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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/6325/177661.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	产品型号
No.	**Company**	**Uniform Social Credit Code**	**Status of Certification / Authorization in Other**	**Product Model**
61	厦门市波生生物技术有限公司 Xiamen Boson Biotech Co.,Ltd	91350200705468594R	CE	2019-nCoV IgG/IgM Combo Test Card Rapid SARS-CoV-2 Antigen Test Card Rapid SARS-CoV-2/Influenza A+B Antigen Duo Test Card

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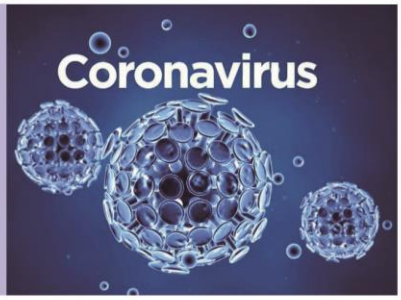
COVID-19

Rapid SARS-CoV-2 Antigen Test Card



Using a nasopharyngeal, oropharyngeal or 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/Oropharyngeal/Nasal swabs 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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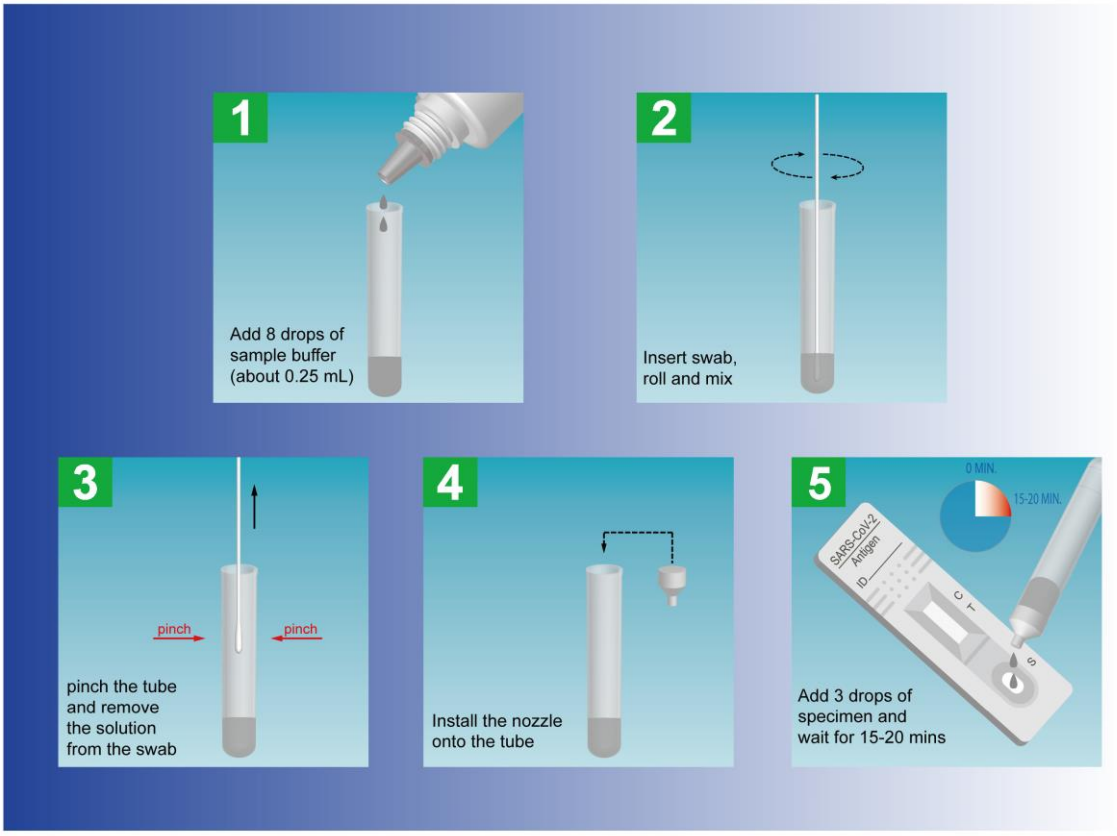
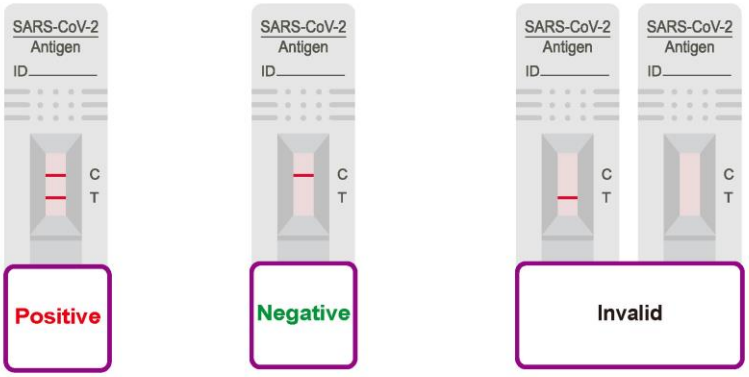
Test Procedure



Interpretation of Results



Please contact us or your agent for details.

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

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Result in 15-20 minutes

Nasopharyngeal/Oropharyngeal/Nasal swabs can be used

Accuracy: 98.25%

High specificity, which means a positive antigen test result can be considered very accurate

Faster and less expensive than molecular tests

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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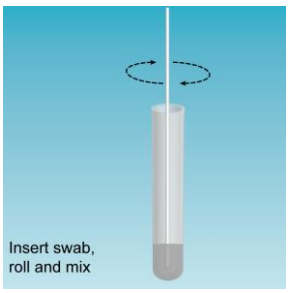
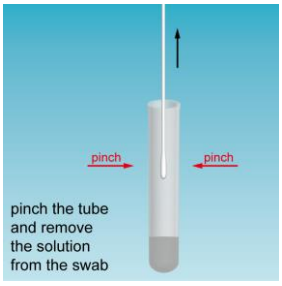
Test Procedure





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

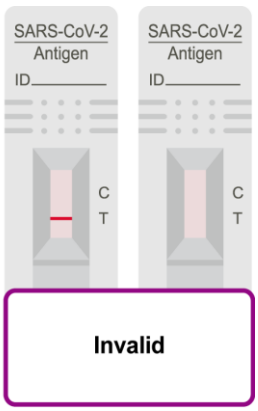
2. Place the swab with specimen into the extraction tube. Roll the swab three to five (3-5) times. **Leave the swab in the extraction buffer for 1 minute**.

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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RAPID SARS-COV-2 ANTIGEN TEST CARD

FOR THE QUALITATIVE ASSESSMENT OF SARS-COV-2 VIRUS ANTIGEN
IN NASAL SWAB, NASOPHARYNGEAL SWAB OR OROPHARYNGEAL 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 nasal swabs, nasopharyngeal swabs or oropharyngeal 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.
Rapid SARS-CoV-2 Antigen Test Card detects the SARS-CoV-2 nucleocapsid protein (N protein). Theoretically, genetic SARS-CoV-2 variants with non-nucleocapsid protein mutations do not affect the product performance.

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. Tube Stand
6. 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°C 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

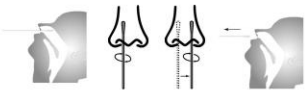
1. For **professional *in vitro*** diagnostic use only.
2. The product is strictly for medical professional use only and not intended for personal use.
3. Do not use the product beyond the expiration date.
4. Do not use the product if the pouch is damaged or the seal is broken.
5. Handle all specimens 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.
8. Specific training or guidance is recommended if operators are not experienced with specimen collection and handling procedures. Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when specimens are collected and evaluated. Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. Standard precautions and institutional guidelines should always be followed in handling, storing, and disposing of all specimens and all items contaminated with blood or other body fluids.

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.

Nasopharyngeal swab specimens:
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.

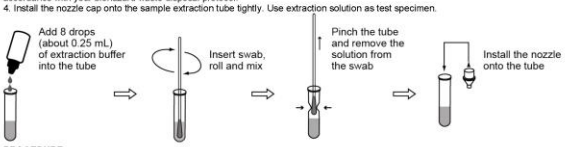
Oropharyngeal swab specimens:
Let the patient's head tilt slightly, mouth open, and make "ah" sounds, exposing the pharyngeal tonsils on both sides. Hold the swab and wipe the pharyngeal tonsils on both sides of the patient with moderate force back and forth for at least 3 times. Avoid touching the tongue, teeth and gums.



Nasal swab specimens:
1. Carefully insert the swab into one nostril of the patient. The swab tip should be inserted no less than 2.5 cm (1 inch) from the edge of the nostril.
2. Roll the swab 3-4 times along the mucosa inside the nostril to ensure that both mucus and cells are collected. Leave the swab in the nostril for several seconds.
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.

SPECIMEN PREPARATION

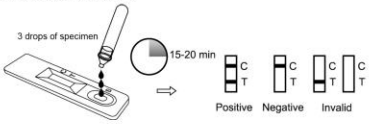
1. Add **8 drops (about 0.25 mL)** of extraction buffer into the extraction tube.
2. Place the swab with specimen into the extraction tube. Roll the swab three to five (3-5) times. **Leave the swab in the extraction buffer for 1 minute.**
3. Pinch the extraction tube with fingers and remove the solution 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 **3 drops (about 75 µL)** of test specimen into the specimen well (S) by gently squeezing the extraction tube. The formation of air bubbles in the specimen well (S) must be avoided.
4. Read the results at **15-20 minutes.**

Note: Results after 20 minutes may not be accurate.

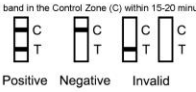


INTERPRETATION OF RESULTS

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.



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.

082027 / 210224

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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 x 10^2 $TCID_{50}$/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 27 microorganisms. None of the microorganisms tested in the following table gave a positive result.

Microorganisms	Concentrations	Microorganisms	Concentrations
Human coronavirus 229E	2.0 x 10^5 $TCID_{50}$/mL	MERS-coronavirus	1.0 x 10^5 $TCID_{50}$/mL
Human coronavirus OC43	2.0 x 10^5 $TCID_{50}$/mL	Chlamydia pneumoniae	2.0 x 10^6 IFU/mL
Human coronavirus NL63	2.0 x 10^5 $TCID_{50}$/mL	Streptococcus pneumoniae	2.0 x 10^6 CFU/mL
Parainfluenza virus 1	2.0 x 10^5 $TCID_{50}$/mL	Streptococcus pyogenes	2.0 x 10^6 CFU/mL
Parainfluenza virus 2	2.0 x 10^5 $TCID_{50}$/mL	Bordetella pertussis	2.0 x 10^6 CFU/mL
Parainfluenza virus 3	2.0 x 10^5 $TCID_{50}$/mL	Mycobacterium tuberculosis	2.0 x 10^6 CFU/mL
Enterovirus EV71	2.0 x 10^5 $TCID_{50}$/mL	Legionella pneumophila	2.0 x 10^6 CFU/mL
Respiratory syncytial virus	2.0 x 10^5 $TCID_{50}$/mL	Mycoplasma pneumoniae	2.0 x 10^6 U/mL
Rhinovirus	2.0 x 10^5 $TCID_{50}$/mL	Haemophilus influenzae	2.0 x 10^6 CFU/mL
Influenza A virus (H1N1)	2.0 x 10^5 $TCID_{50}$/mL	Candida albicans	2.0 x 10^6 CFU/mL
Influenza A virus (H3N2)	2.0 x 10^5 $TCID_{50}$/mL	Staphylococcus aureus	2.0 x 10^6 CFU/mL
Influenza B virus (Yamagata)	2.0 x 10^5 $TCID_{50}$/mL	Pseudomonas aeruginosa	2.0 x 10^6 CFU/mL
Influenza B virus (Victoria)	2.0 x 10^5 $TCID_{50}$/mL	Escherichia coli	2.0 x 10^6 CFU/mL
Adeno virus	2.0 x 10^5 $TCID_{50}$/mL		

Interference

1. Microorganism

Rapid SARS-CoV-2 Antigen Test Card has tested samples with common microorganism. The results showed that these microorganism had no effect on the specificity of the assay up to the listed concentration.

Microorganisms	Concentrations	Microorganisms	Concentrations
Human coronavirus 229E	2.0 x 10^5 $TCID_{50}$/mL	MERS-coronavirus	1.0 x 10^5 $TCID_{50}$/mL
Human coronavirus OC43	2.0 x 10^5 $TCID_{50}$/mL	Chlamydia pneumoniae	2.0 x 10^6 IFU/mL
Human coronavirus NL63	2.0 x 10^5 $TCID_{50}$/mL	Streptococcus pneumoniae	2.0 x 10^6 CFU/mL
Parainfluenza virus 1	2.0 x 10^5 $TCID_{50}$/mL	Streptococcus pyogenes	2.0 x 10^6 CFU/mL
Parainfluenza virus 2	2.0 x 10^5 $TCID_{50}$/mL	Bordetella pertussis	2.0 x 10^6 CFU/mL
Parainfluenza virus 3	2.0 x 10^5 $TCID_{50}$/mL	Mycobacterium tuberculosis	2.0 x 10^6 CFU/mL
Enterovirus EV71	2.0 x 10^5 $TCID_{50}$/mL	Legionella pneumophila	2.0 x 10^6 CFU/mL
Respiratory syncytial virus	2.0 x 10^5 $TCID_{50}$/mL	Mycoplasma pneumoniae	2.0 x 10^6 U/mL
Rhinovirus	2.0 x 10^5 $TCID_{50}$/mL	Haemophilus influenzae	2.0 x 10^6 CFU/mL
Influenza A virus (H1N1)	2.0 x 10^5 $TCID_{50}$/mL	Candida albicans	2.0 x 10^6 CFU/mL
Influenza A virus (H3N2)	2.0 x 10^5 $TCID_{50}$/mL	Staphylococcus aureus	2.0 x 10^6 CFU/mL
Influenza B virus (Yamagata)	2.0 x 10^5 $TCID_{50}$/mL	Pseudomonas aeruginosa	2.0 x 10^6 CFU/mL
Influenza B virus (Victoria)	2.0 x 10^5 $TCID_{50}$/mL	Escherichia coli	2.0 x 10^6 CFU/mL
Adeno virus	2.0 x 10^5 $TCID_{50}$/mL		

2. Endogenous Substances

Rapid SARS-CoV-2 Antigen Test Card has tested samples with common endogenous substances. The results showed that these substances had no effect on the specificity of the assay up to the listed concentration.

Substances	Concentrations	Substances	Concentrations
Whole Blood	1% v/v	Homeopathic (Alkalol)	10% v/v
Mucin	2% w/v	CVS Nasal Drops (Phenylephrine)	15% v/v
Tobramycin	0.0004% w/v	Afrin (Oxymetazoline)	15% v/v
Ricola (Menthol)	0.15% w/v	CVS Nasal Spray (Cromolyn)	15% v/v
Chloraseptic (Benzocaine)	0.15% w/v	Fluticasone Propionate	5% v/v
Mupirocin	0.25% w/v	Zicam	5% w/v
Tamiflu (Oseltamivir Phosphate)	0.5% w/v		

Accuracy

The accuracy of Rapid SARS-CoV-2 Antigen Test Card was established with 1027 specimens 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	301	6	307
	Negative	12	708	720
	Total	313	714	1027

The sensitivity was 96.17% (95%CI: 94.04%~98.29%). The specificity was 99.16% (95%CI: 98.49%~99.83%). The accuracy was 98.25% (95%CI: 97.44%~99.05%).

LIMITATIONS

1. The test is limited to the qualitative detection of SARS-CoV-2 viral antigen in nasal swab, nasopharyngeal swab or oropharyngeal 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.
9. The Rapid SARS-CoV-2 Antigen Test Card can detect both viable and non-viable SARS-CoV-2 material. The Rapid SARS-CoV-2 Antigen Test Card for rapid detection of SARS-CoV-2 performance depends on antigen load and may not correlate with other diagnostic methods performed on the same specimen.
10. The performance of this test has not been evaluated for use in patients without signs and symptoms of respiratory infection and performance may differ in asymptomatic individuals.
11. The kit was validated with the assorted swabs. Use of alternative swabs may result in false negative results.
12. Specimen stability recommendations are based upon stability data from influenza testing and performance may be different with SARS-CoV-2. Users should test specimens as quickly as possible after specimen collection, and within two hours after specimen collection.
13. The validity of Rapid SARS-CoV-2 Antigen Test Card has not been proven for dentification/confirmation of tissue culture isolates and should not be used in this capacity.
14. The sensitivity of nasal swab specimens and oropharyngeal swab specimens might be lower than nasopharyngeal swab specimens. It is recommended to use the nasopharyngeal swab specimens.

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.

EXPLANATION FOR SYMBOLS

IVD	*In Vitro* Diagnostics Use		See Instruction for Use		Expiry Date
Σ	Tests per Kit		Keep Dry	LOT	Batch Number
EC REP	Authorized Representative		Keep away from Sunlight		Manufacturer
	Do not reuse		Do not use if package is damaged	0°C 30°C 4°C	Store between 4 ~ 30°C
CE	CE Mark	REF	Catalogue Number		Warning, please refer to the instruction

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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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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).

Farmatec
Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag
T 070 340 6161
http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
M. Schmitz - Konte
mediche_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.

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

Xiamen Boson Biotech Co.,Ltd.
90-94 Tianfeng Road,Jimei North Industrial Park,
Xiamen, Fujian 361021, P.R. China
Tel : 86-592-3965101 E-mail: info@bosonbio.com
www.bosonbio.com

List of Marketing Authorization

List of Marketing Authorization of Boson's
Rapid SARS-CoV-2 Antigen Test Card

No.	Country	Approval Date	Approval Department
1	European Union	2020.08.13	CIBG (Ministry of Public Health, Welfare and Sport)
2	United Kingdom	2020.11.27	MHRA (Medicines and Healthcare products Regulatory Agency)
3	Bosnia and Herzegovina	2020.12.22	The Agency for Medicinal Products and Medical Devices Bosnia And Herzegovina
4	Peru	2021.01.07	DIGEMID (Directorate General of Drug Supplies and Drugs)
5	Germany	2020.12.17	The Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM)
6	Switzerland	2020.11.02	Bundesamt für Gesundheit BAG
7	Italy	2020.10.24	Ministero della Salute

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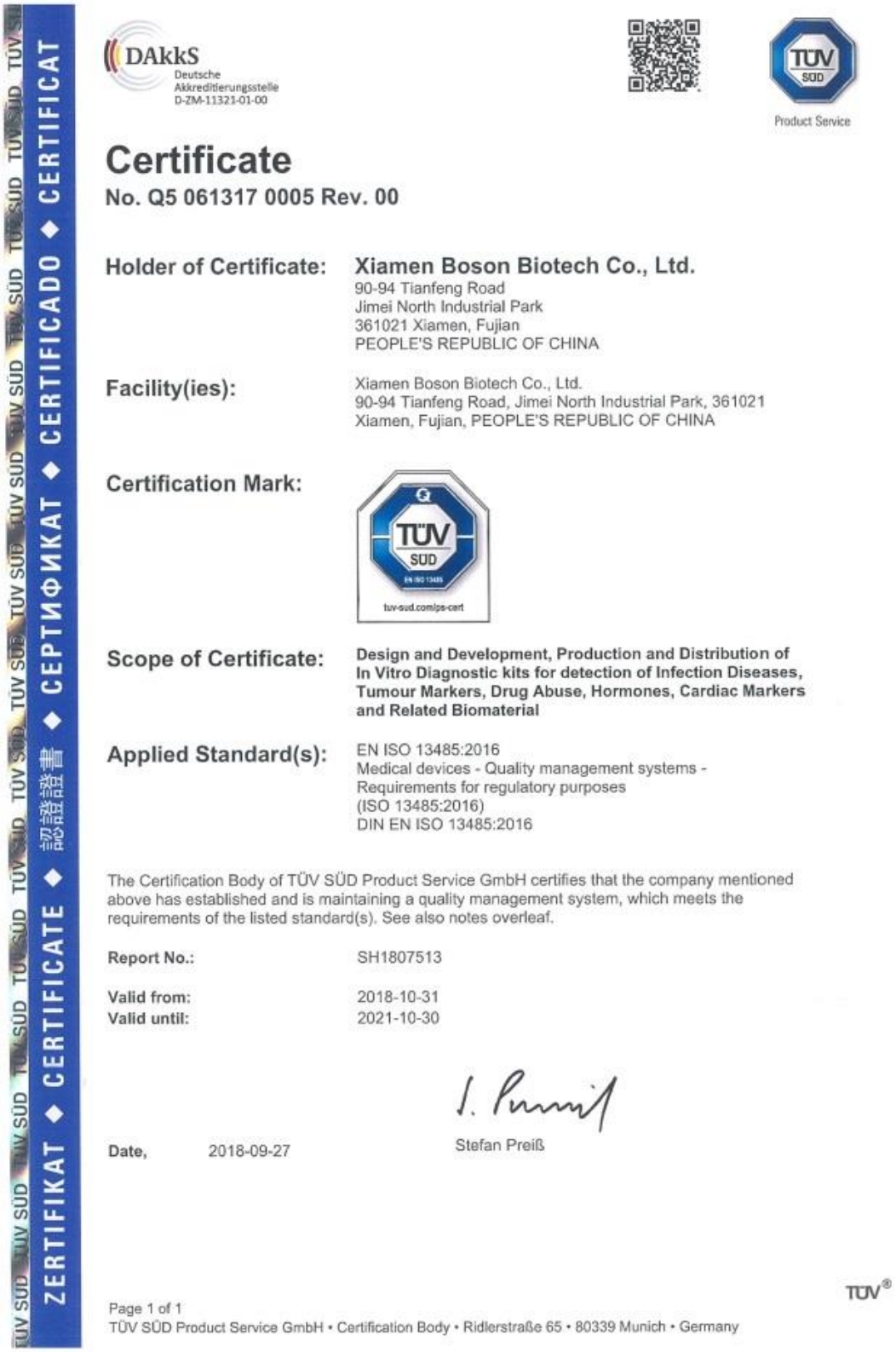
ISO13485 Certificate



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

TÜV®

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

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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.

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Our Market

Our products have been exported to more than 70 countries: Britain, Germany, Italy, Brazil, Argentina, Australia, India, Malaysia, South Africa, etc.

Please contact us or your agent for details