Clinical Report

Coronavirus Ag Rapid Test Cassette (Swab)

Manufacturer: Zhejiang Orient Gene Biotech Co., LTD
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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 Health Care Workers.

Test Interval

September,2020-December,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 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 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 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)

Lot: 2008139

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 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

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 Healthcare Workers that were not familiar with the testing procedure. A total of 865 fresh nasopharyngeal swab samples was collected and tested, which includes 119 positive samples and 746 negative samples. The Coronavirus Ag Rapid Test Cassette (Swab) results were compared to 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: Summary Results of nasopharyngeal swab

Method		**PCR**		**Total Results**
Coronavirus Ag Rapid Test Cassette (Swab)	Results	Positive	Negative	
	Positive	117	3	120
	Negative	2	743	745
Total		119	746	865

Relative Sensitivity: 98.32% (95% Cl* 94.06% to 99.80%)
Relative Specificity: 99.60% (95% CI* 98.83.03% to 99.92%)
Accuracy: 99.42% (95%CI* 98.66% to 99.81%)

Conclusion: From the results above, the relative sensitivity is 98.32% (95% Cl* 94.06% to 99.80%) , the relative specificity: 99.60% (95% CI* 98.83.03% to 99.92%) and the accuracy: 99.42% (95%CI* 98.66% to 99.81%)

A total of 237 fresh nasal swab samples was collected and tested, which includes 109 positive samples and 128 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 2**.

Table 2: Summary Results of Nasal Swab

Method		**PCR**		**Total Results**
Rapid COVID-19 Antigen Test (Nasal Swab)	Results	Positive	Negative	
	Positive	106	0	106
	Negative	3	128	131
Total		109	128	237

Relative Sensitivity: 97.25% (95% Cl*: 92.17% to 99.43%)
Relative Specificity: 100% (95% CI*: 97.16% to 100%)
Accuracy: 98.73% (95%CI*: 96.35% to 99.74%)

Conclusion: From the results above, the relative sensitivity is 97.25% (95% Cl*: 92.17% to 99.43%) , the relative specificity: 99.60% 100% (95% CI*: 97.16% to 100%) and the accuracy: 98.73% (95%CI*: 96.35% to 99.74%).