



REGISTRATION NO. IN720Q10007R25

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM

This is to certify that the quality management system of

Jinan Dubio Biological Technology Co., Ltd.

Registered Address: Room 303, Building 5, Industrial base of small enterprises in biological medicine, No.177, Da Zheng Road, High-tech zone, Jinan, Shandong Province

Manufacturing Address: Room 303, 405 Building 5, Industrial base of small enterprises in biological medicine, No.177, Da Zheng Road, High-tech zone, Jinan

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

GB/T 19001-2016 idt ISO 9001:2015

The certificate is valid for the following scope:

The Design, Development, Production and Service of Vitro Diagnostic Reagent
(Within the scope of administrative licensing)

Date of issue: February 24, 2020

Date of expiry: February 23, 2023

General Manager:

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



中国合格
认证认可
管理体系

MANAGEMENT SYSTEM
CNAS CC47-M



MedPath GmbH, Miss-von-der-Roth-Strasse 8, 80807 Munich, Germany

To whom it may concern

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Munich, 16.04.2021

Confirmation of EU Medical Device(s) Notification

This is to confirm that in accordance of Article 10 of Directive 90/269/EC concerning *In vitro* Diagnostic Medical Devices (IVDD), MedPath GmbH agrees to perform all duties and responsibilities as the Authorized Representative for the manufacturer

JINAN BABIO BIOTECHNOLOGY CO., LTD.

303, Building 5 of SME Industrialization Base of Biomedical Park, 1777 Dazheng Road, High-tech Zone, Jinan City 250101, Shandong Province, China

as stipulated and demanded by the aforementioned Directive. The German Competent Authority is notified of the manufacturer's medical device(s)

- Adenovirus Antigen Detection Kit (Colloidal Gold Method)
- Human Chorionic Gonadotropin Detection Kit (Colloidal Gold Method)
- Dengue Rapid Test Kit (Colloidal Gold)
- Mycoplasma Pneumoniae IgM Test Kit (Colloidal Gold)
- Salmonella Typhi/Paratyphi A Antigen Detection Kit (Colloidal Gold Method)
- Respiratory Syncytial Virus IgM Detection Kit (Colloidal Gold Method)
- Coxsackievirus B IgM Test Kit (Colloidal Gold)
- Human Rotavirus Antigen Test Kit (Colloidal Gold)
- Typhoid IgG/IgM Test Kit (Colloidal Gold Method)
- Procalcitonin (PCT) Test Card (Colloidal Gold)
- Helicobacter Pylori (H. pylori) IgG/IgM Test Kit (Colloidal Gold Method)
- Troponin I/Myoglobin/Creatine Kinase MB Detection Kit (Colloidal Gold Method)

HELICOBACTER PYLORI (H.PYLORI) IGG/ IGM TEST KIT

Home > Products > 13 Colloidal Gold Method Products > Helicobacter pylori (H.pylori) IgG/ IgM Test Kit

PRODUCT CATEGORY

Monkeypox

Fully automatic cap opener

13 Colloidal Gold Method

Products

Microbial Detection Reagents

Sample processing fluid

Biochemical Detection

Reagents

Other Rapid Test Reagents

Air Disinfection Machine

SARS-CoV-2 Detection Kit

Sterile Swab Stick

Virus Transport Kit



Helicobacter pylori (H.pylori) IgG/ IgM Test Kit

Helicobacter pylori (H.pylori) is a gram-negative microaerobic bacteria that parasitizes the stomach and duodenum. Its infection is very common, and the global natural population infection rate exceeds 50%. Factors affecting the rate of Helicobacter pylori infection include economic status, living conditions, education level, occupation and drinking habits, etc.

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Product Description

Helicobacter pylori (H.pylori) is a gram-negative microaerobic bacteria that parasitizes the stomach and duodenum. Its infection is very common, and the global natural population infection rate exceeds 50%. Factors affecting the rate of Helicobacter pylori infection include economic status, living conditions, education level, occupation and drinking habits, etc. Generally speaking, developing countries are higher than developed countries. It is currently believed that in the natural environment, humans are the only source of infection of Helicobacter pylori, and the route of transmission is presumed to be oral infection.

【INTENDED USE】

Babio® Helicobacter pylori (H.pylori) IgG/ IgM Test Kit (Colloidal Gold Method) is used for the in vitro qualitative detection of Helicobacter pylori antibody IgG/IgA in human serum/plasma/whole blood samples. For people who have not been treated for Helicobacter pylori eradication, combined with clinical and other laboratory indicators, it is used for the auxiliary diagnosis of Helicobacter pylori infection.

Note: Antibody detection products cannot be used for the recent judgment of the evaluation of the eradication effect of Helicobacter pylori.

【Test Principle】

This kit uses the principle of colloidal gold immunochromatography technology.

【Reagents And Materials Supplied】

Component Name	1T/box	20T/box	25T/box	50T/box
Disposable Dropper	1	20	25	50
Sample Diluent	0.5ml	4ml	5ml	10ml
Desiccant	1	20	25	50
Disposable Test Card	1	20	25	50
Instruction Manual	1	1	1	1

【Materials Required But Not Supplied】

1. Lancets, sample collection and preparation device and disinfecting sterile wipes
2. Clock or timer

【Shelf Life and Storage】

1. Store in a dry place at 2~30 °C away from light.
2. Transport at 2-37°C for 20 days
3. After opening the inner packaging, the test card will become invalid due to moisture absorption, please use it within 1 hour.
4. The shelf life of the test kit is 12 months from date of manufacture.

Tags

Helicobacter h.pylori antibody rapid test kit

h.pylori igm

Related Products



Disposable Specimen Collection S...



Typhoid IgG/IgM Test Kit(Colloidal...

Babio®Typhoid IgG/IgM Test Kit(Colloidal Gold Met...

NAVIGATION

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