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 Mar.22th,2024 to Mar.21th, 2025.

Zhejiang Orient Gene Biotech Co., Ltd

General Manager：

Date:2024/3/22

Digitally signed by Dolgopol Iulian
Date: 2024.06.18 13:08:05 EEST
Reason: MoldSign Signature
Location: Moldova

地址：浙江省湖州市安吉县递铺镇阳光大道东段 3787 号
Add: **3787#, East Yangguang Avenue, Dipu Street Anji 313300, Huzhou, Zhejiang, China**
电话 Tel:+86-572-5226111　　传真 Fax: +86-572-5226222　邮编 P.C.:313300

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 092305 0001 Rev. 02

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:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

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. 02

Report No.: SH2398804

Valid from: 2024-03-17
Valid until: 2027-03-16

Date, 2024-03-01

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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DAkkS
Deutsche
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D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 092305 0001 Rev. 02

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

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

.

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

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

CE-DOC-OG047
Version 1.0

EC Declaration of Conformity

In accordance with Directive 98/79/EC

Legal Manufacturer: *Zhejiang Orient Gene Biotech Co., Ltd*

Legal Manufacturer Address: *3787#, East Yangguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang, China*

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

Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma)	GDPCT-T402a
Procalcitonin Semi-Quantitative Rapid Test Strip (Whole Blood/Serum/Plasma)	GDPCT-T401a

Classification: *Other*
Conformity assessment route: *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 7, 2018

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

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

CE-DOC-OG080
Version 1.0

EC Declaration of Conformity

In accordance with Directive 98/79/EC

Legal Manufacturer: *Zhejiang Orient Gene Biotech Co., Ltd*

Legal Manufacturer Address: *3787#, East Yangguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang, China*

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

Influenza A & B Ag Rapid Test Strip (Swab)	GCFLU(A/B)-501a
Influenza A & B Ag Rapid Test Cassette (Swab)	GCFLU(A/B)-502a

Classification: *Other*
Conformity assessment route: *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.

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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: November 7, 2017

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

Influenza A & B Ag Rapid Test Cassette (Swab) CE

INTENDED USE

The Influenza A & B Ag Rapid Test Cassette (Swab) is an *in vitro* immunochromatographic assay for the qualitative detection of influenza A (including the subtype H1N1) and B nucleoprotein antigens in nasopharyngeal swabs, nasal swabs, throat swabs or nasal aspirates specimens. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections.

SUMMARY AND EXPLANATION

Influenza is an acute and highly contagious viral infection of the respiratory tract. The causative agents of the disease are immunologically diverse, single-strand RNA virus known as influenza viruses. There are three types of influenza viruses: A, B and C.

Type A Viruses are the most prevalent and are associated with most serious epidemics, while Type B infection is generally milder. Type C virus have never been associated with a large epidemic of human disease. Both type A and B viruses can circulate simultaneously, but usually one type is dominant during a given season and particular epidemic area. The disease is easily transmitted through coughing and sneezing of aerosolized droplets containing live virus. Influenza outbreaks normally occur each year during fall and winter seasons. Rapid diagnosis of influenza infection will help healthcare professionals to treat patients and control the disease more efficiently and effectively.

PRINCIPLE OF THE TEST

The Influenza A&B Ag Rapid Test Cassette (Swab) is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect influenza type A and B nucleoprotein antigens in nasopharyngeal swabs, nasal swabs, throat swabs or nasal aspirates specimens. The test strip is composed of the following parts: namely sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidal-gold conjugated with the monoclonal antibodies against Influenza virus A and B; the reaction membrane contains the secondary antibodies either for virus A or for B. The whole strip is fixed inside a plastic device. When the sample is added into the sample well, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If influenza A presents in the sample, a complex formed between the anti-influenza A conjugate and the virus will be captured by the specific anti-influenza A monoclonal antibodies coated on the A region (A). If the sample contains influenza B, a complex formed between the anti-influenza B conjugate and the virus will be captured by the specific anti-influenza B monoclonal antibodies coated on the B region (B).

Results appear at 10 minutes in the form of a red line that develops on the membrane. To serve as a procedural control, a red line will always appear in the control region (C) indicating that proper volume of sample has been added and membrane wicking has occurred.

MATERIALS PROVIDED

20 Test cassettes
20 Sterile swabs
20 Extraction tubes and tips
1 Workstation
2 Buffers
1 Package inset

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock, timer, or stopwatch

WARNINGS AND PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. The test cassette should remain in the sealed pouch until use.
3. Do not use kit past its expiration date.
4. Swabs, tubes and test cassettes are for single use only.
5. Solutions that contain sodium azide may react explosively with lead or copper plumbing. Use large quantities of water to flush discarded solutions down a sink.
6. Do not interchange or mix components from different kit lots.
7. Humidity and temperature can adversely affect results.
8. Used testing materials should be discarded in accordance with local regulations.

STORAGE AND STABILITY

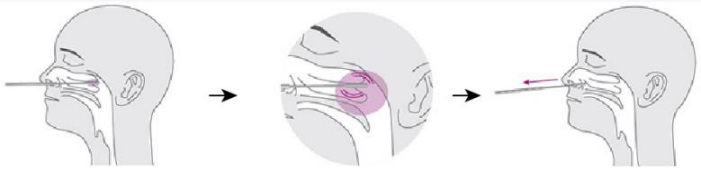
1. The kit can be stored at room temperature or refrigerated (2-30℃).
2. Do not freeze any of the test kit components.
3. Do not use test cassette and reagents after expiration date.
4. Test cassettes that have been outside of the sealed pouch for more than 1 hour should be discarded.
5. Close the kit box and secure its contents when not in use.

SPECIMEN COLLECTION

It is applicable to the diagnosis of the influenza virus A and B from the samples of nasopharyngeal swabs, nasal swabs, throat swabs or nasal aspirates. Use freshly collected samples for optimal test performance. Inadequate sample collection or improper sample handling may yield a false-negative result.

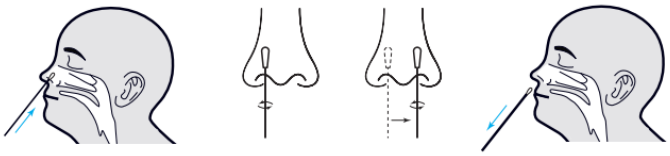
For Nasopharyngeal Swab Specimen Collection:

1. Using the sterile swab provided in the kit, carefully insert the swab in the patient's nostril.
2. Swab over the surface of the posterior nasopharynx and rotate the swab several times.
3. Withdraw the swab from the nasal cavity. The specimen is now ready for preparation using the extraction buffer provided in the test kit.



For Nasal Swab Specimen Collection:

1. Using the sterile swab provided in the kit, carefully insert the swab into one nostril of the patient. The swab tip should be inserted up to 2-4 cm until resistance is met.
2. Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected.
3. Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities.
4. Withdraw the swab from the nasal cavity. The sample is now ready for processing using the Influenza A & B Ag Rapid Test Cassette (Swab).

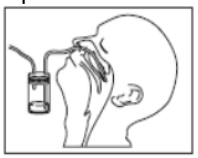


For Throat Swab Specimen Collection:

1. Deeply insert the sterilized swab into the throat and swab several times to collect the epidermal cells of the mucus. Caution has to be paid to avoid the swab to be contaminated with saliva.
2. Withdraw the swab from the throat. The sample is now ready for processing using the Influenza A & B Ag Rapid Test Cassette (Swab).

For Nasal Aspirates Specimen Collection:

Nasal aspirator is not provided in the kit. Collect nasal aspirate fluids according to the instructions for use of the used nasal aspirator.



SAMPLE PREPARATION PROCEDURE

Insert the test extraction tube into the workstation provided in the kit. Make sure that the tube is standing upright and reaches the bottom of the workstation. Add the sample buffer to extraction tube until it reaches the lower mark (about 13-17 drops, 0.5 mL)

For nasopharyngeal, nasal or throat swabs:

Insert the swab into the extraction tube which contains 0.5 mL of the extraction buffer. After mixing, squeeze the tube several times with fingers from outside of the tube to immerse the swab. Remove the swab. The extracted solution will be used as test sample.

For nasal aspirate fluids：

Add 0.5 mL of the nasal aspirate fluids into the extraction tube which contains 0.5 mL of the extraction buffer, and mix well to be used as test sample.

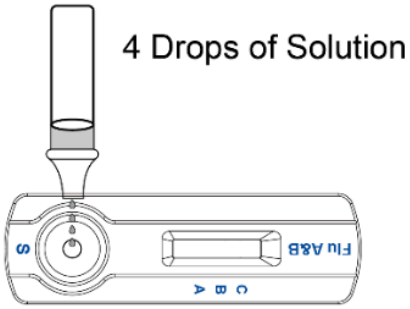
SPECIMEN TRANSPORT AND STORAGE

Specimens should be tested as soon as possible after collection. If transport of the samples is required, the following transport media are recommended and have been tested and shown not to interfere with the performance of the test: Hank's Balanced salt solution, M5 Media, or saline. Alternatively, samples may be stored refrigerated (2-8℃), or at room temperature(15-30℃), in a clean, dry, closed container for up to eight hours prior to testing. Nasal wash/aspirate specimens may also be stored frozen (-70℃ or colder) for up to one month.

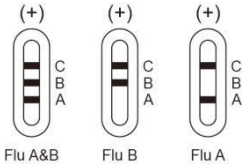
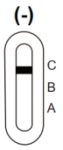
TEST PROCEDURE

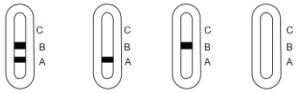
Allow the test cassette, test sample and buffer to equilibrate to room temperature (15-30°C) prior to testing.

1. Just prior to testing remove the test cassette from the sealed pouch and lay it on a flat surface.
2. Push the nozzle which contains the filter onto the extraction tube. Ensure the nozzle has a tight fit.
3. Hold the extraction tube vertically and add 4 drops (approximately 100 µL) of test sample solution tube into the sample well.
4. Start the timer.
5. Read the results at 10 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

	**POSITIVE** **1. Flu A Positive:** The presence of two lines as control line (C) and A test line within the result window indicates a positive result for Influenza A viral antigen. **2. Flu B Positive:** The presence of two lines as control line (C) and B test line within the result window indicates a positive result for Influenza B viral antigen. **3. Flu A+B Positive:** The presence of three lines as control line (C), A test line and B test line within the result window indicates a positive result for Influenza A and Influenza B viral antigen.
	**NEGATIVE** The presence of only control band (C) within the result window indicates a negative result.

	**INVALID** If the control band (C) is not visible within the result window after performing the test, the result is considered invalid. Some causes of invalid results are because of not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test.

NOTE:

1. The intensity of color in the test region (A/B) may vary depending on the concentration of analyses present in the specimen. Therefore, any shade of color in the test region (A/B) should be considered positive. Please note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control line region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this test. However, it is recommended that positive and negative controls are sourced from a local competent authority and tested as a good laboratory practice, to confirm the test procedure and verify the test performance.

LIMITATIONS

1. The Influenza A&B Ag Rapid Test Cassette (Swab) is for professional in vitro diagnostic use, and should only be used for the qualitative detection of influenza A and/or B.
2. The etiology of respiratory infection caused by microorganisms other than influenza A or B virus will not be established with this test. The Influenza A&B Ag Rapid Test Cassette (Swab) is capable of detecting both viable and non-viable influenza particles. The performance of the Influenza A&B Ag Rapid Test depends on antigen load and may not correlate with cell culture performed on the same specimen.
3. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at anytime rule out the presence of influenza A and/or B viral antigens in specimen, as they may be present below the minimum detection level of the test. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. The validity of Influenza A&B Ag Rapid Test Cassette (Swab) has not been proven for identification or confirmation of cell culture isolates.
5. Inadequate or inappropriate specimen collection, storage, and transport may yield false negative test result.
6. Although this test has been shown to detect cultured avian influenza viruses, including avian influenza A subtype H5N1 virus, the performance characteristics of this test with specimens from humans infected with H5N1 or other avian influenza viruses are unknown.
7. Performance characteristics for influenza A were established when influenza A/H3 and A/H1 were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary.
8. Children tend to shed virus for longer periods of time than adults, which may result in differences in sensitivity between adults and children.
9. Positive and negative predictive values are highly dependent on prevalence. False positive test results are more likely during periods of low influenza activity when prevalence is moderate to low.

PERFORMANCE CHARACTERISTICS

1. Analytical Sensitivity

The minimum detection limit is 1.5 x 10^4 $TCID_{50}$/test for the Influenza A virus antigen and is 1.5 x 10^5 $TCID_{50}$/test for the Influenza B virus antigen.

2. Analytical Reactivity

The influenza A strain listed tested positive in the Influenza A&B Ag Rapid Test Cassette (Swab). Although the specific influenza strains causing infection in human can very, all contain the conserved nucleoproteins targeted by Influenza A&B Ag Rapid Test Cassette (Swab).

Strains	Sources	Subtypes	Concentration
Flu A/Hubei/PR 8/2001	Human	H1N1	1.8×10^4 $TCID_{50}$/test
Flu A/New Kaledonia/20/99	Human	H1N1	1.8×10^4 $TCID_{50}$/test
Flu A/Yamagata/32/89	Human	H1N1	1.8×10^4 $TCID_{50}$/test
Flu A/Beijing/262/95	Human	H1N1	1.8×10^4 $TCID_{50}$/test
Flu A/Singapore/1/57	Human	H2N2	3.0×10^4 $TCID_{50}$/test
Flu A/Hubei/3/2005	Human	H3N2	3.0×10^4 $TCID_{50}$/test
Flu A/Akita/1/94	Human	H3N2	3.0×10^4 $TCID_{50}$/test
Flu A/Iowa/15/30	Swine	H1N1	3.0×10^4 $TCID_{50}$/test
Flu A/Hongkong/168/93	Swine	H1N1	3.0×10^4 $TCID_{50}$/test
Flu A/Anhui/24/2004	Swine	H5N1	6.0×10^4 $TCID_{50}$/test
Flu A/Hubei/134/2000	Swine	H9N2	6.0×10^5 $TCID_{50}$/test
Flu A/Hubei/251/2001	Swine	H9N2	6.0×10^5 $TCID_{50}$/test
Flu A/Yuyao/1/2006	Chicken	H5N1	6.0×10^4 $TCID_{50}$/test
Flu A/Yuyao/2/2006	Chicken	H5N1	6.0×10^4 $TCID_{50}$/test
Flu A/Jiangsu/2/2004	Chicken	H5N1	6.0×10^4 $TCID_{50}$/test
Flu A/Hubei/216/83	Duck	H7N8	3.0×10^5 $TCID_{50}$/test
Flu A/Hubei/118/2003	Duck	H9N2	1.5×10^5 TC ID_{50}/test
Flu A/Hubei/155/2003	Duck	H9N2	6.0×10^5 $TCID_{50}$/test
Flu A/Hubei/137/1982	Duck	H10N4	3.0×10^5 $TCID_{50}$/test
Flu A/Singapore/3/97	Duck	H5N3	6.0×10^4 $TCID_{50}$/test
Flu A/Henan/1/2004	Tree sparrow	H5N1	6.0×10^5 $TCID_{50}$/test
Flu A/Henan/2/2004	Tree sparrow	H5N1	3.0×10^5 $TCID_{50}$/test
Flu A/Henan/4/2004	Tree sparrow	H5N1	6.0×10^4 $TCID_{50}$/test
Flu A/Wisconsin/66	Turkey	H9N2	6.0×10^4 $TCID_{50}$/test
Flu A/England/1/63	Turkey	H7N3	6.0×10^4 $TCID_{50}$/test
Flu A/Singapore/1/57	Bird	H5N1	6.0×10^4 $TCID_{50}$/test
Flu A/Hunan/71/2004	Bird	H5N1	6.0×10^4 $TCID_{50}$/test
Flu A/Shanxi/50/2006	Bird	H5N1	6.0×10^4 $TCID_{50}$/test
Flu A/Shanxi/42/2006	Bird	H5N1	$6.0\times10_4$ $TCID_{50}$/test
Flu A/Fujian/320/2004	Bird	H5N1	3.0×10^5 $TCID_{50}$/test

Influenza A&B Ag Rapid Test Cassette (Swab) can detect all nine influenza B strains.

3. Clinical Study Data Summary

The Influenza A&B Ag Rapid Test performance vs. Cell Culture

Kind of samples	Type	Sensitivity (%)	Specificity (%)	Accuracy (%)
Nasopharyngeal/Nasal Swab	A	92.6 (25/27)	96.4 (81/84)	95.5 (106/111)
	B	90.0 (27/30)	95.8 (91/95)	94.4 (118/125)

Throat Swab	A	83.3 (20/24)	95.2 (59/62)	91.9 (79/86)
	B	82.6 (19/23)	91.8 (67/73)	89.6 (86/96)
Nasal Aspirate	A	88.9 (48/54)	93.3 (125/134)	92.0 (173/188)
	B	91.2 (52/57)	95.4 (98/103)	93.8 (150/160)

4. Analytical Specificity and Cross-reactivity

The Influenza A&B Ag Rapid Test Cassette (Swab) was evaluated with a total of 30 bacterial and viral isolates. Bacterial isolates were evaluated at a concentration between 10^7 and 10^9 or g/mL. Viral isolates were evaluated at a concentration of at least 10^4-10^8 $TCID_{50}$/mL. Adenovirus 18 and Parainfluenza virus 3 were tested at 10^2 $TCID_{50}$/mL. None of the organisms or viruses listed below gave a positive result in the Influenza A&B Ag Rapid Test Cassette (Swab).

Bacterial Panel:

Acinetobacter calcoaceticus	Bacteroides fragilis
Neisseria gonorrhoeae	Neisseria meningitidis
Pseudomonas aeruginosa	Staphylococcus aureus
Streptococcus pneumoniae	Streptococcus sanguis
Proteus vulgaris	Streptococcus sp. Gp. B
Streptococcus sp. Gp. C	Streptococcus sp. Gp. G
Mycobacterium tuberculosis	Mycoplasma orale

Viral Panel:

Human Adenovirus B	Human Rhinovirus 2
Human Adenovirus C	Human Rhinovirus 14
Adenovirus type 10	Human Rhinovirus 16
Adenovirus type 18	Measles
Human Coronavirus OC43	Mumps
Human Coxsackievirus A9	Sendai virus
Coxsackievirus B5	Parainfluenza virus 2
Human herpesvirus2	Parainfl uenza virus 3

5. Interfering Substances

Whole blood, and several over-the-counter (OTC) products and common chemicals were evaluated and did not interfere with the Influenza A&B Ag Rapid Test Cassette (Swab) at the levels tested: whole blood (2%); three OTC mouthwashes (25%); three OTC throat drops (25%); three OTC nasal sprays (10%); 4-Acetamidophenol (10 mg/mL); Acetylsalicylic Acid (20 mg/mL); Chlorpheniramine (5 mg/mL); Dextromethorphan (10 mg/mL); Diphenhydramine (5 mg/mL); Ephedrine (20 mg/mL); Guaiacol glyceryl ether (20 mg/mL); Oxymetazoline (10 mg/mL); Phenylephrine (100 mg/mL); and Phenylpropanolamine (20 mg/mL).

REFERENCES

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2. Dowdle, W.R, Kendal, A.P., and Noble, G.R. (1980). Influenza Virus, p 836-844. Manual of Clinical Microbiology, 3rd edition, in Lennette, et. al (ed.). American Society for Microbiology, Washington, D.C.
3. “Key Facts about Avian Influenza (Bird Flu) and Avian Influenza A (H5N1) Virus” CDC Publication, May 24, 2005. http://www.cdc.gov/flu/avian/gen-info/facts.htm
4. “Avian Influenza Infection in Humans” CDC Publication, May 24, 2005. http://www.cdc.gov/flu/avian/gen-info/avian-flu-humans.htm
5. “Updated Interim Guidance for Laboratory Testing of Persons with Suspected Infection with Avian Influenza A (H5N1) Virus in the United States” CDC Health Alert, June 7, 2006. http://www.phppo.cdc.gov/HAN/ArchiveSys/ViewMsgV.asp?AlertNum=00246

INDEX OF SYMBOLS

	Consult instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
30°C 2°C	Store between 2~30°C	LOT	Lot Number	REF	Catalog#

Zhejiang Orient Gene Biotech Co.,Ltd
Address: 3787#, East Yangguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang, China
Tel: +86-572-5226111 Fax: +86-572-5226222
Website: www.orientgene.com

EC REP Shanghai International Holding Corp. GmbH (Europe)
Add: Eiffestrasse 80, 20537 Hamburg, Germany

REF GCFLU(A/B)-502a

Revision Date: 2022-11-14
B21900-03

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., Ltd*

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: *Other*
Conformity assessment route: *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

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

Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma)

CE

A rapid test for the Semi-Quantitative detection of Procalcitonin in whole blood, serum or plasma specimens.

For professional *in vitro* diagnostic use only.

INTENDED USE

The Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) is used for semi-quantitative determination and monitoring of PCT concentrations in whole blood/serum/plasma specimens.

SUMMARY

The Procalcitonin (PCT) is a peptide hormone mainly produced by the C cells of the thyroid and certain endocrine cells of the lung. Under normal expression conditions, procalcitonin is immediately cleaved into three specific fragments, an N terminal residue, calcitonin and katacalcin, Levels of unprocessed procalcitonin rise significantly after bacterial infection, trauma or shock.

The Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid test that semi-qualitatively detects the presence of Procalcitonin in whole blood, plasma or serum specimens at the sensitivity of 0.5ng/mL, 2ng/mL and 10ng/mL. The test utilizes a combination of monoclonal antibodies to selectively detect elevated levels of Procalcitonin in whole blood, plasma or serum. At the level of claimed sensitivity, the Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) shows no cross-reactivity interference from the structurally related CRP or others at high physiological levels.

PRINCIPLE

The Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) detects Procalcitonin through visual interpretation of color development on the internal strip. Anti-PCT antibodies are immobilized on the test region of the membrane. During testing, the specimen reacts with anti-PCT antibodies conjugated to colored particles and precoated on the sample pad of the test. The mixture then migrates through the membrane by capillary action, and interacts with reagents on the membrane. If Test band 3 (T3) appears, it indicates that the PCT level in the specimen is between 0.5-2.0ng/ml. If the Test band 3 and 2 (T3 and T2) appear, it indicates that the PCT level in the specimen is between 2.0-10.0 ng/ml. If all the Test bands (T1, T2, T3), it indicates that the PCT level is above 10.0 ng/ml. The appearance of control line serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

REAGENT

The test contains anti- Procalcitonin particles and anti- Procalcitonin coated on the membrane.

MATERIALS PROVIDED

25 Sealed pouches each containing a test cassette, a dropper and a desiccant

1 Buffer, 4.0 mL

1 Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection container 2. Timer 3. Centrifuge

• PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to any testing.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded in accordance with local regulations.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.

Do not freeze.

Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

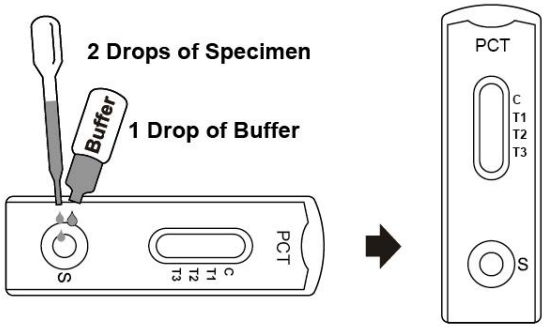
SPECIMEN COLLECTION AND PREPARATION

- The Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum or plasma.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

DIRECTIONS FOR USE

Bring tests, specimens, buffer, and/or controls to room temperature (15-30°C) before use.

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results, the assay should be performed within one hour.
2. Add **2 drops of specimen** above to the specimen well and then add **1 drop of buffer**, start the timer.
3. Wait for the colored bands to appear. The result should be **read at 10 minutes**. Do not interpret the result after 20 minutes.

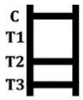


INTERPRETATION OF RESULTS

POSITIVE RESULT:

Possible Interpretation of Procalcitonin Levels

A Control band (C) and a test band (T3) appears indicates a PCT level 0.5 mg/L at least.



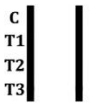
A Control band (C) and two test bands (T3 and T2) appear indicates a PCT level 2.0 mg/L at least.

A Control band (C) and three test bands (T1, T2 and T3) appears indicates a PCT level 10.0 mg/L at least.

NEGATIVE RESULT:

Only a Control band (C) appears and no colored band appears in the test region (T) indicates a PCT level is lower than 0.5 mg/L.

INVALID RESULT:



No Control band appears. Results from any test which has not produced Control band at the specified read 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:

1. The intensity of the color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Please note that this is a semi-quantitative test only, and cannot determine the concentration of analytes in the specimen.

2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. Control band appearing in the control regions is considered an internal positive procedural control, confirming 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

1. The Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) is for professional *in vitro* diagnostic use, and should only be used for the semi-quantitative detection of Patent Cooperation Treaty.

2. The Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the semi-quantitative level of PCT in the specimen and should not be used as the sole criteria for evaluating inflammatory conditions.

3. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

4. PCT values near the cut-off level Test line 3 (T3: 0.5 ng/ml), Test line 2 (T2: 2.0 ng/ml), and Test line 1 (T1: 10.0 ng/ml) should be reported with caution as with all quantitative assays there exists some level of variation. Therefore, a T line with slightly higher intensity than T1 can also represent a value slightly below 10.0 ng/ml. Similar observations may occur with values near 2.0 ng/ml and 0.5 ng/ml. A repeat test or further quantitative test is recommended in such cases.

EXPECTIED VALUES

The Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with a leading commercial Procalcitonin EIA test, demonstrating an overall accuracy of 98.9%.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) has been evaluated with a leading commercial Procalcitonin EIA test using clinical specimens. The results show that the sensitivity of the Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) is 98.8% and the specificity is 99.0% relative to the leading EIA test.

Procalcitonin Semi-Quantitative Rapid Test Cassette vs. EIA

Method		**EIA Test**		Total Results
Semi-Quantitative Rapid Test Cassette	Results	Positive	Negative	
	Positive	84	2	86
	Negative	1	193	194
Total Results		85	195	280

Relative Sensitivity: 98.8%(93.6%-99.9%)*

Relative Specificity: 99.0%(96.3%-99.9%)*

Accuracy: 98.9%(96.9%-99.8%)* *95% Confidence Interval

LITERATURE REFERENCES

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2. Harbarth S. et al.: Diagnostic value of procalcitonin, inter- leukin-6 and interleukin 8 in critically ill patients admitted with suspected sepsis. Am. J. Resp. Crit. Care Med. 2001, 164: 396-402

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INDEX OF SYMBOLS

	Consult instructions for use		Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
30°C 2°C	Store between 2~30°C	LOT	Lot Number	REF	Catalog#

Zhejiang Orient Gene Biotech Co.,Ltd
Address: 3787#, East Yangguang Avenue, Dipu Street,
Anji 313300, Huzhou, Zhejiang, China
Tel: +86-572-5226111 Fax: +86-572-5226222
Website: www.orientgene.com

EC REP Shanghai International Holding Corp. GmbH (Europe)
Add: Eiffestrasse 80, 20537 Hamburg, Germany

REF GDPCT-T402a

Revision Date: 2022-02-15
B22117-02

Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma)

CE

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

The Troponin I Rapid Test Cassette (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 trauma.[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 tissue, Troponin I has recently become the most preferred biomarker for myocardial infarction.[5]

PRINCIPLE

The Troponin I Rapid Test Cassette (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-cTnI 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 cTnI 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.
2. 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.
5. Handle all specimens as if they contain infectious agents. Observe established standard procedure for proper disposal of specimens
6. 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 Cassette (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.

MATERIALS

Materials Provided

25 Sealed pouches each containing a test cassette, a dropper and a desiccant
1 Buffer, 4.0 mL
1 Package insert

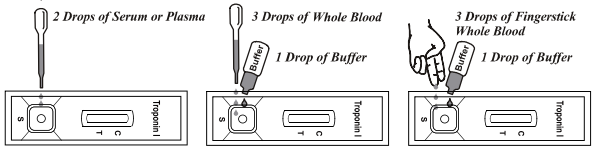
Materials Required But Not Provided

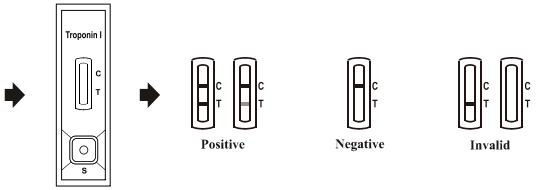
- Specimen collection containers
- Clock or timer
- Centrifuge (for plasma only)

DIRECTIONS FOR USE

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

1. 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.
2. 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.
3. 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:

1. 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

1. The Troponin I Rapid Test Cassette (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.
2. The Troponin I Rapid Test Cassette (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 diagnostic of acute myocardial infarction(AMI).
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.
4. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
5. 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 Test vs. EIA

Method		Troponin I Rapid Test Cassette		Total Results
	Results	Positive	Negative	
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

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5. Alpert JS, et al. Myocardial Infarction Redefined, Joint European Society of Cardiology American College of Cardiology: J. Am. Coll. Cardio., 36(3):959, 2000.

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Website: www.orientgene.com

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REF GDTRO-402a

Revision Date: 2020-01-20
B21775-02