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Rapid SARS-CoV-2 Antigen Test Card

XIAMEN BOSON BIOTECH CO., LTD.
XIAMEN, CHINA

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Name List of Medical Devices and Supplies Companies with Certification/Authorization from other Countries

Source：CHINA CHAMBER OF COMMERCEFOR IMPORT&EXPORT OF MEDICINES &HEALTH PRODUCTS
http://www.cccmhpie.org.cn/Pub/6325/177149.shtml

取得国外标准认证或注册的医疗物资生产企业清单			
Name List of Medical Devices and Supplies Companies with Certification/Authorization from other Countries			
序号	生产企业	统一社会信用代码	国外注册认证情况
No.	**Company**	**Uniform Social Credit Code**	**Status of Certification / Authorization in Other Countires**
五、	新型冠状病毒检测试剂 Coronavirus Reagent Test kits		
63	厦门市波生生物技术有限公司 Xiamen Boson Biotech Co.,Ltd	91350200705468594R	CE

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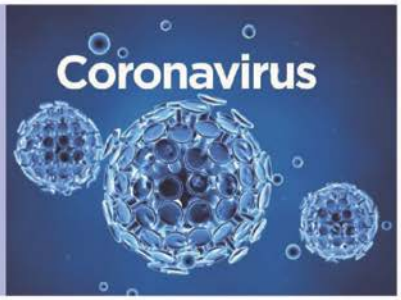
COVID-19

Rapid SARS-CoV-2 Antigen Test Card



Using a nasal swab to get sample fluid, antigen tests can produce results in minutes. Because these tests are faster and less expensive than molecular tests are, experts consider antigen tests more practical to use for large numbers of people. Since the antigen test can be high specificity, a positive antigen test result is considered very accurate.

- **Fast, Easy and Convenient**
  Results in 15-20 minutes, simple to use
  Requires no instruments and special skills
- **Storage**
  Room temperature storage & 18-month shelf life
- **Swabs Test**
  Nasopharyngeal swab can be used

Cat. No.	Product Name	No. per Kit
1N40C5	Rapid SARS-CoV-2 Antigen Test Card	20
1N40C5-2	Rapid SARS-CoV-2 Antigen Test Card	1

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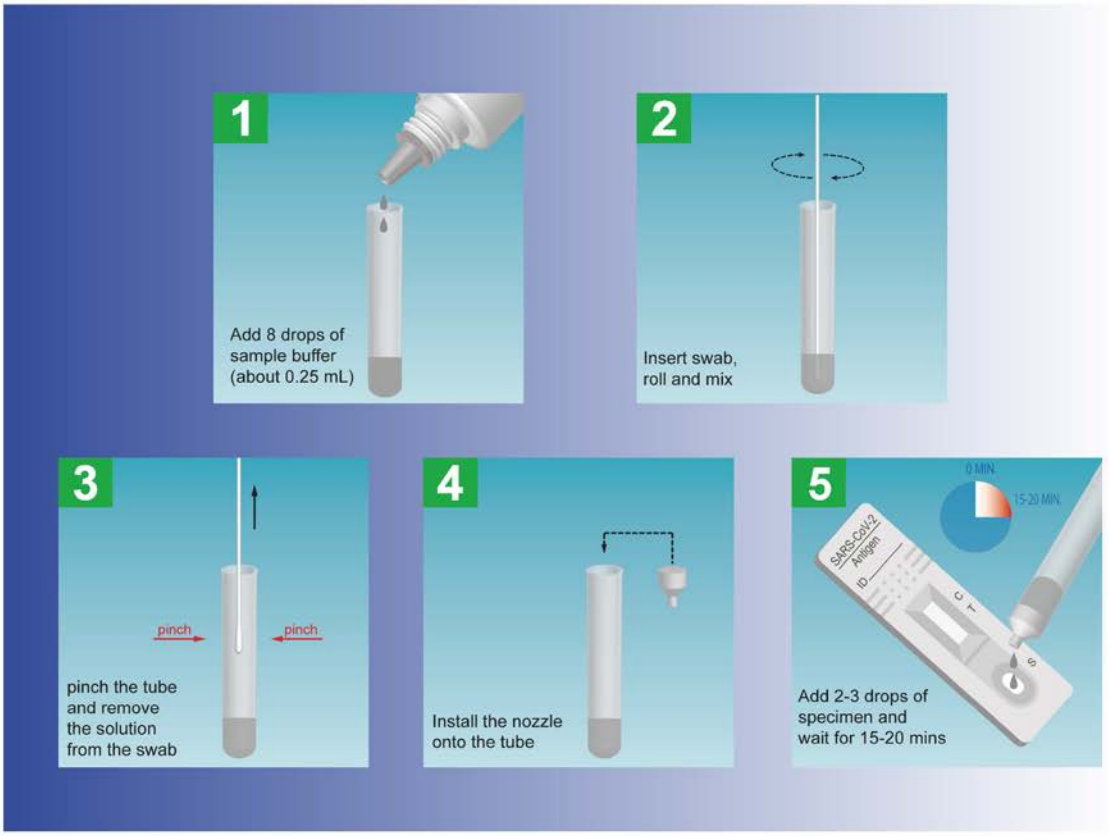
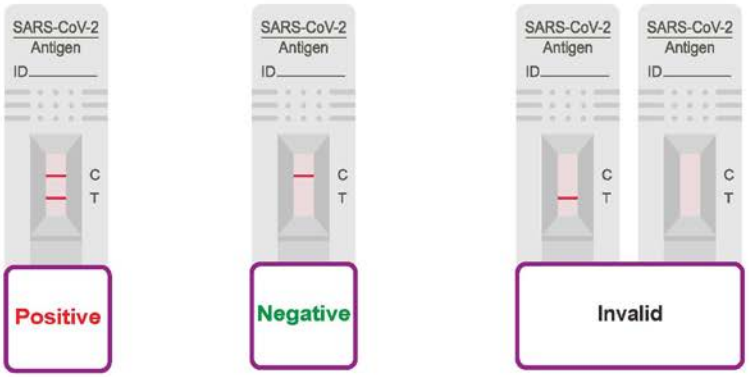
Test Procedure



Interpretation of Results



Please contact us or your agent for details.

BOSON **XIAMEN BOSON BIOTECH CO., LTD.**

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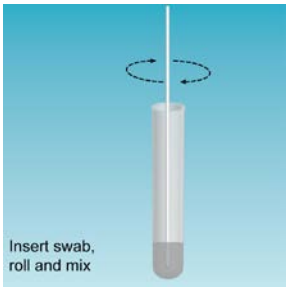
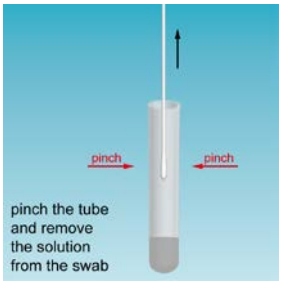
Test Procedure





1. Add **8 drops (about 0.25 mL)** of extraction buffer into the extraction tube

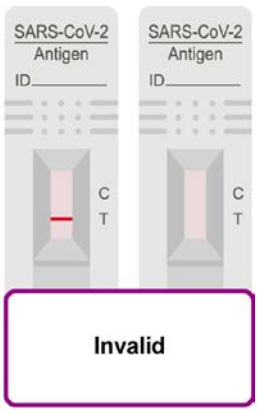
2. Place the swab with specimen into the extraction tube. Roll the swab three to five (3-5) times. **Leave the swab in the extraction buffer for 1 minute**.

3. Pinch the extraction tube with fingers and remove the solution from the swab as much as possible. Dispose of the used swab in accordance with your biohazard waste disposal protocol

4. Install the nozzle cap onto the sample extraction tube tightly. Use extraction solution as test specimen.

5. Read the result at 15-20 minutes. A strong positive sample may show result earlier.

Interpretation of Results



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IFU

RAPID SARS-COV-2 ANTIGEN TEST CARD

FOR THE QUALITATIVE ASSESSMENT OF SARS-CoV-2 VIRUS ANTIGEN
IN NASOPHARYNGEAL SWAB SPECIMENS

Catalog Number: 1N40C5

For In Vitro Diagnostic Use Only

INTENDED USE

Rapid SARS-CoV-2 Antigen Test Card is an immunochromatography based one step in vitro test. It is designed for the rapid qualitative determination of SARS-CoV-2 virus antigen in nasopharyngeal swabs from individuals suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset. Rapid SARS-CoV-2 Antigen Test Card can not be used as the basis to diagnose or exclude SARS-CoV-2 infection.

SUMMARY

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection, asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

PRINCIPLE

Rapid SARS-CoV-2 Antigen Test Card is an immunochromatographic lateral flow device that employs the principle of double antibody sandwich method. Colloidal gold conjugated anti-SARS-CoV-2 antibodies are dry-immobilized on the test device. When the specimen is added, it migrates by capillary diffusion through the strip to re-hydrate the gold conjugate complexes. If present at or above the limit of detection, SARS-CoV-2 viral antigens will react with the gold conjugate complexes to form particles, which will continue to migrate along the strip until the Test Zone (T) where they are captured by the immobilized anti-SARS-CoV-2 antibodies to form a visible red line. If there are no SARS-CoV-2 viral antigens in the specimen, no red line will appear in the Test Zone (T). The gold conjugate complexes will continue to migrate alone until being captured by immobilized antibody in the Control Zone (C) to form a red line, which indicates the validity of the test.

MATERIALS PROVIDED

1. Rapid SARS-CoV-2 Antigen Test Card
2. Sterilized swab
3. Extraction tube
4. Sample extraction buffer
5. Instructions for use

MATERIALS REQUIRED BUT NOT SUPPLIED

Clock or timer, specimen collection container, biohazard waste container. personal protection equipment.

STORAGE

1. Store the test device at 4 to 30℃ in the original sealed pouch. Do Not Freeze.
2. Kit contents are stable until the expiration date printed on the outer box based on the proper storage conditions.
3. The test device should remain in its original sealed pouch until ready for use. After opening, the test device should be used immediately. Do not reuse the device.

PRECAUTIONS

1. For **professional *in vitro*** diagnostic use only.
2. The product is strictly for medical professional use only and not intended for personal use.
3. Do not use the product beyond the expiration date.
4. Do not use the product if the pouch is damaged or the seal is broken.
5. Handle all specimens as potentially infectious.
6. Follow standard Lab procedure and biosafety guidelines for handling and disposal of potentially infectious material.
7. Inadequate or inappropriate specimen collection, storage, and transport may yield inaccurate test results.

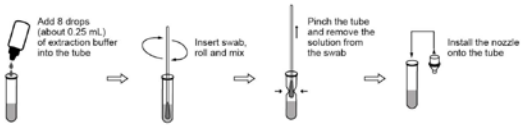
SPECIMEN COLLECTION

Proper specimen collection, storage, and transport are critical to the performance of this test. Specimens should be tested as soon as possible after collection. The training in specimen collection is highly recommended because of the importance of specimen quality. For optimal test performance, use the swabs supplied in the kit.

1. Carefully insert the swab into the nostril of the patient, reaching the surface of posterior nasopharynx that presents the most secretion.
2. Swab over the surface of the posterior nasopharynx. Rotate the swab several times.
3. Withdraw the swab from the nasal cavity.

SPECIMEN PREPARATION

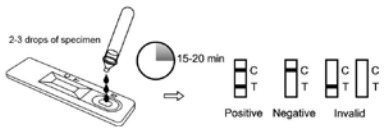
1. Add **8 drops (about 0.25 mL)** of extraction buffer into the extraction tube.
2. Place the swab with specimen into the extraction tube. Roll the swab three to five (3-5) times. **Leave the swab in the extraction buffer for 1 minute**.
3. Pinch the extraction tube with fingers and remove the solution from the swab as much as possible. Dispose of the used swab in accordance with your biohazard waste disposal protocol.
4. Install the nozzle cap onto the sample extraction tube tightly. Use extraction solution as test specimen.



PROCEDURE

1. Bring the kit components to room temperature before testing.
2. Open the pouch and remove the card. Once opened, the test card must be used immediately. Label the test card with patient identity.
3. Invert the extraction tube and add **2-3 drops (50-75 µL)** of test specimen into the specimen well (S) by gently squeezing the extraction tube.
4. Read the results at **15-20 minutes**.

Note: Results after 20 minutes may not be accurate.



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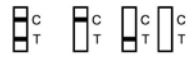
INTERPRETATION OF RESULTS

Positive:
If two colored bands appear within 15-20 minutes with one colored band in the Control Zone (C) and another in the Test Zone (T), the test result is positive and valid. No matter how faint the colored band is in the Test Zone (T), the result should be considered as positive. A positive result does not rule out co-infections with other pathogens.

Negative:
If one colored band appears in the Control Zone (C) and no colored band appears in the Test Zone (T) within 15-20 minutes, the test result is negative and valid. A negative result does not exclude SARS-CoV-2 viral infection and should be confirmed by molecular diagnostic method if COVID-19 disease is suspected.

Invalid result:
The test result is invalid if there is no colored band in the Control Zone (C) within 15-20 minutes. Repeat the test with a new test device.



Positive Negative Invalid

QUALITY CONTROL

1. The control band is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.
2. Good Laboratory Practice recommends the daily use of control materials to validate the reliability of the device. Control materials which are not provided with this test kit are commercially available.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity
The limit of detection (LoD) for the Rapid SARS-CoV-2 Antigen Test Card was established in an analytical sensitivity study performed with one virus strain and one recombinant nucleocapsid protein. The LoD was confirmed in the following table.

No.	Item	Limit of Detection
1	SARS-CoV-2, Virus	1.3 x10^2 $TCID_{50}$/mL
2	SARS-CoV-2, Recombinant nucleocapsid protein	1 ng/mL

Cross Reactivity
The cross reactivity of the Rapid SARS-CoV-2 Antigen Test Card was evaluated with a total of 4 bacteria and 5 viruses. None of the microorganisms tested in the following table gave a positive result.

Bacteria panel	
Candida albicans	*Staphylococcus aureus*
Pseudomonas aeruginosa	*Escherichia coli*
Viral panel	
Influenza A virus (H1N1)	Influenza A virus (H3N2)
Influenza B virus (Yamagata)	Influenza B virus (Victoria)
Adeno virus	

Accuracy
The accuracy of Rapid SARS-CoV-2 Antigen Test Card was established with 236 nasopharyngeal swabs collected from individual symptomatic patients (within 7 days of onset) who were suspected of COVID-19. The following table summarizes the accuracy of the Rapid SARS-CoV-2 Antigen Test Card compared to RT-PCR.

		RT-PCR		
		Positive	Negative	Total
Rapid SARS-CoV-2 Antigen Test Card	Positive	30	4	34
	Negative	2	200	202
	Total	32	204	236

The sensitivity was 93.75% (95%CI: 85.36%~99.99%). The specificity was 98.04% (95%CI: 96.14%~99.94%). The accuracy was 97.46% (95%CI: 95.45%~99.47%).

LIMITATIONS

1. The test is limited to the qualitative detection of SARS-CoV-2 viral antigen in nasopharyngeal swab specimens. The exact concentration of SARS-CoV-2 viral antigen cannot be determined by this assay.
2. Proper specimen collection is critical, and failure to follow the procedure may give inaccurate results. Improper specimen collection, storage or repeated freezing and thawing of specimens can lead to inaccurate results.
3. A negative test result may occur if the level of antigen in a specimen is below the limit of detection of the test.
4. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
5. Negative test results do not rule out other potential non-SARS-CoV-2 viral infections. Negative results should be confirmed by molecular diagnosis if COVID-19 disease is suspected.
6. Positive test results do not rule out co-infections with other pathogens.
7. Monoclonal antibodies may fail to detect, or detect with less sensitivity, SARS-CoV-2 viruses that have undergone minor amino acid changes in the target epitope region.
8. The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after day 5-7 of illness are more likely to be tested negative compared to a RT-PCR assay.

REFERENCES

1. Wu C, Liu Y, Yang Y, Zhang P, Zhong W, Wang Y, et al. (February 2020). "Analysis of therapeutic targets for SARS-CoV-2 and discovery of potential drugs by computational methods". Acta Pharmaceutica Sinica B. doi:10.1016.

IVD 4℃ 30℃ CE

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Medical Device Production License

医疗器械生产许可证

许可证编号：闽药监械生产许20100174号

企业名称：厦门市波生生物技术有限公司

生产地址：厦门市集美北部工业区天凤路90-94号

法定代表人：张长弓

生产范围：二类、三类6840体外诊断试剂；新《医疗器械分类目录》22-04免疫分析设备***

企业负责人：张长弓

住　　所：厦门市集美北部工业区天凤路90-94号

发证部门：福建省药品监督管理局

有效期限：至　2024 年 11 月 05 日

发证日期：2019 年 12 月 31 日

国家食品药品监督管理总局制

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Ministerie van Volksgezondheid, Welzijn en Sport

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http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
M. Schmitz - Konte
medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20203899

Bijlagen
-

Uw aanvraag
9 augustus 2020

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 13 augustus 2020
Betreft: aanmelding In-vitro diagnostica

Geachte heer Wei,

Op 9 augustus 2020 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam Xiamen Boson Biotech Co., Ltd. met Europees gemachtigde Lotus NL B.V. onderstaande producten als in-vitro diagnostica op de Europese markt te brengen.

De producten staan geregistreerd als in-vitro diagnostica onder nummer:

D-Dimer Test, H.Pylori Antigen Test, H.Pylori Antibody Test, Rotavirus Antigen Test, V.Cholerae O1/O139 Duo Test, Salmonella typhi Antigen Test, Salmonella typhi IgG/IgM Combo Test, Rickettsia IgG/IgM Combo Test, Tuberculosis Test,Cardiac Panel Test
(geen merknaam) (NL-CA002-2020-52870)
Rapid SARS-CoV-2 Antigen Test Card, Syphilis Antibody Test, Malaria Antigen Test, Dengue IgG/IgM Combo Test, Dengue NS1 Antigen and IgG/IgM Duo Panel Test, C-reactive Protein Test,HCG Pregnancy Test, LH Test,Troponin I Test,Myoglobin Test,CK-MB Test
(geen merknaam) (NL-CA002-2020-52869)

Hiermee heeft u voldaan aan uw verplichting op grond van artikel 4, BIVD.

In alle verdere correspondentie betreffende bovenvermelde producten verzoek ik u deze nummers te vermelden. Aan deze nummers kunnen geen verdere rechten ontleend worden, ze dienen alleen om de notificatie administratief te vergemakkelijken.

De registratie van in-vitro diagnostica als medisch hulpmiddel op grond van de Classificatiecriteria (Bijlage II) bij Richtlijn 98/79/EG betreffende medische hulpmiddelen voor in-vitro diagnostiek is onderhevig aan mogelijke revisies van Europese regelgeving inzake de classificatie van medische hulpmiddelen en aan voortschrijdend wetenschappelijk inzicht (zie artikel artikel 10, eerste lid van Richtlijn 98/79/EG).

Pagina 1 van 2

BOSON

Declaration of Conformity

Manufacturer	Xiamen Boson Biotech CO,. Ltd. 90-94 Tianfeng Road, Jimei North Industrial Park, Xiamen, Fujian 361021, P. R. China.
European Representative	Lotus NL B.V. Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Device/s	Rapid SARS-CoV-2 Antigen Test Card
Classification	Others
Confirmative Assessment Route	98/79/EC IVDD Annex III

We, Xiamen Boson Biotech Co., Ltd. declare that the above mentiond devices conforms to the relevant provisions of the EC Council Directive 98/79 and is in accordance with the Annex III, ISO 13485:2016 Quality Management System, as implemented by the European Union's Medical Devices Regulations and the Federal and Local Authorities.

Place, Date of Issue Xiamen, 2020-08-04

Signature Changgong Zhang

(Signed By Boson Representative)
Name: Changgong Zhang
Title: General Manager

CE

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ISO13485 Certificate

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

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

TÜV SÜD Product Service

Certificate

No. Q5 061317 0005 Rev. 00

Holder of Certificate: **Xiamen Boson Biotech Co., Ltd.**
90-94 Tianfeng Road
Jimei North Industrial Park
361021 Xiamen, Fujian
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Xiamen Boson Biotech Co., Ltd.
90-94 Tianfeng Road, Jimei North Industrial Park, 361021
Xiamen, Fujian, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic kits for detection of Infection Diseases, Tumour Markers, Drug Abuse, Hormones, Cardiac Markers and Related Biomaterial**

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

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). See also notes overleaf.

Report No.: SH1807513

Valid from: 2018-10-31
Valid until: 2021-10-30

Date, 2018-09-27

Stefan Preiß

A4 / 07.17

Page 1 of 1
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

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Side 1:

Side 2:

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BOSON Introduction

Xiamen Boson Biotech Co., Ltd., as a specialist of in vitro diagnostic kits field was founded in 2001, we develop and manufacture high-quality point of care and other immunoassay kits for world-wide market.

Our 10,000 square meter facility is operated strictly under ISO 13485:2016 and GMP guidelines.

Our product lines provide the immunoassays in various formats to detect cardiac markers, drugs of abuse, fertility hormones, infectious diseases, tumor markers and animal diseases. Many of our products have been approved by NMPA and CE.

Our company presents its product with well-designed Boson and HomeScan packaging. We also provide OEM and private label service for customers.

Xiamen Boson Biotech's mission is to provide the affordable high quality products to help fighting diseases and illicit substance abuse.