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: 2024.10.29 08:22:52 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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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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-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.

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: November 7, 2017

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-OG266
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)

Strep A Rapid Test Strip (Throat Swab)	GCSTR-501a
Strep A Rapid Test Cassette (Throat Swab)	GCSTR-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.

We hereby explicitly appoint

EC Representative's Name: CMC Medical Devices & Drugs S.L

EC Representative's Address: C/Horacio Lengo Nº 18, CP 29006, Málaga, Spain

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: May 20, 2022

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

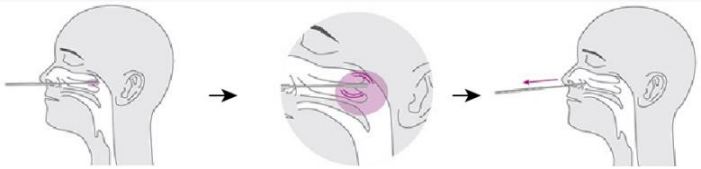
1. The kit can be stored at room temperature or refrigerated (2-30℃).
2. Do not freeze any of the test kit components.
3. Do not use test cassette and reagents after expiration date.
4. Test cassettes that have been outside of the sealed pouch for more than 1 hour should be discarded.
5. Close the kit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

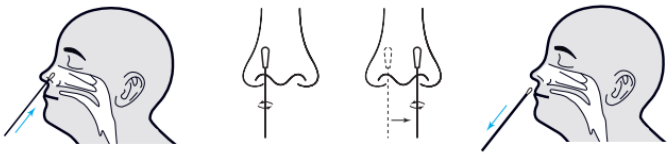
For Nasopharyngeal Swab Specimen Collection:

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).

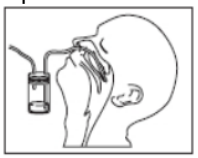


For Throat Swab Specimen Collection:

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.

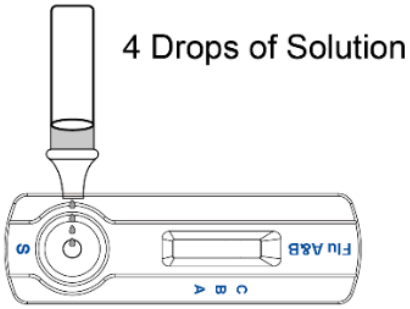
SPECIMEN TRANSPORT AND STORAGE

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.

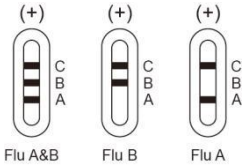
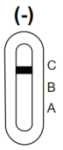
TEST PROCEDURE

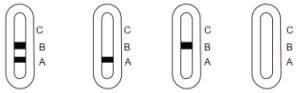
Allow the test cassette, test sample and buffer to equilibrate to room temperature (15-30°C) prior to testing.

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

1. Williams, KM, Jackson MA, Hamilton M. (2002) Rapid Diagnostic Testing for URIs in Children: Impact on Physician Decision Making and Cost. Infect. Med. 19(3): 109-111.
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

Strep A Rapid Test Cassette (Throat Swab)

INTENDED USE

The Strep A Rapid Test Cassette (Throat Swab) is a rapid chromatographic immunoassay for the qualitative detection of Strep A antigen from throat swab specimens to aid in the diagnosis of Group A Streptococcal infection.

INTRODUCTION

Streptococcus pyogenes is non-motile gram-positive cocci, which contains the Lancefield group A antigen that can cause serious infections such as pharyngitis, respiratory infection, impetigo, endocarditis, meningitis, puerperal sepsis, and arthritis.[1] Left untreated, these infections can lead to serious complications, including rheumatic fever and peritonsillar abscess.[2] Traditional identification procedures for Group A Streptococci infection involve the isolation and identification of viable organisms using techniques that require 24 to 48 hours or longer.[3,4] The Strep A Rapid Test Cassette (Throat Swab) is a rapid test to qualitatively detect the presence of Strep A antigen in throat swab specimens, providing results within 5 minutes. The test utilizes antibodies specific for whole cell Lancefield Group A Streptococcus to selectively detect Strep A antigen in a throat swab specimen.

PRINCIPLE

The Strep A Rapid Test Cassette (Throat Swab) is a qualitative, lateral flow immunoassay for the detection of Strep A carbohydrate antigen in a throat swab. In this test, antibody specific to Strep A carbohydrate antigen is coated on the test line region of the test. During testing, the extracted throat swab specimen reacts with an antibody to Strep A that is coated onto particles. The mixture migrates up the membrane to react with the antibody to Strep A on the membrane and generate a color line in the test line region. The presence of this color line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS SUPPLIED

1. 20 Test cassettes 2. 20 Sterile swabs 3. 20 Extraction tubes and tips 4. 1 Workstation and 1 package insert 5. 1 Reagent B (0.2M acetic acid): 10.0 mL		
6. 1 Reagent A (2M sodium nitrite): 10.0 mL	⚠ Warning	Harmful if swallowed. Wash thoroughly after handling.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Clock or timer

WARNINGS AND PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimens and kits are handled.
3. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Humidity and temperature can adversely affect results.
6. Do not use test if pouch is damaged.
7. Reagent B contains an acidic solution. If the solution contacts the skin or eye, flush with large volumes of water.
8. Do not interchange reagent bottle caps.
9. Do not interchange external control solution bottle caps.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

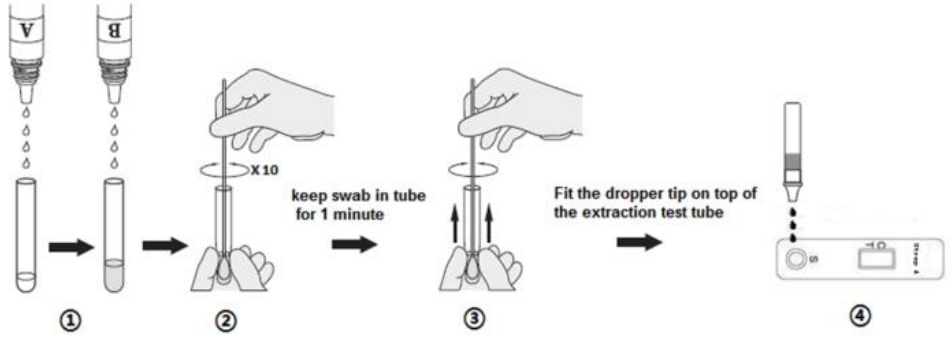
SPECIMEN COLLECTION AND STORAGE

1. Only use reagents and sterile swabs provided in the kit.
2. Collect the throat swab specimen with the sterile swab that is provided in the kit. Swab the posterior pharynx, tonsils and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab.[5]
3. Testing should be performed immediately after the specimens have been collected. Swab specimens may be stored in a clean, dry plastic tube for up to 8 hours at room temperature or 72 hours at 2-8°C. Transport swabs containing modified Stuart's or Amies medium can also be used with this product.
4. If a culture is desired, lightly roll the swab tip onto a Group A selective (GAS) blood agar plate before using the swab in the Strep A Rapid Test Cassette (Throat Swab).

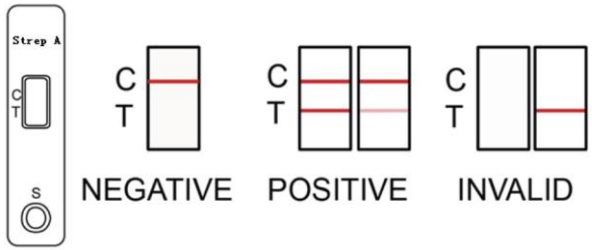
TEST PROCEDURE

Allow the test device, reagents, throat swab specimen, and/or controls to reach room temperature (15-30°C) prior to testing.

1. Remove the test device from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Hold the Reagent A bottle vertically and add 4 full drops of Reagent A to an extraction tube. Reagent A is red in color. Hold the Reagent B bottle vertically and add 4 full drops to the tube. Reagent B is colorless. Mix the solution by gently swirling the extraction tube. The addition of Reagent B to Reagent A changes the color of the solution from red to yellow.
3. Immediately add the throat swab to the extraction tube of yellow solution. Agitate the swab 10 times in the tube. Leave the swab in the tube for 1 minute. Then press the swab against the side of the tube and squeeze the bottom of the tube as the swab is withdrawn. Discard the swab.
4. Fit the dropper tip on top of the extraction tube. Place the test device on a clean and level surface. Add 3 full drops of solution to the specimen well (S) and then start the timer.
5. Wait for the colored line(s) to appear. Read the result at 5 minutes. Do not read the result after 10 minutes.



INTERPRETATION OF RESULTS



Positive: Two lines appear. One coloured line should be in the control line region (C) and another apparent coloured line should be in the test line region (T).
Negative: One coloured line appears in the control line region(C). No line appears in the test line region (T).
Invalid: Control line fails to appear.
NOTE: Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

Internal Quality Control

Internal procedural controls are included in the test. A color line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATIONS

1. The Strep A Rapid Test Cassette (Throat Swab) is for *in vitro* diagnostic use only. The test should be used for the detection of Strep A antigen in throat swab specimens only. Neither the quantitative value nor the rate of increase in Strep A antigen concentration can be determined by this qualitative test.
2. This test will only indicate the presence of Strep A antigen in the specimen from both viable and non-viable Group A streptococcus bacteria.
3. A negative result must be confirmed by culture. A negative result may be obtained if the concentration of the Strep A antigen present in the throat swab is not adequate or is below the detectable level of the test.
4. The sterile swabs provided with this test must be used for specimen collection. Other swabs have not been validated with this test.
5. Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result. Avoid touching the tongue, cheeks, and teeth[5] and any bleeding areas of the mouth with the swab when collecting specimens. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity and Specificity

The Strep A Rapid Test Cassette (Throat Swab) was used to evaluate 368 throat swab specimens collected from three physician offices patients presenting with pharyngitis. The test result compared to the culture method. The below table summarizes the data.

Clinical Performance: Strep A Rapid Test vs. Culture

Strep A Rapid Test Cassette (Throat Swab) Results	Reference Culture Results		Total
	Positive	Negative	
Positive	200	1	201
Negative	6	161	167
Total	206	162	368

Sensitivity: 97.1% (200/206); 95%CI = 93.7% - 98.8%
Specificity: 99.4% (161/162); 95%CI = 96.2% - 100.0%

Clinical Performance Stratified by Age

Age	Sensitivity	Sensitivity(95%CI)	Specificity	Specificity(95%CI)
0 ~ 5	97.4% (74/76)	90.4% - 99.8%	98.1% (52/53)	89.1% - 100.0%
5+ ~ 21	96.7% (119/123)	91.7% - 99.0%	100% (88/88)	95.0% - 100.0%
21+	100% (7/7)	59.6% - 100.0%	100% (21/21)	81.8% - 100.0%
All	97.1% (200/206)	93.7% - 98.8%	99.4% (161/162)	96.2% - 100.0%

Cross-Reactivity

The following organisms were tested at 1.0 x 10^7 organisms per test and were all found to be negative when tested with the Strep A Rapid Test Cassette (Throat Swab). No mucoid-producing strains were tested.

Group B Streptococcus	Neisseria meningitidis	Serratia marcescens
Group F Streptococcus	Neisseria sicca	Klebsiella pneumoniae
Streptococcus pneumoniae	Branhamella catarrhalis	Bordetella pertussis
Streptococcus mutans	Group C Streptococcus	Neisseria gonorrhea
Staphylococcus aureus	Group G Streptococcus	Neisseria subflava
Corynebacterium diphtheria	Streptococcus sanguis	Hemophilus influenza
Candida albicans	Enterococcus faecalis	
Pseudomonas aeruginosa	Staphylococcus epidermidis	

Physician's Office Laboratory (POL) Studies

Three physicians' offices were used to conduct an evaluation of the Strep A Rapid Test Cassette (Throat Swab). Personnel with various educational backgrounds performed the testing. Each physician's office tested a randomly coded panel of samples consisting of negative (20), low positive (20), and medium positive (20) for three days. The results obtained had a 96% correlation with the expected results.

REFERENCE

1. Murray, P.R., et al. Manual of Clinical Microbiology, 6th Edition, ASM Press, Washington D.C. p. 299-307.
2. Webb, KH. Does Culture Confirmation of High-sensitivity Rapid Streptococcal Tests Make Sense? A Medical Decision Analysis. Pediatrics (Feb 1998), 101: 2, 2.
3. Bisno AL, Gerber MA, Gwaltney JM, Kaplan EL, Schwartz RH. Diagnosis and Management of Group A Streptococcal Pharyngitis. Clinical Infectious Diseases (1997), 25: 574-83.
4. Needham CA, McPherson KA, Webb KH. Streptococcal Pharyngitis: Impact of a High-sensitivity Antigen Test on Physician Outcome. Journal of Clinical Microbiology (Dec 1998), 36: 3468-3473.
5. Shea, Y.R., Specimen Collection and Transport, Clinical Microbiology Procedures Handbook, Isenberg, H.D., American Society of Microbiology, Washington D.C., 1.1.1-1.1.30, 1992.
6. Nussinovitch, M, Finkelstein Y, Amir J, Varsano, I. Group A beta-hemolytic streptococcal pharyngitis in preschool children aged 3 months to to 5 years. Clinical Pediatrics (June 1999), 38: 357-360.
7. Woods WA, Carter CT, Stack M, Connors Jr AF, Schlager TA. Group A Streptococcal Pharyngitis in Adults 30 to 65 years of age. Southern Medical Journal (May 1999), 491-492.

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
	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 CMC Medical Devices & Drugs S.L
C/Horacio Lengo Nº 18 CP 29006, Málaga-Spain
Tel: +34951214054 Fax: +34952330100
Email-info@cmcmedicaldevices.com

REF GCSTR-502a

Swab information

Jiangsu ChangFeng Medical Industry Co., LTD
Address: Touqiao Town, Guangling DISTRICT, Yangzhou, Jiangsu 225109 China

CE 0197

EC REP Llins Service & Consulting GmbH
Obere Seegasse 34/2, 69124 Heidelberg, Germany
Email-info@llins-service.com

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