

REF

AKIT-ABC-01

ABC Antigen Test for Flu A, Flu B, and COVID-19 - Instructions For Use (IFU)

For in vitro diagnostic use only.

Sample Collection Method

Nasal

Intended Use

The assaya ABC Flu & COVID-19 Antigen Rapid Test is a rapid in vitro immunochromatographic assay intended for the qualitative detection of antigens from influenza type A, type B and SARS-CoV-2 viruses in nasal secretion from individuals within the first five days of the onset of symptoms. Antigens from influenza type A, type B and SARS-CoV-2 viruses is generally detectable in upper respiratory samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results are presumptive, and confirmation with a molecular assay, if necessary, for patient management may be performed. Negative results do not rule out influenza type A, type B and SARS-CoV-2 virus infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms. The assaya ABC Flu & COVID-19 Antigen Rapid Test is intended for use by medical professionals or trained operators who are proficient in performing tests and trained clinical laboratory personnel.

Materials

Each box contains 50 test kits. Each test kit contains:

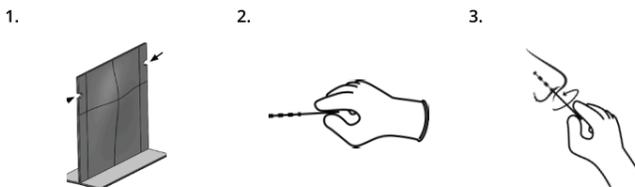
- 1 SWAC – Sterile Wood Abrasive Collector
- 1 Spacket : Containing Reagent – Sodium Azide(<0.1%); Sodium Hydroxide(<0.5%); Albumin Bovine Serum(<1%)
- 1 Test Indicator

Storage And Disposal

The product should be stored at 15-30 °C. Do not refrigerate or freeze. Keep away from direct sunlight. Do not freeze or overheat the test kit or kit reagents. Kit contents are stable until the expiration date printed on the outer box. The indicators must be kept in the foil pouch until use.

Sample Preparation

Before use, check the expiration date of the packaging. If the kit is past its expiration date, do not use. Confirm that all components needed are in the kit.

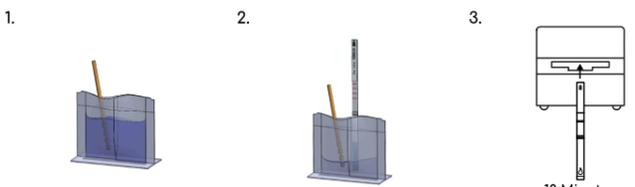


Stand up the Spacket, and tear it open. Be careful not to spill the liquid reagent inside.

Obtain the sterile SWAC. Make sure the SWAC head does not touch anything until sample collection.

Insert the SWAC into the nostril that presents the most secretions under visual inspection. Keep the SWAC near the septum floor of the nose in the nasal anterior. Rotate the SWAC 5 times in each nostril.

Assay Procedure

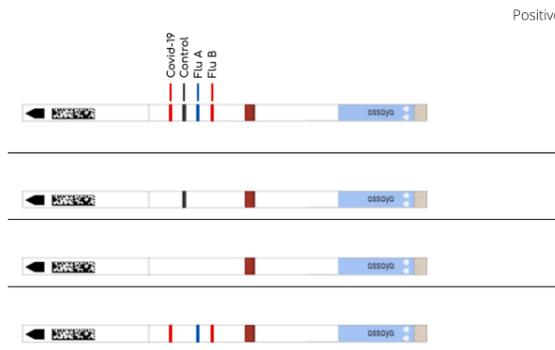


Put the SWAC into the Spacket. Roll the SWAC 5 times. Leave the SWAC in the Spacket for 1 minute before inserting the test indicator.

While the SWAC remains in the Spacket, place the test indicator into the Spacket with the droplets going down. Leave the test indicator in the Spacket for 10 minutes. Use the assaya timerDx to keep track of the test time.

Take out the test indicator and read the result at 10 minutes. Do not read the result after 20 minutes. To confirm the result, the test indicator may also be read by the intelligent analyzer eXpress (iaX-2101) after 10 minutes.

Result Interpretation



Positive Results

At 10 minutes, the appearance of the Control Line and ANY shade of Test Line (Flu A the Test Indicator, indicates a positive result for the presence of Influenza type A, B, viral antigen.

Please refer to the Indicator Line Legend to interpret the test lines.

Negative Results

After 10 minutes, if only Control Line area shows a line, it means a negative result. A indicates that the presence of influenza type A, influenza type B, and/or SARS-CoV-2 negative in the specimen, or the antigen level is below the detection limit.

Invalid Results

If after 10 minutes, the Control Line does not appear, even if any Test Line appears, considered invalid. When invalid, a new test must be performed with a freshly collect sample.

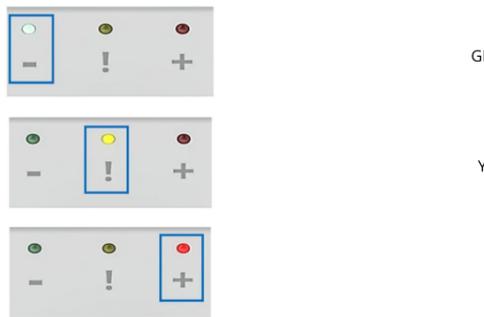
Internal Controls

Two internal procedural controls are needed to confirm correct assay procedure and components. One of two is a line appearing in the "Control Line" area in every run or validity of the test. Another one is a clear background serving as an internal negative background color should be white and not interfere with the reading of the test.

Result Interpretation with the iaX-2101

Please refer to the full iaX-2101 Instructions for Use for complete instructions on how to place the test indicator into the iaX-2101, with the barcode pointing in.

- A Green (-) indicates a negative result for the presences of influenza type A, SARS-CoV-2 viral antigen or that the antigen level is below the detection limit.
- A Yellow (!) indicates that the test is invalid and a new test must be performed collected specimen sample.
- A Red (+) indicates a positive result for the presence of Influenza type A, B and antigen.



Warnings & Precautions

1. This product is for in vitro diagnostic use only.
2. This product has been authorized only for the detection of antigen from influenza type A, type B and SARS-CoV-2 viruses, not for any other viruses or pathogens.
3. To obtain accurate results, follow the instruction for use.
4. Check the expiration date, integrity of package and test indicator pouch before use. Do not use if components beyond the expiration date or package damage.
5. Do not reuse kit components and interchange or mix different lots of tests.
6. Do not insert the test indicator directly into the nasal area.
7. Inappropriate specimen collection, storage, and transport may yield false test results.
8. Use of protective tools is recommended when collecting, handling, storing, and disposing of the components within process.
9. For optimal test performance, use the nasal Sterile Wood Abrasive Collector (SWAC) supplied in the kit. Using swabs other than provided in the kit may lead to incorrect results.
10. Seek specific training or guidance if you are not experienced with specimen collection and handling procedures.
11. Disregard test results beyond 20 minutes.
12. Test is recommended to be performed in a laminar flow hood or in open areas with air flow.
13. Reagents contain sodium azide, which is harmful if inhaled, swallowed or exposed to the skin. Sodium azide will produce very toxic gas when contacting with acids and may react with lead and copper plumbing to form highly explosive metal azides. If the extraction buffer contacts the skin or eyes, flush with copious amounts of water.
14. For additional information on hazard symbols, safety, handling, and disposal of the components of this product, please refer to the Material Safety Data Sheet (MSDS) available at Vstrip official website.

Product Limitations

1. The contents of this kit are to be used for the qualitative detection of Flu A, Flu B, & SARS-CoV-2 antigen by nasal Sterile Wood Abrasive Collector (SWAC). For quantitative detection of the assay, use the iaX-2101. Please refer to the iaX-2101 IFU for full instructions on using the iaX-2101.
2. Positive test results do not rule out co-infections with other pathogens.
3. The amount of antigen in a sample may decrease as the duration of illness increases. Negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
4. Negative test result do not rule out influenza type A, type B and SARS-CoV-2 viral infections. Negative results should be confirmed by molecular test.
5. Antibodies may fail to detect, or detect with less sensitivity, when influenza type A, type B or SARS-CoV-2 viruses that have undergone minor amino acid changes in the target epitope region.

Limit of Detection (LoD)

The limit of detection (LoD) for the assaya ABC Flu & COVID-19 Antigen Rapid Test was established in an analytical sensitivity study performed in clinical nasal matrix. The LoD concentrations identified for each strain tested are listed in the table below.

Viruses	Strain	LoD
1. Flu A	A/TW/121/2017 (H1N1)	6.96x10 ⁴ TCID50/mL
2. Flu B	B/TW/2872/17 (VIC)	1.28x10 ⁴ TCID50/mL
3. SARS-CoV-2	gamma-inactivated SARS-CoV-2 (USA-WA1/2020, NR-52287)	2.8x10 ⁴ TCID50/mL

Interference

Nasal spray products and common chemicals were evaluated and did not interfere with the assaya ABC Flu & COVID-19 Antigen Rapid Test in clinical nasal matrix at the levels tested below.

Interference Substances	Testing Conc.	Interference Substances	Testing Conc.
1. Afrin (Oxymetazoline)	15w/v	15. Magnesium	10mg/ml
2. Aspirin	20mg/ml	16. Nasal Ointment	10%
3. Chloraseptic(Menthol/Benzocaine)	1.5mg/ml	17. Nasal Washing Salt	20mg/ml
4. CVS Nasal Drops (Phenylephrine)	15w/v	18. NASONEX Aqueous Nasal Spray	10%
5. CVS Saline Nasal Spray	15w/v	19. Oxymetazoline HCl	10mg/ml
6. Dextromethorphan	10mg/ml	20. Phenylephrine HCl	100mg/ml
7. Diphenhydramine HCl	5mg/ml	21. Porcelan	20mg/ml
8. Fishermans Friend	1.5mg/ml	22. Bicola (Menthol)	1.5mg/ml
9. Fluocastone Propionate	3% v/v	23. Sore Throat Phenol Spray	15w/v
10. Hemogglader	20mg/ml	24. Serrin Nasal Spray	10%
11. Homeopathic (Akalut)	1:10 dilution	25. Tamiflu (Oseltamivir Phosphate)	5mg/ml
12. Hosson Troches (ROOT)	20mg/ml	26. Tobramycin	4ug/ml
13. Ibuprofen	20mg/ml	27. Whole Blood	4%
14. Mucin	0.5%	28. Zicam	5w/v

Cross Reactivity

The cross-reactivity of assaya ABC Flu & COVID-19 Antigen Rapid Test was performed on the positive and negative clinical matrix containing high levels of non-target microorganisms. Bacteria was tested at a target concentration between 106 and 1010 cfu/mL and viruses were tested at concentrations between 105 and 108 TCID50/mL (or pfu/mL). Each was tested in triplicate in the absence or presence of 2xLoD of gamma inactivated SARS-CoV-2. No cross-reactivity or interference was seen when tested at the potentially interfering concentrations. The bacteria and viruses tested were listed in the below Table.

Bacteria Panel			
1	Bifidobacterium pertusis	5	Haemophilus influenzae
2	Candida albicans	6	Mycobacterium pneumoniae
3	Chlamydia pneumoniae	7	Pseudomonas aeruginosa
4	Escherichia coli	8	Staphylococcus aureus
5	Staphylococcus epidermidis	9	Staphylococcus pneumoniae
6	Streptococcus pneumoniae	10	Streptococcus pyogenes
7	Legionella pneumophila	11	
8		12	
Viral Panel			
1	Adenovirus type 7	7	Enterovirus (EV71)
2	Adenovirus type 41	8	Human Parainfluenza Virus (HPV) Type 1*
3	Human Metapneumovirus (hMPV2) type 1	9	Human Parainfluenza Virus (HPV) Type II*
4	Human coronavirus 229E*	10	Human Parainfluenza Virus (HPV) Type III*
5	Human coronavirus OC43*	11	Human Parainfluenza Virus (HPV) Type IV*
6	Enterovirus type 68	12	Respiratory syncytial virus (RSV) group B*

References

1. Murphy B.R. and Webster R.G., 1996, Orthomyxoviruses, pp. 1397–1445. In: Fie edition, B.N. Fields, D.M. Knipe, P.M.Howley, et al. (eds.), Lippincott-Raven, Phil.
2. Chen N, Zhou M, Dong X, Qu J, Gong F, Han Y, et al. (15 February 2020). "Epider characteristics of 99 cases of 2019 novel coronavirus pneumonia in Wuhan, Ch study". The Lancet. 395 (10223): 507–513.
3. Wu C, Liu Y, Yang Y, Zhang P, Zhong W, Wang Y, et al. (February 2020). "Analysis targets for SARS-CoV-2 and discovery of potential drugs by computational metl Pharmaceutica Sinica B. doi:10.1016.
4. "How to Protect Yourself & Others". Centers for Disease Control and Preventio Archived from the original on 26 February 2020. Retrieved 9 April 2020.
5. Biosafety in Microbiological and Biomedical Laboratories, 5th Edition. U.S. Dep Human Services, CDC, NIH, Washington, DC (2007).

Technical Support

Email: support@assaya.com (mailto:support@assaya.com)

Adverse Events Reporting

Use this link to report any adverse events: assaya.com/ae (https://assaya.com/ae)

Ordering Information

Catalog Number (REF): AKIT-ABC-01
50 pcs per box (Carton of 50 test kits)

Symbol Legend



Catalog Number



Consult Package Insert



Batch Code



Manufacturer



In Vitro Diagnostic Medical Device



Temperature Limit

Contains su

Contains su

Do not use if and consi

Manufacturers

IVD



Panion & BF Biotech Inc. Xizhi Factory
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New Taipei City 22146 Taiwan
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Nasal SWAC and Spacket



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