

Contract No:Co2403079

Date:09/03/2024

Letter of Authorization

Manufacturer: Atlas Medical GmbH Ludwig-Erhard-Ring 3, 15827Blankenfelde-Mahlow, Germany Tel: +49 33 70 83 55 030 Email: <u>amug@atlas-medical.com</u>

Regulatory Office: William James House, Cowley Road, Cambridge, CB4 0WX, UK Tel: +44 1223 858 910 Fax: +44 1223 858 524 Email: <u>info@atlas-site.co.uk</u>

Middle East Site: Sahab Free Zone Area P. O. Box 204, Amman 11512, Jordan. Tel.: +962 6 4026468 Fax: +962 6 4022588 Email: <u>info@atlas-medical.com</u>

Agent: San Medico Republic of Moldova, city Chisina +37368228890

Atlas Medical, hereby appoint the above mentioned agent to import, register and distribute Atlas Medical Products in Maldova

Appointment Conditions:

- 1. This appointment is valid for 3 year from the above mentioned date.
- 2. Either Party can cancel this appointment by giving the other party a 60 day notice.

On behalf of the Manufacturer General Manager Haya Amawi

Atlas Medical Quality Diagnostic Products

Atlas Medical: Ludwig-Erhard-Ring 3, 15827 Blankenfelde-Mahlow, Germany. Tel: +49 33 70 83 55 030 Regulatory Office: William James House, Cowley Road, Cambridge, CB4 0WX, UK. Tel: +44 1223 858 910 Middle East Site : King Abdullah the Second Industrial Estate, Street 19, Sahab Free Zone Area, P.O. Box: 204, Amman 11512, Jordan



GMED certifie que le système de management de la qualité développé par

GMED certifies that the quality management system developed by

ATLAS MEDICAL GmbH Ludwig-Erhard-Ring 3 15827 Blankenfelde-Mahlow GERMANY

pour les activités for the activities

Conception et développement, fabrication et vente de dispositifs médicaux de diagnostic in vitro .

Design and Development, Manufacturing and Sales of in vitro diagnostic medical devices.

réalisées sur le(s) site(s) de performed on the location(s) of

Voir addendum

See addendum

est conforme aux exigences des normes internationales complies with the requirements of the international standards

ISO 13485: 2016

Début de validité / Effective date October 9th, 2023 (included) Valable jusqu'au / Expiry date : October 8th, 2026 (included) Etabli le / Issued on : October 9th, 2023



ő

GMED N° 36655–2 Ce certificat est délivré selon les règles de certification

Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

e sur Renouvelle le certificat 36655-1

GMED • Société par Actions Simplifiée au capital de 300 000 € • Organisme Notifié/Notified Body n° 0459 Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • gmed.fr





Ce certificat couvre les activités et les sites suivants :

This certificate covers the following activities and sites:

French version :

Conception et développement, fabrication et vente de dispositifs médicaux de diagnostic *in vitro* à usage professionnel et/ ou d'autodiagnostic, dans les domaines du groupage sanguin, de la microbiologie, de la biochimie, de la toxicologie, de l'oncologie, de la cardiologie, de l'histologie, de l'endocrinologie et des maladies infectieuses, dans les techniques d'Agglutination/ ELISA/ Tests rapides/ Colorimétrie/ Disques antibiotiques.

English version:

Design and Development, Manufacturing and Sales of in vitro diagnostic medical devices for professional use and/or for selftesting, in the field of Immunohematology, Microbiology, Biochemistry, Toxicology, Oncology, Cardiology, Histology, Endocrinology Biosensors and Infectious diseases, in techniques of Agglutination/ ELISA/ Rapid tests/ Colorimetry/Antibiotic disks.

ATLAS MEDICAL GmbH Ludwig-Erhard-Ring 3 15827 Blankenfelde-Mahlow GERMANY

French version: **Siège social, responsable de la mise sur le marché** *English version: Headquarter, legal manufacturer*

Sahab Industrial Zone Area King Abdullah II Industrial City Amman 11512 JORDAN

French version: **Conception, fabrication et contrôle final** *English version: Design, manufacture and final control*

DocuSigned by

On behalf of the President Béatrice LYS Technical Director



Declaration Ref No: DC21-0035

CE Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

We,

Atlas Medical

Head office: Ludwig-Erhard-Ring 3 Blankenfelde-Mahlow, Germany. Tel: +49 - 33708 – 3550 30 Email: <u>info@atlas-medical.com</u>

Middle East Site: Sahab Free Zone Area, P. O. Box 212555, Amman, Jordan. Tel.: +962 6 4026468 Fax: +962 6 4022588 Email: <u>info@atlas-medical.com</u>

Declare our responsibility that the following product:

See Attached list

- Comply with all essential requirements (AnnexI) of the IVD Directive 98/79/EC. This compliance has been properly documented and covers the items listed in Annex I of the IVD Directive.
- This product is produced under Atlas quality system (ISO13485:2016) issued by GMED: Certificate N⁰.: 36655 rev 1 Expiry Date: October 8 th.2023
- Comply with the essential requirements of following standards (EN 18113-1, -2,-4:2011, EN ISO 15223:2016, EN ISO 23640:2015, EN ISO 14971:2019, ISO 2859/1:1999, EN ISO 13612:2002, EN ISO 13641:2002.

And Intended for In-Vitro Professional use only.

Manufacturer Atlas Medical Ludwig-Erhard-Ring 3 Blankenfelde-Mahlow, Germany.

Blankenf	elde-Mahlow , G	Germany.	Atlas Medical	
Atlas	Issue date	Date of review	Quality Diagnor Management approval	MRXDO10F.10
Medical	March.2021	09.03.2021		08.02.2011



CE Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

Product Description8.00.02.0.0100 : ASO Latex Kit, 100 Tests (4ml Latex, 2x1.0ml controls).8.00.00.0.0100: CRP Latex Kit, 100 Tests (4ml Latex, 2x1.0 ml Controls)8.00.04.0.0100: RF Latex Kit, 100 Tests (4ml Latex, 2x1.0ml controls)8.00.17.0.0100: D-Dimer Latex Kit, 100 Tests8.00.13.0.0300 : Streptococcus Latex Kit, 6 Groups, 6x50 Tests (5x1.5ml Latex(A,B,C,G,F), 1x3ml Latex(D), 1x1.0ml Positive Control, 1x2ml Extraction Reagent E, 1x1.5ml Extraction Reagent 1, 1x1.5ml Extraction Reagent 2, 2x2.5ml Extraction Reagent 3, Stirring Sticks, Glass Slide).8.00.18.3.0500 : RPR Syphilis (Coarse Grain) Kit, 500 Tests (10 ml latex, 2x1ml control)Without card, stirring sticks.

8.00.18.3.1000 RPR Carbon Antigen (Coarse Grain) Kit, 1000 Tests (Reagent only).

Atlas Medical Quality Diagnostic Products

Atlas Medical

ASO LATEX KIT

IVD For in -vitro diagnostic and professional use only

Store at 2-8°C. 2'0 1

CE

INTENDED USE

ATLAS ASO latex Test is used for the qualitative and semiquantitative measurement of antibodies to Antistreptolysin-O in human serum.

INTRODUCTION

The group A ß-hemolytic streptococci produce various toxins that can act as antigens. One of these exotoxins streptolysin-O, was discovered by Todd in 1932.

A person infected with group A hemolytic streptococci produces specific antibodies against these exotoxins, one of which is antistreptolysin-O. The quantity of this antibody in a patient's serum will establish the degree of infection due to the hemolytic streptococcal.

The usual procedure for the determination of the antistreptolysin titer is based on the inhibitory effect that the patient's serum produces on the hemolytic power of a pre-titrated and reduced streptolysin-O. However, the antigen-antibody reaction occurs independently of the hemolytic activity of streptolysin-O. This property enables the establishment of a qualitative and quantitative test for the determination of the antistreptolysin-O by agglutination of latex particles on slide.

PRINCIPLE

ASO test method is based on an immunologic reaction between streptococcal exotoxins bound to biologically inert latex particles and streptococcal antibodies in the test sample. Visible agglutination occurs when increased antibody level is present in the test specimen. MATERIALS

MATERIALS PROVIDED

- · ASO Latex Reagent: Latex particles coated with streptolysin O, pH, 8,2. Preservative.
- ASO Positive Control (Red cap): Human serum with an ASO concentration > 200 IU/mL.Preservative
- ASO Negative Control (Blue cap) Animal serum. Preservative
- Glass Slide.
- Stirring Sticks.

Note: This package insert is also used for individually packed reagent.

MATERIALS REQUIRED BUT NOT PROVIDED

- Mechanical rotator with adjustable speed at 80-100 r.p.m
- Vortex mixer
- Pippetes 50 µL
- Glycine Buffer-20x (1000 mmol/l): add one part to nineteen parts of distilled water before use Packaging contents

REF 8.00.02.0.0100 (1x4ml Latex Reagent, 1x1ml positive control, 1x1ml negative control)

PRECAUTIONS

- All reagents contain 0.1 %(w/v) sodium azide as a preservative
- . Protective clothing should be worn when handling the reagents.
- Wash hands and the test table top with water and soap once the testing is done.
- Reagents containing sodium azide may be combined with copper and lead plumbing to form highly explosive metal azides. Dispose of reagents by flushing with large amounts of water to prevent azide buildup.
- For In Vitro diagnostic use.
- Components prepared using human serum found negative for hepatitis B surface antigen (HBsAg), HCV and antibody to HIV (1/2) by FDA required test. However, handle controls as if potentially infectious.
- Accuracy of the test depends on the drop size of the latex reagent (40µl). Use only the dropper supplied with latex and hold it perpendicularly when dispensing.
- Use a clean pipette tip and stirring stick for each specimen, and glass slides should be thoroughly rinsed with water and wiped with lint-free tissue after each use.
- Check reactivity of the reagent using the controls provided.
- Do not use these reagents if the label is not available or damaged.
- Do not use the kit if damaged or the glass vials are broken or leaking and discard the contents immediately.
- Test materials and samples should be discarded properly in a biohazard container.

REAGENT PREPARATION:

The ASO Latex reagent is ready to use. No preparation is required. Mix gently before use to ensure a uniform suspension of particles. STORAGE AND STABILITY

- Reagents are stable until specified expiry date on bottle label when stored refrigerated (2-8°C). DO NOT FREEZE.
- The ASO Latex Reagent, once shaken must be uniform without visible clumping. When stored refrigerated, a slight sedimentation may occur and should be considered normal.
- Do not use the latex reagent or controls if they become contaminated.
- Always keep vials in vertical position. If the position is changed, gently mix to dissolve aggregates that may
- be present Reagents deterioration: Presence of particles and

turbidity. SAMPLES

- Use fresh serum collected by centrifuging clotted blood.
- If the test cannot be carried out on the same day, store the specimen for 7 days at 2-8°C and for 3 months at -20°C.
- Samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolyzed or lipemic samples.

DO NOT USE PLASMA.

PROCEDURE

- Qualitative method Allow the reagents and samples to reach room 1. temperature. The sensitivity of the test may be
 - reduced at low temperatures. Place (40 $\mu L)$ of the sample and one drop of each Positive and Negative controls into separate circles on the slide test.
 - Mix the ASO-latex reagent vigorously or on a vortex mixer before using and add one drop (40 µL) next to the sample to be tested.
- 4. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
- 5. Place the slide on a mechanical rotator at 80-100 r.p.m. for 2 minutes. False positive results could appear if the test is read later than two minutes.
- Semi-quantitative method
 - 1. Make serial two-fold dilutions of the sample in 9 g/L saline solution

2. Proceed for each dilution as in the qualitative method.

QUALITY CONTROL

- Positive and Negative Controls should be included in each test batch.
- Acceptable performance is indicated when a uniform milky suspension with no agglutination is observed with the ASO Negative Control and agglutination with large aggregates is observed with the ASO Positive Control.

CALCULATIONS

The approximate ASO concentration in the patient sample is calculated as follows:

200 x ASO Titer = IU/mL

READING AND INTERPRETATION

Examine macroscopically the presence or absence of visible agglutination immediately after removing the slide from the rotator. The presence of agglutination indicates an ASO concentration equal or greater than 200 IU/mL The titer, in the semi-quantitative method, is defined as the highest dilution showing a positive result.

REFERENCE VALUES

Up to 200 IU/mL(adults) and 100 IU/mL (children < 5 years old). Each laboratory should establish its own reference range

PERFORMANCE CHARACTERISTICS

Analytical sensitivity: 200 (±50) IU/ml. PROZONE EFFECT

No prozone effect was detected up to 1500 IU/ml. SENSITIVITY

SPECIFICITY

97%

INTERFERENCES NON-INTERFERING SUBSTANCES:

- Hemoglobin (10 g/L)
- Bilirubin(20 mg/dL)
- Lipids (10 g/L) Rheumatoid factors (300 IU/mL)
- Other substances may interfere

LIMITATIONS

- Reaction time is critical. If reaction time exceeds 2 minutes, drying of the reaction mixture may cause false positive result.
- Freezing the ASO Latex Reagent will result in spontaneous agglutination

- Intensity of agglutination is not necessarily indicative of relative ASO concentration; therefore, screening reactions should not be graded.
- False positive results may be obtained in conditions such as, rheumatoid arthritis, scarlet fever, tonsilitis, several streptococcal infections and healthy carriers.
- Early infections and children from 6 months to 2 years may cause false negative results. A single ASO determination does not produce much information about the actual state of the disease.
- Titrations at biweekly intervals during 4 or 6 weeks are advisable to follow the disease evolution
- Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

REFERENCES

- Haffejee . Quarterly Journal of Medicine 1992. New 1. series 84; 305: 641-658.
- Ahmed Samir et al. Pediatric Annals 1992; 21: 835-2 842.
- Spaun J et al. Bull Wid Hith Org 1961; 24: 271-279. The association of Clinical Pathologists 1961. 4 Broadsheet 34.
- Picard B et al. La Presse Medicale 1983; 23: 2-6.
- Klein GC. Applied Microbiology 1971; 21: 999-1001.
- Young DS. Effects of drugs on clinical laboratory test, 7 4th ed. AACC Press, 1995

ATLAS Medical GmbH Ludwig-Erhard Ring 3

15827 Blankenfelde-Mahlow Germany

Tel: +49 - 33708 - 3550 30 Email: Info@atlas-medical.com Website: www.atlas-medical.com

Catalogue Number

medical device

size

Batch code

handle with care

Manufacturer fax

Manufacturer

Positive control

telephone number

Fragile,

numbe

Кеер away

sunlight

In Vitro diagnostic

Contains sufficient fo

<n> tests and Relative

Temperature limit

Consult instructions

Caution

for use (IFU)

Manufacturer

Use-by date

Do not use if

Keep dry

Negative control

package is damaged

Date of Manufacture

4

A

[]i]

-

2

m

5

CONTROL -

fror

PPI2325A01 Rev A (05.01.2023)

REF

E

LOT

-

温

4

淡

CONTROL



RF LATEX KIT

IVD For In-Vitro diagnostic and professional use only

2° C Store at 2-8°C

INTENDED USE

Atlas RF latex test for the qualitative and semi-quantitative measurement of RF in human serum. INTRODUCTION

Rheumatoid factors (RF) are antibodies directed against antigenic sites in the Fc fragment of human and animal IgG. Their frequent occurrence in rheumatoid arthritis makes them useful for diagnosis and monitoring of the disease.

One method used for rheumatoid factor detection is based on the ability of rheumatoid arthritis sera to agglutinate sensitized sheep red cells, as observed by Waaler and Rose A more sensitive reagent consisting of biologically inert latex beads coated with human gamma globulin was later described by Singer and Plotz. The RF kit is based on the principle of the latex agglutination assay of Singer and Plotz^{. The} major advantage of this method is rapid performance (2-minutes reaction time) and lack of heterophile antibody interference. **PRINCIPLE**

The RF reagent is based on an immunological reaction between human IgG bound to biologically inert latex particles and rheumatoid factors in the test specimen. When serum containing rheumatoid factors is mixed with the latex reagent, visible agglutination occurs.

MATERIALS

MATERIALS PROVIDED

- RF Latex Reagent: Latex particles coated with human gamma-globulin, pH, 8,2. Preservative.
- RF Positive Control Serum (Red Cap): Human serum with a RF concentration > 30 IU/MI. Preservative.
- RF Negative Control Serum (Blue Cap): Animal serum.
 Preservative.
- Glass Slide
- Stirring sticks

NOTE: This package insert is also used for individually packed reagent.

MATERIALS REQUIRED BUT NOT PROVIDED

- Mechanical rotator with adjustable speed at 80-100 r.p.m.
- Vortex mixer.

- Pippetes 50 µL
- Glycine Buffer 20x (1000mmol/L): add one part to nineteen parts of distilled water before use.

Packaging contents

REF 8.00.04.0.0100 (1x4ml Latex Reagent, 1x1ml positive control, 1x1ml negative control)

PRECAUTIONS

- All reagents contain 0.1 %(w/v) sodium azide as a preservative.
- Protective clothing should be worn when handling the reagents.
 Wash hands and the test table top with water and soap
- Wash hands and the test table top with water and soap once the testing is done.
- Reagents containing sodium azide may be combined with copper and lead plumbing to form highly explosive metal azides. Dispose of reagents by flushing with large amounts of water to prevent azide buildup.
- For In Vitro diagnostic use.
- Components prepared using human serum found negative for hepatitis B surface antigen (HBsAg), HCV and antibody to HIV (1/2) by FDA required test. However, handle controls as if potentially infectious.
- Accuracy of the test depends on the drop size of the latex reagent (40µl). Use only the dropper supplied with latex and hold it perpendicularly when dispensing.
- Use a clean pipette tip and stirring stick for each specimen, and glass slides should be thoroughly rinsed with water and wiped with lint-free tissue after each use.
- Check reactivity of the reagent using the controls provided.
- Do not use these reagents if the label is not available or damaged.
- Do not use the kit if damaged or the glass vials are broken or leaking and discard the contents immediately.
- Test materials and samples should be discarded properly in a biohazard container.

REAGENT PREPARATION:

- The RF Latex reagent is ready to use. No preparation is required. Mix gently before use to ensure a uniform suspension of particles.
 STORAGE AND STABILITY
- Reagents are stable until specified expiry date on
- bottle label when stored refrigerated (2-8°C).
- Do not freeze.

- Always keep vials in vertical position. If the position is changed, gently mix to dissolve aggregates that may be present.
 The RF latex reagent, once shaken must be uniform
 - The KE Takes Teagent, once shaken must be uniform without visible clumping. When stored refrigerated, a slight sedimentation may occur and should be considered normal.
- Do not use the latex reagent or controls if they become contaminated.
- Reagents deterioration: Presence of particles and turbidity.

SPECIMEN COLLECTION AND STORAGE

- Use fresh serum collected by centrifuging clotted blood.
- If the test cannot be carried out on the same day, store the specimen for 7 days at 2-8°C and for 3 months at -20°C.
- Samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolyzed or lipemic samples.
- Do not use PLASMA.

PROCEDURE

Qualitative method

ATLAS Medical GmbH

Tel: +49 - 33708 - 3550 30

15827 Blankenfelde-Mahlow

Email: Info@atlas-medical.com

Website: www.atlas-medical.com

Catalogue Number

medical device

Contains

Relative size

handle with care

Manufacturer fax

telephone number

Manufacturer

Keep away

Positive control

sunlight

Batch code

Fragile,

number

In Vitro diagnostic

for <n> tests and

sufficient

Ludwig-Erhard Ring 3

Germany

PPI2326A01

REF

IVD

V

-

4

淡

CONTROL

Rev A (05.01.2023)

- Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
- 2. Place (40 $\mu L)$ of the sample and one drop of each Positive and Negative controls into separate circles on the slide test.
- 3. Mix the RF-latex reagent rigorously or on a vortex mixer before using and add one drop (40 $\mu L)$ next to the sample to be tested.
- Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
- Place the slide on a mechanical rotator at 80-100 r.p.m. for 2 minutes. False positive results could appear if the test is read later than two minutes.
 Semi-quantitative method
- Make serial two-fold dilutions of the sample in 9 g/L saline solution.
- 2. Proceed for each dilution as in the qualitative method.

Temperature

instructions for

limit

Caution

Consult

use (IFU)

Manufacturer

Use-by date

Do not use if

Manufacture

Negative control

package is

damaged

Date of

Keep dry

1

个

III

(&)

m

CONTROL -

from

READING AND INTERPRETATION

Examine macroscopically the presence or absence of visible agglutination immediately after removing the slide from the rotator. The presence of agglutination indicates a RF concentration equal or greater than 8 IU/mL (Note 1). The titer, in the semi-quantitative method, is defined as the

highest dilution showing a positive result. CALCULATIONS

The approximate RF concentration in the patient sample is

calculated as follows: 8 x RF Titer = IU/mL

INTERFERENCES

NON-INTERFERING SUBSTANCES:

- Hemoglobin (10g/L)
- Bilirubin (20mg/dl)
- Lipids (10g/L)

Other substances may interfere.

QUALITY CONTROL

- Positive and Negative controls are recommended to monitor the performance of the procedure, as well as a comparative pattern for a better result interpretation.
- All result different from the negative control result, will be considered as a positive.

PERFORMANCE CHARACTERISTICS

Analytical sensitivity

8 (6-16) IU/ml, under the described assay conditions. <u>PROZONE EFFECT</u>

No prozone effect was detected up to 1500 IU/ml.

DIAGNOSTIC SENSITIVITY

100%.

DIAGNOSTIC SPECIFICITY

100%.

The diagnostic sensitivity and specificity have been obtained using 139 samples compared with the same method of a competitor.

LIMITATIONS

- Reaction time is critical. If reaction time exceeds 2 minutes, drying of the reaction mixture may cause false positive result.
- Freezing the RF Latex Reagent will result in spontaneous agglutination.
- Intensity of agglutination is not necessarily indicative of relative RF concentration; therefore, screening reactions should not be graded.

diseases other than rheumatoid arthritis such as infectious mononucleosis, sarcoidosis, lupus erythematosus, Sjogren's syndrome.
Certain patients with rheumatoid arthritis will not

Increased levels of RF may be found in some

- have the RF present in their serum.
- The incidence of false positive results is about 3-5 %. Individuals suffering from infectious mononucleosis, hepatitis, syphilis as well as elderly people may give positive results.
- Diagnosis should not be solely based on the results of latex method but also should be complemented with a Waaler Rose test along with the clinical examination.

REFERENCE VALUES

Up to 8 IU/mL. Each laboratory should establish its own reference range.

NOTES

 Results obtained with a latex method do not compare with those obtained with Waaler Rose test. Differences in the results between methods do not reflect differences in the ability to detect rheumatoid factors.

REFERENCES

2.

6

- Robert W Dorner et al. Clinica Chimica Acta 1987; 167: 1 – 21.
 - Frederick Wolfe et al. Arthritis and Rheumatism 1991; 34: 951- 960.
- Robert H Shmerling et al. The American Journal of Medicine 1991; 91: 528 –534.
- Adalbert F. Schubart et al. The New England Journal of Medicine 1959; 261: 363 – 368.
 Charles M. Plotz 1956; American Journal of

Young DS. Effects of drugs on clinical laboratory

Medicine; 21:893 - 896.

test, 4th ed. AACC Press, 1995.



STATEMENT

We, Zhejiang Orient Gene Biotech Co., Ltd , having a registered office at 3787#, East Yangguang Avenue, Dipu Street Anji 313300, Huzhou, Zhejiang, China assign SRL SANMEDICO having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova, as non-exclusive authorized representative for Orient Gene Brand product in correspondence with the conditions of directive 98/79/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

This Statement letter will be valid from Feb.21th,2023 to Feb.20th, 2024.









Certificate

No. Q5 092305 0001 Rev. 01

Holder of Certificate:

Zhejiang Orient Gene Biotech Co., Ltd.

3787#, East Yangguang Avenue, Dipu Street Anji 313300 Huzhou, Zhejiang PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

Design and Development, Production and Distribution of In Vitro Diagnostic Reagent and Instrument for the Detection of Drugs of Abuse, Fertility, Infectious Diseases, Oncology, Biochemistry, Cardiac Diseases, Allergic Disease based on Rapid Test, PCR and Liquid Biochip Method.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 092305 0001 Rev. 01

Report No.:

SH2198802

Valid from: Valid until: 2022-04-11 2024-03-16

Date,

2022-04-11

Christoph Dicks Head of Certification/Notified Body





Certificate

No. Q5 092305 0001 Rev. 01

Applied Standard(s): EN ISO 13485:2016 Medical devices - Quality management systems -Requirements for regulatory purposes (ISO 13485:2016) DIN EN ISO 13485:2016

Facility(ies):

Zhejiang Orient Gene Biotech Co., Ltd. 3787#, East Yangguang Avenue, Dipu Street Anji, 313300 Huzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate



浙江东方基因生物制品股份有限公司 Zhejiang Orient Gene Biotech Co., LTD



CE-DOC-OG038 Version 2.0

EC Declaration of Conformity

In accordance with Directive 98/79/EC

Legal Manufacturer: Zhejiang Orient Gene Biotech Co., L	td
---	----

Legal Manufacturer Address:

3787#, East Yangguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang, China

Declares, that the products Product Name and Model(s)

Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma)	GDTRO-402a
Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma)	GDTRO-402b

Classification: Conformity assessment route:

Other Annex III (EC DECLARATION OF CONFORMITY)

We, the Manufacturer, herewith 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 hereby explicitly appoint

EC Representative's Name: Shanghai International Holding Corp. GmbH (Europe)

EC Representative's Address: Eiffestrasse 80, 20537 Hamburg, Germany

to act as our European Authorized Representative as defined in the aforementioned 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

Date Signed: August 11, 2020

Type Pay.

Name of authorized signatory: Joyce Pang Position held in the company: Vice-President

Troponin

Troponin I Rapid Test Device

(Whole Blood/Serum/Plasma)

Package Insert

A rapid visual immunoassay for the qualitative presumptive detection of cardiac Troponin I in human whole blood, serum, or plasma specimens. For professional in vitro diagnostic use only.

INTENDED USE

INTENDED 03E

The Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid visual immunoassay for the qualitative presumptive detection of cardiac Troponin I in human whole blood, serum, or plasma specimens. This kit is intended to be used as an aid in the diagnosis of myocardial infarction (MI).

SUMMARY

Cardiac Troponin I (cTnI) is a protein found in cardiac muscle with a molecular weight of 22.5 kDa.¹ Troponin I is part of a three subunit complex comprising of Troponin T and Troponin C. Along with tropomyosin, this structural complex forms the main component that regulates the calcium sensitive ATPase activity of actomyosin in striated skeletal and cardiac muscle.² After cardiac injury occurs, Troponin I is released into the blood 4-6 hours after the onset of pain. The release pattern of cTnI is similar to CK-MB, but while CK-MB levels return to normal after 72 hours, Troponin I remains elevated for 6-10 days, thus providing for a longer window of detection for cardiac injury. The high specificity of cTnI measurements for the identification of myocardial damage has been demonstrated in conditions such as the perioperative period, after marathon runs, and blunt chest traum.³ cTnI release has also been documented in cardiac conditions other than acute myocardial infarction (AMI) such as unstable angina, congestive heart failure, and ischemic damage due to coronary artery bypass surgery.⁴ Because of its high specificity and sensitivity in the myocardial lifarction.⁵

PRINCIPLE

The Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) has been designed to detect cardiac Troponin I through visual interpretation of color development in the strip. The membrane was immobilized with anti-cTni antibodies on the test region.

During the test, the specimen is allowed to react with colored anti-cTnl antibodies colloidal gold conjugates, which were precoated on the sample pad of the test. The mixture then moves on the membrane by a capillary action, and interact with reagents on the membrane. If there were enough cTnl in specimens, a colored band will form at the test region of the membrane.

Presence of this colored band indicates a positive result, while its absence indicates a negative result. Appearance of a colored band at the control region serves as a procedural control. This indicates that proper volume of specimen has been added and membrane wicking has occurred.

PRECAUTIONS

- 1. For professional In Vitro diagnostic use only.
- Warning: the reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
- 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.
- Handle all specimens as if they contain infectious agents. Observe established standard procedure for proper disposal of specimens
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assay.
- 7. Humidity and temperature can adversely affect results

STORAGE AND STABILITY

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test is not stable out off the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

SPECIMEN COLLECTION AND PREPARATION

- The Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) is intended only for use with human whole blood, serum, or plasma specimens.
- Only clear, non-hemolyzed specimens are recommended for use with this test.
- Serum or plasma should be separated with soonest possible opportunity to avoid hemolysis.
- Perform the testing immediately after the specimen collection. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.

- Pack the specimens in compliance with applicable regulations for transportation of etiological agents, in case they need to be shipped.
- Icteric, lipemic, hemolysed, heat treated and contaminated sera may cause erroneous results.
- There is a slight possibility that some whole blood specimens with very high viscosity
 or which have been stored for more than 2 days may not run properly on the test
 device. Repeat the test with a serum or plasma specimen from the same patient using
 a new test device.

Disposable Droppers

MATERIALS

Materials Provided Test devices Buffer

- Test devices
 - Package insert

Materials Required But Not Provided

Specimen collection containers
 Clock or Timer
 Centrifuge (for plasma only)

DIRECTIONS FOR USE

Allow test device, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

- Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. To obtain a best result, the assay should be performed within one hour.
- Transfer 2 drops of serum or plasma to the specimen well of the device with a disposable pipette provided in the kit, and then start the timer. OR

Transfer 3 drops of whole blood specimen to the specimen well of the device with a disposable pipette provided in the kit, then add 1 drop of buffer, and start the timer. OR

Allow 3 hanging drops of fingerstick whole blood specimen to fall into the center of the specimen well (S) on the device, then add 1 drop of buffer, and start the timer. Avoid trapping air bubbles in the specimen well (S), and do not drop any solution in observation window.

As the test begins to work, you will see color move across the membrane. Wait for the colored band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.





INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

NEGATIVE:Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).

INVALID:Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be discarded.

Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

3.

- The intensity of the color in test region (T) may vary depending on the concentration
 of aimed substances present in the specimen. Therefore, any shade of color in the
 test region should be considered positive. Besides, the substances level can not be
 determined by this qualitative test.
- Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.

External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

- The Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) is for professional in vitro diagnostic use, and should be used for the qualitative detection of cardiac Troponin I only. There is no meaning attributed to linen color intensity or width.
- The Troponin I Rapid Test Device (Whole Blood/Serum/Plasma) will only indicate the presence of Troponin I in the specimen and should not be used as the sole criteria for the diagnosis of tuberculosis.
- 3. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. The test cannot detect less than 0.5 ng/mL of cTnI in specimens. Thus, a negative result does not at anytime rule out the existence of Troponin I in blood, because the antibodies may be absent or below the minimum detection level of the test.
- Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
- Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor (RF) may affect expected results. Even if the test results are positive, further clinical evaluation should be considered with other clinical information available to the physician.

PERFORMANCE CHARACTERISTICS

Table: Troponin I Rapid Te	est vs. EIA
----------------------------	-------------

Method		Troponin I Rapid Test Device		Total
	Results	Positive	Negative	Results
EIA	Positive	138	2	140
	Negative	1	315	316
Total Results		139	317	456

Relative Sensitivity: 98.6% (94.9%-99.8%)*

Relative Specificity: 99.7% (98.3%-99.9%)*

Overall Agreement: 99.3% (98.1%-99.9%)*

*95% Confidence Interval

BIBLIOGRAPHY

- Adams, et al. Biochemical markers of myocardial injury, Immunoassay Circulation 88: 750-763, 1993.
- Mehegan JP, Tobacman LS. Cooperative interaction between troponin molecules bound to the cardiac thin filament. J.Biol.Chem. 266:966, 1991.
- Adams, et al. Diagnosis of Perioperative myocardial infarction with measurements of cardiac troponin I. N.Eng.J.Med 330:670, 1994.
- Hossein-Nia M, et al. Cardiac troponin I release in heart transplantation. Ann. Thorac. Surg. 61: 227, 1996.
- Alpert JS, et al. Myocardial Infarction Redefined, Joint European Society of Cardiology American College of Cardiology: J. Am. Coll. Cardio., 36(3):959, 2000.