QUICK PROFILE™ COVID-19 Antigen Test Card

FOR THE QUALITATIVE ASSESSMENT OF SARS-COV-2 VIRUS IN THE NASAL SECRETIONS

REF 71110

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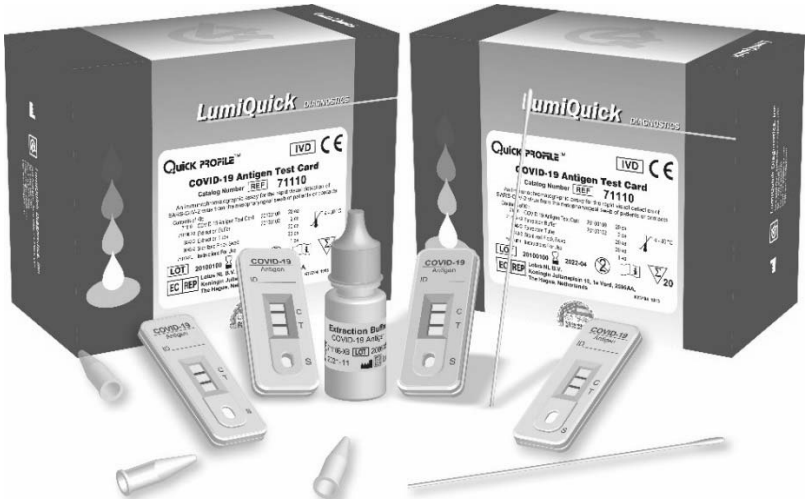

Note: The kit components featured in the procedural illustrations may differ from those provided in the kit. Refer to the Materials Provided section of this document for details.

INTENDED USE

QuickProfile™ COVID-19 Antigen Test is a rapid in vitro immunochromatographic assay for the qualitative detection of SARS-CoV-2 virus antigen present in human nasopharynx. The test is intended for professional and laboratory use as an aid in the rapid diagnosis of SARS-CoV-2 virus infections. According to CDC's guidance, COVID-19 antigen test has the best sensitivity from day 1 to day 5 after the onset of symptoms. Antigen levels in specimens collected beyond 5-7 days of the onset of symptoms may drop below the limit of detection of the test.

SUMMARY

SARS-CoV-2 is single-stranded RNA virus with envelope, the virion is approximately 50–200 nanometers in diameter. It has four structural proteins, known as the spike (S), envelope (E), membrane (M), and nucleocapsid (N) proteins; the N protein holds the RNA genome, and the S, E, and M proteins together create the viral envelope. The incubation period for COVID-19 typically ranges from 2 to 14 days. Those infected with the virus may be asymptomatic or develop common respiratory symptoms, including fever, cough and fatigue (other symptoms may include muscle pain, diarrhea, sore throat, loss of taste and smell, and abdominal pain). Severe patients may progress to acute respiratory distress syndrome (ARDS), septic shock, diffuse alveolar damage (DAD) and even death.

QuickProfile™ COVID-19 Antigen Test provides a quick and easy to use test to help in the diagnosis of SARS-CoV-2 infection to humans.

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PRINCIPLE

QuickProfile™ COVID-19 Antigen Test is a rapid immunochromatographic assay that utilizes specific monoclonal antibodies to detect Nucleocapsid protein of SARS-CoV-2 virus in nasopharyngeal swab specimens. Anti-SARS-CoV-2 antibodies are coated on nitrocellulose membrane as the capture zone and conjugated to colloidal gold as the detection probe. When sample extracts from the nasopharyngeal swab are applied to the test device's sample port, if the extracted specimen contains SARS-CoV-2 viral antigens, the antigens will form the antigen-antibody complex with anti-SARS-CoV-2-colloidal gold conjugate. The complex will continue to move on the membrane and can be captured by anti-SARS-CoV-2 antibodies coated on the test zone to form a colored band indicating a positive result. Absence of the color band on the test zone indicates a negative result. A built-in control band will always appear when the test is performed properly regardless of the presence or absence of SARS-CoV-2 antigen in the specimen.

PRECAUTIONS

Read the package insert carefully prior to testing the kit and follow the instructions to obtain accurate results.

1. For in vitro diagnostic use.
2. Do not use the kit contents beyond the expiration date printed on the outside of the box.
3. Do not interchange or mix different lots of components of QuickProfile™ COVID-19 Antigen Test.
4. Do not insert the test device directly into the sampling area (mouth, nostrils).
5. Disregard test results beyond the specified time (20 minutes).
6. Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.
7. Use of protective tools are recommended when handling patient samples.
8. Dispose of containers and used contents in accordance with Federal, State and Local requirements.
9. Do not reuse kit components.
10. The test device must remain sealed in the protective foil pouch until use.
11. Inadequate or inappropriate specimen collection, storage, and transport may yield inaccurate test results.
12. Seek specific training or guidance if you are not experienced with specimen collection and handling procedures.
13. If infection with a novel SARS-CoV-2 virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent SARS-CoV-2 viruses and sent to state or local health departments for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

STORAGE AND STABILITY

1. Store the test device at 4-30ºC in the original pouch. Do Not Freeze.
2. Kit contents are stable until the expiration date printed on the outer box based on the proper storage conditions.
3. The test device must be kept in the sealed pouch until use.

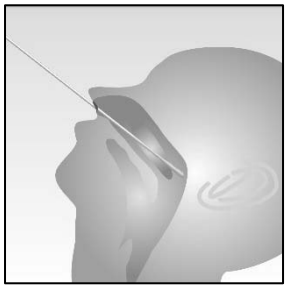
MATERIALS PROVIDED

1. Test card (20 devices):
   Each test houses a strip incorporated with a pair of anti-SARS-CoV-2 specific mouse monoclonal antibodies and packed in individual foil pouch.
2. Extraction buffer: Solution contains salt and detergent (1 bottle at 8 mL or 2 bottles at 4 mL each, please refer to the kit label).
3. Sample extraction tube (20 tubes)
4. Nasopharyngeal Swab (20 pieces)
5. Sample transfer pipet (20 pieces): one each enclosed with test device in the foil pouch.
6. Instructions for Use (1 copy)

MATERIALS REQUIRED BUT NOT SUPPLIED

1. Specimen collection container
2. Timer
3. Personal Protective Equipment

SAMPLE COLLECTION



Proper specimen collection, storage, and transport are critical to the performance of this test. Specimens should be tested as soon as possible after collection. The training in specimen collection is highly recommended because of the importance of specimen quality. For optimal test performance, use the swabs supplied in the kit.

It is important to obtain as much secretion as possible. Therefore, to collect a nasopharyngeal swab sample, carefully insert the sterile swab into the nostril that presents the most secretions under visual inspection. Keep the swab near the septum floor of the nose while gently pushing the swab into the posterior nasopharynx. Rotate the swab several times then remove it from the nasopharynx.

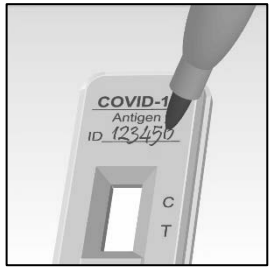
QUALITY CONTROL

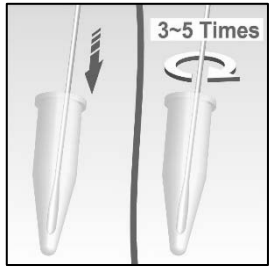
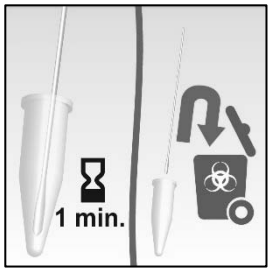
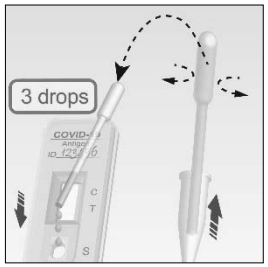
1. The control band is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.
2. Good laboratory practice recommends the daily use of control materials to validate the reliability of the device. Control materials, which are not provided with this test kit, may be commercially available.

PROCEDURE

All specimens must be handled and assay procedures performed at room temperature.

1	2
	
Check the expiration date on each component's package or outer box before use. Do not use any test material beyond the labelled expiration date.	Bring the kit components to room temperature before testing.

3	4
	
Open the pouch and remove the test device and the transfer pipet. Once opened, the test device must be used immediately.	Label the test device with sample identification (ID).

5	6
	
Add 10 full drops (approx. 360 µL) of extraction buffer into the extraction tube.	Place the swab with sample into the extraction tube. Roll the swab three to five (3-5) times.
7	**8**
	
Leave the swab in the extraction buffer for 1 minute. Roll the swab head against the side of the extraction tube as you remove it. Dispose of the used swab in accordance with your biohazard waste disposal protocol.	Use the enclosed transfer pipet to transfer extracted sample, adding three (3) drops (75-90µL) to the test device's sample port ("S").

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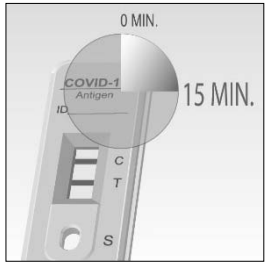

Read result at 15 minutes. Some positive results may appear earlier. ***Note: Results after 20 minutes may not be accurate.***

LIMITATIONS

1. The contents of this kit are to be used for the qualitative detection of SARS-CoV-2 viral antigen from the nasopharyngeal swab.
2. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
3. According to CDC's guidance, COVID-19 antigen test has the best sensitivity from day 1 to day 5 after the onset of symptoms. Antigen levels in specimens collected beyond 5-7 days of the onset of symptoms may drop below the limit of detection of the test.
4. Failure to follow the Test Procedure and interpretations of Test Results may adversely affect test performance and/or invalidate the Test Results.
5. Test Results must be evaluated in conjunction with other clinical data available to the physician.
6. Negative test results do not rule out other potential non-SARS-CoV-2 viral infections. Negative results should be confirmed by molecular diagnosis if COVID-19 disease is suspected.
7. Positive test results do not rule out co-infections with other pathogens.

Monoclonal antibodies may fail to detect, or detect with less sensitivity, SARS-CoV-2 viruses that have undergone minor amino acid changes in the target epitope region.

INTERPRETATION OF RESULTS

Positive result

At 15 minutes, in addition to the distinct red-purple color line on the C Line region, the appearance of any shade of a red color band on the T line region indicates a positive result for the presence of SARS-CoV-2 viral antigen. Report positive test results as 'Positive for SARS-CoV-2 viral antigen'. A positive result does not rule out co-infections with other pathogens.

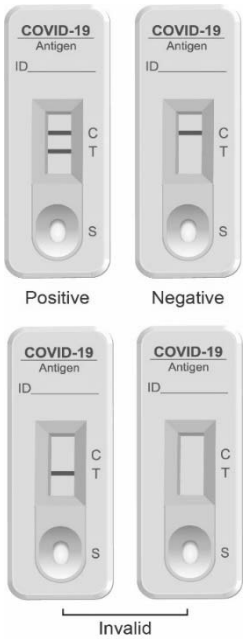
Negative result

At 15 minutes, the appearance of ONLY the red- purple control band on C Line region indicates SARS-CoV-2 viral antigen was not detected. A negative result indicates that the sample is negative for antigen or the antigen level is below the detection limit.

A negative result does not exclude SARS-CoV-2 viral infection and should be confirmed by molecular diagnostic method if COVID-19 disease is suspected.

Invalid result

If at 15 minutes, the red-purple control band does not appear on the C Line region, regardless if a test band appears, the result is considered invalid. If the test is invalid, a new test should be performed with a new patient sample and a new test device.



PERFORMANCE CHARACTERISTICS

Clinical Evaluation

The clinical evaluation was conducted in different countries. The nasopharyngeal swab samples were confirmed by RT-PCR. One hundred and twenty-seven (127) positive samples and eighty-six (86) negative samples were tested. The results are summarized below.

		RT-PCR Positive	RT-PCR Negative
	Number of Samples	127	86
QuickProfile™ COVID-19 Ag Test	Positive	119	1
	Negative	8	85

Clinical Sensitivity = 119 / 127 = 94 % (CI 95%: 89.5% - 97.9%)
Positive Predictive Value = 119 / (119 +1) = 99%
Clinical Specificity = 85 / 86 = 99 % (CI 95%: 96.5% - 99.99%)
Negative Predictive Value = 85 / (85 + 8) = 91%

Analytical Sensitivity

The limit of detection (LoD) for the QuickProfile™ COVID-19 Antigen Test was established in an analytical sensitivity study performed with three virus strains and three recombinant nucleocapsid proteins. The LoD was determined as the analytical concentration corresponding to 95% positive rate. A total of 10 replicates at the target concentration of each analyte listed in the table showed 100% positive results.

No.	Item	Limit of Detection
1	SARS-CoV-2, USA-WA 1/2020	3.80 x10^2 $TCID_{50}$/mL
2	SARS-CoV-2, HK/VM20001061/2020	3.16 x10^2 $TCID_{50}$/mL
3	SARS-CoV-2, Italy-INMI1	9.55 x10^2 $TCID_{50}$/mL
4	Recombinant N Protein 1	< 1 ng/mL
5	Recombinant N Protein 2	< 1 ng/mL
6	Recombinant N Protein 3	< 1 ng/mL

Cross Reactivity

The cross reactivity of the QuickProfile™ COVID-19 Antigen Test was evaluated with a total of 6 bacteria and 18 viruses. None of the microorganisms tested in the following table gave a positive result at the defined concentration. The specificity of non-cross reactivity is 100%.

Bacteria panel	Test concentration CFU/mL
Escherichia coli, Clinical Isolate	7.92 x 10^8
Haemophilus influenzae, Type B Egypt	5.43 x 10^7
Pseudomonas aeruginosa, Clinical Isolate	8.44 x 10^8
Staphylococcus aureus, MRSA;COL	1.84 x 10^8
Staphylococcus epidermidis, MRSE, RP62A	9.27 x 10^8
Streptococcus pneumoniae, Z022 19F	4.16 x 10^5
Viral panel	**Test concentration $TCID_{50}$/mL**
Corona virus (HCoV-OC43)	1.65 x 10^5
Corona virus (HCoV-NL63)	1.41 x 10^4
Corona virus (HCoV-229E)	4.17 x 10^4
Rhinovirus A2	3.89 x 10^3
Influenza A virus H1N1 Brisbane/59/07	7.24 x 10^4

Influenza A virus H3N2 Brisbane/10/07	4.17×10^4
Influenza B virus Florida/02/06	1.26×10^5
Parainfluenza virus Type 1	5.01×10^4
Parainfluenza virus Type 2	1.05×10^5
Parainfluenza virus Type 3	8.51×10^7
Parainfluenza virus Type 4A	1.51×10^5
Human Metapneumovirus 16 Type A1	1.26×10^5
Adeno virus type 4	5.01×10^4
Respiratory syncytial virus Type A	1.26×10^5
Respiratory syncytial virus Type B	1.26×10^5
Enterovirus Type 68	3.80×10^5
Enterovirus Type 71	1.65×10^5
MERS-Cov Virus Florida / USA-2_Saudi Arabia_2014	3.55×10^4

Interference

Exogenous (Nasal spray product, common chemicals) and endogenous substances listed in the table below were evaluated by spiking into extraction buffer with or without 1 x LOD SARS-CoV-2 virus and tested by six replicates. The results showed 100% positive on samples spiked with 1 x LOD and 100% negative without virus. These substances did not interfere with the QuickProfile™ COVID-19 Antigen Test at the levels tested below.

Interference substances	Testing Concentration	Interference substances	Testing Concentration
Aspirin	20 mg/ml	Oxymetazoline HCl	10 mg/ml
Dextromethorphan	10 mg/ml	Phenylephrine HCl	10 mg/ml
Diphenhydramine HCl	5 mg/ml	Saline nasal sprays	10%
Hemoglobin	20 mg/ml	Whole blood	5%
Mucin	0.04%	Ibuprofen	20 mg/ml

REFERENCES

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IVD	*In Vitro* Diagnostics Use		See Instruction for Use		Expiry Date
Σ	Tests per Kit		Keep Dry	LOT	Batch Number
EC REP	Authorized Representative		Keep away from Sunlight		Manufacturer
	Do not reuse		Do not use if package is damaged	4°C 30°C	Store between 4 ~ 30°C

LumiQuick Diagnostics, Inc.
2946 Scott Blvd.
Santa Clara, CA 95054, USA
Tel : (408) 855.0061
Fax: (408) 855.0063
Email: info@lumiquick.com
www.lumiquick.com

Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA,
The Hague, Netherlands