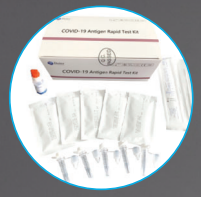
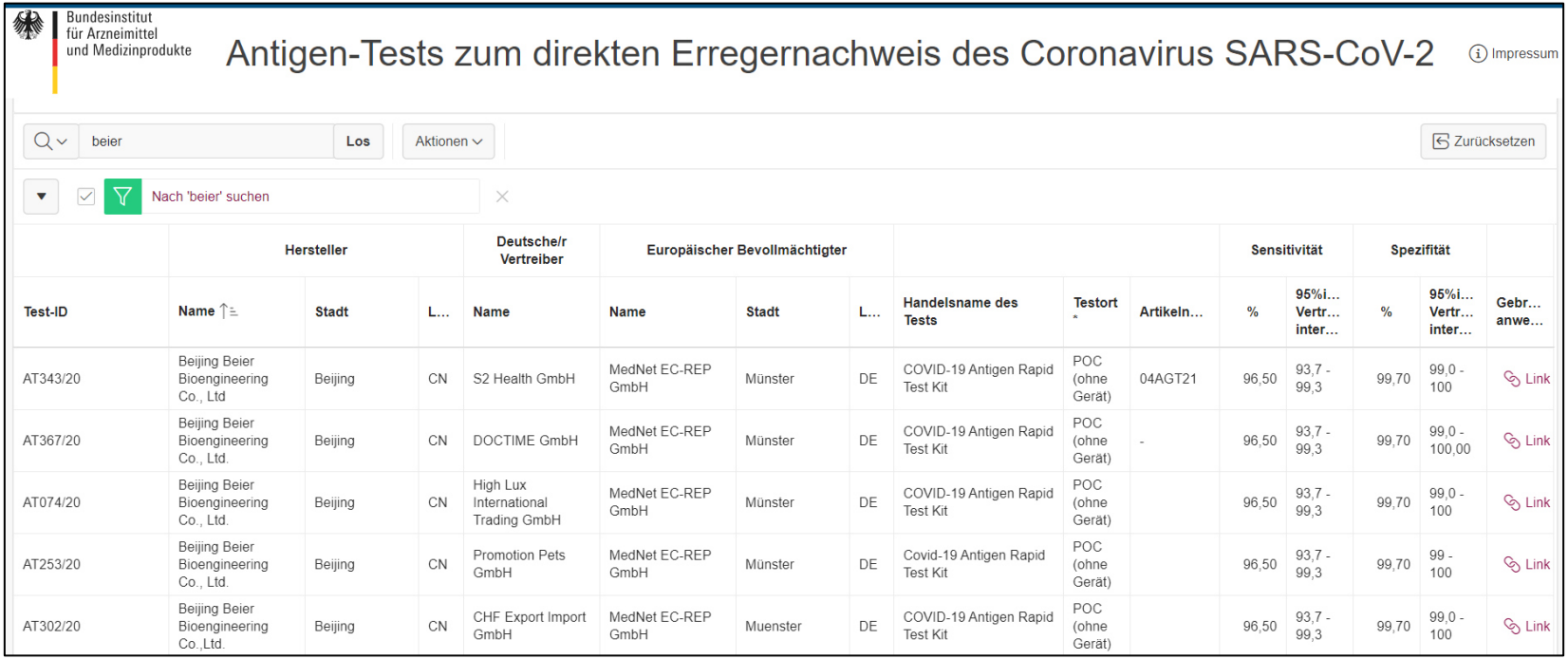


COVID-19
ANTIGEN RAPID TEST KIT

MATTHIAS & ASSOCIATES

The product of the manufacturer Beijing Beier Bioengineering Co., Ltd. is approved in the European Union



Bundesinstitut für Arzneimittel und Medizinprodukte

Antigen-Tests zum direkten Erregernachweis des Coronavirus SARS-CoV-2

Impressum

beier | Los | Aktionen | Zurücksetzen

Nach 'beier' suchen

	Hersteller			Deutsche/r Vertreiber	Europäischer Bevollmächtigter						Sensitivität		Spezifität		
Test-ID	Name	Stadt	L…	Name	Name	Stadt	L…	Handelsname des Tests	Testort *	Artikeln…	%	95%i… Vertr… inter…	%	95%i… Vertr… inter…	Gebr… anwe…
AT343/20	Beijing Beier Bioengineering Co., Ltd	Beijing	CN	S2 Health GmbH	MedNet EC-REP GmbH	Münster	DE	COVID-19 Antigen Rapid Test Kit	POC (ohne Gerät)	04AGT21	96,50	93,7 - 99,3	99,70	99,0 - 100	Link
AT367/20	Beijing Beier Bioengineering Co., Ltd.	Beijing	CN	DOCTIME GmbH	MedNet EC-REP GmbH	Münster	DE	COVID-19 Antigen Rapid Test Kit	POC (ohne Gerät)	-	96,50	93,7 - 99,3	99,70	99,0 - 100,00	Link
AT074/20	Beijing Beier Bioengineering Co., Ltd.	Beijing	CN	High Lux International Trading GmbH	MedNet EC-REP GmbH	Münster	DE	COVID-19 Antigen Rapid Test Kit	POC (ohne Gerät)		96,50	93,7 - 99,3	99,70	99,0 - 100	Link
AT253/20	Beijing Beier Bioengineering Co., Ltd.	Beijing	CN	Promotion Pets GmbH	MedNet EC-REP GmbH	Münster	DE	Covid-19 Antigen Rapid Test Kit	POC (ohne Gerät)		96,50	93,7 - 99,3	99,70	99 - 100	Link
AT302/20	Beijing Beier Bioengineering Co.,Ltd.	Beijing	CN	CHF Export Import GmbH	MedNet EC-REP GmbH	Muenster	DE	COVID-19 Antigen Rapid Test Kit	POC (ohne Gerät)		96,50	93,7 - 99,3	99,70	99,0 - 100	Link

Link: Federal Institute for Drugs and Medical Devices - Antigen tests for direct detection of the pathogen of the coronavirus

One COVID-19 antigen rapid kit contains material for 20 tests

Attached documents

No.	Document	Page
1	Operating instructions in English	5 - 8
2	Brochure in English	9 - 10
3	Permission for distribution in Europe	11
4	EC Declaration of conformity	12
5	Certificate of registration: legal representation of Beijing Beier Bioengineering Co., Ltd.	13
6	SDS Report - Safety Data Sheet	14 - 23
8	Clinical test from September 10th, 2020	24 - 28
9	Internal performance evaluation report from October 24th, 2020	29 - 31

COVID-19 Antigen Rapid Test Kit

INTENDED USE

The COVID-19 Antigen Rapid Test Kit is an immunochromatographic intended for the direct and qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasopharyngeal swab and oropharyngeal swab from individuals who are suspected of COVID-19 by their healthcare provider. The test is to be used as an aid in the diagnosis of coronavirus infection disease (COVID-19), which is caused by SARS-CoV-2.

The COVID-19 Antigen Rapid Test Kit does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in upper respiratory specimen during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Negative results do not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

For *in vitro* diagnostic use only. For professional use only.

SUMMARY

A novel coronavirus (2019-nCoV) was identified in December 2019, which has resulted in hundreds of thousands of confirmed human infections worldwide. On February 11, 2020 the International Committee for Taxonomy of Viruses (ICTV) renamed the virus SARS-CoV-2.The symptoms of COVID-19 are similar to other viral respiratory diseases and include fever, cough, shortness of breath.

PRINCIPLE

The COVID-19 Antigen Rapid Test Kit is designed to detect the presence or absence of SARS-CoV or SARS-CoV-2 nucleocapsid proteins by sandwich method. When specimen are processed and added to the sample well, the specimen is absorbed into the device by capillary action. If SARS-CoV or SARS-CoV-2 antigens present in the specimen, it will bind to the SARS-CoV-2 Antibody-labeled conjugated and flows across the coated nitrocellulose membrane in the test strip.

When the SARS-CoV or SARS-CoV-2 antigens level in the specimen is at or above the detection limit of the test, the antigens bound to the SARS-CoV-2 antibody-labeled conjugate are captured by another SARS-CoV-2 antibody immobilized in the Test line (T) of the device, and this produces a colored test band that indicates a positive result. When the SARS-CoV or SARS-CoV-2 antigens level in the specimen does not exist or detection limit of the test, there is not a visible colored band in the Test line (T) of the device. This indicates a negative result.

PRECAUTION

1. This kit is for in vitro diagnostic use only.
2. For healthcare professionals and professionals at point of care sites.
3. Do not touch the reaction area of test strip.
4. Please read all the information in this leaflet before performing the test.
5. The test cassette should remain in the sealed pouch until use.
6. All specimen should be considered potentially hazardous and handled in the same manner as an infectious agent.
7. Do not use test kit beyond the expiration date.
8. To avoid erroneous results, specimen must be processed as indicated in the test procedure section.
9. Testing should be applied by professionally trained staff working in certified laboratories or clinics at which the sample(s) is taken by qualified medical personnel. Wear protective clothing such as laboratory coats, disposable gloves, and eye protection.
10. Do not reuse any components of the kit.
11. When collecting a sample, use the swab supplied in the kit. Use of alternative swabs may result in false.
12. The test result should be interpreted by the physician along with clinical findings and other laboratory test results.
13. Disposal of the diagnostic: All specimen and the used-kit has the infectious risk. The used test cassette should be discarded according to federal, state and local regulations.

MATERIAL

Material Provided

1. 20×Sterile Swabs
2. 20×Extraction tube
3. 2×Sample Lysis Solution
4. 20×Test cassette
5. 1×Instructions for use

Material Required but Not Provided

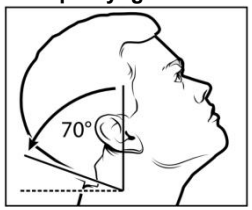
1. 1mL Micropipette with pipette tips
2. Viral Transport Media
3. Personal protective equipment, such as protective gloves, medical mask, goggles and lab coat.
4. Timer

STORAGE AND STABILITY

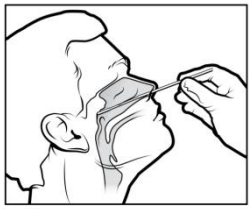
1. Store as packaged in the sealed pouch at temperature (4-30°C or 40-86 F).
2. Once open the pouch, the test should be used within 30 minutes. Prolonged exposure to hot and humid environment will cause product deterioration.
3. The cassette is stable within the expiration date printed on the labeling.
4. The LOT and the expiration date were printed on the labeling.

SPECIMEN COLLECTION AND PREPARATION

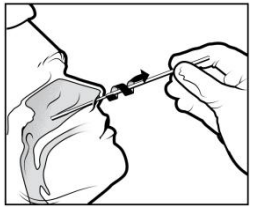
Nasopharyngeal Swab Specimen Collection



1.Tilt patient's head back 70 degrees

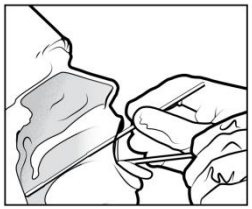


2. Insert swab into nostril. (Swab should reach depth equal to distance from nostrils to outer opening of the ear.) Leave swab in place for several seconds to absorb secretions.



3. Slowly remove swab while rotating it. (Swab both nostrils with same swab.)

Oropharyngeal Swab Specimen Collection



1. For oropharyngeal swab, take a second dry polyester swab, insert into mouth, and swab the posterior pharynx and tonsillar areas. (Avoid the tongue.)

Specimen Transport and Storage

Freshly collected specimen should be processed as soon as possible.The oropharyngeal or nasopharyngeal swabs are stable for up to 24-hours at room temperature or 2° to 8°C.

TEST PROCEDURE

Please read the instruction for use carefully before performing the test.
Allow the Test cassette, Sample Lysis Solution and specimen to equilibrate to temperature (15-30℃ or 59-86℉) before testing.

1

1.Take an extraction tube from the kit and remove a test cassette from the foil pouch by tearing at the notch. Place them on a level surface.

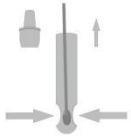
2

2. Add 10 drops(or 450~500μL) of sample lysis solution into the Extraction tube.

3

3. Place and soak the Patient Swab in the Sample Lysis Solution for 15 seconds. Stir well by rotating the swab against the side of the vial 5 times.

4



4. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab. Discard the swab in biohazard waste.

5

5. Firmly attach Dropper Lid to the top of the Extraction tube. Then gently invert the Extraction tube 5 times.

6

6. Transfer 2~3 drops (80μL) specimen to the sample area of the Test Strip.

Note: If using a frozen sample, the sample must be at room temperature before testing.

7. Read the results in 15-20 minutes. Do not interpret the result exceed 20 minutes.

RESULT INTERPRETATION

Positive Result

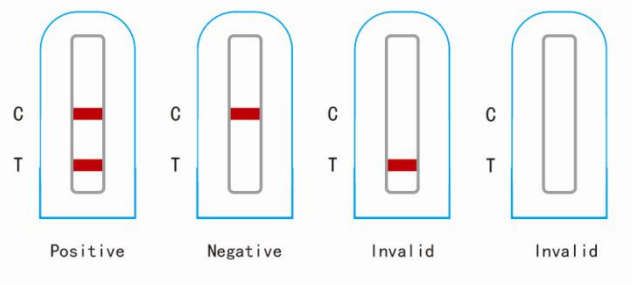
Colored bands appear at both test line (T) and control line (C). It indicates a positive result for the SARS-CoV or SARS-CoV-2 antigens in the specimen.

Negative Result

Colored band appear at control line (C) only. It indicates that the concentration of the SARS-CoV or SARS-CoV-2 antigens does not exist or below the detection limit of the test.

Invalid Result

No visible colored band appear at control line after performing the test. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.



QUALITY CONTROL

A procedural control is included in the test. The control line is used as the internal procedural control. The appearance of control line indicate a correct procedure, the absence of control line indicate an inappropriate procedure, specimen volume or degenerative product.

Good laboratory practice recommends the use of the control materials. Users should follow the appropriate federal state, and local guidelines concerning the frequency of assaying external quality control materials.

LIMITATIONS OF PROCEDURE

1. The contents of this kit are to be used for the qualitative detection of SARS-CoV or SARS-CoV-2 antigens from nasopharyngeal swab and oropharyngeal swab.
2. This reagent is a qualitative assay. It is not designed to determine the quantitative concentration of SARS-CoV or SARS-CoV-2 antigens.
3. The accuracy of the test depends on the sample collection process. Improper sample collection, improper sample storage, or repeated freezing and thawing of the sample will affect the test result.
4. The results from this test are intended to be an aid in clinical reference only. Each physician must interpret the results in conjunction with the patient's history, physical findings, and other diagnostic procedures.
5. Limited by the method of antigen detection reagents, for negative test results, it is recommended to use nucleic acid detection or virus culture identification methods for review and confirmation.
6. A false-negative test result may occur if the level of viral antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly; Therefore, a negative test result does not eliminate the possibility of SARS-CoV or SARS-CoV-2 infection.
7. Positive test results do not rule out co-infections with other pathogens.
8. Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
9. Negative test results are not intended to rule in other non-SARS-CoV or SARS-CoV-2 viral or bacterial infections.
10. Sensitivity of the test after the first five days of the onset of symptoms has been demonstrated to decrease as compared to a RT-PCR SARS-CoV or SARS-CoV-2 assay.
11. This test detects both viable (live) and non-viable SARS-CoV or SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.

PERFORMANCE CHARACTERISTICS

A. Limit of detection（LOD）
The LOD for the COVID-19 Antigen Rapid Test Kit was established using limiting dilutions of a viral sample by Heat inactivation. The

material was supplied at a concentration of 2.6 x 10^5 $TCID_{50}$/mL. Using this concentration, the LOD was further refined with a 10-fold dilution series. The last dilution demonstrating 100% positivity was then tested in an additional 20 replicates tested in the same way.

Based on this testing the concentration was confirmed as: 1.3 x 10^2 $TCID_{50}$/mL

B. Sensitivity and Specificity

474 clinical case samples which include 171 confirmed case samples* and 303 confirmed excluded case samples*, were obtained for testing, and then compared the test results between The COVID-19 Antigen Rapid Test Kit's result and the clinical diagnosis. The results of sensitivity and specificity between the two methods are show below.

Reagents		Clinical diagnosis		Total
		Positive	Negative	
Beier Reagents	Positive	165	1	166
	Negative	6	302	308
Total		171	303	474

*Confirmed cases were the patients diagnosed according to the treatment plan and PCR result.
*Confirmed excluded cases were identified by negative PCR results.

Results analysis：
Sensitivity=96.5%(95% CI: 93.7%~99.3%)
Specificity=99.7%(95% CI: 99.0% -100%)
Positive predictive values= 99.4%(95% CI: 98.2% -100%)
Negative predictive values= 98.0%(95% CI: 96.5%-99.6%)
Total consistent: 98.5% (95%CI: 97.4%~99.6%)

C. Cross-reactivity
Cross-reactivity of the COVID-19 Antigen Rapid Test Kit was evaluated by testing a panel of high prevalence respiratory pathogens that could potentially cross-react with the COVID-19 Antigen Rapid Test Kit. Each organism and virus was tested in triplicate. The final concentration of each organism is documented in the following table.

Cross-Reactivity: COVID-19 Antigen Rapid Test Kit- Wet Testing

Virus/Bacteria/Parasite*	Concentration	Cross-Reactivity (Yes/No)
Human coronavirus 229E	1.0 x 10^5 U/mL	No
Human coronavirus OC43	1.0 x 10^5 $TCID_{50}$/mL	No
Human coronavirus NL63	1.0 x 10^5 $TCID_{50}$/mL	No
Adenovirus	1.0 x 10^5 $TCID_{50}$/mL	No
Human Metapneumovirus	1.0 x 10^5 $TCID_{50}$/mL	No
Parainfluenza virus 1	1.0 x 10^5 $TCID_{50}$/mL	No
Parainfluenza virus 2	1.0 x 10^5 $TCID_{50}$/mL	No
Parainfluenza virus 3	5.1 x 10^5 $TCID_{50}$/mL	No
Parainfluenza virus 4	1.5 x 10^4 $TCID_{50}$/mL	No
Influenza A	2.7 x 10^5 $TCID_{50}$/mL	No
Influenza B	3.0 x 10^5 $TCID_{50}$/mL	No
Enterovirus D68	3.6 x 10^5 $TCID_{50}$/mL	No
Respiratory syncytial virus	4.2 x 10^5 $TCID_{50}$/mL	No
Rhinovirus	1.0 x 10^5 PFU/mL	No
MERS-coronavirus	1.5 x 10^5 $TCID_{50}$/mL	No
Haemophilus influenza	1.5 x 10^6 CFU/mL	No
Streptococcus pneumoniae	1.1 x 10^6 CFU/mL	No
Streptococcus pyogenes	1.5 x 10^6 CFU/mL	No
Candida albicans	2.0 x 10^6 CFU/mL	No
Bordetella pertussis	1.5 x 10^6 CFU/mL	No
Mycoplasma pneumoniae	1.0 x 10^6 CFU/mL	No
Chlamydia pneumoniae	1.0 x 10^6 IFU/mL	No
Legionella pneumophila	1.0 x 10^5 CFU/mL	No
HCoV-HKU1	1.0 x 10^5 $TCID_{50}$/mL	No
Negative Nasal Matrix	N/A	No

D. Interferences

The test result of The COVID-19 Antigen Rapid Test Kit do not be interfered with the substance at the following concentration:

Interfering substance	Concentration
Purified Mucin	5%
Human blood	4%
Nasal spray(0.9% NaCl)	150μL
Afrin (Oxymetazoline)	15%
Tobramycin	3mg/dL
Fluticasone	126ng/dL
Budenoside	630ng/dL
Dexamethasone	1.2mg/dL

E. Precision

Reproducibility studies were performed for the COVID-19 Antigen Rapid Test Kit at three physician office laboratories(POL). One hundred fifty (150) clinical swab specimen including 50 negative, 50 borderline positive and 50 positive, were used in this study.

Each specimen was run in triplicate for three days at each POL. The intra-assay agreements were 100%. The inter-site agreement was 100%.

REFERENCES

[1] Lai et al. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and coronavirus disease-2019 (COVID-19): The epidemic and the challenges. International Journal of Antimicrobial Agents. 55:3; 2020.

[2] Chen Wang, Peter W Horby, Frederick G Hayden, George F Gao. (2020). A novel coronavirus outbreak of global health concern. The Lancet, 395(10223), 470-473.

[3] World Health Organization: Clinical management of severe acute respiratory infection when Novel coronavirus (nCoV) infection is suspected: Interim Guidance. 12 January, 2020

[4] Clinical and Laboratory Standards Institute. Viral Culture; Approved Guidelines. CLSI document M41-A [ISBN 1562386239] Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne

INDEX OF SYMBOL

IVD	For *in vitro* diagnostic use only		Do not reuse
	Expiry date		See instruction for use
	Warning,please refer to the instructions in the annex		Manufacturer
30℃ 4℃	Temperature scope within which the product is reserved	LOT	Batch number
Σ	Tests per kit		Date of manufacturer
EC REP	European union authorized representative	CE	CE mark

Beijing Beier Bioengineering Co., Ltd.
No.99 Chuangxin Road, Lucheng Industrial Development Zone, Huangcun Town, Daxing District, Beijing, P. R. China
Tel: +86 010-61208560
Fax:+86 010-61208569

EC REP MedNet EC-REP GmbH
Borkstrasse 10, 48163 Muenster, Germany

Swab

Jiangsu Changfeng Medical Industry Co., Ltd.
Touqiao Town, Guangling District, Yangzhou, Jiangsu, P. R. China

EC REP Llins Service & Consulting GmbH
Obere Seegasse 34/2, 69124 Heidelberg, Germany

Revision：October 2020

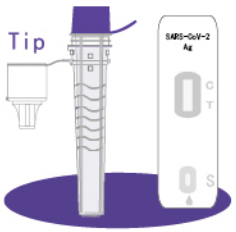
COVID-19 Antigen Rapid Test Kit

The COVID-19 Antigen Rapid Test Kit is an immunochromatographic intended for the direct and qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasopharyngeal swab and oropharyngeal swab from individuals who are suspected of COVID-19 by their healthcare provider. The test is to be used as an aid in the diagnosis of coronavirus infection disease (COVID-19), which is caused by SARS-CoV-2.

• Test Procedure

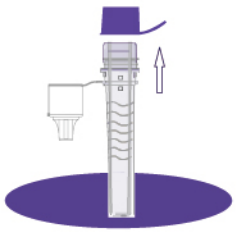
1

Take an extraction tube from the kit and remove a test cassette from the foil pouch by tearing at the notch.



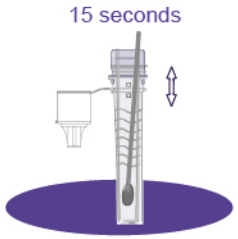
2

Add 10 drops (or 450-550uL) of sample lysis solution into the extraction tube.



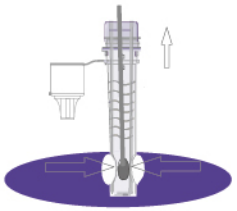
3

Place and soak the patient swab in the sample lysis solution for 15 seconds.



4

While squeezing the tube, specimen Pull the swab out.



5

Firmly attach dropper lid to the top of the extraction tube. Gently invert the tube 5 times.

6

Transfer 2-3 drops (80uL) To the sample well of the test strip. Read the results in 15-20 mins.

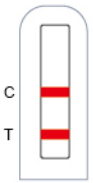
COVID-19 Antigen Rapid Test Kit

• Components

- 20 x Sterile Swabs
- 20 x Extraction tube
- 2 x Sample Lysis Solution
- 20 x Test Cassette

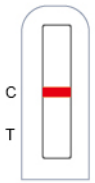
• Result Interpretation

Positive



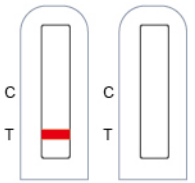
Colored bands appear at both test line (T) and control line (C). not It indicates a positive result for the SARS-CoV-2 antigens in the specimen.

Negative



Colored band appear at control line (C) only. It indicates that the concentration of the SARS-CoV-2 antigens does not exist or below the detection limit of the test.

Invalid



No visible colored band appear at control line. The directions may have been followed correctly or test may have deteriorated.

		Clinical diagnosis		
		Positive	Negative	Total
Beier COVID-19 Antigen Rapid Test	Positive	165	1	166
	Negative	6	302	308
	Total	171	303	474

- Sensitivity=96.5%(95% CI: 93.7%~99.3%)
- Specificity=99.7%(95% CI: 99.0% -100%)
- Positive predictive values= 99.4%(95% CI: 98.2% -100%)
- Negative predictive values= 98.0%(95% CI: 96.5%-99.6%)
- Total consistent: 98.5% (95%CI: 97.4%~99.6%)

EC Declaration of Conformity

We,
Manufacturer Name: BEIJING BEIER BIOENGINEERING CO., LTD
Address: NO.99, ChuangXin road LuCheng Industrial development zone, HuangCun Town, Daxing district, Beijing, China

as the Manufacturer of
Product Name: COVID-19 Antigen Rapid Test Kit

Model: 20/40 tests per kit
Analyte: SARS-CoV or SARS-CoV-2 Antigen
Classification: Other
Conformity assessment: IVDD 98/79/EEC Annex III

herewith declare under our sole responsibility that the mentioned products meet the provisions of the Council Directive 98/79/EC concerning In-Vitro Diagnostic Medical Devices and the following standards which apply to them.

The following standards were used to prove conformity:

-EN ISO 9001:2015
-EN ISO 13485:2016
-EN 13612-2002
-EN ISO 15223-1-2016
-EN ISO 18113-1-2001
-EN ISO 18113-2-2001
-EN ISO 23640-2015
-EN ISO 14971-2012
-EN ISO 13641:2002
-EN ISO 17511-2003

The authorized representative within the EU who has been empowered to enter into commitments on our behalf:

MedNet EC-REP GmbH
Borkstrasse 10, 48163 Muenster, Germany

北京贝尔生物工程股份有限公司 1101150288381

Name, Position

September 30, 2020, Beijing, China

CERTIFICATE OF REGISTRATION

MedNet EC-REP GmbH
Borkstraße 10
48163 Münster
Germany

in its function of the European Authorized Representative, in accordance with the In Vitro Diagnostic Directive 98/79/EC, hereby confirms the registration of the following in vitro diagnostic medical device(s) into the German DIMDI data base

COVID-19 Antigen Rapid Test Kit, Other device
DIMDI Registration Number DE/CA22/1311-419.1-IVD

on behalf of

Beijing Beier Bioengineering Co., Ltd
NO.99, ChuangXin road LuCheng Industrial development zone, HuangCun Town,
Daxing district, Beijing,
China

according to the directive 98/79/EC of the European Parliament and of the Council of the European Union relating to *in vitro* diagnostic medical devices.

Münster, 09.10.2020

on behalf of MedNet EC-REP GmbH

MedNet EC-REP GmbH
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SDS Report

No.: CANEC2017791501 Date: 21 Oct 2020 Page 1 of 1

BEIJING BEIER BIOENGINEERING CO.,LTD
NO.99 CHUANGXIN ROAD, LUCHENG INDUSTRIAL ZONE, DAXING DISTRICT, BEIJING, CHINA

SGS Job No.	:	21253680-CQ
Sample Name	:	COVID-19 Antigen Rapid Test Kit
Manufacturer	:	BEIJING BEIER BIOENGINEERING CO.,LTD
Country of Origin	:	CHINA
End Uses	:	COVID-19 Antigen detection
Composition/Ingredient of sample (as per client submission)	:	See *section 3 Composition/information on ingredients* on the SDS report
Job Receiving Date	:	14 Oct 2020
SDS Preparation Period	:	14 Oct 2020-21 Oct 2020
Service Requested	:	Safety Data Sheet (SDS) for the sample with submitted composition.
Summary	:	As per request, the contents and formats of the SDS are prepared in accordance with European Commission Regulation (EC) No 1907/2006, Regulation (EC) No 1272/2008 and Regulation (EU) No 2015/830, and is provided per attached.

Remark:
The SDS is prepared based on the information provided by client.

* This sample is likely to be classified as medical device and is out of scope of a SDS as set out in Regulation (EC) No 1907/2006. This SDS is generated for client's reference only.

Signed for and on behalf of
SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch

Zm guan
Approved Signatory

SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch Testing Center Chemical Laboratory.

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Safety data sheet
Regulation (EC) No. 1907/2006 and 1272/2008

Printing date 20.10.2020 Version number 1 Revision: 20.10.2020

SECTION 1: Identification of the substance/mixture and of the company/undertaking

· **1.1 Product identifier**

· **Trade name: COVID-19 Antigen Rapid Test Kit**

· **1.2 Relevant identified uses of the substance or mixture and uses advised against**
· **Application of the substance / the mixture:** COVID-19 Antigen detection

· **1.3 Details of the supplier of the safety data sheet**
· **Manufacturer / Supplier:** BEIJING BEIER BIOENGINEERING CO.,LTD
· **Full address:**
NO.99 CHUANGXIN ROAD, LUCHENG INDUSTRIAL ZONE, DAXING DISTRICT, BEIJING, CHINA
· **Phone number:** 010-61208560
· **Email:** beier1995@beierbio.com

· **Only Representative / other EU contact point:** Not available

· **Further information obtainable from:** BEIJING BEIER BIOENGINEERING CO.,LTD

· **1.4 Emergency telephone number:**
GERMANY
Poison Center Berlin - Institute of Toxicology
Tel: +49 030 192 40

18811051979 LI TAO

· **1.5 Reference Number:** CANEC2017791501,21253680 - CQ

· **1.6 Remark:**
* This sample is likely to be classified as medical device and is out of scope of a SDS as set out in Regulation (EC) No 1907/2006. This SDS is generated for client's reference only.

SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008**

GHS07

Skin Sens. 1 H317 May cause an allergic skin reaction.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

· **Information concerning particular hazards for human and environment:**
The product has to be labelled due to the calculation procedure of Regulation (EC) No.1272/2008.

· **Classification system:**
The classification is according to the latest edition of EU Regulation (EC) No. 1272/2008, and extended by company and literature data.

· **2.2 Label elements**
· **Labelling according to Regulation (EC) No. 1272/2008**
The product is classified and labelled according to the CLP regulation.
· **Hazard pictograms**

GHS07

· **Signal word** Warning

· **Hazard-determining components of labelling:**
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)

(Contd. on page 2)

Safety data sheet
Regulation (EC) No. 1907/2006 and 1272/2008

Printing date 20.10.2020 *Version number 1* *Revision: 20.10.2020*

Trade name: COVID-19 Antigen Rapid Test Kit

(Contd. of page 1)

· ***Hazard statements***
H317 May cause an allergic skin reaction.
H412 Harmful to aquatic life with long lasting effects.
· ***Precautionary statements***
P101 If medical advice is needed, have product container or label at hand.
P102 Keep out of reach of children.
P103 Read label before use.
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P273 Avoid release to the environment.
P280 Wear protective gloves.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P321 Specific treatment (see on this label).
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· ***2.3 Other hazards:***
· ***Results of PBT and vPvB assessment***
· ***PBT:*** *Not applicable.*
· ***vPvB:*** *Not applicable.*

SECTION 3: Composition/information on ingredients

· ***3.2 Mixtures***
· ***Description:***
Mixture of the substances listed below with nonhazardous additions.
For the wording of the listed hazard statements refer to section 16.

· ***Composition:***

CAS: 7732-18-5 *EINECS: 231-791-2*	*Water*	*93.55%*
CAS: 9002-86-2	*Polyvinyl chloride* *substance with a Community workplace exposure limit*	*2.83%*
CAS: 57-50-1 *EINECS: 200-334-9*	*Sucrose* *substance with a Community workplace exposure limit*	*1.5%*
CAS: 65997-17-3 *EINECS: 266-046-0*	*glass, oxide, chemicals*	*0.5%*
CAS: 9004-70-0	*Cellulose nitrate* *Expl. 1.1, H201*	*0.5%*
CAS: 9004-34-6 *EINECS: 232-674-9*	*Cellulose* *substance with a Community workplace exposure limit*	*0.5%*
CAS: 7647-14-5 *EINECS: 231-598-3*	*Sodium chloride*	*0.456%*
CAS: 10039-32-4 *EINECS: 231-448-7*	*Disodium hydrogen phosphate dodecahydrate*	*0.14%*
CAS: 13472-35-0	*Phosphoric acid, sodium salt, hydrate (1:1:2)*	*0.02%*
CAS: 55965-84-9 *Index number: 613-167-00-5*	*reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)* *Acute Tox. 3, H301; Acute Tox. 2, H310; Acute Tox. 2, H330; Skin Corr. 1C, H314; Eye Dam. 1, H318; Aquatic Acute 1, H400; Aquatic Chronic 1, H410; Skin Sens. 1A, H317*	*0.004%*

EU

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Safety data sheet
Regulation (EC) No. 1907/2006 and 1272/2008

(Contd. of page 2)

SECTION 4: First aid measures

· **4.1 Description of first aid measures**
· **General description:** Immediately remove any clothing soiled by the product.
· **After inhalation:**
Supply fresh air and to be sure call for a doctor.
In case of unconsciousness place patient stably in side position for transportation.
· **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
· **After eye contact:** Rinse opened eye for several minutes under running water.
· **After swallowing:** If symptoms persist consult doctor.

· **4.2 Most important symptoms and effects, both acute and delayed:**
No further relevant information available.

· **4.3 Indication of any immediate medical attention and special treatment needed:**
No further relevant information available.

SECTION 5: Firefighting measures

· **5.1 Extinguishing media**
· **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.

· **5.2 Special hazards arising from the substance or mixture:** No further relevant information available.

· **5.3 Advice for firefighters**
· **Protective equipment:** No special measures required.

SECTION 6: Accidental release measures

· **6.1 Personal precautions, protective equipment and emergency procedures:** Not required.

· **6.2 Environmental precautions:**
Do not allow product to reach sewage system or any water sourse.
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to enter sewers/ surface or ground water.

· **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Dispose contaminated material as waste according to section 13.
Ensure adequate ventilation.

· **6.4 Reference to other sections:**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

· **7.1 Precautions for safe handling:**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
For the general occupational hygienic measures refer to Section 8.
· **Information about fire - and explosion protection:** No special measures required.

· **7.2 Conditions for safe storage, including any incompatibilities**
· **Requirements to be met by storerooms and receptacles:** No special requirements.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:** None.

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Regulation (EC) No. 1907/2006 and 1272/2008

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· **7.3 Specific end use(s):** No further relevant information available.

SECTION 8: Exposure controls/personal protection

· **8.1 Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**	
9002-86-2 Polyvinyl chloride (2.83%)	
WEL (Great Britain)	Long-term value: 10* 4** mg/m³ *inhalable dust **respirable dust
AGW (Germany)	Long-term value: 1.25* 10** mg/m³ 2(II);*alveolengängig**einatembar; AGS, DFG
57-50-1 Sucrose (1.5%)	
WEL (Great Britain)	Short-term value: 20 mg/m³ Long-term value: 10 mg/m³
VME (France)	Long-term value: 10 mg/m³
9004-34-6 Cellulose (0.5%)	
WEL (Great Britain)	Short-term value: 20* mg/m³ Long-term value: 10* 4** mg/m³ *inhalable dust **respirable
VME (France)	Long-term value: 10 mg/m³
55965-84-9 reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1) (0.004%)	
MAK (Germany)	Long-term value: 0.2E mg/m³ vgl.Abschn.Xc

· **Regulatory information**
WEL (Great Britain): EH40/2018
AGW (Germany): TRGS 900
VME (France): ED 984, 10.2016
MAK (Germany): MAK- und BAT-Liste
· **DNELs:** Not available
· **PNECs:** Not available

· **Additional information:** The lists valid during the making were used as basis.

· **8.2 Exposure controls**
Based on the composition shown in Section 3, the following measures are suggested for occupational safety measure.
· **Appropriate engineering controls:**
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
See Section 7 for information about design of technical facilities.

· **Personal protective equipment**
· **Respiratory protection:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
· **Protection of hands:**

Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

(Contd. on page 5)

Safety data sheet
Regulation (EC) No. 1907/2006 and 1272/2008

(Contd. of page 4)

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

· **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **Penetration time of glove material:**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:** *Goggles recommended during refilling*

· **Environmental exposure controls:**
Control measures must be made in accordance with Community environmental protection legislation.

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**	
· **Appearance**	
Form:	*Liquid*
Colour:	*White*
· **Odour:**	*Odourless*
· **Odour threshold:**	*Not available*
· **pH-value:**	*Not available*
· **Change in condition**	
Melting point/Freezing point:	*Not available*
Initial boiling point and boiling range:	*Not available*
· **Flash point:**	*Not available*
· **Flammability (solid, gas):**	*Not available*
· **Auto-ignition temperature:**	*Not available*
· **Decomposition temperature:**	*Not available*
· **Self-igniting:**	*Product is not selfigniting.*
· **Explosive properties:**	*Product does not present an explosion hazard.*
· **Explosion limits**	
Lower:	*Not available*
Upper:	*Not available*
· **Oxidising properties:**	*Not available*
· **Vapour pressure:**	*Not available*
· **Density:**	*Not available*
· **Relative density:**	*Not available*
· **Vapour density:**	*Not available*
· **Evaporation rate:**	*Not available*
· **Solubility in / Miscibility with**	
water:	*Not available*
· **Partition coefficient: n-octanol/water:**	*Not available*
· **Viscosity**	
Dynamic:	*Not available*

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Safety data sheet
Regulation (EC) No. 1907/2006 and 1272/2008

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Kinematic:	Not available
· **9.2 Other information**	No further relevant information available.

SECTION 10: Stability and reactivity

· **10.1 Reactivity:** Data not available

· **10.2 Chemical stability:** Data not available

· **10.3 Possibility of hazardous reactions:** No dangerous reactions known.

· **10.4 Conditions to avoid:** No further relevant information available.

· **10.5 Incompatible materials:** No further relevant information available.

· **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

SECTION 11: Toxicological information

· **11.1 Information on toxicological effects**
· **Acute toxicity** Based on available data, the classification criteria are not met.

· **LD/LC50 values relevant for classification:**		
57-50-1 Sucrose		
Oral	LD50	29,700 mg/kg (rat)
9004-70-0 Cellulose nitrate		
Oral	LD50	>5,000 mg/kg (rat)
9004-34-6 Cellulose		
Oral	LD50	>5,000 mg/kg (rat)
55965-84-9 reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)		
Oral	LD50	60 mg/kg (mouse) 53 mg/kg (rat)

· **Skin corrosion/irritation:** Based on available data, the classification criteria are not met.
· **Serious eye damage/irritation:** Based on available data, the classification criteria are not met.
· **Respiratory or skin sensitization:**
May cause an allergic skin reaction.
· **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
· **Carcinogenicity** Based on available data, the classification criteria are not met.
· **Reproductive toxicity** Based on available data, the classification criteria are not met.
· **STOT-single exposure** Based on available data, the classification criteria are not met.
· **STOT-repeated exposure** Based on available data, the classification criteria are not met.
· **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

· **12.1 Toxicity**
· **Aquatic toxicity:** No further relevant information available.

· **12.2 Persistence and degradability:** No further relevant information available.

· **12.3 Bioaccumulative potential:** No further relevant information available.

· **12.4 Mobility in soil:** No further relevant information available.

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Regulation (EC) No. 1907/2006 and 1272/2008

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· **12.5 Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

· **12.6 Other adverse effects** No further relevant information available.

· **12.7 Additional ecological information:**
· **General notes:**
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.
Harmful to aquatic organisms

SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**
· **Recommendation:**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· **Uncleaned packaging**
· **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

· **14.1 UN-Number**	
· **ADR/RID/ADN, IMDG, IATA**	Not applicable
· **14.2 UN proper shipping name**	
· **ADR/RID/ADN, IMDG, IATA**	Not applicable
· **14.3 Transport hazard class(es)**	
· **ADR/RID/ADN, IMDG, IATA**	
· **Class**	Not applicable
· **Label**	-
· **14.4 Packing group**	
· **ADR/RID/ADN, IMDG, IATA**	Not applicable
· **14.5 Environmental hazards**	
· **Marine pollutant:**	No
· **14.6 Special precautions for user:**	Not applicable
· **Danger code (Kemler):**	-
· **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**	Not applicable
· **UN "Model Regulation":**	Void

SECTION 15: Regulatory information

· **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **MAK(German Maximum Workplace Concentration)**
None of the ingredients is listed.

· **Directive 2012/18/EU**
· **Named dangerous substances - ANNEX I** None of the ingredients is listed.
· **Seveso category** Not applicable

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Safety data sheet
Regulation (EC) No. 1907/2006 and 1272/2008

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· ***Qualifying quantity (tonnes) for the application of lower-tier requirements*** Not applicable
· ***Qualifying quantity (tonnes) for the application of upper-tier requirements*** Not applicable
· ***National regulations:***

· ***Waterhazard class:*** Water hazard class 2 (Self-assessment): hazardous for water.

· ***Other regulations, limitations and prohibitive regulations***

· ***SVHC Candidate List of REACH Regulation Annex XIV Authorisation (25/6/2020)***
None of the ingredients is listed

· ***REACH Regulation Annex XVII Restriction (20/06/2019)***   ***See Section 16 for information about restriction of use.***
None of the ingredients is listed

· ***REACH Regulation Annex XIV Authorisation List (06/2/2020)***
None of the ingredients is listed

· ***15.2 Chemical safety assessment:*** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

· ***Relevant hazard statements***
H201 Explosive; mass explosion hazard.
H301 Toxic if swallowed.
H310 Fatal in contact with skin.
H314 Causes severe skin burns and eye damage.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H330 Fatal if inhaled.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

· ***Classification according to Regulation (EC) No. 1272/2008***	
Skin sensitisation Hazardous to the aquatic environment - long-term (chronic) aquatic hazard	The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No. 1272/2008.

· **********
The contents and format of this SDS are in accordance with Regulation (EC) No 1907/2006, 1272/2008 and Regulation (EU) No 2015/830.

DISCLAIMER OF LIABILITY
The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. The conditions or methods of handling, storage, use or disposal of the product are beyond our control and may be beyond our knowledge. For this and other reason, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product. This SDS was prepared and is to be used only for this product. If the product is used as a component in another product, this SDS information may not be applicable.

Remark:
* This sample is likely to be classified as medical device and is out of scope of a SDS as set out in Regulation (EC) No 1907/2006. This SDS is generated for client's reference only.

· ***Abbreviations and acronyms:***
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances

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Safety data sheet
Regulation (EC) No. 1907/2006 and 1272/2008

Printing date 20.10.2020 *Version number 1* *Revision: 20.10.2020*

Trade name: COVID-19 Antigen Rapid Test Kit

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CAS: Chemical Abstracts Service (division of the American Chemical Society)
DNEL: Derived No-Effect Level (REACH)
PNEC: Predicted No-Effect Concentration (REACH)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Expl. 1.1: Explosives – Division 1.1
Acute Tox. 3: Acute toxicity – Category 3
Acute Tox. 2: Acute toxicity – Category 2
Skin Corr. 1C: Skin corrosion/irritation – Category 1C
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Skin Sens. 1: Skin sensitisation – Category 1
Skin Sens. 1A: Skin sensitisation – Category 1A
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

****

End of document

Clinical sensitivity and specificity of three rapid SARS-CoV-2 antigen Tests on a hospitalized patient cohort: Company A, Company B and Beier

September 10, 2020

1. Background

Antigen detection of COVID-19 is key to see whether infection has already taken place however whether this also correlate with protection we still do not know. In addition to antigen testing there is big urgency to have validated rapid diagnostic test (RDT) ready to be rolled out if found to be suitably sensitive and specific to test large populations quickly.It should be noted that there are limited data on whether antigen content will be the same in all patients independent of severity of illness. There are countless RDTs developed/in development and offered to diagnostic laboratories. We have used the following criteria to consider inclusion of a RDT in our validation as the capacity of testing and clinical samples are limited:

1. A wide range of diagnostic tests are commercially available for SARS-CoV-2, some of which have received authorizations for use by various national regulatory agencies like CE marking or FDA(EUA)、NMPA approval. Checking r the company qualification can ensure high QC in place.
2. Due to the pandemic situation high and continuous quantities should to be available within a short period eg a week.
3. Manufacturer should provide all paperwork for their validation studies.
4. Manufacturer should provide relevant details about the test details eg antibody or sanple used for a antigen assay.
5. Specificity and sensitivity should be within an acceptable range; and it is important to check on which population the validation was done eg hospitalized patients, ambulant patients. Relevant controls should have been included eg healthy population and other infections with potential differential diagnosis and cross-reactive nature.
6. Right to share and publish data from validation/comparisons should be clarified.

We have selected Savant, OrientGene and Beier tests as they fulfilled most criteria, and were available in big quantities enough to perform validation on a bigger sample set. The products of these three companies are detection reagents for nucleocapsid antigen.

2. Purpose

This study was conducted at Savibio R&D Center between August 3, 2020 to analyze the clinical sensitivity and specificity of the following rapid tests:

1) COVID-19 Antigen Rapid Test Cassette of Company A
2) Novel Coronavirus(2019-nCov) Rapid Test Cassette of Company B
3) COVID-19 Antigen Rapid Test Kit of Beijing Beier Bioengineering Co., Ltd

3. Sample and reagent

□70 Swab samples from PCR confirmed COVID-19 patients and 100 samples with similar symptoms were used in this test at various time point post symptom onset.

1) COVID-19 Antigen Rapid Test Cassette of Company A. of lot 20200815. Expiry date: 20220214

2) Coronavirus Ag Rapid Test Cassette Rapid(Swab) of Company B lot 20200917. Expiry date: 20220316

3) COVID-19 Antigen Rapid Test Kit of Beijing Beier Bioengineering Co., Ltd. lot 20200902; Expiry date: 2022-03-22

Table 1. Sample panel used to validate the sensitivity and specificity of the antibody RDT for COVID-19

Sensitivity				
Country	Sample source	Infection	No. samples	Post symptom onset range
China	RT-PCR confirmed COVID-19	Moderate/Seriously	70	Within 7 days
China	Healthy donors	NA	20	Within 7 days
China	Non-CoV respiratory infections	Adenovirus	5	Within 7 days
		Human Metapneumovirus	5	Within 7 days
		Parainfluenza virus	5	Within 7 days
		Influenza A	10	Within 7 days
		Influenza B	10	Within 7 days
		Enterovirus	5	Within 7 days
		RSV	5	Within 7 days
		Rhinovirus	5	Within 7 days
		Chlamydia pneumoniae	5	Within 7 days
		Mycoplasma pneumoniae	5	Within 7 days
China	Virus culture	hCoV-229E	5	NA
		hCoV-OC43	5	NA
		hCoV-NL63	5	NA
		hCoV-HKU1	5	NA

Equipment:

Disposables including tips for the pipette

Manual pipette

Timer

Personal protective equipment

4. Test principle

The tests were operated according to the test inserts. Samples were collected from COVID-19 suspected patients at Savibio R&D Center for diagnostic purpose and following PCR confirmation.Then collect throat swabs (three throat swabs were taken from each patient) within 7 days for this evaluation. Patients were mostly moderate/seriously ill.Each sample was tested by one test and interpreted by two operators in parallel from hospital.

5. Test results and data analysis

5.1 Various samples showed (false)negative results with the tests compared to RT-PCR results (Table 3, 4, 5)

Possible reasons for the (false)negative results could be:

□The patients were at the very early infection stage, antigen concentration is below the limit of detection of the test.

□Unknown drugs or other interfering substances.

Table 3 Clinical sensitivity/specificity of the Company A test on SARS-CoV-2/other samples collected within 7 days from the symptom onset

Reagents		PCR		Total
		Positive	Negative	
Company A;s Reagents	Positive	61	5	66
	Negative	9	95	104
Total		70	100	170

The sensitivity on samples collected within 7 days from the symptom onset is 87.14% (95%CI: 79.10% to 95.18%) and the specificity is 95.00% (90.65% to 99.35%).

Table 4 Clinical sensitivity/specificity of the Company B test on SARS-CoV-2/other samples collected within 7 days from the symptom onset

Reagents		PCR		Total
		Positive	Negative	
Company B's Reagents	Positive	59	8	67
	Negative	11	92	103
Total		70	100	170

The sensitivity on samples collected within 7 days from the symptom onset is 84.29% (95%CI: 75.55% to 93.03%) and the specificity is 92.00% (86.59% to 97.14%).

Table 5 Clinical sensitivity/specificity of the Beier's test on SARS-CoV-2/other samples collected within 7 days from the symptom onset

Reagents		PCR		Total
		Positive	Negative	
Beier's Reagents	Positive	68	1	69
	Negative	2	99	101
Total		70	100	170

The sensitivity on samples collected within 7 days from the symptom onset is 97.14% (95%CI: 93.14% to 100%) and the specificity is 99.00% (97.02% to 100.00%).

5.2 Positive results broken down by days since symptom onset

Table 6. Results of cumulative positive rate of Company A' Kit

Days Since Symptom Onset	Cumulative RT-PCR Positive (+)	Cumulative Company A'Kit Positive (+)	PPA
1	3	3	100.00%
2	12	12	100.00%
3	21	21	100.00%
4	36	35	97.22%
5	49	46	93.88%
6	59	54	91.53%
7	70	61	87.14%

Table 7. Results of cumulative positive rate of Company B' Kit

Days Since Symptom Onset	Cumulative RT-PCR Positive (+)	Cumulative Company A'Kit Positive (+)	PPA
1	3	3	100.00%
2	12	12	100.00%
3	21	21	100.00%
4	36	35	97.22%
5	49	46	93.88%
6	59	53	89.83%
7	70	59	84.29%

Table 8. Results of cumulative positive rate of Beier' Kit

Days Since Symptom Onset	Cumulative RT-PCR Positive (+)	Cumulative Company A'Kit Positive (+)	PPA
1	3	3	100.00%
2	12	12	100.00%
3	21	21	100.00%
4	36	36	100.00%
5	49	49	100.00%
6	59	59	100.00%
7	70	68	97.14%

6. Conclusion

According to the test results of the 70 Swab samples from PCR confirmed COVID-19 patients and 100 samples with similar symptoms were used in this test at various time point post symptom onset, the sensitivity/specificity of the tests are:

1) COVID-19 Antigen Rapid Test Cassette of Company A.

The sensitivity on samples collected within 7 days from the symptom onset is 87.14% (95%CI: 79.10% to 95.18%) and the specificity is 95.00% (90.65% to 99.35%). False positive began to appear at 4th day Since Symptom Onset.

2) Coronavirus Ag Rapid Test Cassette Rapid(Swab) of Company B

The sensitivity on samples collected within 7 days from the symptom onset is 84.29% (95%CI: 75.55% to 93.03%) and the specificity is 92.00% (86.59% to 97.14%). False positive began to appear at 4th day Since Symptom Onset.

3) COVID-19 Antigen Rapid Test Kit of Beijing Beier Bioengineering Co., Ltd. lot 20200902; Expiry date: 2022-03-22

The sensitivity on samples collected within 7 days from the symptom onset is 97.14% (95%CI: 93.14% to 100%) and the specificity is 99.00% (97.02% to 100.00%). False positive only appear at 7th day Since Symptom Onset.

Compared to RT-PCR, Beier's kit product showed the highest overall sensitivity followed by Company A and Company B. Samples ＜7 days post symptom onset were detected more often.

Caveat of the specificity owing to limited availability of test kits, the validation was limited on this point. The sensitivity of this reagent is ＞90% and the specificity is ＞95%, which meets our requirements.

Performance evaluation report for COVID-19 Antigen Rapid Test Kit

Beijing Beier Bioengineering Co., Ltd.

October 24, 2020

1. Limit of detection study

1.1 SARS-CoV-2 inactivated virus test result

The SARS-CoV-2 inactivated virus was diluted by 1:1000 (1k) with sample lysis solution, and then gradient diluted (1:2k, 1:4k, 1:8k, 1:16k, 1:32k, 1:64k, 1:128k, 1:256k, 1:512k). The corresponding concentrations were detected and detected by colloidal gold detector (the pictures showed the detection results at 15mins, 20mins and 30mins).

Picture 1. ARS-CoV-2 inactivated virus (vaccines) test results

Conclusion: The original concentration of inactivated virus was 36μg/mL. When diluted 1:128000k, the color of T-line could be seen. The LoD of the kit is ≤0.28ng/ml.

1.2 SARS-CoV-2 recombinant N protein test result

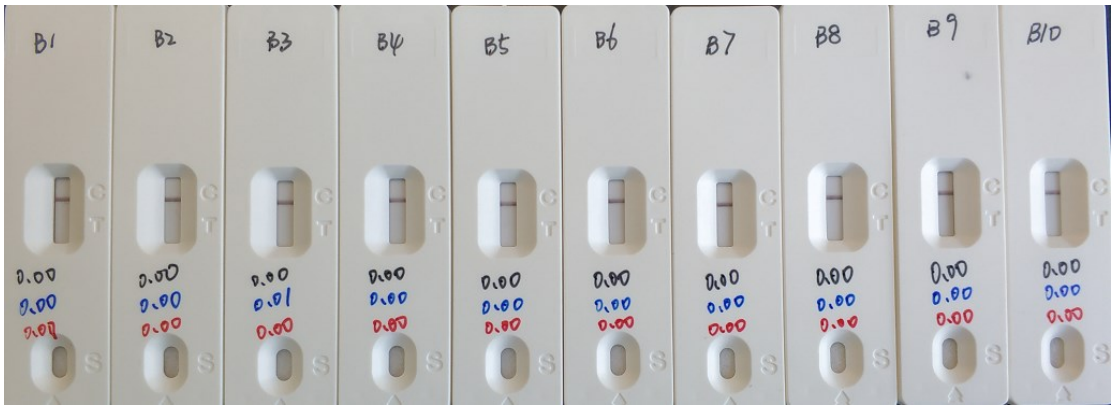
The original concentration of antigen was 1mg / ml, diluted into 100ng/mL, 50ng/mL, 10ng/ml, 5ng/ml, 2.5ng/ml, 1.25ng/ml, 0.63ng/ml, 0.31ng/ml, 0.15ng/ml, 0.08ng/ml, and then tested.

Picture 2. SARS-CoV-2 recombinant N protein test result

Conclusion: The color of T-line could be observed in 0.08ng/ml. The detection limit of the kit is≤ 0.08ng/ml.

1.3 Background value of negative samples

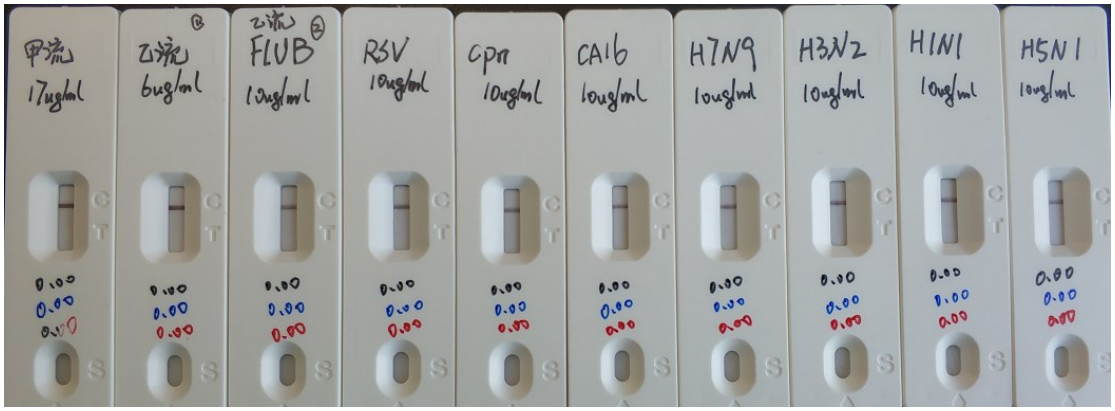
The background value of 10 swabs were 0.00~0.01.



Picture 3. Result of negative samples

2. Specificity study(cross-reactivity)

The following inactivated viruses were treated with the sample lysis solution, including 5 Influenza A viruses (H1N1, H7N9, H5N1, H3N2), 2 Influenza B viruses, Respiratory syncytial virus, CA16 virus, Chlamydia pneumoniae, and the detection concentrations were as follows:



Picture 1. Detection results of inactivated virus

Result: All the results were negative.

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