25 Tests/kit

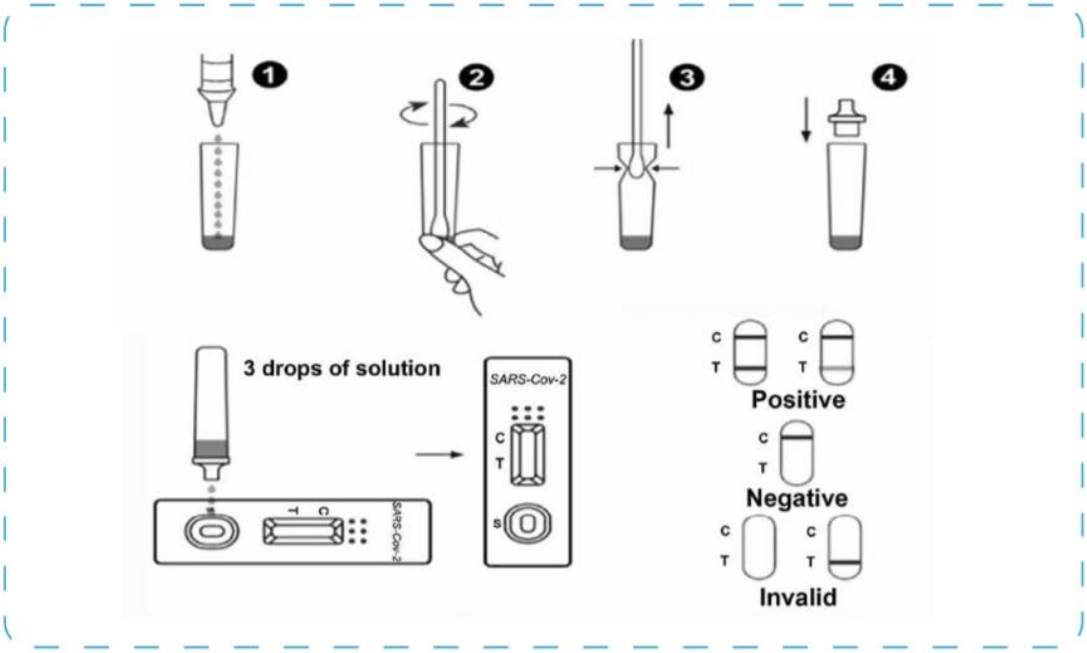
Features:

- Specimen types: Nasal Aspirate Fluid/ Nasal Swab
- Testing time: 10 minutes
- Sensitivity: 84.4%
- Specificity:>99%

Product name	Ref.	Size	Storage Temp
Novel Coronavirus (SARS-COV-2) Antigen Rapid Test Cassette (Swab)	K511416D	25 Test/kit	2-30℃
Novel Coronavirus (SARS-COV-2) Antigen Rapid Test Cassette (Swab)	K511416D	5 Test/kit	2-30℃

(Swab) is a rapid chromatographic immunoassay for the qualitative detection of specific antigens to SARS-CoV-2 present in human nasopharynx.

DIRECTIONS FOR USE:



EC Declaration of Conformity

in accordance with Directive 98/79/EC

Product/s	*Catalogue number*
Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	K511416D

Category: Other Devices (All devices except Annex II and self-testing devices)

Conformity assessment route: Annex III,except Point 6,of Directive

Applicable Standards:EN ISO 13485:2016;EN ISO 15223-1:2016; EN ISO 14971:2012 ;EN ISO 13612:2002;EN ISO 17511:2003; EN ISO 18113-1:2011;EN ISO 18113-2:2011,EN ISO 23640:2015.

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint Luxus Lebenswelt GmbH,located at Kochstr.1,47877, Willich,Germany to act as our European Authorised Representative as defined in the aforementioned Directive.

2020.8.17

(Place and date of issue)

(Signature and position)

Signed for and on behalf of the manufacturer

Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) Package Insert

A RAPID TEST FOR THE QUALITATIVE DETECTION OF NOVEL CORONAVIRUS ANTIGENS IN NASAL SWAB AND NASAL ASPIRATE SPECIMENSS.
For professional In Vitro Diagnostic Use Only.

INTENDED USE

The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) is an *in vitro* diagnostic test for the qualitative detection of novel coronavirus antigens in Nasal Swab and nasal aspirate samples, using the rapid immunochromatographic method. The identification is based on the monoclonal antibodies specific for the novel coronvirus antigen. It will provide information for clinical doctors to prescribe correct medications.

SUMMARY

The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) is used for the in vitro qualitative detection of novel coronavirus in the throat swabs, sputum samples of suspected pneumonia patients infected by novel coronavirus, suspected clustering cases and others needing diagnosis or differential diagnosis for novel coronavirus.
The definitions of "suspected cases" and "patients with suspected aggregated cases" and other groups are implemented with reference to the "Diagnosis and Treatment Plan for Pneumonia Infected in novel coronavirus" and "Monitoring Plan for Pneumonia Infected in novel coronavirus" and other documents (current version) issued by CDC.
The product is only used for auxiliary diagnosis of related cases and emergency reserve for in vitro diagnosis of this epidemic during the pneumonia epidemic infected by novel coronavirus (SRAS-Cov-2) since December 2019 and it cannot be used as routine in vitro diagnostic reagents in clinical practice. The kit shall comply with the relevant requirements of the "Diagnosis and Treatment Plan for Pneumonia Infected in novel coronavirus" and "Prevention and Control Plan for Pneumonia Infected in novel coronavirus" and other documents in use.
The detection results of this kit are for clinical reference only and should not be used as the sole criteria for clinical diagnosis. It is recommended to conduct a comprehensive analysis on the condition in combination with the clinical manifestations and other laboratory tests.

PRINCIPLE

The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to Novel coroinavirus .
The test device is composed of the following three parts, namely sample pad, reagent pad and reaction membrane. The whole strip is fixed inside a plastic device. The reagent membrane contains the colloidal-gold conjugated with the monoclonal antibodies against Novel coroinavirus;the reaction membrane contains the secondary antibodies for Novel coroinavirus, and the polyclonal antibodies against the mouse globulin, which are pre-immobilized on the membrane.
When the sample is added into the sample window,conjugates dried in the reagent pad are dissolved and migrate along with the sample. If Novel coroinavirus is present in the sample, a complex formed between the anti- Novel coroinavirus conjugate and the virus will be caught by the specific anti- Novel coronavirus monoclonal coated on the T region. Results appear in 10 minutes in the form of a red line that develops on the strip.
Whether the sample contains the virus or not, the solution continues to migrate to encounter another reagent (an anti-mouse IgG antibody) that binds the remaining conjugates, thereby producing a red line on the region C.

REAGENTS

The reagent membrane contains the colloidal-gold conjugated with the monoclonal antibodies against Novel coroinavirus; the reaction membrane contains the secondary antibodies for Novel coroinavirus,and the polyclonal antibodies against the mouse globulin, which are pre-immobilized on the membrane.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not use after the expiration date.
- Ensure foil pouch containing test device is not damaged before opening for use.
- Perform test at room temperature 15 to 30°C.
- Wear gloves when hanging the samples, avoid touching the reagent membrane and sample window.
- All samples and used accessories should be treated as infectious and discarded according to local regulations.
- Avoid using bloody samples.

STORAGE AND STABILITY

Store the Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) at room temperature or refrigerated (2-30°C). Do not freeze. All reagents are stable until the expiration dates marked on their outer packaging and buffer vial.

SPECIMEN COLLECTION AND PREPARATION

1. Specimen collection:
It is applicable to the diagnosis of the Novel coroinavirus from the samples of nasal swabs or nasal aspirates.Use freshly collected samples for optimal test performance. Inadequate sample collection or improper sample handling may yield a false-negative result.

1) Nasal Aspiration
Collect nasal aspirate fluids using the specific aspirator as instructed.

2) Nasal Swabbing
Completely insert the sterilized swab supplied in this kit into the nasal basin, and swab several times to collect the epidermal cells of the mucus.**It is recommended to collect sample from nasal basin for more accurate results.**
2. Specimen preparation:
Add **10 drops (about 0.3 ml)** of the sample extraction buffer into the extraction tube supplied in this kit up to the lower memory line, and put it on the tube stand.
1) Nasal Aspirate Fluids
Add **10 drops (about 0.3 ml)** of the nasal aspirate fluids into the extraction tube which contains **0.3 ml** of the extraction buffer up to the upper memory line, and mix well to be used as test sample.
2) Nasal Swabs
Insert the swab into the extraction tube which contains **10 drops (about 0.3 ml)** of the extraction buffer. Rotate the swab inside the tube using a circular motion to roll the side of the extraction tube so that liquid is expressed and reabsorbed from the swab.Remove the swab. The extracted solution will be used as test sample.

MATERIALS

Materials provided

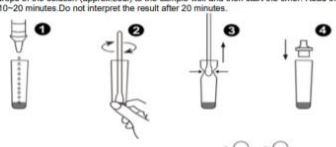
- Test Device
- Sterilized Swab
- Extraction Tube
- Tube Stand
- Nozzle With Filter
- Sample Extraction Buffer
- Package Insert

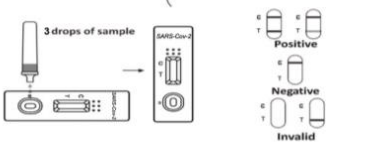
Materials required but not provided

- Timer
- Transfer pipette

DIRECTIONS FOR USE

Allow the test, specimen, extraction buffer to equilibrate to room temperature (15-30°C) prior to testing.
1.Remove the test device from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
2. Unscrew the whole cap of the specimen collection tube,
3. Add **10 drops (about 0.3 ml)** of the sample extraction buffer into the extraction tube.
4.Place the swab specimen in the Covid Ag Buffer. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab.
5.Remove the swab while squeezing the swab head against the inside of Buffer as you remove it to expel as much liquid as possible from the swab. Discard the swab in accordance with your biohazard waste disposal protocol.
6. Screw on and tighten the cap onto the specimen collection tube,then **shake the specimen collection tube vigorously** to mix the specimen and the Buffer. Place the test device on a clean and level surface. See illustration 4.
7.Add 3 drops of the solution (approx.80ul) to the sample well and then start the timer. Read the result at 10~20 minutes.Do not interpret the result after 20 minutes.





INTERPRETATION OF RESULTS

(Please refer to the illustration above)
POSITIVE: Two red lines appear. One red line appears in the control region(C), and one red line in the test region(T). The shade of color may vary，but it should be considered positive whenever there is even a faint line.
NEGATIVE: Only one red line appears in the control region(C), and no line in the test region(T). The negative result indicates that there are no Novel coroinavirus particles in the sample or the number of viral particles is below the detectable range.
INVALID: No red line appears in the control region(C). The test is invalid even if there is a line on test region(T). Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the test procedure and repeat the test using a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

- The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) is an acute-phase screening test for qualitative detection. Sample collected may contain antigen titles below the reagent's sensitivity threshold, so a negative test result does not exclude infection with novel coronavirus
- The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) detects viable and non-viable novel coronavirus antigen. Test performance depends on antigen load in the sample and may not correlate with cell culture performed on the same sample. A positive test does not rule out the possibility that other pathogens may be present.Therefore,the results must be compared with all other available clinical and laboratory information to make an accurate diagnosis.
- A negative test result may occur if the level of extracted antigen in a specimen is below the sensitivity of the test or if a poor quality specimen is obtained
- Performance of the test has not been established for monitoring antiviral treatment of novel coronavirus.
- Positive test results do not rule out co-infections with other pathogens.
- Negative test results are not intended to rule in other coronavirus infection except the SARS-Cov-1
- Children tend to shed virus for longer periods of time than adults, which may result in differences in sensitivity between adults and children List.
- A negative result may occur if the concentration of antigen or antibody in a specimen is below the detection limit of the test or if the specimen was collected or transported improperly, therefore a negative test result does not eliminate the possibility of SARS-Cov-2 infection, and should be confirmed by viral culture or an molecular assay or ELISA

PERFORMANCE CHARACTERISTICS

Clinical Evaluation

Clinical evaluation was performed to compare the results obtained by Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) and PCR. The results were summarized below:

Table: Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) vs. PCR

		SARS-Cov-2 Ag Rapid Test		Total Result
		+	-	
PCR	+	27	5	32
	-	0	200	200
Total Results		27	205	232

Relative sensitivity: 84.4% Relative specificity: >99%
Overall agreement: 97.8%

Cross Reaction

No cross reaction has been confirmed of the Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) with the following pathogens:

①Bacteria
Acinetobacter baumannii, Bordetella pertussis,Branhamella catarrhalis,Candida albicans, Candida glabrata,Cardiobacterium hominis,Eikenella corrodens,Enterococcus faecalis, Enterococcus gallinarum.Escherichia coli,Group C streptococcus,Group G streptococcus, Haemophilus aphrophilus,Haemophilus influenzae, Haemophilus paraphrophilus, Klebsiella pneumoniae,Neisseria gonorrhoeae Peptococcus asaccharolyticus,Peptostreptococcus anaerobius, Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Serratia marcescens, Staphylococcus epidermidis,Streptococcus agalactiae(group B),Streptococcus mutans, Streptococcus pneumoniae, Streptococcus pyogenes(group A), Veillonella parvula

②Virus
Influenza A,Influenza B,Adenovirus Type 1～8,11,19,37,Coxsackie virus Type A16,B1～5, Cytomegalovirus,Echovirus Type 3,6,9,11,14,18,30,Enterovirus Type 71,HSV-1,Mumps virus, Tyep I simple herpes virus Parainfluenza virus Type 1～3, Poliovirus Type 1～3,Respiratory syncytial virus,Rhinovirus Type 1A,13,14, Type I simple herpes virus.

③Mycoplasma etc.
No cross reaction with Chlamydia pneumoniae,Chlamydia psittaci,Chlamydia trachomatis, Mycoplasma pneumoniae.

SYMBOLS

Symbol	Meaning	Symbol	Meaning
IVD	In vitro diagnostic medical device		Storage temperature limit
	Manufacturer	EC REP	Authorized representative in the European Community
	Date of Manufacture		Use by date
	Do not reuse		Consult instruction foe use
LOT	Batch code	CE	Meet the requirements of EC Directive 98/79/EC

Clinical Validation report of Novel Coronavirus(SARS-Cov-2) Antigen Rapid Test Cassette (Swab)

Product name: Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette

Package Specification: 25 tests

Validated by: Shanghai Public Health Clinical Center

Xuzhou infectious disease hospital

File No. MF-GICT-0031
Version: 1.0
Effective date:2020-08-20

I Clinical validation time

This clinical evaluation was conducted from July 2020 to Aug 14th,2020.

II Background information for clinical evaluation

Since December 2019, world has successively discovered multiple cases of patients with new-type coronavirus pneumonia. With the spread of the epidemic, China and abroad have also been found.As an acute respiratory infectious disease,the disease has been included in the Class B infectious diseases stipulated in the Law of the People's Republic of China on the Prevention and Control of Infectious Diseases,and is managed as a Class A infectious disease.Based on the current epidemiological investigation, the incubation period is 1-14 days,mostly 3-7 days.

The main manifestations are fever, dry cough, and fatigue. A few patients have symptoms such as nasal congestion, runny nose, sore throat, myalgia and diarrhea. Severe patients usually have dyspnea and / or hypoxemia one week after the onset of symptoms, and severe patients can quickly progress to acute respiratory distress syndrome, septic shock,difficult to correct metabolic acidosis, coagulation dysfunction and multiple organ Functional failure,etc.It is worth noting that in the course of severe and critically ill patients, there may be moderate to low fever, even without obvious fever.

Mild patients showed only low fever, mild fatigue, and no pneumonia. Judging from the current cases, most patients have a good prognosis, and a few patients are critically ill. The elderly and those with chronic underlying disease have a better prognosis. Symptoms in children are relatively mild.

The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette(Swab) developed by our company can help diagnose whether patients are infected with the Novel Coronavirus. It has further enriched the detection methods of Novel Coronavirus, expanded the supply of detection reagents, and fully served the needs of epidemic prevention and control.

III. Test purposes

The purpose of research of the clinical test is to calculate the consistency percentage of negative/positive and the total consistency percentage and Kappa coefficient by statistically analyzing test results through comparative experimental research.

IV. Test design

1. Test plan selection and reasons

All information subject to final confirmation.
Exporter Ningbo Pylon International Trading Co., Ltd. , A 100% German Owned Company

In vitro diagnostic reagents for testing and reference reagents were used to conduct comparative research tests on clinically suspected Novel Coronavirus Nasopharyngeal swab samples, and it was proved that the in vitro diagnostic reagents used in the test can achieve the expected assistance in infection of the Novel Coronavirus.

2. Sample volume required

The total number of clinical trials of this product is not less than 100 cases. The samples is classified into the positive group and the negative group as per the test results of the reference product. Meanwhile, the samples shall be tested via the qualitative test strip tested and by reference product from the same patient and then the test results of the product tested and the reference product shall be compared, with statistical analysis being made.

3. Sample inclusion/exclusion certification.

The positive group and negative group in this experiment are applicable to the following inclusion/exclusion criteria

Positive group inclusion: Meets 2 of the following 3 criteria, it is inclusion into positive sample group:

Antibody test is positive;

PCR Test is positive;

CT test results and symptoms are clinically positive;

Positive group exclusion:

Samples only Meet 1 of the 3 criteria of inclusion; it is exclusion out of positive sample group.

Negative inclusion: Meets 3 of the following 4 criteria, it is inclusion into negative sample group:

Antibody test is negative;

PCR test is negative;

CT test results and symptoms are clinically negative;

No history of novel coronavirus exposure within 14 day.

Negative exclusion:

Any sample that does not meet the inclusion criteria is excluded out of the negative group.

4. Sample collection, processing and storage

Sample collection: It is applicable to the diagnosis of the Novel coroinavirus from the samples of nasal swabs or nasal aspirates.Use freshly collected samples for optimal test performance. Inadequate sample collection or improper sample handling may yield a false-negative result.

Completely insert the sterilized swab supplied in this kit into the nasal basin, and swab several times to collect the epidermal cells of the mucus.It is recommended to collect sample from nasal basin for more accurate results.

5. In vitro diagnostic reagents and reference products for testing

5.1 Test in vitro diagnostic reagents

Name: The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette(Swab)

Specification:25 tests/kit

LOT: 202007046

All information subject to final confirmation.
Exporter Ningbo Pylon International Trading Co., Ltd. , A 100% German Owned Company

Expiry: June,2022(Tentative)

Storage Conditions: Store in a dry place at 2-30°C, protected from light. After opening the inner package, the test card will become invalid due to moisture absorption. Please use it within 1 hour.

5.2 Reference products

Name: 2019-nCoV nucleic acid test kit（RT-PCR）

Storage Conditions: Store in a dry place at 2-8°C, protected from light.

V. Experiment method

1. Get the Swab specimens from patients in positive and negative groups.
2. Pre-process the swab samples according to the instructions of the The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette(Swab) , and label the samples randomly.

2.1 Add 10 drops (about 0.3 ml) of the sample extraction buffer into the extraction tube.

2.2 Place the swab specimen in the SARS-Cov-2 antigen Buffer. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab.

2.3 Remove the swab while squeezing the swab head against the inside of Buffer as you remove it to expel as much liquid as possible from the swab. Discard the swab in accordance with your biohazard waste disposal protocol.

2.4 Screw on and tighten the cap onto the specimen collection tube,then shake the specimen collection tube vigorously to mix the specimen and the Buffer. Place the test device on a clean and level surface.

3. The operation steps of the in vitro diagnostic reagents for the test are as follows. For details, please refer to the product instruction manual:

3.1 remove the test sample and required reagents from the storage conditions and equilibrate to room temperature (15-30°C).

3.2 When preparing for testing, open the aluminum foil bag from the tear. Remove the test card and lay it flat on a horizontal table.

3.3 Label the sample number on the test card.

3.4 Add 3 drops of the solution (approx.80ul) to the sample well and then start the timer.

3.5 Time counting and interpret the results within 10 minutes.

Note: The detection steps need to be completed under protection against infection.

VI. Statistical methods of statistical analysis of clinical research data

All information subject to final confirmation.
Exporter Ningbo Pylon International Trading Co., Ltd. , A 100% German Owned Company

A Methods evaluating clinical performance

Whether various indexes can reach the standards of clinical evaluation shall be judged by calculating the consistency percentage of negative/positive and the total consistency percentage in the test results of the product tested and the reference product, to validate the accuracy and applicability of the product in clinical applications. The product tested shall be subject to tests through the sample of different types, with statistics on the results. Meanwhile,different types of sample of the subjects shall be subject to determination by the product tested synchronously,and then the determination results of both shall be compared.The test results recorded shall be subject to statistical analysis upon completion of determination of all clinical samples,to calculate the consistency percentage of negative/positive and the total consistency percentage. Afterwards, equivalence of both shall be evaluated as per these statistical indexes

B Statistical method

The products launched on the market shall be subject to comparative study and evaluation.Kappa inspection: each sample shall be tested with the product tested and the reference product respectively, and then the consistency in statistical results of these two inspection methods shall be compared through Kappa inspection.

The data shall be subject to Kappa inspection and analysis and the Kappa coefficient shall be calculated.Favorable consistency can be proven if Kappa is＞0.8. The consistency in test results of the product tested and the reference product is evaluated as per the evaluation standards.

VII Standards of clinical evaluation

The coincidence rate shall be calculated by comparing with the reference product whose marketing is approved. The product performance shall meet the following requirements.

1)Coincidence rate of negative: the sample whose test results are negative for both the product tested and the reference product and the proportion in the sample whose test results are negative for the reference product shall be more than 95%.

2)Coincidence rate of positive: the sample whose test results are positive for both the product tested and the reference product and the proportion in the sample whose test results are positive for the reference product shall be more than 85%.

3)Total coincidence rate: the sample whose test results are the same for the product tested and the reference product and its proportion in the total number of samples shall be more than 90%.

Method	2019-nCoV nucleic acid	Total Results

All information subject to final confirmation.
Exporter Ningbo Pylon International Trading Co., Ltd. , A 100% German Owned Company

		test kit（RT-PCR）		
The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette(Swab)	Result	positive	negative	
	positive	A	B	A+B
	negative	C	D	C+D
Total Results		A+C	B+D	A+B+C+D

Clinical sensitivity =A/(A+C)*100%

Clinical specificity = D/(B+D)*100%

Accuracy: (A+D)/(A+B+C+D)*100%

If the coincidence rate of positive/negative can meet clinical requirements, two methods or Products are considered as equivalent; If the coincidence rate of positive/negative is greatly different, the clinical scheme should be re-designed.

4)Kappa consistency analysis shall be adopted for statistical analysis of reference reagents.

The results of the product tested are statistical materials and can be per the table below:

Method		2019-nCoV nucleic acid test kit（RT-PCR）		Total Results
The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette(Swab)	Result	positive	negative	
	positive	A	B	A+B
	negative	C	D	C+D
Total Results		A+C	B+D	A+B+C+D

P_{0}= (A+D)/(A+B+C+D)*100%

P_e=((A+B)(A+C) +(A+B)(B+D)) /$(A+B+C+D)^2$

Kappa:(P_0 - P_e)/(1-p_e)

If conducting Kappa consistency analysis for the base data above, high consistency can be judged if the Kappa coefficient is >0.8,and both systems are considered as equivalent. Consistency is considered if 0.4<Kappa coefficient <0.8, and the coincidence rate of positive/negative shall be compared, with statistical analysis being made. Two such systems are considered as inconsistent and in-equivalent if the Kappa coefficient is <0.4.

VIII Provisions for amendments to clinical validation

In general, the clinical validation should not be changed. Any modification to the project during the test should be explained, and the time,reason,process of change, and whether there is a record of the change are explained in detail and its impact on the evaluation of the entire research result is explained.

All information subject to final confirmation.
Exporter Ningbo Pylon International Trading Co., Ltd. , A 100% German Owned Company

IX. Results and Analysis of Clinical Tests

In total, 232 test samples are included for the unit and all test samples included are tested. Statistics on test results and those of the product tested are as follows:

Method		2019-nCoV Nucleic Acid Test Kit (RT-PCR)		Total Results
The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette(Swab)	Results	Positive	Negative	
	Positive	**27**	**0**	**27**
	Negative	**5**	**200**	**205**
Total Results		**32**	**200**	**232**

Clinical sensitivity = 27/32=84.38%(67.77% to 93.61%)

Clinical specificity = 200/200=100%(97.73% to 100%)

Accuracy: (27+200)/(27+0+5+200)*100%=97.84%(94.91% to 99.22%)

P_e=(27*32+27*200)/(232*232)=0.17

Kappa:(P_0 - P_e)/(1-p_e) =0.97

According to the above table,200 are proven negative of 200 negative specimens, 27 are proven positive of 32 positive specimens. The sensitivity and accuracy are more than 90%, indicating favorable consistency with the reference product. The Kappa=0.97 > 0.8,indicating favorable and high consistency of two methods and equivalence of two such systems.

X Analysis on Inconsistency in Test Results

NO.	Age	Sex	Novel Coronavirus Antigen Rapid Test Cassette (swab)	2019-nCoV nucleic acid test kit (RT-PCR)	Clinical diagnostic
209	23	F	Negative	Positive (N and E gene)	Infection 37 days
210	14	M	Negative	Positive (RdRP and N gene)	Infection 17 days
216	44	M	Negative	Positive (RdRP gene)	Infection 18 days
218	33	F	Negative	Positive (N gene)	Infection 41 days
229	20	M	Negative	Positive (N gene)	Infection 27 days

XI Discussion and Conclusions

1.discussion

A Results of comparative analysis of the product tested and the reference product:

Test results of Swab specimen tested and the reference result: both the coincidence rate of negative/positive and the total coincidence rate are larger than 85%, indicating favorable consistency with the reference product. In the analysis results of Kappa inspection, Kappa was proven >0.8, indicating favorable and high consistency of both methods. Both systems were proven equivalent.

2.Test conclusions

By analyzing the test results of the product tested and the reference product, the consistency percentage of negative/positive and the total consistency percentage are

All information subject to final confirmation.
Exporter Ningbo Pylon International Trading Co., Ltd. , A 100% German Owned Company

proven high. Moreover, according to the results of statistical analysis, there is no remarkable difference in test results of both, indicating favorable consistency in diagnosis and equivalence of two such systems and can be used for auxiliary diagnosis of those suffering from pneumonia triggered by COVID-19.

X. Quality control methods

On-site quality control

1） During the course of this study, clinical implementors appointed clinical inspectors to conduct regular on-site supervision visits to the research hospital. Through monitoring visits, it was found that all the contents of the research plan were strictly observed, and the correctness of the research data was also guaranteed. Participating researchers have undergone unified training, unified recording methods and judgment standards. The entire clinical trial process is conducted under strict operation, and the test content is complete and authentic. All observations and findings in the clinical trials have been verified and the data are reliable. The conclusions in the clinical trials are derived from the original data.

2） Quality control of clinical experiment process

During the evaluation, quality control was performed daily to ensure that the product was under control. Strict quality control is performed for each trial to ensure the quality of clinical trials.

XI. Prediction of adverse events

Because The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette(Swab) is an in vitro diagnostic reagent product, no direct contact with patients is required in clinical trials, no test report is provided to patients, and the test results are only used for comparative studies. It involves personal privacy, does not serve as a basis for auxiliary diagnosis, does not bring any risk to the subject, and does not cause adverse events.

References:

1.The "Technical Review Points for the Registration of New Coronavirus Antigen / Antibody Detection Reagents in 2019 (Trial)" issued by the State Drug Administration Medical Device Technical Evaluation Center on February 25, 2020;

2. "Pneumonitis Diagnosis and Treatment Program for New Coronavirus Infection (Trial Version 7)" issued by the National Health Committee on February 19, 2020.

All information subject to final confirmation.
Exporter Ningbo Pylon International Trading Co., Ltd. , A 100% German Owned Company

Annex 2: Data of Clinical Tests

NO.	Age	Sex	Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	2019-nCoV nucleic acid test kit (RT-PCR)
1	21	M	Negative	Negative(Ct/Cq) >43
2	24	M	Negative	Negative(Ct/Cq) >43
3	29	F	Negative	Negative(Ct/Cq) >43
4	58	F	Negative	Negative(Ct/Cq) >43
5	14	M	Negative	Negative(Ct/Cq) >43
6	21	M	Negative	Negative(Ct/Cq) >43
7	23	M	Negative	Negative(Ct/Cq) >43
8	15	M	Negative	Negative(Ct/Cq) >43
9	42	F	Negative	Negative(Ct/Cq) >43
10	83	M	Negative	Negative(Ct/Cq) >43
11	54	M	Negative	Negative(Ct/Cq) >43
12	86	F	Negative	Negative(Ct/Cq) >43
13	54	M	Negative	Negative(Ct/Cq) >43
14	30	F	Negative	Negative(Ct/Cq) >43
15	68	M	Negative	Negative(Ct/Cq) >43
16	64	M	Negative	Negative(Ct/Cq) >43
17	67	F	Negative	Negative(Ct/Cq) >43
18	30	M	Negative	Negative(Ct/Cq) >43
19	30	F	Negative	Negative(Ct/Cq) >43
20	23	M	Negative	Negative(Ct/Cq) >43
21	55	M	Negative	Negative(Ct/Cq) >43
22	65	M	Negative	Negative(Ct/Cq) >43
23	75	M	Negative	Negative(Ct/Cq) >43
24	56	F	Negative	Negative(Ct/Cq) >43
25	66	M	Negative	Negative(Ct/Cq) >43
26	22	M	Negative	Negative(Ct/Cq) >43
27	56	F	Negative	Negative(Ct/Cq) >43
28	31	M	Negative	Negative(Ct/Cq) >43
29	30	F	Negative	Negative(Ct/Cq) >43
30	70	M	Negative	Negative(Ct/Cq) >43
31	87	F	Negative	Negative(Ct/Cq) >43
32	35	F	Negative	Negative(Ct/Cq) >43
33	61	M	Negative	Negative(Ct/Cq) >43

All information subject to final confirmation.
Exporter Ningbo Pylon International Trading Co., Ltd. , A 100% German Owned Company

34	31	M	Negative	Negative(Ct/Cq) >43
35	21	M	Negative	Negative(Ct/Cq) >43
36	92	M	Negative	Negative(Ct/Cq) >43
37	29	M	Negative	Negative(Ct/Cq) >43
38	28	F	Negative	Negative(Ct/Cq) >43
39	18	M	Negative	Negative(Ct/Cq) >43
40	29	F	Negative	Negative(Ct/Cq) >43
41	52	F	Negative	Negative(Ct/Cq) >43
42	62	M	Negative	Negative(Ct/Cq) >43
43	57	F	Negative	Negative(Ct/Cq) >43
44	55	F	Negative	Negative(Ct/Cq) >43
45	73	M	Negative	Negative(Ct/Cq) >43
46	62	M	Negative	Negative(Ct/Cq) >43
47	64	M	Negative	Negative(Ct/Cq) >43
48	74	M	Negative	Negative(Ct/Cq) >43
49	26	M	Negative	Negative(Ct/Cq) >43
50	51	F	Negative	Negative(Ct/Cq) >43
51	50	M	Negative	Negative(Ct/Cq) >43
52	16	F	Negative	Negative(Ct/Cq) >43
53	59	M	Negative	Negative(Ct/Cq) >43
54	14	F	Negative	Negative(Ct/Cq) >43
55	29	M	Negative	Negative(Ct/Cq) >43
56	39	M	Negative	Negative(Ct/Cq) >43
57	61	M	Negative	Negative(Ct/Cq) >43
58	62	F	Negative	Negative(Ct/Cq) >43
59	70	M	Negative	Negative(Ct/Cq) >43
60	57	M	Negative	Negative(Ct/Cq) >43
61	26	M	Negative	Negative(Ct/Cq) >43
62	72	M	Negative	Negative(Ct/Cq) >43
63	16	M	Negative	Negative(Ct/Cq) >43
64	23	M	Negative	Negative(Ct/Cq) >43
65	53	F	Negative	Negative(Ct/Cq) >43
66	55	M	Negative	Negative(Ct/Cq) >43
67	32	M	Negative	Negative(Ct/Cq) >43
68	77	M	Negative	Negative(Ct/Cq) >43
69	21	M	Negative	Negative(Ct/Cq) >43
70	39	M	Negative	Negative(Ct/Cq) >43
71	11	F	Negative	Negative(Ct/Cq) >43
72	25	M	Negative	Negative(Ct/Cq) >43

All information subject to final confirmation.
Exporter Ningbo Pylon International Trading Co., Ltd. , A 100% German Owned Company

73	27	M	Negative	Negative(Ct/Cq) >43
74	40	M	Negative	Negative(Ct/Cq) >43
75	24	M	Negative	Negative(Ct/Cq) >43
76	36	F	Negative	Negative(Ct/Cq) >43
77	81	M	Negative	Negative(Ct/Cq) >43
78	16	F	Negative	Negative(Ct/Cq) >43
79	86	F	Negative	Negative(Ct/Cq) >43
80	31	F	Negative	Negative(Ct/Cq) >43
81	60	M	Negative	Negative(Ct/Cq) >43
82	35	M	Negative	Negative(Ct/Cq) >43
83	69	F	Negative	Negative(Ct/Cq) >43
84	29	M	Negative	Negative(Ct/Cq) >43
85	24	M	Negative	Negative(Ct/Cq) >43
86	27	F	Negative	Negative(Ct/Cq) >43
87	50	M	Negative	Negative(Ct/Cq) >43
88	38	F	Negative	Negative(Ct/Cq) >43
89	25	F	Negative	Negative(Ct/Cq) >43
90	53	F	Negative	Negative(Ct/Cq) >43
91	15	M	Negative	Negative(Ct/Cq) >43
92	18	M	Negative	Negative(Ct/Cq) >43
93			Negative	Negative(Ct/Cq) >43
94	18	M	Negative	Negative(Ct/Cq) >43
95	33	F	Negative	Negative(Ct/Cq) >43
96	68	M	Negative	Negative(Ct/Cq) >43
97	31	M	Negative	Negative(Ct/Cq) >43
98	55	F	Negative	Negative(Ct/Cq) >43
99	46	M	Negative	Negative(Ct/Cq) >43
100	71	M	Negative	Negative(Ct/Cq) >43
101	24	F	Negative	Negative(Ct/Cq) >43
102	51	M	Negative	Negative(Ct/Cq) >43
103	43	M	Negative	Negative(Ct/Cq) >43
104	80	M	Negative	Negative(Ct/Cq) >43
105	71	F	Negative	Negative(Ct/Cq) >43
106	49	M	Negative	Negative(Ct/Cq) >43
107	64	M	Negative	Negative(Ct/Cq) >43
108	54	M	Negative	Negative(Ct/Cq) >43
109	23	M	Negative	Negative(Ct/Cq) >43
110	52	F	Negative	Negative(Ct/Cq) >43
111	32	M	Negative	Negative(Ct/Cq) >43

All information subject to final confirmation.
Exporter Ningbo Pylon International Trading Co., Ltd. , A 100% German Owned Company

112	19	M	Negative	Negative(Ct/Cq) >43
113	16	F	Negative	Negative(Ct/Cq) >43
114	23	M	Negative	Negative(Ct/Cq) >43
115	51	F	Negative	Negative(Ct/Cq) >43
116	25	M	Negative	Negative(Ct/Cq) >43
117	77	F	Negative	Negative(Ct/Cq) >43
118	22	M	Negative	Negative(Ct/Cq) >43
119	57	M	Negative	Negative(Ct/Cq) >43
120	18	M	Negative	Negative(Ct/Cq) >43
121	61	M	Negative	Negative(Ct/Cq) >43
122	30	M	Negative	Negative(Ct/Cq) >43
123	64	M	Negative	Negative(Ct/Cq) >43
124	57	M	Negative	Negative(Ct/Cq) >43
125	71	M	Negative	Negative(Ct/Cq) >43
126	31	M	Negative	Negative(Ct/Cq) >43
127	50	M	Negative	Negative(Ct/Cq) >43
128	58	M	Negative	Negative(Ct/Cq) >43
129	25	M	Negative	Negative(Ct/Cq) >43
130	75	M	Negative	Negative(Ct/Cq) >43
131	52	F	Negative	Negative(Ct/Cq) >43
132	46	M	Negative	Negative(Ct/Cq) >43
133	16	M	Negative	Negative(Ct/Cq) >43
134	28	M	Negative	Negative(Ct/Cq) >43
135	76	M	Negative	Negative(Ct/Cq) >43
136	13	F	Negative	Negative(Ct/Cq) >43
137	45	M	Negative	Negative(Ct/Cq) >43
138	38	M	Negative	Negative(Ct/Cq) >43
139	49	M	Negative	Negative(Ct/Cq) >43
140	16	M	Negative	Negative(Ct/Cq) >43
141	70	M	Negative	Negative(Ct/Cq) >43
142	33	M	Negative	Negative(Ct/Cq) >43
143	54	F	Negative	Negative(Ct/Cq) >43
144	66	M	Negative	Negative(Ct/Cq) >43
145	46	M	Negative	Negative(Ct/Cq) >43
146	40	M	Negative	Negative(Ct/Cq) >43
147	25	M	Negative	Negative(Ct/Cq) >43
148	20	M	Negative	Negative(Ct/Cq) >43
149	79	M	Negative	Negative(Ct/Cq) >43
150	32	M	Negative	Negative(Ct/Cq) >43

All information subject to final confirmation.
Exporter Ningbo Pylon International Trading Co., Ltd. , A 100% German Owned Company

151	15	M	Negative	Negative(Ct/Cq) >43
152	25	F	Negative	Negative(Ct/Cq) >43
153	44	M	Negative	Negative(Ct/Cq) >43
154	96	M	Negative	Negative(Ct/Cq) >43
155	31	M	Negative	Negative(Ct/Cq) >43
156	28	M	Negative	Negative(Ct/Cq) >43
157	30	F	Negative	Negative(Ct/Cq) >43
158	51	M	Negative	Negative(Ct/Cq) >43
159	96	M	Negative	Negative(Ct/Cq) >43
160	46	M	Negative	Negative(Ct/Cq) >43
161	56	M	Negative	Negative(Ct/Cq) >43
162	33	M	Negative	Negative(Ct/Cq) >43
163	15	F	Negative	Negative(Ct/Cq) >43
164	25	M	Negative	Negative(Ct/Cq) >43
165	52	F	Negative	Negative(Ct/Cq) >43
166	31	F	Negative	Negative(Ct/Cq) >43
167	57	M	Negative	Negative(Ct/Cq) >43
168	31	M	Negative	Negative(Ct/Cq) >43
169	57	F	Negative	Negative(Ct/Cq) >43
170	22	M	Negative	Negative(Ct/Cq) >43
171	35	M	Negative	Negative(Ct/Cq) >43
172	74	M	Negative	Negative(Ct/Cq) >43
173	51	M	Negative	Negative(Ct/Cq) >43
174	59	M	Negative	Negative(Ct/Cq) >43
175	56	M	Negative	Negative(Ct/Cq) >43
176	47	M	Negative	Negative(Ct/Cq) >43
177	50	M	Negative	Negative(Ct/Cq) >43
178	57	F	Negative	Negative(Ct/Cq) >43
179	32	M	Negative	Negative(Ct/Cq) >43
180	56	M	Negative	Negative(Ct/Cq) >43
181	65	M	Negative	Negative(Ct/Cq) >43
182	78	M	Negative	Negative(Ct/Cq) >43
183	29	M	Negative	Negative(Ct/Cq) >43
184	50	F	Negative	Negative(Ct/Cq) >43
185	2	F	Negative	Negative(Ct/Cq) >43
186	6	M	Negative	Negative(Ct/Cq) >43
187	19	F	Negative	Negative(Ct/Cq) >43
188	27	M	Negative	Negative(Ct/Cq) >43
189	59	M	Negative	Negative(Ct/Cq) >43

All information subject to final confirmation.
Exporter Ningbo Pylon International Trading Co., Ltd. , A 100% German Owned Company

190	59	M	Negative	Negative(Ct/Cq) >43
191	35	F	Negative	Negative(Ct/Cq) >43
192	6	M	Negative	Negative(Ct/Cq) >43
193	68	M	Negative	Negative(Ct/Cq) >43
194	69	F	Negative	Negative(Ct/Cq) >43
195	55	M	Negative	Negative(Ct/Cq) >43
196	2	F	Negative	Negative(Ct/Cq) >43
197	70	M	Negative	Negative(Ct/Cq) >43
198	81	M	Negative	Negative(Ct/Cq) >43
199	76	M	Negative	Negative(Ct/Cq) >43
200	22	M	Negative	Negative(Ct/Cq) >43
201	49	F	Positive	Positive (RdRP and N gene)
202	32	F	Positive	Positive (RdRP and N gene)
203	31	F	Positive	Positive (RdRP and N gene)
204	32	F	Positive	Positive (RdRP and N gene)
205	21	F	Positive	Positive (RdRP and N gene)
206	51	M	Positive	Positive (RdRP and N gene)
207	22	F	Positive	Positive (RdRP and N gene)
208	46	F	Positive	Positive (RdRP and N gene)
209	23	F	Negative	Positive (N and E gene)
210	14	M	Negative	Positive (RdRP and N gene)
211	42	M	Positive	Positive (RdRP and N gene)
212	51	M	Positive	Positive (RdRP and N gene)
213	80	M	Positive	Positive (RdRP and N gene)
214	39	F	Positive	Positive (RdRP and N gene)
215	67	M	Positive	Positive (RdRP and N gene)
216	44	M	Negative	Positive (RdRP gene)
217	26	F	Positive	Positive (RdRP and N gene)
218	33	F	Negative	Positive (N gene)
219	38	F	Positive	Positive (RdRP and N gene)
220	36	F	Positive	Positive (RdRP and N gene)
221	3	F	Positive	Positive (RdRP and N gene)
222	35	F	Positive	Positive (RdRP and N gene)
223	23	F	Positive	Positive (RdRP and N gene)
224	43	M	Positive	Positive (RdRP and N gene)
225	43	F	Positive	Positive (RdRP and N gene)
226	46	F	Positive	Positive (RdRP and N gene)
227	55	F	Positive	Positive (RdRP and N gene)
228	22	F	Positive	Positive (RdRP and N gene)

All information subject to final confirmation.
Exporter Ningbo Pylon International Trading Co., Ltd. , A 100% German Owned Company

229	20	M	Negative	Positive（N gene)
230	42	M	Positive	Positive（RdRP and N gene)
231	56	F	Positive	Positive（RdRP and N gene)
232	55	M	Positive	Positive（RdRP and N gene)

All information subject to final confirmation.
Exporter Ningbo Pylon International Trading Co., Ltd. , A 100% German Owned Company