BioMedomics
TEST S FOR LIFE

SARS-CoV-2 Antigen Test Kit (LFIA)

BioMedomics
TESTS FOR LIFE

Content

Certifications

SARS-CoV-2
Antigen Test Kit (LFIA)

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

BioMedomics, Inc
1100 Perimeter Park Dr
Suite 104
Morrisville
North Carolina
27560
USA

Holds Certificate No: **FM 644662**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design, development and manufacture of in-vitro diagnostic medical devices used in the detection of hemoglobin disorders and/or adaptive immune responses including laboratory and point-of-care in-vitro diagnostic medical devices.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2016-10-31
Latest Revision Date: 2020-12-18

Effective Date: 2019-10-31
Expiry Date: 2022-10-30

Page: 1 of 1

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This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated online. Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.

ISO 13485

BioMedomics

CE

DECLARATION OF CONFORMITY

Product Designation: SARS-Cov-2 Antigen Test Kit (LFIA)

REF #s: 41-001

We herewith declare that the products listed above are in compliance with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning In-Vitro-Diagnostic Directive 98/79/EC. The Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Conformity Assessment Procedure: Annex III (IVD 98/79/EC)

Classification of the product: General; Not a referred product in Annex II, List A and List B
EDMA Code: 15.04.80.90.00 – Other Virology (Infect. Immunology) Other Viral Antigen/Antibody Detection

Applied Harmonized Standards:

EN ISO 13485:2016	Quality Management Systems – Requirements for regulatory purposes (ISO13485:2016)
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic medical devices – Statistical aspects
EN 13975:2003	Sampling procedures
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General Requirements
EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
EN ISO 23640:2015	In vitro diagnostic medical device – Evaluation of stability of in vitro diagnostic reagents

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Company Name: **BioMedomics, Inc.**
Street Address: 1100 Perimeter Park Dr., Suite 104
Morrisville, NC 27560
USA

Frank Wang, Ph.D.
CEO

Signature _____ Date 01/20/2021

QMS 007 (Rev 03)
DCO 21-002; Effective 01/20/2021 CONFIDENTIAL Page 1 of 1

CE Certification

Product Information & Advantages

INFECTIOUS DISEASE

SARS-CoV-2

Antigen Test Kit (LFIA)

The Importance of Antigen Tests

- Infection rates are still increasing around the globe which **inhibits the safe reopening society.**
- Unlike other SARS-CoV-2 testing methods, **antigen tests** are **quick, inexpensive,** and **detect an active SARS-CoV-2 infection.**
- **Frequent antigen rapid testing** will significantly assist in identifying infectious individuals and quarantining.

SARS-CoV-2 Antigen Test Kit (LFIA)

- BioMedomics has continued to put their passion of fast and reliable COVID-19 testing methods into the new **SARS-CoV-2 Antigen Test Kit (LFIA).**
- While PCR tests take days to reveal results and requires complex and expensive equipment, the **SARS-CoV-2 Antigen Test Kit (LFIA)** enables early detection of an acute coronavirus infection, enabling healthcare providers to administer faster and more accurate treatment methods.
- Knowledge of active infection in the fastest time possible is epidemiologically important and is crucial in the spread and management of the COVID-19 pandemic.

SARS-CoV-2 Antigen Test Kit (LFIA)

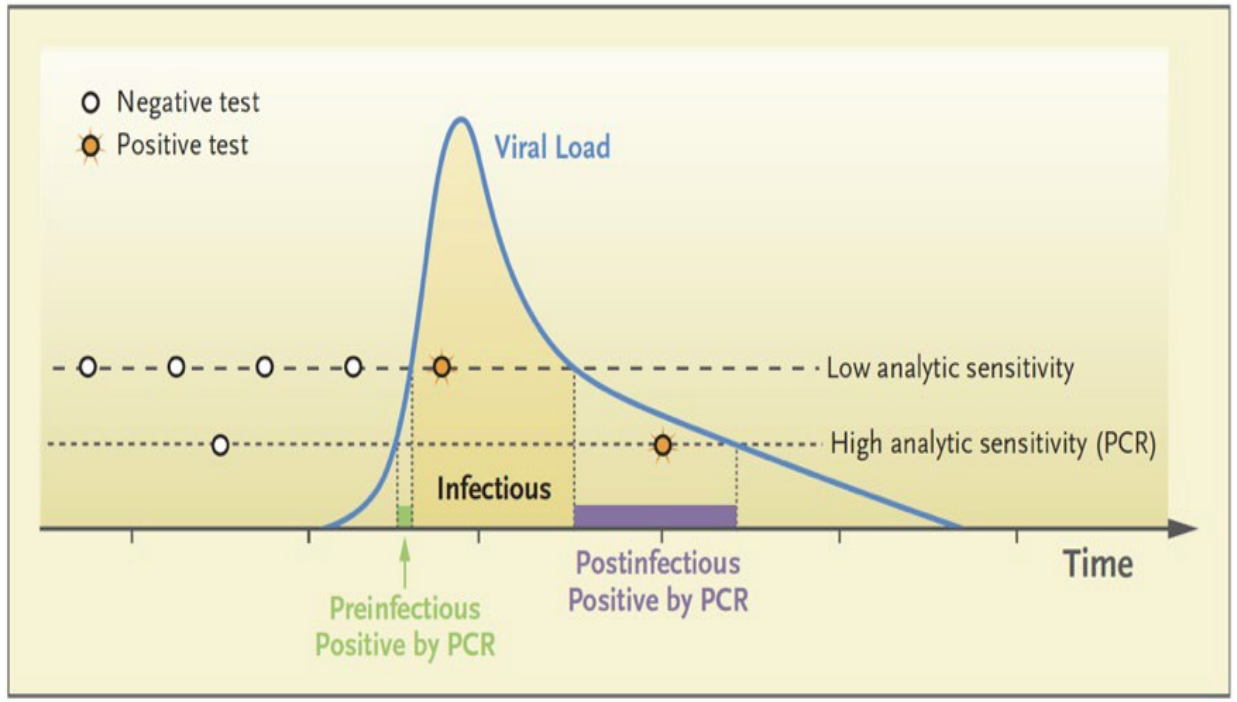
Overview

- **Packing size:** 20 tests/kit
- **Specimen type:** nasopharyngeal & throat secretion
- **Instrumentation:** not required
- **Detection time:** 15-20 minutes
- **Storage:** room temperature (2-30°C)
- **Shelf Life:** 24 months

SARS-CoV-2 Antigen Test Kit (LFIA)

- A frequently administered low analytic sensitivity test (rapid antigen test) has a better chance of identifying a person during peak viral load – when risk of transmission is highest – than a high analytic sensitivity test (PCR) administered less frequently.
- A PCR test can miss the earliest stages of infection and remain positive even after the patient is no longer infectious.

Analytic Sensitivity Graph

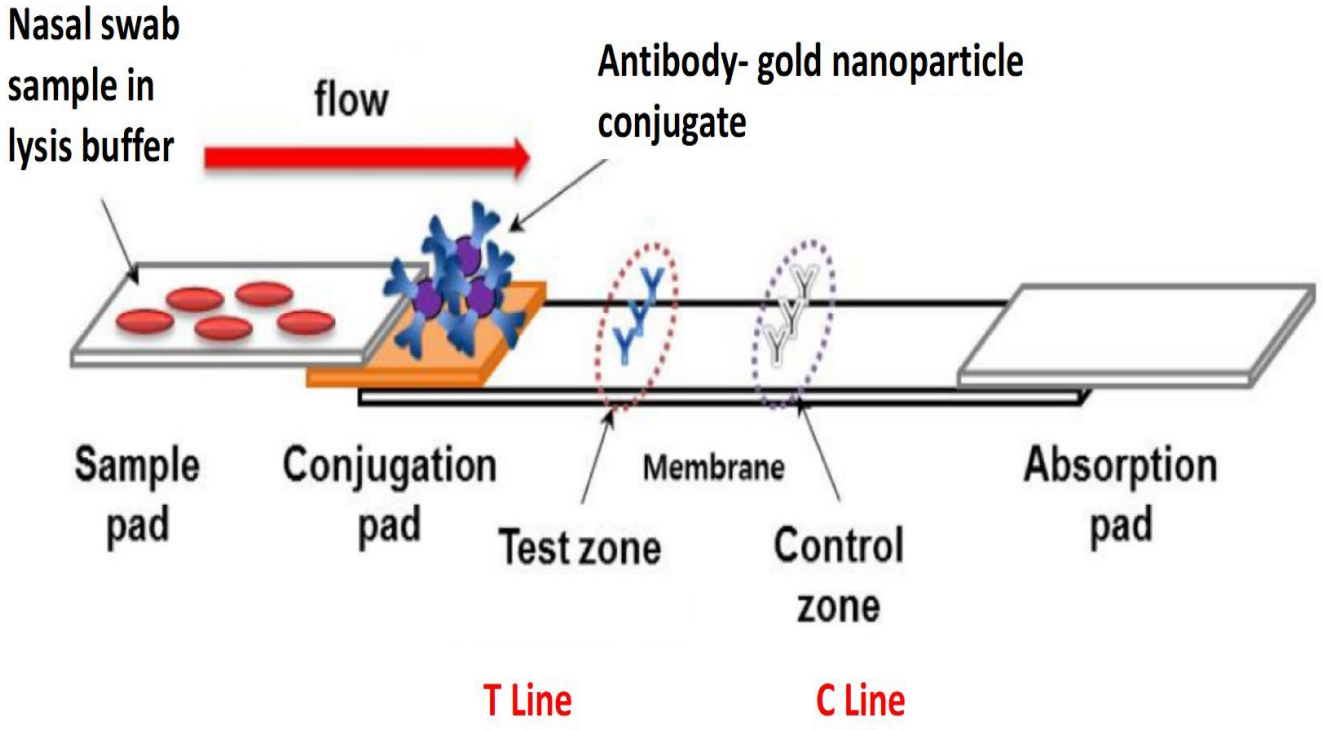


High frequency testing with low analytic sensitivity outperforms low-frequency testing with high analytic sensitivity.

SARS-CoV-2 Antigen Test Kit (LFIA)

Technical Specifications

- The SARS-CoV-2 Antigen Test is a lateral flow immunoassay (LFIA) that detects the most abundant protein (NP) antigen of SARS-CoV-2 using a double antibody sandwich assay.



Schematic of the BioMedomics lateral flow immunoassay with SARS-CoV-2 monoclonal antibodies

Analytical Performance: Sensitivity (Limit of Detection- LOD)

- **In Limit of Detection (LoD)** studies determined the lowest detectable concentration of SARS-CoV-2 at which 100% of all (true positive) replicates test positive.

- Because all concentrations tested positive, the SARS-CoV-2 Antigen Test demonstrates a **high sensitivity.**

Limit of Detection

SARS-CoV-2 tested ($TCID_{50}$/mL)	Test Result
1000	20/20 positive
200	20/20 positive
100	20/20 positive
50	20/20 positive
10	20/20 positive

SARS-CoV-2 virus were diluted with lysis buffer to a final concentration gradient of **10, 50, 100, 200, 1000 $TCID_{50}$/mL.**

Clinical Sample Test Performance

- Total **627** nasopharyngeal and throat swabs were collected from patients.
- A PCR test was used as the comparator method to confirm the status of samples for this study.
- BioMedomics' s antigen test demonstrated a **sensitivity of 97.73%** and a **specificity of 99.51%**

Clinical Sample Performance

RT-PCR			
BioMedomics Ag Test	Positive	Negative	Total
Positive	215	2	217
Negative	5	405	412
Total	220	407	627

***95% Confidence Interval**

Sensitivity: 97.73% (94.78%-99.26%) PPV: 99.08% (96.71%-99.89%)
Accuracy: 98.88% (97.71-99.55%) Specificity: 99.51% (98.24%-99.94%)
NPV: 98.78% (97.18%-99.60%)

Two nasopharyngeal swabs were collected from patients and one swab was tested directly using BioMedomics SARS-CoV-2 Antigen Test Cassette.

Competitive Product Analysis

SARS-CoV-2
Antigen Test Kit (LFIA)

SARS-CoV-2 Antigen Test Kit (LFIA)

Comparison with PCR Nucleic Acid Tests

	PCR Nucleic Acid Tests	BioMedomics Antigen Test (LFIA)
Turnaround Time	>1 Hour	15-20 Minutes
Facility Requirement	PCR laboratory	No special facilities needed
Operation	Requires expensive equipment	No electronic equipment needed
	Prone to false negatives	Results are clear & easy to read
Clinical Value	Commonly used, gold standard	Helps identify active infection

Overall Protocol

INFECTIOUS
DISEASE

SARS-CoV-2
Antigen Test Kit (LFIA)

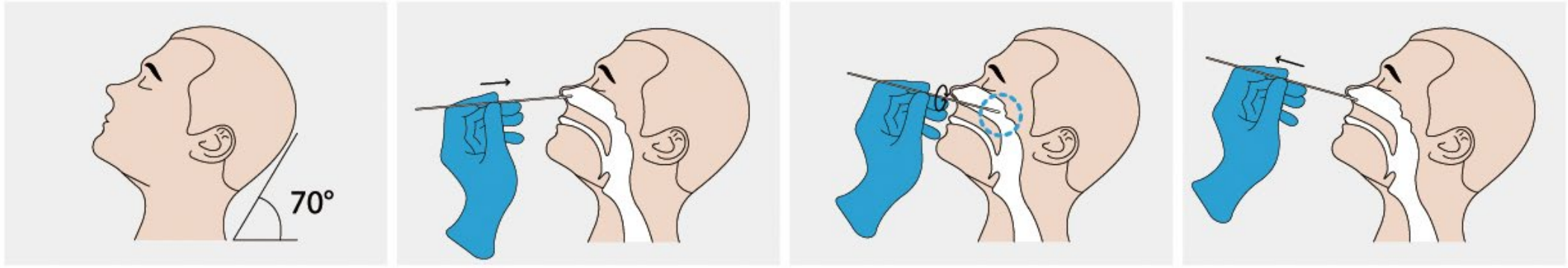
SARS-CoV-2 Antigen Test Kit (LFIA)

Sample Type

Sample Type	Method	Storage
Secretion	Nasopharyngeal	Short term: 2-8°C for 8 hours Long term: store at -70°C
Secretion	Throat	Short term: 2-8°C for 8 hours Long term: store at -70°C

SARS-CoV-2 Antigen Test Kit (LFIA)

Nasopharyngeal Secretion Collection



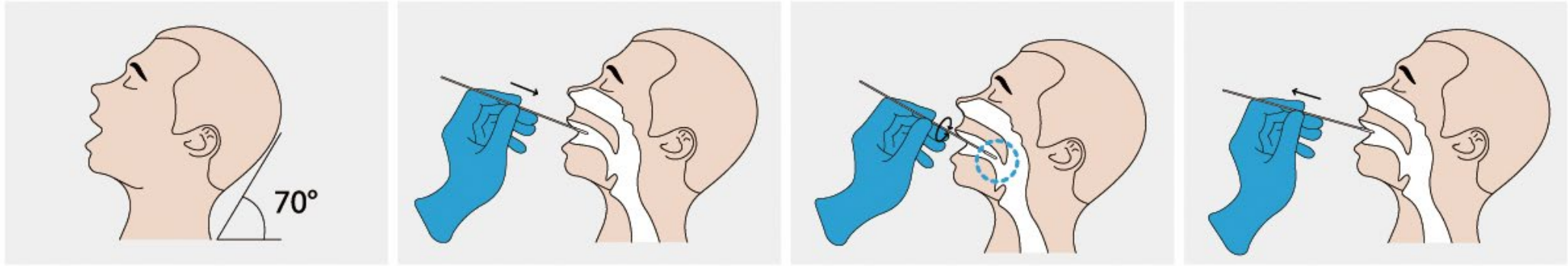
1. Take out a swab from the pouch.

2. Insert the swab into one of the patient's nostrils until it reaches the posterior nasopharynx where there is the most secretion.

3. Gently rotate and rub the swab over the surface of the posterior nasopharynx for several times before taking it out.

SARS-CoV-2 Antigen Test Kit (LFIA)

Throat Secretion Collection



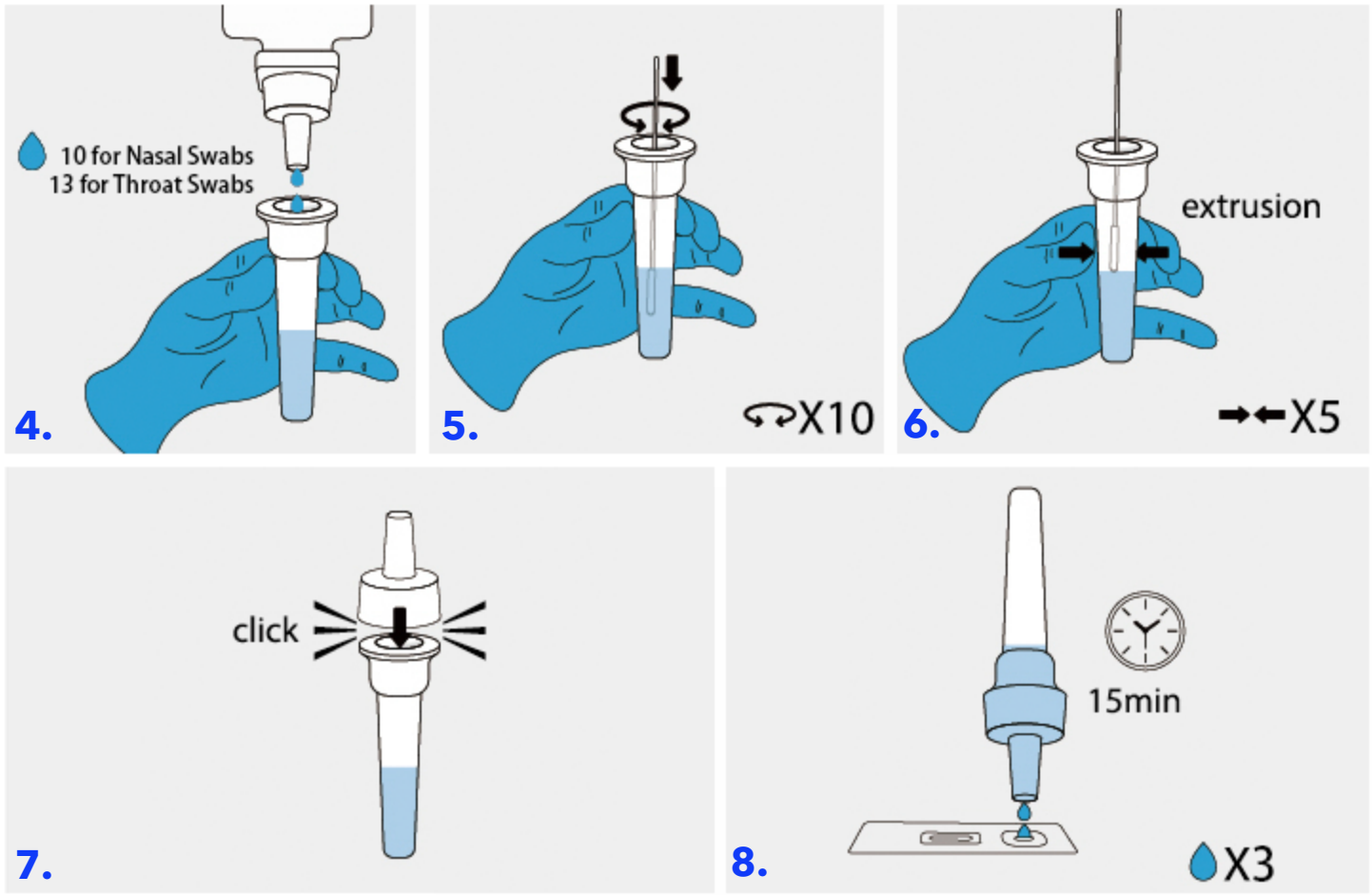
1. Take out a swab from the pouch.

2. Insert the whole swab completely into the throat from the mouth, centering on the throat wall and the reddened area of the tonsil.

3. Wipe both sides of the pharyngeal tonsil and posterior pharyngeal wall with moderate force. Try to avoid the tongue before taking it out.

SARS-CoV-2 Antigen Test Kit (LFIA)

Test Procedure



4. For **nasopharyngeal swabs**, vertically add 230 uL (about **10 drops**) lysis buffer into the sampling tube; for **throat swabs**, vertically add 300 uL (about **13 drops**) lysis buffer into the sampling tube. Insert the swab (after collection) into the solution.

5. Rotate the swab against the inner tube wall about 10 times.

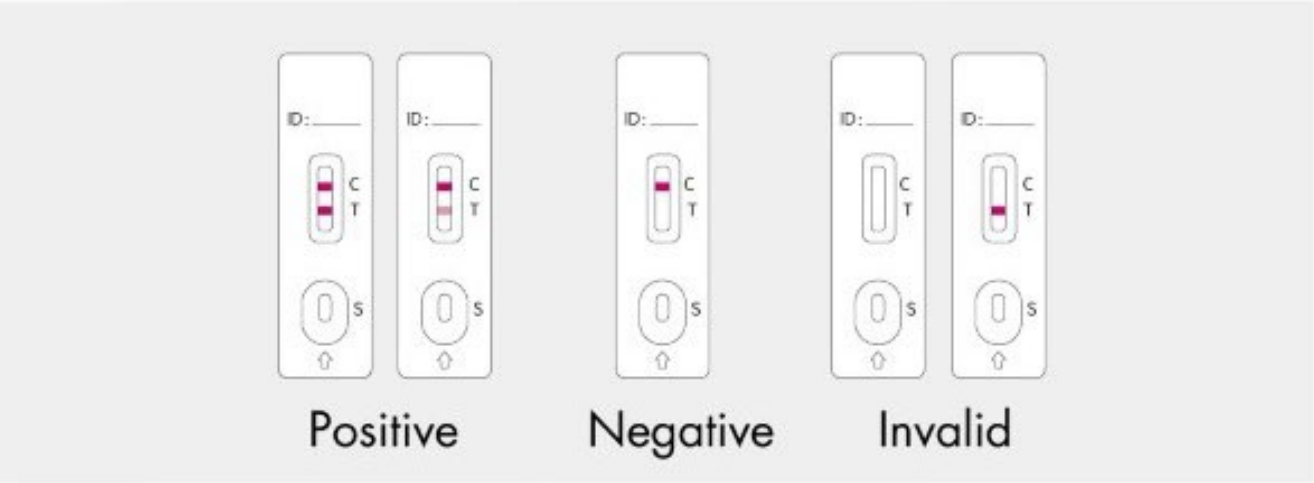
6. Squeeze the swab from the outer tube wall to completely dissolve the sample in the solution.

7. Remove and discard the swab, cover the tube with the dropper.

8. Place 3 drops of buffer in sample well. Read results after 15 minutes and no more than 20 minutes.

SARS-CoV-2 Antigen Test Kit (LFIA)

Results



A total of two detection lines are possible, with the control (C) line appearing when sample has flowed through the cassette.

1| Invalid Result: If the quality control line (C) does not appear, then the test result is invalid and sample must be retested with a new cassette.

2| Negative Result: If only the quality control line (C) appears and the detection T line is not visible, the sample contains no novel coronavirus antigen or the antigen concentration is lower than the limit of detection and the result is negative.

3| Positive Result: If both the quality control line (C) and the detection line T appears, then the novel coronavirus has been detected and the result is positive. Result should be determined by whether the T-line is colored or not regardless of the color intensity.

Internal Quality Control Procedure

- Each Test Cassette device has a **built-in control**.
- A red colored line in the detection window at the Control line can be considered an internal positive procedural control.
- The **Control line will appear** if the test procedure has been correctly performed.
- If the **Control line does not appear**, the test is invalid and a new test must be performed.
- If the problem persists, please contact your local vendor or BioMedomics for technical support.

Instructions for Use

BioMedomics™ INFECTIOUS DISEASE

SARS-CoV-2
Antigen Test Kit (LFIA)
Instructions For Use

Intended Use |
The BioMedomics SARS-CoV-2 Antigen Test Kit (LFIA) is a chromatographic immunoassay intended for the direct and qualitative detection of nucleocapsid antigen from SARS-CoV-2 in nasopharyngeal/throat swabs specimen directly collected from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms

Summary |
Coronavirus (CoV) belongs to the order Nidovirales under the Coronaviridae family with 4 genera: α, β, γ and δ. The α and β genera are only pathogenic to mammals, while γ and δ genera mainly causes bird infections. CoV is mainly transmitted through direct contact with secretions or through aerosols and droplets. There is also evidence supporting fecal-oral transmission.

The novel coronavirus 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.

Test Principle |
BioMedomics SARS-CoV-2 Antigen Test is a lateral flow immunochromatographic assay for the detection of extracted nucleocapsid protein antigens specific to SARS-Cov-2 in nasopharyngeal or throat swab specimens directly collected from individuals who are suspected of COVID-19 within the first five days of symptom onset. The test cassette contains (1) colloidal gold-labeled anti-SARS-CoV-2 antibody and quality control antibody colloidal gold marker, (2) one detection line (T line) and one quality control line(C) fixed on a nitrocellulose membrane.

When the appropriate amount of test sample treated with lysis buffer is added to the sample well of the test cassette, the sample will move forward along the test strip via capillary action. If the sample contains the novel coronavirus antigens and concentration of antigens is higher than the limit of detection, the antigen will bind to the colloidal gold-labeled anti-SARS-CoV-2 antibody. The immune complex will be captured by paired anti-SARS-CoV-2 antibody immobilized on the membrane, forming a red T line and indicating a positive result for the novel coronavirus antigens. If the sample contains no novel coronavirus antigens or the antigens concentration is lower than the limit of detection, a negative result is displayed.

Additionally, the test cassette also contains a quality control line(C). Regardless of what antigens are present the C line should appear, to indicate that the sample has been transported properly through the membrane. If the C line does not appear, it indicates that the test result is invalid and the sample is required to retest.

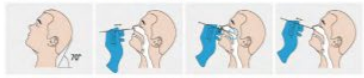
Contents of the Kit |
One test kit contains:
20 Test Cassettes | 1 Lysis Buffer | 1 Package Insert | 20 Sampling tubes | 20 Droppers | 20 Sterile Swabs

One test cassette contains:
- A test strip in a plastic cassette
- Colloidal gold-labeled anti-SARS-CoV-2 antibody
- C-line fixed with control antibody
- T-line fixed with anti-SARS-CoV-2 antibody

Warnings and Precautions |
- For human in vitro clinical diagnostics only.
- The product should only be used by trained healthcare professionals.
- After opening the sealed cassette pouch the test cassette should be used within one hour.
- Do not immerse test cassette in water.
- Do not freeze test cassette or buffer solution.
- Handle specimens in accordance to the OSHA Standard on Bloodborne Pathogens.
- Wear protective gloves, clothing, and eyewear.
- Wash hands thoroughly after handling specimens.
- Dispose of all used or damaged test cassettes, capillary samplers, or other kit components as biohazardous materials.
- Do not use test cassette, buffer solution, or any other kit components if the pouch is damaged or the seal is broken.
- This package insert must be read completely before performing the test. Failure to follow directions in insert may yield inaccurate test results.
- Do not use test cassette, buffer solution, or any kit component beyond the indicated expiration date.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.

Storage Instructions |
The test kit should be stored away from direct light at room temperature (2°C to 30°C) and has a shelf-life of 24 months. Do not freeze.

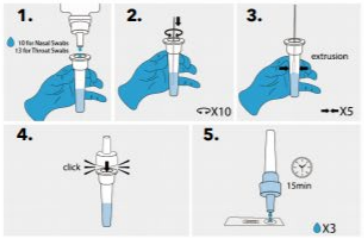
Sample Requirements |
Note: One test cassette can only be used to test one throat swab or nasopharyngeal swab. Nasopharyngeal swab or throat swab should be collected according to actual needs.
- Nasopharyngeal secretion collection: Take out a swab from the pouch. Insert the swab into one of the patient's nostrils until it reaches the posterior nasopharynx where there is the most secretion, gently rotate and rub the swab over the surface of the posterior nasopharynx for several times before taking it out.



- Throat secretion collection: Insert the whole swab completely into the throat from the mouth, centering on the throat wall and the reddened area of the tonsil, wipe both sides of the pharyngeal tonsil and posterior pharyngeal wall with moderate force. Try to avoid the tongue before taking it out.

- Sample should be treated with lysis buffer provided in this kit as soon as possible after collection. If the sample cannot be processed immediately, it should be stored immediately in a dry, sterilized and strictly sealed plastic tube. It can be stored at 2°C-8°C for 8 hours. Long term storage is available at -70°C.

Test Procedure |
Do not open pouch until ready to use. Prep necessary materials: Timer | Tube rack for sampling tubes and specimens | Any necessary personal protective equipment.
1 | Sampling:
- For nasopharyngeal swabs, vertically add 230 uL (about 10 drops) lysis buffer into the sampling tube; for throat swabs, vertically add 300 uL (about 13 drops) lysis buffer into the sampling tube. Insert the swab (after collection) into the solution.
- Rotate the swab against the inner tube wall about 10 times and squeeze the swab from the outer tube wall to completely dissolve the sample in the solution. Remove and discard the swab, cover the tube with the dropper.



2 | Testing:
- Open the aluminum foil bag, take out the test cassette and lay it on a clean flat surface. then mark the cassette with the patient ID or sample number. Add 75 uL (about 3 drops) processed sample extract into the sample well.

3 | Read Results:
- Results should be read within 15-20 minutes
- Results observed after 20 minutes are invalid

Test Method Limitations |
- Proper sample collection is critical for optimal test performance. Failure to follow the collection and sampling requirements may give inaccurate results.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
- Negative results may be caused by low concentrations of the SARS-CoV-2 antigens in the sample and therefore cannot completely rule out the possibility of infection.
- This product is only for qualitative testing and the specific concentration of each indicator must be measured using other quantitative methodologies.
- Results from antigen testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status. Results should be used in combination with clinical observations and other testing methods.

Display of Results/Expected Values |
A total of two detection lines are possible, with the control (C) line appearing when sample has flowed through the cassette.

1 | Invalid Result: If the quality control line (C) does not appear, then the test result is invalid and sample must be retested with a new cassette.

2 | Negative Result: If only the quality control line (C) appears and the detection T line is not visible, the sample contains no novel coronavirus antigens or the antigens concentration is lower than the limit of detection and the result is negative.

3 | Positive Result: If both the quality control line (C) and the detection line T appears, then the novel coronavirus has been detected and the result is positive. Result should be determined by whether the T-line is colored or not regardless of the color intensity.

Quality Control Procedure |
- Each Test Cassette has a built-in control. A red colored line in the detection window at the Control line can be considered an internal positive procedural control. The

Instructions for Use

Control line will appear if the test procedure has been correctly performed. If the Control line does not appear, the test is invalid and a new test must be performed. If the problem persists, please contact your local vendor or BioMedomics for technical support.

Product Performance |

- Appearance: complete outer packing box; intact swab package; aluminum foil pouch with no damage; the test cassette should be neat, complete, and free of damage and contamination; the plastic cassette should be firmly assembled; dessicant with no damage; lysis buffer with no sediment, flocculent suspended solid or leakage.

- Repeatability

1 | Repeatability within lots

Test 10 times with kits from the same lot by weak-positive quality control. The reaction results should be consistent, and the color rendering should be uniform (10/10).

Test 10 times with kits from the same lot by strong-positive quality control. The reaction results should be consistent, and the color rendering should be uniform (10/10).

2 | Repeatability across lots

Perform the test for the kits from three different lots with a weak-positive quality control. The reaction results should be consistent, and the color rendering should be uniform (30/30)

Perform the test for the kits from three different lots with a strong-positive quality control. The reaction results should be consistent, and the color rendering should be uniform (30/30).

- Analytical Performance

Sensitivity (Limit of Detection - LOD)

Limit of Detection (LoD) studies determined the lowest detectable concentration of SARS-CoV-2 at which 100% of all (true positive) replicates test positive. SARS-CoV-2 virus were diluted with lysis buffer to a final concentration gradient of 10, 50, 100, 200, 1000 $TCID_{50}$/mL, results are as follows:

SARS-CoV-2 tested ($TCID_{50}$/mL)	Test Result
1000	20/20 positive
200	20/20 positive
100	20/20 positive
50	20/20 positive
10	20/20 positive

- Cross Reactivity

Cross reactivity and potential interference of BioMedomics SARS-CoV-2 Antigen Test Kit (LFIA) were evaluated by testing commensal and pathogenic microorganisms listed in the following table that may be present in the clinical samples. Each of the bacterium, viruses and yeast was tested in triplicate in the absence or presence of inactivated SARS-CoV-2 virus.

Potential Cross-Reactant	Concentration Tested	Cross-Reactivity (Yes/No)
Human coronavirus 229E	1.0 x 10^5 $TCID_{50}$/mL	No
Human coronavirus OC43	1.0 x 10^5 $TCID_{50}$/mL	No
Human coronavirus NL63	1.0 x 10^5 $TCID_{50}$/mL	No
MERS-coronavirus	1.0 x 10^5 $TCID_{50}$/mL	No
SARS-coronavirus	1.0 x 10^5 $TCID_{50}$/mL	No
Influenza A H1N1	1.0 x 10^5 $TCID_{50}$/mL	No
Influenza A H3N2	1.0 x 10^5 $TCID_{50}$/mL	No
Influenza A H5N1	1.0 x 10^5 $TCID_{50}$/mL	No
Influenza A H7N9	1.0 x 10^5 $TCID_{50}$/mL	No
Influenza B Victoria	1.0 x 10^5 $TCID_{50}$/mL	No
Influenza B Yamagata	1.0 x 10^5 $TCID_{50}$/mL	No
Parainfluenza virus Type 1	1.0 x 10^5 $TCID_{50}$/mL	No
Respiratory syncytial virus	1.0 x 10^5 $TCID_{50}$/mL	No
Enterovirus CA 16e	1.0 x 10^5 $TCID_{50}$/mL	No
Adenovirus	1.0 x 10^5 $TCID_{50}$/mL	No
Mycoplasma pneumoniae	1.0 x 10^6 CFU/mL	No
Staphylococcus aureus	1.0 x 10^6 CFU/mL	No
Staphylococcus epidermidis	1.0 x 10^6 CFU/mL	No
Bordetella pertussis	1.0 x 10^6 CFU/mL	No
Legionella pneumophila	1.0 x 10^6 CFU/mL	No
Streptococcus pneumoniae	1.0 x 10^6 CFU/mL	No
Haemophilus influenza	1.0 x 10^6 CFU/mL	No
Streptococcus pneumoniae	1.0 x 10^6 CFU/mL	No
Mycobacterium tuberculosis	1.0 x 10^6 CFU/mL	No
Candid albicans	1.0 x 10^6 CFU/mL	No

- Endogenous Interfering Substances Effect

A study was performed to evaluate and demonstrate that the endogenous substances naturally present or drugs that may be artificially introduced into clinical samples do not interfere with the detection of SARS-CoV-2 in the BioMedomics SARS-CoV-2 Antigen Test Kit (LFIA) at the concentrations listed below.

Substance	Potential Interfering Substances	Concentration	Interference (Yes/No)
Endogenous	Mucin	2 % w/v	No
	Whole Blood	5 % v/v	No
Nasal spray or drops	Phenylephrine	0.05 mg/mL	No
Nasal steroids	Dexamethasone	0.8 mg/mL	No
	Triamcinolone acetonide	0.8 mg/mL	No
	Budesonide	0.5 mg/mL	No

Clinical Performance |

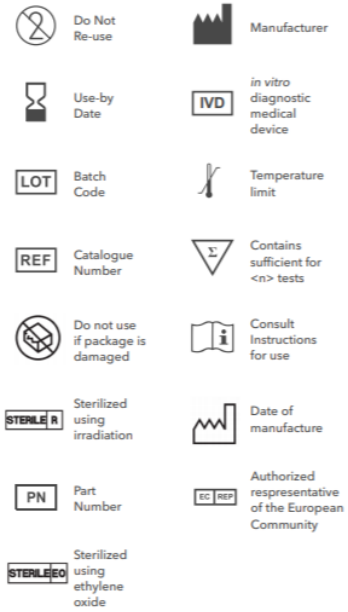
The performance of BioMedomics SARS-CoV-2 Antigen Test Kit (LFIA) was established with 627 nasopharyngeal swabs or throat swabs collected from patients. Two nasopharyngeal swabs were collected from patients and one swab was tested directly using BioMedomics SARS-CoV-2 Antigen Test Cassette. The real-time Polymerase Chain Reaction (RT-PCR) assay for the detection of SARS-CoV-2 was used as the comparator method to confirm the status of samples for this study.

RT-PCR			
BioMedomics Ag Test	Positive	Negative	Total
Positive	215	2	217
Negative	5	405	412
Total	220	407	627
***95% Confidence Interval**			
Sensitivity: 97.73% (94.78%-99.26%) PPV: 99.08% (96.71%-99.89%) Accuracy: 98.88% (97.71-99.55%) Specificity: 99.51% (98.24%-99.94%) NPV: 98.78% (97.18%-99.60%)			

References |

1. LY Wang, PR Chen, G W Zheng, et al. Research progress on novel coronavirus test methods. Modern Medicine and Clinic, 2020, 35(3): 411-416.

2. K Tugba, W Ralph, L Hakho. Molecular and Immunological Diagnostic Tests of COVID-19: Current Status and Challenges. IScience, 2020, 23 (8): Doi: 10.1016/j.isci.2020.101406



Scan for instructions in other languages

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41-PI-001.CE (Rev 02); Effective 01/20/2021

Requirements

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DISEASE

SARS-CoV-2
Antigen Test Kit (LFIA)

SARS-CoV-2 Antigen Test Kit (LFIA)

Requirements

- **Facility Requirement:** laboratory or healthcare facility
- **Intended User:** trained healthcare professionals
- **Storage**: reagent should be stored at 2-30°C. Do not freeze.

Packaging

SARS-CoV-2
Antigen Test Kit (LFIA)

Kit Components

Component/Material	Quantity (20 Tests p/Kit)
Test Cassettes	20
Sterile Swabs	20
Positive / Negative Control Swab	1 each
Sampling Tubes	20
Droppers	20
Buffer Solution	1
Package Insert	1

Summary

INFECTIOUS
DISEASE

SARS-CoV-2
Antigen Test Kit (LFIA)

SARS-CoV-2 Antigen Test Kit (LFIA)

Product Summary

- Rapid antigen test
- Detects SARS-CoV-2 antigens in 15-20 minutes
- Simple to use. No instrumentation required.
- Faster & more affordable than PCR
- Intuitive visual representation
- Offer real time results

BioMedomics
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OUR PARTNERS

- We have a global network of trusted distributors at both the regional and national level.

- Our products are sold in 40+ countries including Mexico, UK, France, India, Germany, Japan, China, Chile.

- We provide products to Hospitals, Government Agencies, NGO's, Clinicians, Researchers and more.

CONCLUSION

- **High-Quality Manufacturing**: BioMedomics operates under an **ISO-13485** certified quality system with dual production capacity in both the USA and China.
- **Name Recognition with Established Customers**: BioMedomics has customers in over 40 countries around the world, serving as a foundation for current and future global sales and marketing activities.
- **Strategic Relationships with Key Opinion Leaders**: BioMedomics maintains strong relationships with key opinion leaders around world to offer support and understand clinical needs, product design implementation, along with sales and marketing strategies.

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CONTACTS

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Quotations & Orders:

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Customer Service:

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Technical Support:

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