CE-DOC-H070
Version 1.0

EC Declaration of Conformity

In accordance with Directive 98/79/EC

Legal Manufacturer: *Healgen Scientific Limited Liability Company*

Legal Manufacturer Address: *3818 Fuqua Street, Houston, TX 77047, USA.*

Declares, that the products
Product Name and Model(s)

Coronavirus Ag Rapid Test Cassette (Swab)	GCCOV-502a

Classification: *Other*
Conformity assessment route: *Annex III (EC DECLARATION OF CONFORMITY)*

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

We hereby explicitly appoint

EC Representative's Name: Shanghai International Holding Corp. GmbH (Europe)

EC Representative's Address: Eiffestrasse 80, 20537 Hamburg, Germany

to act as our European Authorized Representative as defined in the aforementioned Directive.

I, the undersigned,hereby declare that the medical devices specified above conform with the directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements

Date Signed: July 20, 2020

Name of authorized signatory: Joyce Pang
Position held in the company: Vice-President

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Zhejiang Orient Gene Biotech Co., Ltd.
3787#, East Yangguang Avenue, Dipu Street
Anji, Huzhou
313300 Zhejiang
China

has established and applies a quality management system for medical devices for the following scope:

(see attachment for scope)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2018-03-17
Certificate Registration No.:	SX 60126352 0001
An audit was performed. Report No.:	15077992 008
This Certificate is valid until:	2021-03-16

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2018-01-30

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierstelle

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60126352 0001
Report No.: 15077992 008

Organization:
Zhejiang Orient Gene Biotech Co., Ltd.
3787#, East Yangguang Avenue, Dipu Street
Anji, Huzhou
313300 Zhejiang
China

Scope:

Design and Development, Manufacture and Distribution of In Vitro Diagnostic Reagents for Cardiac Diseases, Infectious Diseases Oncology and for Biochemistry as well as Rapid Tests for Fertility, Rapid Tests for Drugs of Abuse, Chlamydia Trachomatis Antigen, Toxoplasma gondii(Toxo) IgG/IgM, Toxoplasma gondii(Toxo) IgG, Toxoplasma gondii(Toxo) IgM, Digital Pregnancy Tests for Self-testing, and Distribution of Urine Analyzer as well

Certification Body

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

X. Ren

Date: 2018-01-30

10/020 d 04.08 ® TÜV, TÜEV and TUV are registered trademarks. Utilisation and application requires prior approval.

Manufacturer's Authorization Letter

To whom it may concern,

This statement is to certify that we, Zhejiang Orient Gene Biotech Co., Ltd. with registered office located at 3787#, East Yangguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang, China hereby, would like to authorize **Dr. Adams LaboratoriesLTD** based on **Unit 2, Oyster Park, Greenstead Road, Colcheser, Essex** to direct sell our Coronavirus Ag Rapid Test Cassette (Swab) Healgen Brand for **UK(Dr. Adams LaboratoriesLTD is not allowed to participate in UK government tenders, only authorised distribution)** market under Healgen Brand with non-Exclusive Distributorship.

This authorization letter will be valid in 6 months from January 9th, 2021 until Jun 9th, 2021, and shall be renewed upon written mutual agreement with written notice no later than 1 month before the expiration date.

Manufacturer:

Zhejiang Orient Gene Biotech Co., Ltd.

Name: Ying Zhang

Title: Sales Manager

Address:

3787#, East Yangguang Avenue, Dipu Street,

Anji 313300, Huzhou, Zhejiang, China

Sincerely,

January 9th, 2021

Stamped

Signed:

Clinical Report

Coronavirus Ag Rapid Test Cassette (Swab)

Sponsor: Healgen Scientific Liability Limited Company
3818 Fuqua street Houston, TX 77047 USA

Manufacturer: Zhejiang Orient Gene Biotech Co., LTD
Address: 3787#, East Yangguang Avenue, Dipu Street, Anji 313300,Huzhou,Zhejiang,China.

Product Name
Coronavirus Ag Rapid Test Cassette (Swab)

Manufacturer
Zhejiang Orient Gene Biotech Co., LTD

Clinical Site
Clinical Performance of the Coronavirus Ag Rapid Test Cassette (Swab) was evaluated by being involved in 7 Point of Care sites within the US, where patients were enrolled and tested. Testing was performed by 11 Health Care Workers.

Test Interval

September,2020-October,2020

Introduction
Coronaviruses are enveloped RNA viruses that are distributed broadly among humans, other mammals, and birds that cause respiratory, enteric, hepatic, and neurologic diseases. Seven coronavirus species are known to cause human disease. Four viruses (229E, OC43, NL63, and HKU1) are prevalent and typically cause common cold symptoms in immunocompetent individuals. The three other strains (SARS-CoV, MERS-CoV, SARS-CoV-2) are zoonotic in origin and have sometimes been linked to fatalities.

The Coronavirus Ag Rapid Test Cassette (Swab) is an in vitro immunochromatographic assay for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct nasopharyngeal (NP) swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider. It is intended to aid in the rapid diagnosis of SARS-CoV-2 infections. The Rapid COVID-19 Antigen Test does not differentiate between SARS-CoV and SARS-CoV-2.

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

This test is for detection of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Rapid diagnosis of SARS-CoV-2 infection will help healthcare professionals to treat patients and control the disease more efficiently and effectively.

Principle

The Coronavirus Ag Rapid Test Cassette (Swab) is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect nucleocapsid protein from SARS-CoV-2 in nasopharyngeal (NP) swab. The test strip is composed of the following parts: namely sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidal-gold conjugated with the monoclonal antibodies against the nucleocapsid protein of SARS-CoV-2; the reaction membrane contains the secondary antibodies for nucleocapsid protein of SARS-CoV-2. The whole strip is fixed inside a plastic device. When the sample is added into the sample well, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If SARS-CoV-2 antigen presents in the sample, a complex formed between the anti-SARS-2 conjugate and the virus will be captured by the specific anti-SARS-2 monoclonal antibodies coated on the test line region (T). Absence of the T line suggests a negative result. To serve as a procedural control, a red line will always appear in the control line region (C) indicating that proper volume of sample has been added and membrane wicking has occurred.

Purpose

The primary objective is to determine the sensitivity and specificity of the Coronavirus Ag Rapid Test Cassette when testing intended use populations who meet the criteria of having COVID-19 infection by Centers for Disease Control and Prevention (CDC). The test is to be performed by healthcare professionals at clinical settings.

Design

Sample population and size

The clinical evaluation will be conducted at the actual user site and the study population will be"real-world"patients. To support the test performance, clinical specimens will be tested with the goal of testing a minimum of 40 positive specimens and 200 negative specimens in a randomized, blinded fashion.

The testing to be conducted will include the following:

A. Enroll 40 subjects known to be positive for COVID-19 by a RT-PCR assay within 14 days. These would be the patients that are already under the PI's care.

B. Enroll 250 subjects where the healthcare provider suspects the individual may have COVID-19 infection based on the CDC description of COVID-19 symptoms.

C. All the subjects will agree to be simultaneously sampled for a COVID-19 RT-PCR test and sampled for an antigen test at the clinical site.

D. If a subject has a known RT-PCR result less than 14 days ago, the RT-PCR test can be waived.

Inclusion and Exclusion Criteria

Inclusion Criteria

1. Must be 21 years old or older.
2. Has symptoms that lead the healthcare provider to suspect the individual of possibly having SARS-CoV-2 infection.
3. Was exposed to a COVID-19 patient within 14 days that leads the healthcare provider to suspect the individual of possibly having SARS-CoV-2 infection
4. Has an immediate need to determine COVID-19 status for occupational purposes.

5. Must be willing to provide a sample for COVID-19 RT-PCR testing if the subject has not been previous tested for COVID-19 RT-PCR within 14 days.
6. Must be willing to provide a sample for additional tests required by the study site.
(antigen test or RT-PCR).
7. Must be able to sign a consent form.
8. Must be able to provide nasopharyngeal swab samples.

Exclusion Criteria

1. Is receiving treatment with infusion of convalescent plasma or other antibody therapy related to SARS-CoV-2 infections.
2. Is participating in a SARS-CoV-2 vaccine study.
3. Tested positive for COVID-19 positive more than 14 days ago.

Candidate Test

Coronavirus Ag Rapid Test Cassette (Swab)

Comparator Test

The comparator tests included high sensitivity Emergency Use Authorized RT-PCR tests used at each testing site as the routine testing method for COVID-19 diagnostics. The EUA RT-PCR tests use a chemical lysis step followed by solid phase extraction of nucleic acid. The patient specimens were all prospective collected and immediately tested by operators.

FDA Emergency Use Authorized RT-PCR tests routinely are used as the testing method for COVID-19 diagnostics. Multiple RT-PCR tests were used as the comparator assay because Manufacturer had no control of which assay the test site used for patient testing. Sometimes, a testing site used multiple RT-PCR assays due to test supply constraints. In addition, it is very burdensome to collect multiple samples from one subject to accommodate an additional, separate RT-PCR test because the subject was already sampled twice (once for the clinical testing and once for the investigational testing).

Test Procedure

Perform the Test according to the Instructions for Use (IFU)package insert.

The technique is described and illustrated in the Quick Reference Instruction (QRI)

The test device and nasopharyngeal swab is provided with the test kit. The fresh specimens were tested immediately, and no transport media was used for shipping the samples to a different location for testing. All clinical specimens tested in this submission were tested and evaluated in accordance with the proposed diagnostic algorithm.

Results, Data process and Analysis

The study was conducted at a total of seven sites located in US , with 317 specimens tested using Coronavirus Ag Rapid Test Cassette (Swab) at clinical setting (**Table 1**).

Table 1: Clinical Study Sites and Specimen Numbers Tested with RT-PCR

Testing Site	Total Number of the specimens tested	RT-PCR Positive	RT-PCR Negative
Site 1*	57	7	50
Site 2	103	21	82
Site 3	150	29	121
Site 4	7	4	3
Total	317	61	256

*Site 1 has four point sites participated the study

Table 2:

Correlation of RT-PCR tests and Coronavirus Ag Rapid Test Cassette (Swab) at each site

Testing Site	RT-PCR Results		Coronavirus Ag Rapid Test Cassette (Swab)	
			Positive	Negative
Site 1	Positive	7+	6	1*
	Negative	50-	0	50
Site 2	Positive	21+	20	1*
	Negative	82-	0	82
Site 3	Positive	29+	29	0
	Negative	121-	2*	119
Site 4	Positive	4+	4	0
	Negative	3-	0	3

* false positive or false negative

Overall Summary:

- Total specimens tested within seven study sites: 317.
- Total RT-PCR positive specimens tested: 61.
- Total RT-PCR negative specimens tested: 256.
- Total Antigen positive specimens of the total 61 RT-PCR positive: 59
- Total Antigen negative specimens of the total 256 RT-PCR negative: 254

Performance Analysis

The agreement between the RT-PCR test and the Coronavirus Ag Rapid Test Cassette (Swab) were calculated with all the valid results, as indicated in **Table 3.**

Table 3: Clinical Study Performance Analysis

Method		**RT-PCR Test**		**Total**
Coronavirus Ag Rapid Test Cassette (Swab)		**Pos**	**Neg**	
	Pos	59	2	61
	Neg	2	254	256
Total		61	256	317

Relative Sensitivity: 59/61=96.72% (95%CI*: 88.65%-99.60%)
Relative Specificity: 254/256=99.22% (95%CI*: 97.21%-99.91%)
Accuracy: 313/317=98.74 (95%CI*: 96.80%-99.66%)
*Confidence Intervals

Conclusion: The sensitivity of the Coronavirus Ag Rapid Test Cassette (Swab) is 96.72% (95%CI*: 88.65%-99.60%) and specificity is 99.22% (95%CI*: 97.21%-99.91%), and the accuracy is 98.74% (95%CI*: 96.80%-99.66%).

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Tel: +1 713-733-8088 Fax: +1 713-733-8848
Website: www.healgen.com

Revision Date: 2020-11-13
B21934-05

Coronavirus Ag Rapid Test Cassette (Swab)

For Rapid Detection of SARS-CoV-2

INTENDED USE

The Coronavirus Ag Rapid Test Cassette (Swab) is an in vitro immunochromatographic assay for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct nasopharyngeal (NP) swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first ten days of symptom onset. It is intended to aid in the rapid diagnosis of SARS-CoV-2 infections. Negative results from patients with symptom onset beyond ten days should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. The Coronavirus Ag Rapid Test Cassette (Swab) does not differentiate between SARS-CoV and SARS-CoV-2.

SUMMARY AND EXPLANATION

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

This test is for detection of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Rapid diagnosis of SARS-CoV-2 infection will help healthcare professionals to treat patients and control the disease more efficiently and effectively.

PRINCIPLE OF THE TEST

The Coronavirus Ag Rapid Test Cassette (Swab) is an immunochromatographic membrane assay that uses highly sensitive

monoclonal antibodies to detect nucleocapsid protein from SARS-CoV-2 in direct nasopharyngeal (NP) swab. The test strip is composed of the following parts: namely sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidal-gold conjugated with the monoclonal antibodies against the nucleocapsid protein of SARS-CoV-2; the reaction membrane contains the secondary antibodies for nucleocapsid protein of SARS-CoV-2. The whole strip is fixed inside a plastic device. When the sample is added into the sample well, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If SARS-CoV-2 nucleocapsid antigen is present in the sample, a complex forms between the anti-SARS-2 conjugate and the virus will be captured by the specific anti-SARS-2 monoclonal antibodies coated on the test line region (T). Absence of the test line (T) suggests a negative result. To serve as a procedural control, a red line will always appear in the control line region (C) indicating that proper volume of sample has been added and membrane wicking has occurred.

MATERIALS PROVIDED

1.20 Test Cassettes
2.2 Extraction Buffer Vials
3.20 Sterile Swabs
4.20 Extraction Tubes and Tips
5.1 Workstation
6.1 Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

Clock, timer, or stopwatch

WARNINGS AND PRECAUTIONS

1.For in vitro diagnostic use only.
2.The test device should remain in the sealed pouch until use.

3.Do not use kit past its expiration date.
4.Swabs, tubes, and test devices are for single use only.
5.Solutions that contain sodium azide may react explosively with lead or copper plumbing. Use large quantities of water to flush discarded solutions down a sink.
6.Do not interchange or mix components from different kit lots.
7.Testing should only be performed using the swabs provided within the kit.
8.To obtain accurate results, do not use visually bloody or overly viscous samples.
9.Wear appropriate personal protection equipment and gloves when running each test and handling patient specimens. Change gloves between handling of specimens suspected of COVID-19.
10.Specimens must be processed as indicated in the SPECIMEN COLLECTION and SAMPLE PREPARATION PROCEDURE sections of this Product Insert. Failure to follow the instructions for use can result in inaccurate results.
11.Proper laboratory safety techniques should be followed at all times when working with SARS-CoV-2 patient samples. Used Test Strips and used extraction buffer vials may be potentially infectious. Proper handling and disposal methods should be established by the laboratory in accordance with local regulatory requirements.
12.Inadequate or inappropriate specimen collection and storage can adversely affect results.
13.Humidity and temperature can adversely affect results.
14.Dispose of test device and materials as biohazardous waste in accordance with federal, state, and local requirements.

STORAGE AND STABILITY

1.The kit can be stored at room temperature or refrigerated (2-30°C).
2.Do not freeze any of the test kit components.
3.Do not use test device and reagents after expiration date.

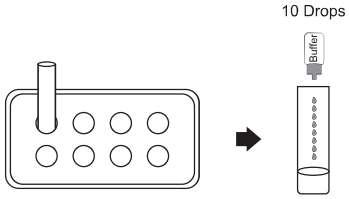
4.Test devices that have been outside of the sealed pouch for more than 1 hour should be discarded.
5.Close the kit box and secure its contents when not in use.

SPECIMEN COLLECTION

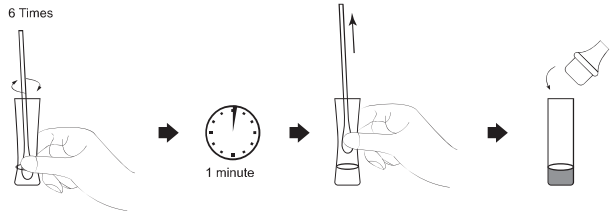
1.Using the sterile nasopharyngeal swab provided in the kit, carefully insert the swab in the patient's nostril.
2.Swab over the surface of the posterior nasopharynx and rotate the swab several times.
3.Withdraw the swab from the nasal cavity.

SAMPLE PREPARATION PROCEDURE

1.Insert the test extraction tube into the workstation provided in the kit. Make sure that the tube is standing upright and reaches the bottom of the workstation.
2.Add 0.3 mL (approximately 10 drops) of the sample extraction buffer into the extraction tube.



3.Insert the swab into the extraction tube which contains 0.3 mL of the extraction buffer.
4.Roll the swab at least 6 times while pressing the head against the bottom and side of the extraction tube.
5.Leave the swab in the extraction tube for 1 minute.
6.Squeeze the tube several times from the outside to immerse the swab. Remove the swab.



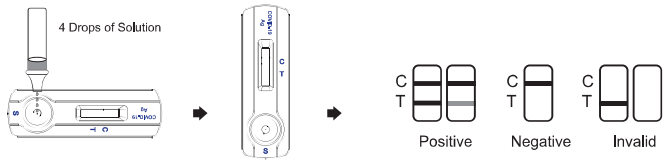
SPECIMEN TRANSPORT AND STORAGE

Do not return the nasopharyngeal swab to the original paper packaging. Specimen should be tested immediately after collection. If immediate testing of specimen is not possible, insert the swab into an unused general-purpose plastic tube. Ensure the breakpoint swab is level with the tube opening. Bend the swab shaft at a 180 degrees angle to break it off at the breaking point. You may need to gently rotate the swab shaft to complete the breakage. Ensure the swab fits within the plastic tube and secure a tight seal. The specimen should be disposed and recollected for retesting if untested for longer than 1 hour.

TEST PROCEDURE

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

1.Just prior to testing remove the test device from the sealed pouch and lit it on a flat surface.
2.Push the nozzle which contains the filter onto the extraction tube. Ensure the nozzle has a tight fit.
3.Hold the extraction tube vertically and add 4 drops (approximately 100 µL) of test sample solution tube into the sample well.
4.Start the timer.
5.Read the results at 15 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

1. POSITIVE:
The presence of two lines as control line (C) and test line (T) within the result window indicates a positive result.
2. NEGATIVE:
The presence of only control line (C) within the result window indicates a negative result.
3. INVALID:
If the control line (C) is not visible within the result window after performing the test, the result is considered invalid. Some causes of invalid results are because of not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test.
NOTE:
1.The intensity of color in the test line region (T) may vary depending on the

concentration of analyses present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive. This is a qualitative test only and cannot determine the concentration of analytes in the specimen.

2.Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control line region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this test. However, it is recommended that positive and negative controls are sourced from a local competent authority and tested as a good laboratory practice, to confirm the test procedure and verify the test performance.

LIMITATIONS

1.The etiology of respiratory infection caused by microorganisms other than SARS-CoV-2 will not be established with this test. The Coronavirus Ag Rapid Test Cassette (Swab) can detect both viable and non-viable SARS-CoV-2. The performance of the Coronavirus Ag Rapid Test Cassette (Swab) depends on antigen load and may not correlate with viral culture results performed on the same specimen.

2.Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.

3.If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time rule out the presence of SARS-CoV-2 antigens in specimen, as they may be present below the minimum detection level of the test or if the sample was collected or transported improperly.

4.As with all diagnostic tests, a confirmed diagnosis should only be made by

a physician after all clinical and laboratory findings have been evaluated.

5.Positive test results do not rule out co-infections with other pathogens.

6.Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.

7.The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after day 10 of illness are more likely to be negative compared to a RT-PCR assay.

8.Negative results from patients with symptom onset beyond ten days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.

9.Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

PERFORMANCE CHARACTERISTICS

1. Clinical Sensitivity, Specificity and Accuracy

Clinical Performance of the Coronavirus Ag Rapid Test Cassette (Swab) was evaluated by being involved in 7 sites within the US, where patients were enrolled and tested. Testing was performed by 24 Health Care Workers that were not familiar with the testing procedure. A total of 317 fresh nasopharyngeal swab samples was collected and tested, which includes 61 positive samples and 256 negative samples. The Coronavirus Ag Rapid Test Cassette (Swab) results were compared to results of USFDA Emergency Use Authorized RT-PCR assays for SARS-CoV-2 in nasopharyngeal swab specimens. Overall study results are shown in Table 1.

Table 1: The Coronavirus Ag Rapid Test vs PCR

Method		PCR		Total Results
Coronavirus Ag Rapid Test Cassette (Swab)	Results	Positive	Negative	
	Positive	59	2	61
	Negative	2	254	256
Total		61	256	317

Relative Sensitivity: 96.72% (95%CI*: 88.65%-99.60%) *Confidence Intervals
Relative Specificity: 99.22% (95%CI*: 97.21%-99.91%)
Accuracy: 98.74 (95%CI*: 96.80%-99.66%)

2. Limit of Detection (LOD)

LOD studies determine the lowest detectable concentration of SARS-CoV-2 at which approximately 95% of all (true positive) replicates test positive. Heat inactivated SARS-CoV-2 virus, with a stock concentration of 4.6×10^5 $TCID_{50}$ / mL, was spiked into negative specimen and serially diluted. Each dilution was ran in triplicate on the Coronavirus Ag Rapid Test Cassette (Swab). The Limit of Detection of the Coronavirus Ag Rapid Test Cassette (Swab) is 1.15×10^2 $TCID_{50}$ / mL (Table 2).

Table 2: Limit of Detection (LOD) Study Results

Concentration	No. Positive/Total	Positive Agreement
1.15 x 10^2 $TCID_{50}$ / mL	180/180	100%

3. High Dose Hook Effect

No high dose hook effect was observed when testing up to a concentration of 4.6 x 10^5 $TCID_{50}$ / mL of heat inactivated SARS-CoV-2 virus.

4. Cross Reactivity

Cross reactivity with the following organisms has been studied. Samples positive for the following organisms were found negative when tested with the Coronavirus Ag Rapid Test Cassette (Swab).

Pathogens	Concentration
Respiratory syncytial virus Type A	5.5×10^7 PFU/mL
Respiratory syncytial virus Type B	2.8×10^5 $TCID_{50}$/mL
Novel influenza A H1N1 virus (2009)	1×10^6 PFU/mL
Seasonal influenza A H1N1 virus	1×10^5 PFU/mL
Influenza A H3N2 virus	1×10^6 PFU/mL
Influenza A H5N1 virus	1×10^6 PFU/mL
Influenza B Yamagata	1×10^5 PFU/mL

Influenza B Victoria	1×10^6 PFU/mL
Rhinovirus	1×10^6 PFU/mL
Adenovirus 3	$5\times10^{7.5}$ $TCID_{50}$/mL
Adenovirus 7	2.8×10^6 $TCID_{50}$/mL
EV-A71	1×10^5 PFU/mL
Mycobacterium tuberculosis	1×10^3 bacteria/mL
Mumps virus	1×10^5 PFU/mL
Human coronavirus 229E	1×10^5 PFU/mL
Human coronavirus OC43	1×10^5 PFU/mL
Human coronavirus NL63	1×10^6 PFU/mL
Human coronavirus HKU1	1×10^6 PFU/mL
Parainfluenza virus 1	7.3×10^6 PFU/mL
Parainfluenza virus 2	1×10^6 PFU/mL
Parainfluenza virus 3	5.8×10^6 PFU/mL
Parainfluenza virus 4	2.6×10^6 PFU/mL
Haemophilus influenzae	5.2×10^6 CFU/mL
Streptococcus pyogenes	3.6×10^6 CFU/mL
Streptococcus pneumoniae	4.2×10^6 CFU/mL
Candida albicans	1×10^7 CFU/mL
Bordetella pertussis	1×10^4 bacteria/mL
Mycoplasma pneumoniae	1.2×10^6 CFU/mL
Chlamydia pneumoniae	2.3×10^6 IFU/mL
Legionella pneumophila	1×10^4 bacteria/mL

5. Interfering Substance

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated with the Coronavirus Ag Rapid Test Cassette (Swab) at the concentrations listed below and were found not to affect test performance.

Substance	Concentration
Human blood (EDTA anticoagulated)	20% (v/v)
Mucin	5 mg/mL

Oseltamivir phosphate	5 mg/mL
Ribavirin	5 mg/mL
Levofloxacin	5 mg/mL
Azithromycin	5 mg/mL
Meropenem	5 mg/mL
Tobramycin	2 mg/mL
Phenylephrine	20% (v/v)
Oxymetazoline	20% (v/v)
0.9% sodium chloride	20% (v/v)
A natural soothing ALKALOL	20% (v/v)
Beclomethasone	20% (v/v)
Hexadecadrol	20% (v/v)
Flunisolide	20% (v/v)
Triamcinolone	20% (v/v)
Budesonide	20% (v/v)
Mometasone	20% (v/v)
Fluticasone	20% (v/v)
Fluticasone propionate	20% (v/v)

INDEX OF SYMBOLS

	Consult instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2~30°C	LOT	Lot Number	REF	Catalog#

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