GENESIS

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KaiBiLi™ COVID-19 Antigen

This kit is designed for testing freshly collected swab samples.

INTENDED USE

The KaiBiLi™ COVID-19 Antigen Rapid Test Device is an *in vitro* diagnostic test based on the principle of immuno-chromatography for the qualitative detection of 2019 Novel Coronavirus nucleocapsid protein antigens in nasal swab or nasopharyngeal swab. The detection is based on the antibodies which were developed specifically recognizing and reacting with the nucleoprotein of 2019 Novel Coronavirus. It is intended to aid in the rapid diagnosis of SARS-CoV-2 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.

Patients with negative result should be treated as presumptive. 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. Negative results should be confirmed with a molecular assay, if necessary, for patient management.

BACKGROUND

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 symptoms including manifestations include fever, fatigue and dry cough, nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

PRINCIPLE

The KaiBiLi™ COVID-19 Antigen Rapid Test is an immunochromatographic assay for the qualitative detection of 2019 Novel Coronavirus antigens. This assay is intended for rapid screening in laboratory. This test should be conducted by trained technician, wearing appropriate personal protective equipment (PPE). The COVID-19 Antigen Rapid Test has two letters on the surface of the test device indicating test line (T) and control line (C). Test line and control line in the result window are not visible before applying any samples. The control line is a reference line which indicates the test is performing properly. The control line must appear every time when the test is performed. If SARS-CoV-2 is present in the sample, the test line would appear. The highly selective antibodies to SARS-CoV-2 are used as capture and detector in the assay. These antibodies can detect SARS-CoV-2 antigens directly, with a high accuracy.

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STORAGE CONDITIONS

Test devices must be stored at 2~30°C. DO NOT FREEZE. Devices must be brought back to room temperature at time of testing.

Warnings and Precautions

1. For in vitro Diagnostic Use
2. Pathogenic microorganisms may be present in clinical specimens. All specimen and the related contaminated items need to be handled, stored and disposed following “Standard Precautions” and institutional guidelines.
3. Use the Flocked swab supplied in the kit for collection nasal or nasopharyngeal sample.
4. Proper specimen collection, storage and transport are critical to the performance of this test.
5. Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when specimens are collected and evaluated.
6. Do not use kit components beyond the expiration date.
7. Apply universal precaution when performing the test.
8. The test plate should be used immediately after opening the packaging. When it absorbs moisture, the quality deteriorates and an accurate result cannot be obtained.
9. Please do not touch the sample drop and the judgment part of the test board directly by hand.
10. Do not reuse the device.
11. If the test is invalid, one should consider the possible improper handling, inaccurate operation procedure, or device quality. Repeat the test with a new device ensuring that the test procedure has been followed accurately.
12. Assessment must be conducted exactly 15 minutes after starting the reaction. Given the nature of the measurement, the reaction and color development

may slightly continue and progress even after 15 minutes.

13. The color tone of the line may vary depending on the color tone and specimen properties. However, the test result is valid as long as a red line is present.
14. If the line is not red at all (e.g. black), the test result is invalid and another test should be performed.
15. A highly viscous specimen may affect sample migration and/or the reaction, resulting in weak coloration, delayed or no formation of the line, or a nonspecific reaction because of specimen retention.

SAMPLE COLLECTION AND PREPARATION

DOs and DON'Ts of Sample Collection

- Do collect sample as soon as possible after onset of symptoms.
- Do use freshly collected samples of nasal swabs or nasopharyngeal swabs for optimum test performance.
- Do test sample immediately.
- Use only swabs provided with the kit.
- This kit is not intended for testing liquid samples

Prepare test samples with sample extraction buffer for immediate testing after collection. If immediate testing is not possible, collected samples can be held refrigerated (2~8°C) for up to 48 hours prior to testing. Inadequate sample collection or improper sample handling may yield a false-negative result.

Nasal Swabbing

Insert nasal swab into one nostril, and the tip should be inserted up to 2.5 cm from the edge of the nostril. Gently rotate the swab 5 times or more against the nasal wall for collecting cells and mucus. Using the same swab, repeat sample collection in the other nostril.

Nasopharyngeal Swabbing

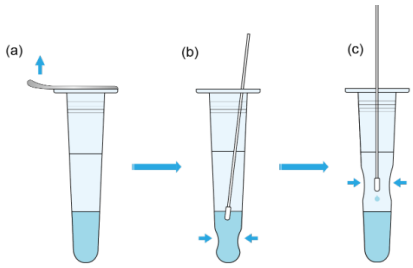
Insert sterilized swab into nostril parallel to the palate and leave in place for a few second to absorb secretions. Collect samples with nasopharyngeal (NP) swabs for optimum results.

PROCEDURE

Reagents, specimens and devices must be at room temperature (15–30 °C) for testing. Please read the instruction completely before beginning to test specimens.

1. Sample Extraction

Insert swab with collected sample into extraction tube containing 0.5 ml of sample extraction buffer. Squeeze the swab several times by compressing the outside walls of the tube end against the swab to mix well. Finally squeeze the swab to make most of the solution stays in the extraction tube and remove the swab. Use extraction solution as test sample.（step A~C）

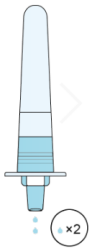


2. Test Reaction

(1) Remove test device from sealed foil pouch prior to testing and lay flat on work bench.

(2) Insert filtered nozzle into the extraction tube with test sample.

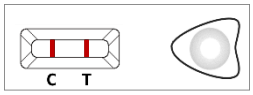
(3) Invert the extraction tube and add 2 drops (70μl) of test sample into sample well by gently squeezing the extraction tube.



(4) Read results at 15 minutes. Do not read test result after 30 minutes. A positive result may be visible at 3 minutes. However, the complete reaction time of 15 minutes is required to confirm a negative result.

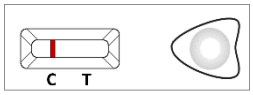
INTERPRETATION OF RESULTS

Allow the samples to run according to the instruction and read the test result in the reading area.



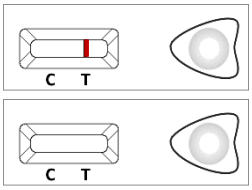
Positive

Two red lines appear. One red line appears in the control region (C), and one red line in the test region (T). This indicates that the specimen contains detectable amount of 2019 Novel Coronavirus antigen. The shade of color may vary，but it should be considered positive whenever there is even a faint line.



Negative

Only one reddish line appears in the control region of the device. No reddish line is visible next to the Test "T". This indicates that there is no detectable 2019 Novel Coronavirus antigen in the sample.



Invalid Result

No red line appears in the control region (C). The test is invalid even if there is a line in the region (T). Review testing procedures and repeat the test using a new rapid test device.

REPORTING OF RESULTS

Positive Test	Positive results indicate the presence of 2019 Novel Coronavirus antigen, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status.
Negative Test	Negative for the presence of 2019 Novel Coronavirus antigen. Infection due to 2019 Novel Coronavirus cannot be ruled-out and should not be used as the sole basis for treatment or other patient management decisions, including infection control decisions. It is recommended that these results be confirmed by a molecular testing method, if necessary, for patient management.
Invalid Test	Test result is inconclusive. Do not report results. Repeat the test.

QUALITY CONTROL

Internal control

Each KaiBiLi™ COVID-19 antigen rapid test device contains internal/procedural controls. The appearance of a control line at the Control "C" position validates the proper reagent function and assures that the correct test procedure was followed.

PERFORMANCE CHARACTERISTICS

Minimum detection limit

The minimum detection limit for the KaiBiLi™ COVID-19 Antigen Rapid Test is 140 $TCID_{50}$/mL.

High Dose Hook Effect

No high dose hook effect was observed when tested with up to a concentration of 5.6 x 10^5 $TCID_{50}$/mL of live SARS-CoV-2 virus with the KaiBiLi™ COVID-19 Antigen Rapid Test.

Clinical study（Nasal swab）

The clinical evaluations for KaiBiLi™ COVID-19 Antigen Rapid Test Device were performed in the US with specimens of 272 outpatients have respiratory symptoms onset within 7 days.

Two nasal swabs were collected from the participants by anterior nares technique. One swab was tested by KaiBiLi™ COVID-19 Antigen Rapid Test Device, and the other was shipped to a reference laboratory for an FDA Emergency Use Authorized real-time Polymerase Chain Reaction (RT-PCR) assay for detection of SARS-CoV-2.

		PCR		
		+	−	Total
KaiBiLi™ COVID-19 Antigen	+	84	0	84
	−	3	185	188
	Total	87	185	272

Positive Percent Agreement：96.6%(95%CI：90.3%-99.3%)

Negative Percent Agreement：100% (95%CI：98.0%-100%)

Overall Percent Agreement：98.9%(95%CI：96.8%-99.8%)

Clinical study（nasopharyngeal swab）

The clinical evaluations for KaiBiLi™ COVID-19 Antigen Rapid Test Device were performed in Novamedik Bioresearch laboratory in the Netherlands, we conducted rapid antigen and RT-PCR tests on nasopharyngeal swab samples from non-symptomatic passengers from several countries.

A total of 215 nasopharyngeal swabbing specimens from individual patients were enrolled for the evaluation. The SARS-CoV-2 RT-PCR were performed for the patient before or in parallel with KaiBiLi™ COVID-19 Antigen Rapid Test.

		PCR		
		+	−	Total
KaiBiLi™ COVID-19 Antigen	+	97	2	99
	−	3	113	116
	Total	100	115	215

Positive Percent Agreement：97.0%(95%CI：91.5%-99.4%)

Negative Percent Agreement：98.3% (95%CI：93.9%-99.8%)

Overall Percent Agreement：97.7%(95%CI：94.7%-99.2%)

Cross-reactivity evaluation

1. Bacteria and Yeast

   No cross reactivity with the following bacteria.

Potential Cross-Reactant	Concentration
Streptococcus pneumoniae	1.5 x 10^6 CFU/mL
Haemophilus infiuenzae	1.5 x 10^6 CFU/mL
Staphylococcus aureus	1.5 x 10^6 CFU/mL
Streptococcus pyogenes	1.5 x 10^6 CFU/mL
Staphylococcus epidermidis	1.5 x 10^6 CFU/mL
Mycobacteria tuberculosis	1.5 x 10^6 CFU/mL
Legionella pneumophila	1.5 x 10^6 CFU/mL
Candida albicans	1.5 x 10^6 CFU/mL
Bordetella pertussis	1.5 x 10^6 CFU/mL
Mycoplasma pneumoniae	1.5 x 10^6 CFU/mL
Chlamydia pneumoniae	1.5 x 10^6 IFU/mL

2. Virus
No cross reaction with the following pathogens,

Potential Cross-Reactant	Concentration Inactive Virus suspension
Influenza A, H1N1	1.0×10^6 $TCID_{50}$/mL
Influenza A, H3N2	1.0×10^6 $TCID_{50}$/mL
Influenza B, Victoria	1.0×10^6 $TCID_{50}$/mL
Influenza B, Yamagata	1.0×10^6 $TCID_{50}$/mL
Respiratory Syncytial Virus	1.0×10^6 $TCID_{50}$/mL
Adenovirus	1.0×10^6 $TCID_{50}$/mL
Enterovirus	1.0×10^6 $TCID_{50}$/mL
Human metapneumovirus	1.0×10^6 $TCID_{50}$/mL
Human coronavirus OC43	1.0×10^6 $TCID_{50}$/mL
Human coronavirus 229E	1.0×10^6 $TCID_{50}$/mL
Human coronavirus NL63	1.0×10^6 $TCID_{50}$/mL
Rhinovirus	1.0×10^6 $TCID_{50}$/mL
Parainfluenza virus Type 1	1.0×10^6 $TCID_{50}$/mL
Parainfluenza virus Type 2	1.0×10^6 $TCID_{50}$/mL
Parainfluenza virus Type 3	1.0×10^6 $TCID_{50}$/mL
Parainfluenza virus Type 4	1.0×10^6 $TCID_{50}$/mL

3. To estimate the likelihood of cross-reactivity of SARS-CoV-2 with organisms that were not available for wet testing, In silico analysis using the Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI) was used to assess the degree of protein sequence homology, including：
   - *Pneumocystis jirovecii* (PJP)：No protein sequence homology was found between SARS-CoV-2 and *Pneumocystis jirovecii*, and thus homology-based cross-reactivity can be ruled out.
   - Human coronavirus HKU1：Homology is relatively low, at 36.7% across 82% of sequences, but cross-reactivity cannot be ruled out.
   - SARS-coronavirus：Homology is relatively high, at 91% homology across 100% of sequences.
   - MERS-coronavirus：Homology is relatively low, at 50% homology across 88% of sequences, but cross-reactivity cannot be ruled out.
4. Endogenous/Exogenous Interference Substances
The following potential interfering substances have been tested using the KaiBiLi™ COVID-19 Antigen Rapid Test Device and no interference was observed：

Substance	Concentration
Whole Blood	4%
Mucin	0.3%
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL
Naso GEL (NeilMed)	5% v/v
OTC Nasal Drops (Phenylephrine)	15% v/v
Afrin (Oxymetazoline)	15% v/v
OTC Nasal Spray (Cromolyn)	15% v/v
Zicam	5% v/v
Homeopathic (Alkalol)	1:10 dilution
Sore Throat Phenol Spray	15% v/v
Tobramycin	4 μg/mL
Mupirocin	10 mg/mL
Fluticasone Propionate	1% v/v
Tamiflu (Oseltamivir Phosphate)	5 mg/mL

LIMITATIONS OF THE PROCEDURE

1. This kit is a qualitative test and cannot determine the amount of antigen in the sample.
2. The COVID-19 Antigen Rapid Test detects both viable and non-viable SARS-CoV-2 antigens. Therefore, the results must be compared with all other available clinical and laboratory information to make an accurate diagnosis.
3. Users should perform tests as quickly as possible after specimen is collected.
4. Positive test results do not rule out co-infections with other pathogens.
5. A false-negative result may occur if the antigen amount in the specimen was below the LoD of the reagent, or if the specimen was collected or transported improperly. A negative result does not eliminate the possibility of SARS-CoV-2 virus infection.
6. Specimens which obtained early while the onset of symptoms will have the highest viral titers and are recommended for the test.
7. Failure to follow proper test procedure may lead to inaccurate result.
8. Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary, for clinical management.

AVAILABILITY

Product	Cat. No.	Contents
KaiBiLi™ COVID-19 Antigen	P211139	20 Tests

Index of Symbols

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

EC REP **Lotus NL B.V.**
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