Ainos SARS-CoV-2 Antigen Rapid Test Kit IFU for In Vitro Diagnostic Medical Device

For use by trained physicians and medical examiners only

Information of Pharmaceutical Manufacturer and Medical Device Company

Indicating the names and addresses of pharmaceutical manufacturer and Medical Device Company, and shall be consistent with those in the license.

Model: C1925A
Product Name: Ainos SARS-CoV-2 Antigen Rapid Test Kit
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1. Performance

The Ainos SARS-CoV-2 Antigen Rapid Test Kit is an immunochromatographic assay used for the qualitative detection of SARS-CoV-2 NP (nucleocapsid protein) antigen from nasopharyngeal swab specimens. Results of this assay may provide physicians as auxiliary reference to monitor patient's conditions. During the acute phase of infection, the antigen can normally be detected in specimens collected from upper respiratory tract. Positive results indicate the presence of virus, but do not rule out bacterial infection or co-infection with other viruses. If you have tested positive, please take further tests as sooner as possible.

The Ainos SARS-CoV-2 Antigen Rapid Test Kit is used for the qualitative detection of nucleocapsid protein from SARS-CoV-2 in nasopharyngeal swab specimens directly collected from individuals. According to the World Health Organization (WHO), currently there are 14 common symptoms of COVID-19, including fever, dry cough, tiredness, phlegm, shortness of breath, muscle soreness or achy joints, sore throat, headache, chills, nausea or vomiting, nasal congestion, diarrhea, hemoptysis and conjunctivitis (Ref:2020/08).

2. Method and Principle

The Ainos SARS-CoV-2 Antigen Rapid Test Kit is a lateral flow immunoassay technique used for qualitative analysis. After the nasopharyngeal specimen collection, place the sterile flocked collection swab contained respiratory mucosa into the Extraction Buffer. Twist the handle to rotate the swab 10 times and leave it in place for 1-2 minute. Then transfer 100 uL of extraction buffer contained specimen with a pipette to the specimen well of rapid test kit. The detection results are based on a visual readout. Red line(s) in the result window shall be visible in 15 minutes. Do not read the results after 20 minutes.

3. Specimen Collection and Processing

It is required to make sure the nasal cavity is clean by removing any foreign objects or other blockages such as nasal mucus or booger from nostrils prior to the collection of specimen. Please carefully insert the sterile flocked collection swab through one of the nostrils. Keep the swab near the septum floor of the nose while gently pushing the swab into the posterior nasopharynx. Rotate the swab 3~5 times against the nasal wall and gently remove from nostril. Open the bottle of Extraction Buffer and insert the Sterile Flocked Collection Swab until the tip is at the bottom of the bottle. Then twist the swab handle to rotate the tip 10 times, break off the shaft and close the bottle cap. The specimen is stable to be used immediately and directly without storage. The remaining specimens should be destroyed by the hospital.

4. Packaging and Kit Components

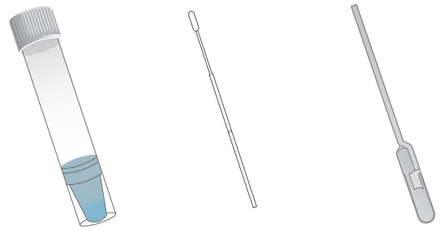
- Ainos SARS-CoV-2 Antigen Rapid Test Kit – 25 units
- Extraction Buffer - 25 bottles
- Sterile Flocked Collection Swab – 25 pieces
- Detection Dropper – 25 pieces
- User Manual – 1 sheet

5. Procedure

Step. 1

Open the package to check all the following kit components are included prior to the test.

Ainos SARS-CoV-2 Antigen Rapid Test Kit and a desiccant bag.



One bottle with Extraction Buffer | One Sterile Flocked Collection Swab | One Detection Dropper

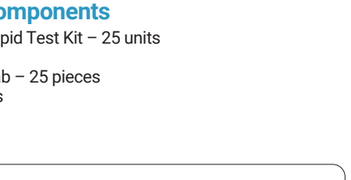
Step. 2

Take the Ainos SARS-CoV-2 Antigen Rapid Test Kit out of the foil pack.

Ainos SARS-CoV-2 Antigen Rapid Test Kit

Step. 3

Collect nasopharyngeal (NP) specimen with sterile flocked collection swab. After the sample is taken, carefully observe whether there is mucus present on the swab. If not, please re-collect.



Step. 4

Open the bottle of Extraction Buffer

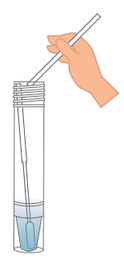
Step. 5

Insert the Sterile Flocked Collection Swab contained specimen into the Extraction Buffer. Rotate the swab tip by twisting the handle 10 times to mix with the Extraction Buffer.

Rotate the swab back and forth 10 times
Leave the swab tip in place for 1-2 minute

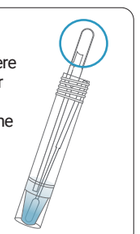
Step. 6

Break off the shaft and tightly close the cap. Leave the bottle for 1-2 minute.



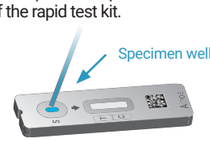
Step. 7

After confirming there is no air in the upper soft bulb section, draw solution into the detection dropper.



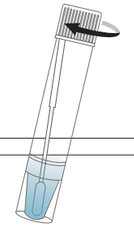
Step. 8

Add 4 drops of solution (around 100 uL) into the specimen well of the rapid test kit.



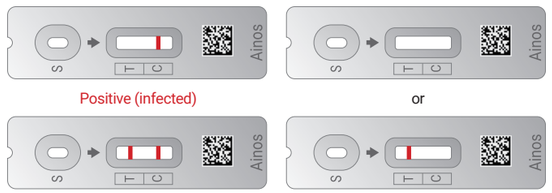
Step. 9

Recap the bottle and discard the excess solution remaining in the bottle properly in accordance with hospital guidance.



Step. 10

Interpretation of results



6. Rapid Test Transportation and Storage

Please store the Ainos SARS-CoV-2 Antigen Rapid Test Kit at 15-30° C. An expiration date is imprinted on both outer packaging and container of the Ainos SARS-CoV-2 Antigen Rapid Test Kit. Make sure that all kit components are at room temperature before use.

7. Precautions

- This assay reagent has been authorized only for the detection of proteins in SARS-CoV-2, not for any other viruses or pathogens.
- Negative results do not rule out other non-SARS viral or bacterial infections.
- Improper collection, storage and transportation of specimens may lead to erroneous test results. A negative result does not exclude the possibility of SARS-CoV-2 infection
- Like many molecular tests, the Ainos SARS-CoV-2 Antigen Rapid Test Kit is typically highly specific for the SARS-CoV-2 virus. However, false-negative results may occur with any type of tests, especially in areas with very low prevalence, and it needs to be carefully evaluated.
- A false-negative result may be given if the level of antigen in a sample is lower than detection limits or the specimen is collected and handled improperly. Therefore, a negative result does not exclude the possibility of SARS-CoV-2 infection.
- The Ainos SARS-CoV-2 Antigen Rapid Test Kit has not been evaluated in patients without respiratory tract infection symptoms. Performance of this assay may differ in asymptomatic individuals.
- As the disease course, the amount of antigens in the specimen may decline over time. Comparing with the molecular test, the specimen collected >5 days after the symptom onset may show a false-negative result.
- Further tests may require if certain strain of SARS virus needs to be identified.
- Appropriate precautions should always be followed while collecting, processing, storing and disposing patient specimen and the used kit components. When handling patient specimen, the use of nitrile, latex gloves (or other appropriate type of protective gloves) and medical-grade face mask are recommended.
- Do not reuse kit components (Ainos SARS-CoV-2 Antigen Rapid Test Kit, Detection Dropper, Sterile Flocked Collection Swab and Extraction Buffer).
- Do not open the foil pack of rapid test kit and expose it to the ambient environment until the kit is ready for immediate use.
- Do not use any defective test kit or components. If the Extraction Buffer comes into contact with the skin or eyes, please rinse immediately with plenty of water.
- To obtain accurate results, the Instructions for Use must be followed.
- Improper collection, storage and transportation of specimens may lead to erroneous test results.
- Specimen collection and processing require specialized training and instructions.
- The specimen is stable to be used immediately and directly without storage. The remaining specimens should be destroyed by the hospital.
- In order to get an accurate result, please use the recommended Extraction Buffer provided in the package.
- When collecting the NP specimen, please use the sterile flocked collection swab included in this kit.
- Disposal of all containers and unused materials must be in accordance with applicable regulations.
- Appropriate protective clothing, gloves and eye/facial protective items should be worn whenever handling the kit components. Wash hands thoroughly after handling specimens.
- Do not use the kit if package is damaged before opening.

8. Performance Evaluation

8.1 Limit of Detection

After adding the SARS-CoV-2 virus into the extraction buffer, dilute the sequence two times in the clinical matrix. Determine the lowest concentration in each dilution, and add the Ainos SARS-CoV-2 Antigen Rapid Test Kit into solution of the lowest concentration mixed with clinical matrix for result interpretation within 15 minutes.

Item	Minimum Detectable Concentration	Detection Rate(%)
1	1.565*10² $TCID_{50}$/mL	100%

8.2 Specificity and Cross-Reactivity

For pathogens that are homologous or may have similar antigens or are likely to cause similar clinical symptoms, the evaluation of possible cross-reactivity and potential interferences that may exist in the nasal cavity has be conducted. The common pathogenic microorganisms are listed in the following table. This assay has passed 8 types of virus and 11 types of bacteria tests.

Analytical Specificity and Cross-Reactivity		Concentration Tested
Virus	HCoV-229E	1.0 x 10^5 $TCID_{50}$/mL
	HCoV-OC43	1.0 x 10^5 $TCID_{50}$/mL
	FluA (A/California/07/2009)	10^5 pfu/mL
	FluB (B/Taiwan/81863/2014)	10^5 pfu/mL
	Parainfluenza-3 virus	10^5 pfu/mL
	Respiratory syncytial virus typeA	10^5 pfu/mL
	Rhinovirus	10^5 pfu/mL
	Adenovirus Type7	10^5 pfu/mL

Analytical Specificity and Cross-Reactivity		Concentration Tested
Bacteria	Acinetobacter calcoaceticus baumannii complex	>10^6 cfu/mL
	Escherichia coli	>10^6 cfu/mL
	Klebsiella pneumoniae group	>10^6 cfu/mL
	Pseudomonas aeruginosa	>10^6 cfu/mL
	Staphylococcus aureus	>10^6 cfu/mL
	Streptococcus pneumoniae	>10^7 cfu/mL
	Streptococcus pyogenes	>10^7 cfu/mL
	Haemophilus influenzae	>10^6 cfu/mL
	Neisseria meningitidis	>10^6 cfu/mL
	Bordetella pertussis	>10^6 cfu/mL
	Legionella spp	>10^6 cfu/mL

8.3 Analytical Specificity and Interference

The following substances are naturally present in the specimens from respiratory tract or may be artificially produced. The evaluation of the Ainos SARS-CoV-2 Antigen Rapid Test Kit to intranasal or intra nasopharyngeal medications has been conducted. It is found that these 8 medications and their concentrations listed in the following table do not interfere with the Ainos SARS-CoV-2 Antigen Rapid Test Kit.

Item	Medication Name	Concentration Tested
1	Oxymetazoline HCl	0.15 mg/mL
2	Tobramycine	3 µg/mL
3	Mucin: Bovine submaxillary glands	100 µg/mL
4	Biotin	100 µg/mL
5	Olopatadine Hydrochloride (OLOP)	10 mg/mL
6	Cromolyn sodium salt (Crom)	20 mg/mL
7	Oseltamivir phosphate (Ose)	10 mg/mL
8	Zanamivir (Zana)	5 mg/mL

8.4 Clinical Assessment

Clinical assessment of the Ainos SARS-CoV-2 Antigen Rapid Test Kit has been determined by 120 negative cases and 31 positive cases with COVID-19 symptoms. the collection of sterile flocked collection swab specimens was conducted in accordance with the Instructions for Use, and all the specimen were collecting and processing directly by medical technologists. The clinical assessment based on results analysis was compared with the results obtained by RT-PCR (Roche cobas® SARS-CoV-2). The results of both test methods show sensitivity of 97% and specificity of 100%.

9. Symbol list

CE marking	In vitro diagnostic medical device	Contains sufficient for <n> tests
Keep away from sunlight	Keep dry	Temperature limit
Do not re-use	Consult instructions for use	Caution
Date of manufacture	Use-by date	Batch code
Serial number		