien, Drogenmissbrauch und Fruchtbarkeit.

Dank des umfassenden Qualitätsmanagementsystems, welches internationale Standards (EN ISO 13485) anwendet, wird eine hohe Qualität der Testergebnisse und Genauigkeit gewährleistet. Die meisten ihrer Produkte sind CE- und CFDA-zertifiziert.

VERPACKUNGEN

1er-Pack & 20er-Pack

www.easycheck-test.de

ZERTIFIKATE / LISTUNGEN

Konformitätserklärung

EC Declaration of Conformity

Manufacturer:
Name: JOYSBIO (Tianjin) Biotechnology Co., Ltd.
Address: Tianjin International Joint Academy of Biotechnology & Medicine 9th floor, No.220, Dongting Road, TEDA 300457 Tianjin China
Tel: +86-022-65378415
Email: molly@joysbio.com

Whose Authorized Representative:
Name: Lotus NL B.V.
Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands
E-mail: peter@lotusnl.com

We, the manufacturer, here with declare that the product(s)

Product Name	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	**Specification**	20Tests/box (1Test/bag ×20 Bags) , 40 Tests /box (1Test / bag ×40 Bags)
Intended Use	For in vitro qualitative detect of SARS-CoV-2 nucleocapsid antigen in nasal/NP swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first 5 days of the onset of the symptoms. This test is only provided for use by clinical laboratories or to healthcare workers for point-of-care testing, and not for at home testing.		
Classification	Others		

Conformity Assessment Route: IVDD98/79/EC Annex III.

Applicable Standards:

ISO 13485:2016 · EN ISO 18113-1:2011 · EN 13612:2002
ISO 14971:2019 · EN 13641:2002 · ISO 23640:2015
EN ISO 18113-2:2011 · ISO 15223-1:2016 · EN 62366-1:2015
EN ISO 18113-3:2011

CE

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We agree to develop,implement and maintain a documented post-production monitoring process.

Name of General Manager	王春
Signature	
Date	2020-08-25
Place	Tianjin, China
Seal (Manufacturer)	

EU Registrierung „In Vitro Diagnostic Products"

CIBG
Ministry of Health, wellbeing and sports

> Return address PO Box 16114 2500 BC The Hague

Lotus NL B.V.
Attn. Mr. X. Wei
Koningin Julianaplein 10
2595 AA The Hague

Formatec
Visiting address:
Hofloren
Rijnstraat 50
2515 KP The Hague
T 070 340 6161

http://hulpmiddelen.farmatec.nl

Information about:
M.P. Meijer - Michiels

Medische_hulpmiddelen@minvws.nl
registration number:
CIBG-20200411

Attachments

Date of Application
Aug 13, 2020

Correspondence should only be addressed to the return address, stating the date and reference of this letter.

Date : Aug 18, 2020
Subject : Notification in-vitro diagnostics

Dear Mr. Wei
I hereby acknowledge receipt on 29 April 2020 of the Article 4. 1st paragraph of the Dutch Decree in vitro diagnostics (BIVD) that company name JOYSBIO (Tianjin) Biotechnology Co., Ltd with European authorized Lotus NL B.V. market the product below as an in vitro diagnostic product on the European market.

The product is registered as an in vitro diagnostic under number:

SARS-CoV-2 IgG/Neutralizing antibody Rapid Test Kit(Colloidal Gold) ,
SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold),
Immunochromatography analyzer (no brand name) (NL-CA002-2020-53008)

Tuberculosis Antibody Test Kit (Colloidal Gold) ,
Mycoplasma Pneumonia IgM Antibody Test Kit (Colloidal Gold),
Treponema Pallidum Antibody Test Kit (Colloidal Gold),
Morphine/Methamphetamine/Ketamine Test Kit (Colloidal Gold)
(no brand name) (NL-CA002-2020-53009)

It means that you have fulfilled your obligation under Article 4 of the BIVD.

In all further correspondence regarding the above-mentioned product, I request that you state this number. No further rights can be derived from this number, it only serves to facilitate the administrative notification.

The registration of in vitro diagnostics as a medical device under the Classification Criteria (Annex II) to Directive 98/79/EC on medical devices for in vitro diagnostics is subject to possible revisions of European regulations on the classification of medical devices and to advancing scientific understanding (see Article 10 (1) of Directive 98/79/EC).

Page 1 of 2

FDA Einreichung

U.S. FOOD & DRUG ADMINISTRATION

Acknowledgment Letter

9/11/2020

Hongyan Li
JOYSBIO (Tianjin) Biotechnology Co., Ltd.
Tianjin
Tianjin TEDA 300457
CHINA

Dear Hongyan Li:

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: EUA202733
Received: 9/11/2020
Applicant: JOYSBIO (Tianjin) Biotechnology Co., Ltd.
Device: SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

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

EN ISO 13485: 2016 Qualitätsnachweis

TÜVRheinland

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

JOYSBIO (Tianjin) Biotechnology Co., Ltd.
Tianjin International Joint Academy of Biotechnology & Medicine 9th Floor
No.220, Dongting Road, TEDA
300457 Tianjin
P.R. China

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

(see attachment for scope)

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:	2020-06-07
Certificate Registration No.:	SX 60143180 0001
An audit was performed, Report No.:	16806279 004
This Certificate is valid until:	2022-10-12

Certification Body

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-14169-01-02

Date 2020-06-05

Jing Zhang

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

ZERTIFIKATE / LISTUNGEN

World Health Organization

WHO Prequalification

World Health Organization

Prequalification Unit Inspection services
WHO DESK ASSESSMENT REPORT
Emergency Use Listing (EUL)
Review of Quality Management System Documentation

Part 1	General information
Company information	
Name of manufacturer	Joysbio (Tianjin) Biotechnology Co., Ltd
Corporate address of manufacturer	Tianjin International Joint Academy Biotechnology & Medicine 9th Floor, No. 220, Dongting Road, TEDA 300457 Tianjin, China
Contact person	Ms Yang Man Director Registration Department Email: molly@joysbio.com Tel: +86-13821759311
Manufacturing site(s) under assessment	
Address of manufacturing site if different from that given above	Same as above
Desk assessment details	
Date of review	18-23 November 2020
EUL number(s)	EUL 0582-223-00
Inspector(s)	Conrad Mark
Products covered by this desk assessment	SARSV-2 Antigen Rapid Test Kit (Colloidal Gold)
List of documents submitted	WHO-EUL Quality System Information 312 pages
Any documents missing?	

Abbreviations	Meaning
NC	Non-conformity
QC	Quality control
QMS	Quality management system

Part 2	Summary of the assessment of supporting documentation

1. Certification and audit reports:
ISO 13485:2016 certificate number SX 60143180 0001 was provided.

Organization:F
JOYSBIO (Tianjin) Biotechnology CO., Ltd.

WHO Prequalification

World Health Organization

Tel. direct: +41 22 791 47 61
Fax direct: +41 22 791 47 30
Email: prequalinspection@who.int
In reply please refer to: PI-447-UKR/EUL
Your reference:

Ms Yang Man
Joysbio (Tianjin) Biotechnology Co. Ltd
Tianjin International Joint Academy of Biotechnology & Medicine
9th floor, No. 220 Dongting Road
TEDA 300457, Tianjin
République Populaire de Chine

24 November 2020

Dear Ms Man,

OUTCOME OF DESK ASSESSMENT
EUL Emergency Use Listing
WHO Prequalification Unit – Inspection Services
Joysbio (Tianjin) Biotechnology Co. Ltd

Thank you for your email correspondence dated 12 October 2020 and the documents that were sent to the WHO PQT: Inspections Team for the Emergency Use Listing of SARS-CoV-2 (EUL) desk assessment of the Quality Management System of Joysbio (Tianjin) Biotechnology Co. Ltd. Kindly be advised that your application for a desk assessment was reviewed as described in the desk assessment report (enclosed). Those related to the site, indicated as:

Name: Joysbio (Tianjin) Biotechnology Co. Ltd
Address: Tianjin International Joint Academy of Biotechnology & Medicine, 9th floor, No. 220 Dongting Road, TEDA 300457, Tianjin, China

The documents submitted for the desk assessment were found to be satisfactory and are considered to constitute adequate evidence of compliance with ISO 13485 and the requirements described in the "*Instructions and requirements for Emergency Use Listing (EUL) submission: In vitro diagnostics detecting SARS-CoV-2 nucleic acid and rapid diagnostics tests detecting SARS-CoV-2 antigens* (PQDx_347 version 4; 09 June 2020)".

Furthermore, this desk assessment allows Prequalification Inspection Team to recommend to the Prequalification Assessment Team that the site may be named as a manufacturing site in the dossier for the following product:

PQT Number	Product
EUL 0582-223-00	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

Please do not hesitate to send an email to **prequalinspection@who.int** should you require any further information regarding the closure of this inspection.

Yours sincerely,

Dr Joey Gouws
Team Lead, Inspection Services
Prequalification Unit
Regulation and Prequalification Department
Access to Medicines and Health Products Division

Bestätigung der Wirksamkeit bei neuartigen Mutationen

JOYSBIO(Tianjin)Biotechnology Co., Ltd.

Address: Tianjin International Joint Academy of Biotechnology& Medicine 9th floor, No.220, Dongting Road, TEDA 300457 Tianjin China
TEL: 86-22-65378415
Web: en.joysbio.com
E-mail: bd@joysbio.com

To: The Federal Institute for Drugs and Medical Devices
1/20/2020

Letter of Declaration

We, JOYSBIO (Tianjin) Biotechnology Co., Ltd. (hereinafter "JOYSBIO"), with the address of Tianjin International Joint Academy of Biotechnology& Medicine 9th floor No.220, Dongting Road TEDA 300457 Tianjin, China, hereby declare that our product "JOYSBIO SARS-COV-2 Antigen Rapid Test Kit (Colloidal Gold)" is compatible with the new virus strain VUI – 202012/01.

This product is for qualitative detection of SARS-CoV-2 nucleocapsid antigen. We confirm this information is available on the IFU under section [Verwendungszweck], described as "Dieses Produkt wird zum extrakorporalen qualitativen Test der Infektion mit neuartiger Coronavirus-Pneumonie (COVID-19) oder des Proteins aus Nucleocapsid des neuartigen Coronavirus (SARS-CoV-2) ___".

If you have any questions or concerns, please feel free to contact us.

Sincerely Yours,

JOYSBIO (Tianjin) Biotechnology Co., Ltd.

BfArM-Listung

Bundesinstitut für Arzneimittel und Medizinprodukte

Antigen-Tests zum direkten Erregernachweis des Coronavirus SAF