ARISTA™ COVID-19 Antigen Rapid Test

Instructions for Use

For Professional Use Only
For In Vitro Diagnostic Use Only

V4 Effective date: 18-Mar-2021

Intended Use

The ARISTA™ COVID-19 antigen rapid test is for the qualitative in vitro detection of the SARS-CoV-2 virus nucleocapsid (N)-Protein antigen in the anterior nasal and in the nasopharyngeal swab provided directly by the patient who show COVID-19 symptoms or who are suspected of having COVID-19. The test is intended for use by healthcare professionals in the laboratory or at the point of care.

Principle of the Test

This test is developed using the lateral flow detection technology (LFD) to detect the nucleocapsid (N) protein, which coats the nucleic acid in the intact SARS-CoV-2 virus, in the test specimen. The test uses a pair of monoclonal antibodies that recognize two distinct structural region of the viral N-protein. One of the antibodies is conjugated with a colloidal gold tag and present in the sample well which will mix with the specimen when applied.

The second antibody is immobilized as a narrow band on the test strip along the "T" line to capture the N-protein, and if the N-protein is present, it will bind to the colloidal gold complex and will result in the formation of a colour band along the "T" line. Hence, in the absence of the N-protein, a colour band will not form along the "T" line.

As an internal control, an anti-antibody is immobilized on the "C" line to capture the colloidal gold complex to form a colour band on the "C" line. This is to confirm the correct operation of the test.

Materials Provided

Disposable swab | Dropper cap | Tube with diluent | Test cassette | Product Insert

Component	Quantity (in a Kit)	Description
Disposable Swab	1	Sterile swab for specimen collection
Dropper Cap	1	Transparent plastic cap to pierce the seal on the tube containing the diluent
Tube with Diluent	1	Extract viral protein from applied specimen
Test Cassette	1	Test device with detection anti-SARS-CoV-2 antibodies, sealed in foil pack
Product Insert	1	Instruction for Use

* Material required but not provided: hand sanitizer containing at least 60% alcohol, Personal Protective Equipment (PPE), pair of nitrile or latex gloves, timer.

Warning and Protection

- Do not use the product after the expiration date printed on the outer pack.
- This test is developed to detect the presence of the SARS-CoV-2 virus only and not for any other viruses or pathogens.
- Follow this "Instructions for Use" for optimal performance of this test.
- Follow standard precautions when handling specimens, using the product and disposing of used materials.
- Only open the foil pack immediately before use. Do not use if it is damaged or has been exposed to environmental conditions outside of those specified. The test cassette is sensitive to humidity and heat.
- Only use the swab and diluent solution provided. Do not use the diluent if it is discolored or turbid.
- Do not reuse any materials or components.
- The test should be performed at 15°C to 30°C (59°F to 86°F).

Storage and Stability

The ARISTA™ COVID-19 Antigen Rapid Test should be stored between 3°C to 30°C (37°F to 86°F), away from direct sunlight. The product is stable until the expiration date indicated on the outer package.

Quality Control

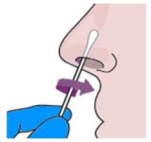
There are two types of quality controls available for the ARISTA™ COVID-19 Antigen Rapid Test (i) internal built-in procedural controls; and (ii) external positive and negative controls.

For internal procedural controls, regardless of whether or not there is SARS-CoV-2 antigen present in the specimen, a colour band will appear at the quality control "C" line to confirm whether the detection processing is normal.

External positive and negative controls are available for laboratory use and are not included in this product package. If required, please contact info@aristabio.com.

Methods for Sample Collection

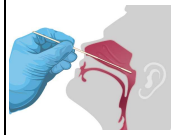
I. Anterior nares nasal swab specimen



1. Thoroughly sanitize your hands .
2. Remove the sterile swab from the peel-pack being careful to avoid contacting the tip with any foreign surface.
3. Insert the swab tip no more than 1.5cm (3/4 of an inch) into your nostril.
4. Slowly rotate the swab in a circular path against inside of your nostril at least 4 times for a total of 15 seconds. Be sure to collect any nasal drainage that may be present on the swab.
5. Using the same swab, repeat steps 3-4 in the other nostril.

Continue to "**Conducting the test**"

II. Nasopharyngeal swab specimen



1. Thoroughly sanitize your hands.
2. Tilt the patient's head back 70 degrees.
3. Remove the sterile swab stick from the peel-pack being careful to avoid contacting the tip with any foreign surface.
4. Gently and slowly insert the swab through the nostril parallel to the palate until resistance is encountered.
5. Gently rub and roll the swab, leaving it in place for several seconds to absorb secretions. If a deviated septum or blockage creates difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.
6. Slowly remove swab while rotating it.

Continue to "**Conducting the test**"

Sample Transportation and Storage

It is recommended to test the specimen as soon as possible. If immediate testing is not possible, store the diluted specimen in the provided dropper tube at room temperature 15°C to 25°C (59°F to 77°F) for up to 24 hours, or refrigerated at 2°C to 8°C (36°F to 46°F) for up to 48 hours.

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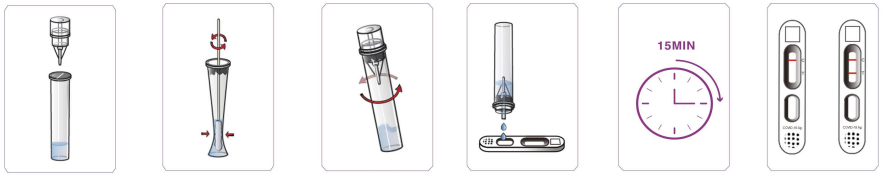
Refrigerated specimens should be returned to room temperature prior to testing. Specimens stored in corresponding conditions beyond the time limit should be disposed, and a new sample should be collected for testing.

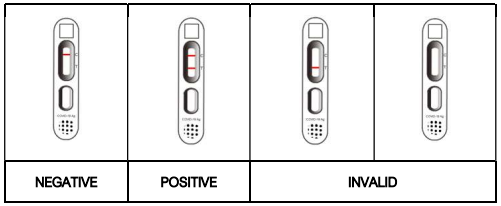
For specimen requiring to be stored in VTM for transportation, please enquire at info@aristabio.com.

Conducting the Test



1. Equilibrate the specimen and the test kit components to room temperature.
2. Pierce the seal of the tube containing the diluent by pushing the pointed dropper cap onto the tube seal.
3. Remove the dropper cap and place it upright on the workbench with the protective top facing down.
4. Insert the swab stick into the diluent inside the tube and rinse it in the solution for 30 seconds with a turning motion. Squeeze the tube and stir the swab for 5 times.
5. Squeeze the tube whilst removing the swab stick from the tube. Dispose the used swab safely.
6. Replace the dropper cap back onto the tube with diluent. Mix the tube gently by shaking for 5 seconds.
7. Remove the protective top from the dropper cap, invert the dropper tube containing the specimen, squeeze and discard 2 drops of specimen into cap. Then squeeze 3 drops of remainder specimen into the sample well on the test cassette.
8. Wait for 15 minutes.
9. Read and record your result immediately.
10. Dispose all materials in a plastic bag and sanitize your hands thoroughly.

Interpretating the Test Result



1. The “T” line detects the presence of the SARS-CoV-2 antigen. The “C” line is an internal control to confirm that the test is valid.
2. Negative result: if the “T” line is blank and the “C” line displays a visible colour band, then the test result is negative.
3. Positive result: if both the “T” line and “C” line display visible colour bands, then the test result is positive.
4. Invalid result: if the “C” line is blank, then the test result is invalid.

Note: After 30 minutes, test results are no longer considered valid.

Troubleshooting

It is important to read the Instructions for Use before beginning the test operation. Troubleshooting steps are as follows:

Conditions	Troubleshooting methods
Delay in reading test results beyond 30 minutes	Repeat the test.
Faint or missing colour band on the “C” line	Check if the right number of drops is added to the sample well; Check if the test cassette is placed on an even surface; Check if test is conducted within the recommended 15°C to 30°C room temperature range. Make the corrections where necessary. Repeat the test.
Other significant disturbances during operation such as dropping the cassette after activation	Repeat the test.

Clinical Performance

The performance of the ARISTA™ COVID-19 Rapid Antigen Test was determined using 500 nasophayngeal swabs and 500 anterior nasal swabs. 364 negative and 136 positive samples were identified using RT-PCR.

The 500 swab samples were blindly tested one after the other and the results compared with the RT-PCR results.

Table 1 Performance summary of the Antigen Rapid Test and RT-PCR test on the detection of SARS-CoV-2 in study specimens

ARISTA™ COVID-19 Antigen Rapid Test (Anterior nasal swab)	Reference PCR Results			ARISTA™ COVID-19 Antigen Rapid Test (NP swab)	Reference PCR Results		
	POS	NEG	Total		POS	NEG	Total
POS	112	1	113	POS	131	1	132
NEG	24	363	387	NEG	5	363	368
Total	136	364	500	Total	136	364	500
PPA	82.35%	Estimated Sensitivity = 82.35% (95% CI: 74.68% to 88.15%) Estimated Specificity =99.73 % (95% CI: 98.24% to 99.99%)		PPA	96.32%	Estimated Sensitivity = 96.32% (95% CI: 91.19% to 98.64%) Estimated Specificity =99.73% (95% CI: 98.24% to 99.99%)	
NPA	99.73%			NPA	99.73%		
PPV	99.12%			PPV	99.24%		
NPV	93.80%			NPV	98.64%		
Overall agreement percent		95.00%		Overall agreement percent		98.80%	

Analytical Performance

I. Limit of Detection (Analytical Sensitivity)

The limit of detection (LoD) of the ARISTA™ COVID-19 Antigen Rapid Test was established using serial dilutions of concentrated inactivated virus samples. The specimens were diluted with the prescribed diluent in triplicate. Each series of diluted specimen was evaluated with twenty separate test cassettes. The LoD was determined as the lowest virus concentration that was detected equal to or greater than 95% of the time (i.e., the concentration at which at least 19 out of 20 replicates tested positive).

The results indicate that the LoD for the ARISTA™ COVID-19 Antigen Rapid Test is $TCID_{50}$ value of 100/mL.

II. Cross Reactivity (Analytical Specificity)

Cross reactivity of ARISTA™ COVID-19 Antigen Rapid Test was evaluated by testing a panel of high prevalence respiratory pathogens that could potentially cross-react with the test cassette. Each organism and virus sample were tested in triplicate.

No cross-reactivity or interference was observed with the following microorganisms when tested at the concentration presented in the table below.

Table 2 Potential cross-reactants

Virus number	Virus	Type	Concentration
1	Adenovirus	Type 1	1 x 105 PFU/mL
2	Coronavirus	229e	1 x 105 PFU/mL
3	Coronavirus	OC43	3 x 105 TCID50/mL
4	Coronavirus	NL63	5 x 104 PFU/mL
5	MERS-CoV	-	1.2x 105 TCID50/mL
6	Mycoplasma pneumonia	M129	3 x 106 CCU/mL
7	Influenza A H3N22	-	1 x 105 PFU/mL
8	Influenza A H1N1	-	1 x 105 PFU/ mL
9	Influenza B	-	1 x 105 PFU/mL
10	Parainfluenza virus	Type 1	1 x 105 PFU/mL
11	Parainfluenza virus	Type 2	1 x 105 PFU/mL
12	Parainfluenza virus	Type 3	6x 105 TCID50/mL
13	Parainfluenza virus	Type 4b	1 x 105 PFU/mL
14	Enterovirus	Type 68	1 x 105 PFU/mL
15	Respiratory syncytial virus	Type A	1 x 105 PFU/mL
16	Rhinovirus	Type 1A	1 x 105 PFU/mL
17	Coronavirus	HKU	1 x 105 PFU/mL
18	Chlamydia pneumoniae		1 x 106 PFU/mL
19	Measles	-	1 x 105 PFU/mL
20	EBV	-	1 x 105 PFU/mL
21	SARS-CoV-1 N protein	-	10 ng/mL
22	Bacillus pertussis		1 x 106 CFU/mL
23	Haemophilus influenzae		1 x 106 CFU/mL
24	Non-toxic Mycobacterium tuberculosis		1 x 106 CFU/mL

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25	Staphylococcus aureus		1 x 106 CFU/mL
26	Staphylococcus epidermis		1 x 106 CFU/mL
27	Streptococcus pneumoniae		1 x 106 CFU/mL
28	Streptocossus pyogenes		1 x 106 CFU/mL

III. High Dose Hook Effect

No high dose hook effect was observed up to a concentration of 3 x 10^5 $TCID_{50}$/mL of inactivated SARS-CoV-2 virus or N-protein concentration of 1.23ng/mL with the ARISTA™ COVID-19 Antigen Rapid Test.

IV. Endogenous Interfering Substances

A series of substances were evaluated with the ARISTA™ COVID-19 Antigen Rapid Test at the concentrations listed below. No testing substance was found to interfere with the test performance.

Table 3 Potential interfering substances

Name	Recommended concentration	Solvent	20 × concentration
Mucin	200 ng/mL	PBS	4000 ng/mL
Interferon α – 2b	300U/mL	PBS	6000U/mL
lopinavir	33μg/mL	PBS	660μg/mL
Ritonavir	3μg/mL	PBS	60μg/mL
Levofloxacin	10ug/mL	PBS	200ug/mL
Azithromycin	3μg/mL	PBS	60μg/mL
Cefatriaxone	3μg/mL	Methanol	60μg/mL
Tobramycin	10ug/mL	PBS	200ug/mL
Histamine hydrochloride	3μg/mL	PBS	60μg/mL
Phenylephrine	3μg/mL	PBS	60μg/mL
Oxazoline	3μg/mL	PBS	60μg/mL
Sodium chloride (including preservatives)	30ug/mL	PBS solution	600ug/mL
Beclomethasone	30ug/mL	Methanol	600ug/mL
Dexamethasone	30ug/mL	Methanol	600ug/mL
Fluconazole	30ug/mL	Methanol	600ug/mL
Blood	-	-	Stock solution
Fluticasone	24μg/mL	Methanol	480ug/mL
Benzocaine	1.5mg/mL	Ethanol	30mg/mL
Menthol	180μg/mL	Ethanol	3.6mg/mL
Phenyephrine	75μg/mL	Ethanol	150μg/mL
Mupirocin	30μg/mL	Methanol	600μg/mL
Oseltamivir phosphate	1.8μg/mL	PBS solution	39μg/mL
Cromolyn sodium salt	12ng/mL	PBS solution	240ng/mL

Limitations

1. This product can only be used for the qualitative detection of the N-protein antigen of the SARS-CoV-2 virus.
2. This kit is able to detect the nucleocapsid protein from the B.1.1.7 SARS-COV-2 variant. The effect of other emerging SARS-CoV-2 variants on the product's performance would be evaluated and results available on request.
3. The test results should only be interpreted as explained in this Instruction for Use. Results from this product should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
4. A negative test result does not rule out the possibility of a SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions. Further diagnostic procedures including nucleic acid tests are recommended.
5. A positive test result indicates the presence of viral antigens but does not rule out co-infection with other pathogens. The agent detected may not be the definite cause of disease. Clinical correlation with patient history and other diagnostic information is necessary to determine infection status.
6. Test performance was evaluated as described in this Instruction for Use only and has not been validated with large-scale clinical trials.

Ordering information

ARISTA-AG-SBEN-001: ARISTA™ COVID-19 Antigen Rapid Test (1 test in single pack)

ARISTA-AG-BPEN-020: ARISTA™ COVID-19 Antigen Rapid Test (20 tests in aggregate pack)

ARISTA-AG-BPEN-200: ARISTA™ COVID-19 Antigen Rapid Test (200 tests bulk pack)

Symbols

	Medical device manufacturer	REF	Catalog number
EC REP	Authorized Representative in the European Community /European Union		Do not re-use
	Consult instructions for use or consult electronic instructions for use		Use-by-date
CE	CE Marking	LOT	Batch code
IVD	*In vitro* diagnostic medical	STERILE EO	Sterilized using ethylene oxide
	Temperature limit	Σ	Contains sufficient for <n> tests
	Keep away from sunlight		Do not use the swab if the packaging is damaged

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