Aidian® LF SARS-CoV-2 Ag Test

Cat. no. 154980

5012-2EN
Instructions for use
English

In vitro diagnostic rapid test for qualitative detection of nucleocapsid protein SARS-CoV-2 antigens.

INTENDED PURPOSE

Intended use

Aidian LF SARS-CoV-2 Ag Test is a manual lateral flow immunoassay for the qualitative detection of nucleocapsid protein SARS-CoV-2 antigens in swab specimens from individuals who are suspected of having COVID-19 to aid in the diagnosis of a COVID-19 infection by their healthcare provider. For professional *in vitro* diagnostics use only.

SARS-CoV-2 antigens can be detected in the upper respiratory tract during the acute phase of infection. Aidian LF SARS-CoV-2 Ag Test detects the nucleocapsid protein SARS-CoV-2 antigen in upper respiratory specimens. While a positive result indicates the existence of the viral antigen, further evaluation of the patient's history and diagnostics are necessary for confirmation. A patient may experience concurrent infections with other viruses or a bacterial infection that are not ruled out by a positive SARS-CoV-2 antigen result. Antigen detection does not conclusively identify the cause of the disease. Negative results should be treated as presumptive and confirmation with a molecular assay may be necessary for patient management. 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 measures. Negative results should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

Summary and explanation of the test

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 information, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and a dry cough. Some cases include nasal congestion, a runny nose, a sore throat, myalgia and diarrhea.

PRINCIPLE OF THE PROCEDURE

Aidian LF SARS-CoV-2 Ag Test is a lateral flow immunochromatographic assay for the detection of extracted nucleocapsid protein antigens specific to SARS-CoV-2 in swab specimens. The swab specimens require a sample preparation step. The extracted specimen is added to the sample well of the test cassette to initiate the test. When the specimen migrates in the test strip, SARS-CoV-2 antigens (if present) bind to anti-SARS-CoV-2 nucleocapsid protein conjugated to the indicator and capture particles in the conjugate pad, forming an immune complex. The complex is then captured by the test line on the nitrocellulose membrane as it migrates through the strip. The presence of two colored lines in the control line region "C" and test line region "T" indicates a SARS-CoV-2 Antigen positive result. The presence of one colored line in the control line region "C" indicates a SARS-CoV-2 Antigen negative result. If there is no colored line in the control region "C", this indicates an invalid test.

KIT COMPONENTS

• Test cassettes • Sterile swabs (EO) • Extraction buffer • Workstation
• Procedure card • Instructions for use
Material required but not provided: Timer

STORAGE AND STABILITY

Store the kit at 2…30°C. DO NOT FREEZE. The kit is stable through the expiration date printed on the packaging. The test must remain in the sealed pouch until use.
Kit components must be at room temperature (15…30°C) when used for testing.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- For professional use only.
- This instructions for use must be read completely before performing the test. Failure to follow directions in instructions for use may yield inaccurate test results.
- Do not use the product after the expiry date marked on the outer package.
- Leave the test cassette sealed in its foil pouch until just before use. Do not use if the pouch is damaged or open. Do not use the swabs if the package is damaged. Do not exceed the indicated stability periods for opened reagents.
- Do not eat, drink, or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout in the collection, handling, storage, and disposal of patient samples and used kit contents.
- 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.
- Wash hands thoroughly after handling.
- Proper sample collection, storage and transport are essential for correct results.
- Do not mix components from different lot numbers or different tests. The components are disposable; never reuse components already used for performing a test.
- Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
- Do not store or test specimens in viral transport media, as it may result in false positive or false negative results. Extracted specimens for PCR tests cannot be used for the test.
- All components of this kit should be discarded as biohazard waste according to local regulations.
- In case of a serious incident, please report it to the manufacturer or its representative and/or national authority.
- Humidity and temperature can adversely affect results.

QUALITY CONTROL

Procedural Controls

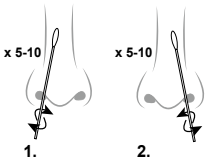
This test includes a positive procedural control within the test strip in the "C" control region. A visible line in the marked "C" region indicates the specimen volume has correctly travelled up the test strip and the technician correctly handled the test. A clear or light pink background elsewhere on the test strip should not contain any dark color, which shows that this negative procedural control confirms an adequately functioning test.

External Quality Control

Good Laboratory Practice (GLP) compliance dictates the use of external positive and negative controls.[1] It is recommended these controls be used; however, they are not currently included with this test kit. Use product SARS-CoV-2 Antigen Control (Cat. no. SCSCO-D-L) as external quality control (provided by AllTest Biotech Co.,Ltd). Before starting a control measurement, read and follow the SCSCO-D-L SARS-Cov-2 Antigen Control instructions for use.

SPECIMEN COLLECTION AND HANDLING

Nasal Swab Specimen Collection



1. Insert a sterilized swab less than 2 cm into a nostril (until resistance is met at the turbinates). Rotate the swab 5–10 times against the nasal wall.
2. Using the same swab, repeat the collection procedure in the other nostril. Withdraw the swab; avoid excess volume and high-viscous nasal discharge.

Caution: If the swab stick breaks during specimen collection, repeat the specimen collection with a new swab.

SPECIMEN TRANSPORT AND STORAGE

For best performance, swab specimens should be tested as soon as possible after collection. If immediate testing is not possible, it is highly recommended that the nasal swab be placed in a sterile, unused plastic tube labelled with patient information and capped tightly at 2…8°C for up to 24 hours prior to testing to preserve sample integrity and to allow the best performance and avoid possible contamination.

TEST PROCEDURE

Allow the test components, specimen and/or controls to reach the room temperature (15…30 °C) before testing.

Specimen Preparation

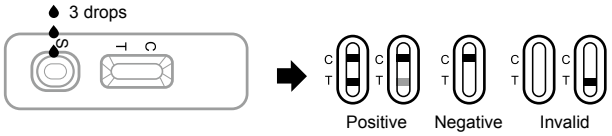
Use only the extraction buffer and tubes provided in the kit for swab specimen preparation.

3. Place the collected swab specimen into the extraction tube with the extraction buffer. Press the swab against the tube and rotate the swab for **10–15 seconds**. (See the procedure card for detailed information on Specimen Preparation.)
4. Remove the swab while squeezing the swab head against the inside of the extraction tube to get as much liquid as possible from the swab. Discard the swab. Fit the tube tip on top of the extraction tube.

*NOTE: The extracted specimen solution is stable for 2 hours at room temperature or 24 hours at 2…8°C. If extracted the specimen was stored at 2…8°C, allow it to reach the room temperature before testing.

Test Reaction

5. Remove the test cassette from the sealed foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
6. Invert the specimen extraction tube, add **3 drops** of extracted specimen (approx. 75–100µl) to the specimen well (S) and then start the timer.
7. Read the result in the test window **15 minutes** after sample application. Results should not be read after 20 minutes.



TEST INTERPRETATION

NEGATIVE: A negative specimen will have a single colored line in the control region (C) in the test window, indicating a negative result.
This control line means that the detection part of the test was done correctly, but no SARS-CoV-2 Antigen was detected.

POSITIVE: A positive specimen will have two colored lines. One colored line in the control region (C) and another colored line in test region (T).
This means that SARS-CoV-2 antigens were detected. Specimens with low levels of antigen may have a faint line. Any visible colored line in the test region (T) is considered a positive.

INVALID: If no control line is present, the test is invalid.
Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for a control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

TEST LIMITATIONS

1. The test is intended for direct swab specimens only. Viral Transport Media (VTM) should not be used with this test as it may cause false results.
2. When testing for detection of nucleocapsid protein SARS-CoV-2 antigens, it is imperative to that the provided procedure, results interpretation, and specimen collection be carefully followed for a valid test result. Deviating from these instructions may lead to erroneous results.
3. The performance of Aidian LF SARS-CoV-2 Ag Test was evaluated using the procedures provided in this instructions for use only. Modifications to these procedures may alter the performance of the test.
4. Neither the quantitative value nor the rate of increase in the concentration of SARS-CoV-2 antigens can be determined by this qualitative test.
5. Aidian LF SARS-CoV-2 Ag Test will only indicate the presence of SARS-CoV-2 antigens in the specimen and should not be used as the sole criteria for the diagnosis of COVID-19 infections.
6. If the test result is negative or non-reactive and clinical symptoms persist, it is recommended

to resample the patient and test again or test with a molecular diagnostic device to rule out infection in these individuals.

7. A negative test result may occur if the level of antigens in a sample is below the detection limit of the test or if the sample was collected improperly. The optimal sampling time (peak virus concentration) after infection has not been verified, so collecting samples at different times for the same patient may avoid false negatives.
8. The results obtained with the test should be considered with other clinical findings from other laboratory tests and evaluations.
9. Negative results do not rule out COVID-19 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.
10. Positive results for SARS-CoV-2 may be due to infection with non-SARS-CoV-2 coronavirus strains or other interference factors.

PERFORMANCE CHARACTERISTICS

1. Clinical performance

Clinical performance characteristic of Aidian LF SARS-CoV-2 Ag Test was evaluated with 423 swab specimens. RT-PCR was used as the reference method. The data is summarised in the table below:

Nasal swab specimen

Aidian LF SARS-CoV-2 Ag Test		RT-PCR (Nasopharyngeal swab)		Total
		Positive	Negative	
SARS-CoV-2 Antigen	Positive	115	2	117
	Negative	8	298	306
Total		123	300	423
Relative Sensitivity		115/123=93.5% (95%CI*: 87.6%~97.2%)		
Relative Specificity		298/300>99.3% (95%CI*: 97.6%~99.9%)		
Accuracy		413/423=97.6% (95%CI*: 95.7%~98.9%)		

*Confidence Intervals

2. Limit of Detection

Aidian LF SARS-CoV-2 Ag Test was confirmed to detect 100$TCID_{50}$/ml of SARS-CoV-2.

3. Cross Reactivity (Analytical Specificity) and Microbial Interference

The following viral strains were tested at concentrations in following table and all found to be negative when tested with Aidian LF SARS-CoV-2 Ag Test:

Test items		Test Concentration
Virus strain	Respiratory syncytial virus	8.89 x 10^4 $TCID_{50}$/ml
	Parainfluenza virus 3	1.58 x 10^8 $TCID_{50}$/ml
	Parainfluenza virus 2	1.58 x 10^7 $TCID_{50}$/ml
	Mumps virus	1.58 x 10^4 $TCID_{50}$/ml
	Measles virus	1.58 x 10^4 $TCID_{50}$/ml
	Influenza B	3.16 x 10^6 $TCID_{50}$/ml
	Influenza A H3N2	1 x 10^5 $TCID_{50}$/ml
	Influenza A H1N1	3.16 x 10^5 $TCID_{50}$/ml
	Human Rhinovirus 2	2.81 x 10^4 $TCID_{50}$/ml
	Human Rhinovirus 16	8.89 x 10^6 $TCID_{50}$/ml
	Human Rhinovirus 14	1.58 x 10^6 $TCID_{50}$/ml
	Human coronavirus OC43	1 x 10^6 $TCID_{50}$/ml
	Human coronavirus NL63	1x 10^6 $TCID_{50}$/ml
	Human coronavirus HKU1	1x 10^6 $TCID_{50}$/ml
	Human coronavirus 229E	5x 10^5 $TCID_{50}$/ml
	MERS coronavirus Florida	1.17x$10^4$$TCID_{50}$/ml
	Adenovirus type 7	1.58 x 10^5 $TCID_{50}$/ml
	Adenovirus type 3	3.16 x 10^4 $TCID_{50}$/ml
Bacteria	*Arcanobacterium*	1.0x10^8 org/ml
	Corynebacterium	1.0x10^8 org/ml
	Escherichia coli	1.0x10^8 org/ml
	Moraxella catarrhalis	1.0x10^8 org/ml
	Neisseria lactamica	1.0x10^8 org/ml
	Neisseria subflava	1.0x10^8 org/ml
	Pseudomonas aeruginosa	1.0x10^8 org/ml
	Staphylococcus aureus subspaureus	1.0x10^8 org/ml
	Staphylococcus epidermidis	1.0x10^8 org/ml
	Streptococcus pneumoniae	1.0x10^8 org/ml
	Streptococcus pygenes	1.0x10^8 org/ml
	Streptococcus salivarius	1.0x10^8 org/ml
	Streptococcus sp group F	1.0x10^8 org/ml
Yeast	*Candida albicans*	1.0x10^8 org/ml

$TCID_{50}$ = Tissue Culture Infectious Dose is the dilution of virus that under the conditions of the assay can be expected to infect 50% of the culture vessels inoculated.

4. Interference Substances

The following substances were evaluated and found to have no impact on Aidian LF SARS-CoV-2 Ag Test at the concentrations listed below.

Substance	Concentration
Whole Blood	20 µl/ml
Mucin	50 µg/ml
Budesonide Nasal Spray	200 µl/ml
Dexamethasone	0.8 mg/ml
Flunisolide	6.8 ng/ml
Mupirocin	12 mg/ml
Oxymetazoline	0.6 mg/ml
Phenylephrine	12 mg/ml
Rebetol	4.5 µg/ml
Relenza	282 ng/ml
Tamiflu	1.1 µg/ml
Tobramycin	2.43 mg/ml

5. Repeatability and Reproducibility

Within-run and Between-run precision has been determined by using three specimens of SARS-CoV-2 standard control. Three different lots of Aidian LF SARS-CoV-2 Ag Test have been tested using negative and two positive specimens. Ten replicates of each level were tested each day for 3 consecutive days. The specimens were correctly identified >99% of the time.

DISPOSAL

Dispose of contents according to national and local law.

- All patient samples, controls and used test components should be handled and disposed of as potentially infectious material.
- Paper: Instructions for use, part of the swab pouch
- Cardboard: Kit box, workstation and procedure card
- Plastic: Part of the swab pouch
- Several (not to be recycled): unused test cassettes, unopened tube with extraction buffer, unused swabs
- When used in accordance with Good Laboratory Practice, good occupational hygiene, and the instructions for use, the reagents supplied should not present a hazard to health.

BIBLIOGRAPHY

1. Westgard JO, Barry PL,Hunt MR, Groth T. A multi-rule Shewhart for quality control in clinical chemistry, Clinical Chemistry 1981;27:493-501

Explanation of symbols may be used on the products					
IVD	*In vitro* diagnostic medical device	Σ	Sufficient for		Do not reuse
	Temperature limitation		Use by	REF	Catalogue number
	Do not use if package is damaged	LOT	Batch code	STERILE EO	Sterilised using ethylene oxide
	Manufacturer		Consult Instructions For Use	EC REP	Authorised Representative in the European Community
	Do not resterilize		Importer		

Sterile swabs

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Touqiao Town, Guangling District,
Yangzhou, Jiangsu 225109 China

CE 0197

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CE 0143

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