

REF

AKIT-SN-AB-01

SN-Ab Dual Antibody Test for COVID-19 - Instructions For Use (IFU)

For in vitro diagnostic use only.

Sample Collection Method

Intended Use

The assaya SN-Ab Dual Antibody Test for COVID-19 is a rapid in vitro immunochromatographic assay intended for the qualitative detection of antibodies from blood from individuals who are suspected of COVID-19. It should not be used to confirmed or rule out acute infection with SARS-CoV-2, and the test result should not be used as the only basis for diagnosis, treatment or patient management decisions since the immune response for SARS-CoV-2 infection has not been fully established.

The assaya SN-Ab Dual Antibody Test for COVID-19 is a rapid immunochromatographic assay that is composed of two test indicators combined. The N indicator utilizes specific N antigen to detect antibodies in human blood specimens from individuals have antibodies from a natural infection. The S indicator utilizes double specific S-RBD antigen to detect antibodies in human blood specimens from individuals who have been vaccinated with a COVID-19 vaccine.

Negative results do not rule out SARS-CoV-2 infection. Therefore, the test result should not be used as the only basis for patient management decisions. Test result must be combined with clinical observations, patient history and epidemiology to make an overall judgment. At present, it is unknown how long the antibodies exists after SARS-CoV-2 infection.

SARS-CoV-2 is positive-sense 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. A rapid anti-N IgG test uses a similar approach to detect human IgG antibodies that are reactive to SARS-CoV-2. The spike protein (S) is composed of S1 and S2 subunits, and the S1 subunit contains the receptor-binding domain (RBD), which can bind at a specific location of angiotensin-converting enzyme 2 (ACE2) in the human host. This binding domain can assist the virus to infect specific cell, including epithelial/ endothelial cell of respiratory tract and gastrointestinal tract, monocytes/ macrophages cell of alveolar. This provides crucial information related to whether a patient has been exposed to SARS-CoV-2 naturally or by vaccination, and where they are temporally in the clinical course of the disease.

This product is for professional use only.

Materials

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

- 1 Spacket: Containing Reagent – Sodium Azide(<0.1%); Albumin Bovine Serum(<1%)
- 1 Dual Test Indicator

Kit does not include a finger prick lancet or blood specimen collection container.

Storage And Disposal

The product should be stored at 15-30°C , 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

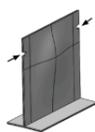
Before use, check the expiration date of the packaging. If the kit is past its expiration date, do not use. Confirm that all components needed are in the kit.

Whole blood is collected in anticoagulant tubes by lancet via finger prick.

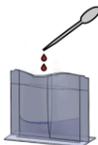
Whole blood specimens should be tested as soon as possible after collection in standard laboratory. Specimen could be stored at 2-8°C for up to 72 hours, or could also be stored below -20°C for long-term until before used. Specimen should be avoided to repeat freezing and thawing. The frozen specimen should be thawed and mixed well before testing. In addition, inadequate or inappropriate sample collection, storage, and transport may yield false test results. The training in specimen collection is highly recommended because of the importance of specimen quality.

Assay Procedure

- 1.
- 2.

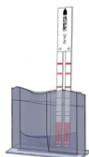


Stand up the Spacket, and tear it open. Be careful not to spill the liquid reagent inside.

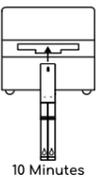


Sample 10 uL of blood into the Spacket.

- 3.
- 4.

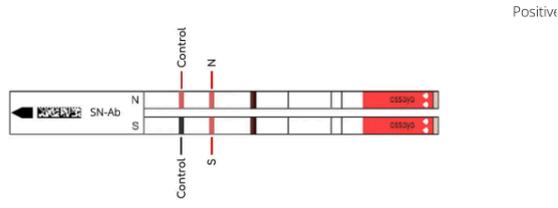


Place the test indicator in the Spacket with the droplets going down. Leave the test indicator in the Spacket for 10 minutes. Use the assaya timerDx to keep track of the test time.

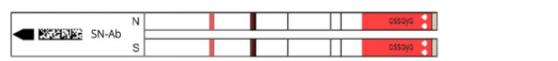
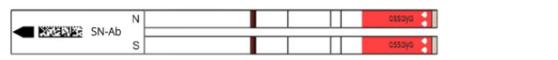
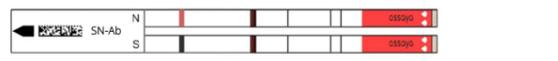


10 Minutes

Result Interpretation



Positive



Positive Results

At 10 minutes, the appearance of the Control Line and ANY shade of Test Line (S or I Indicators, indicates a positive result for the presence of antibodies for SARS-CoV-2. Test results only mean the antibodies for SARS-CoV-2 S-RBD and/or SARS-CoV-2 N exist in the specimen.

- The appearance of a Control Line and Test Line of the S indicator indicates a presence of antibodies for SARS-CoV-2 S-RBD.
- The appearance of a Control Line and Test Line of the N indicator indicates a presence of antibodies for SARS-CoV-2 N.
- The appearance of a Control Line and Test line on both of the S and N indicators result for the presence of antibodies for SARS-CoV-2 S-RBD and SARS-CoV-2 N.

Negative Results

At 10 minutes, the appearance of only Control Line on both S and N indicators indicate for the presence of antibodies for SARS-CoV-2 N and SARS-CoV-2 S-RBD.

Invalid Results

If at 10 minutes, the Control Line does not appear, even if a Test Line appears in either indicator, 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 Indicator.

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 color interferes with the reading, it is recommended to repeat the test.

Result Interpretation with the iaX-2101

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

- A Green (-) indicates a negative result for the presences of antibodies for SARS-CoV-2 N, or that the antibody level is below the detection limit.
- A Yellow (!) indicates that the test is invalid and a new test must be performed with a new collected specimen sample.
- A Red (+) indicates a positive result for the presences of antibodies for SARS-CoV-2 N.



GI



Y

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



Warnings & Precautions

1. For in vitro diagnostic use only.
2. This test has been authorized for the detection of antibodies against SARS-CoV-2 N and SARS-CoV-2 S-RBD only.
3. To obtain accurate results, you must follow the Package Insert.
4. Check if the device package is complete; test indicator must be sealed in foil pouch and the expiration date of the device must be shown. Do not use if any of the test materials is broken or beyond the labelled expiration date.
5. Do not interchange or mix different lots of assaya SN-AB Dual Antibody Test for COVID-19.
6. Do not reuse kit components.
7. Use of protective tools is recommended when collecting, handling, storing, and disposing of the components within process.
8. Dispose of used contents as biohazardous wastes in accordance with federal, state, and local requirements.
9. Seek specific training or guidance if you are not experienced with specimen collection and handling procedures.
10. Disregard test results beyond the specified time (20 min).
11. Test results must be interpreted together with other clinical information available to the physician.
12. Reagents contain sodium azide, which is harmful if inhaled, swallowed or exposed to skin. When contacted acidic substances, it may produce highly toxic gases. In case of accidental contact with the skin, please wash immediately with plenty of water.
13. For additional information on hazard symbols, safety, handling and disposal of the components within this kit, please refer to the Material Safety Data Sheet (MSDS) located at Vstrip.com.
14. SARS-CoV-2 N and SARS-CoV-2 S-RBD antibodies are usually found in blood-related samples in the middle and late stages of infection or after infection recovery. The literature indicates that the amounts of antibodies collected less than 7 days after symptom onset may be low, and immune response for SARS-CoV-2 infection has not been fully established. Therefore, assaya SN-Ab Dual Antibody Test for COVID-19 should not be used as the sole diagnosis basis or as a basis for calculating the infection time.

Product Limitations

1. The contents of this kit are to be used for the qualitative detection of antibodies for SARS-CoV-2 S-RBD and/or SARS-CoV-2 N. 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. The amounts of antibodies in the specimen may decrease or increase as the duration of illness increases.
3. Test result must be combined with clinical observations, patient history and epidemiology to make an overall judgment.
4. Positive test results only mean antibodies for SARS-CoV-2 S-RBD and/or SARS-CoV-2 N exist in the specimen. Negative test result may occur if the level of antibodies in a specimen is below the detection limit of the test.
5. As the production of antibodies in the immune response varies among individuals, the device may fail to detect, or detect with less sensitivity.

Clinical Performance

Venous blood specimens were collected for testing by medical technologists. A total of 150 blood specimens were collected, including 60 uninfected subjects, 30 infected patients (1-14 days after symptom onset), 30 infected patients (15-21 days after symptom onset), and 30 infected patients (over than 21 days after symptom onset). Product performance tests were conducted and the results are as follows.

| PCR Positive | assaya SN-Ab Dual Antibody Test for COVID-19 | | | | | |
|--------------|--|----------|----------|-----|---------------|---------------|
| | | Positive | Negative | PPA | NPA | 95%CI |
| | 1-14 days | 20 | 10 | 67% | - | 47.19%-82.71% |
| 15-21 days | 29 | 1 | 97% | - | 82.78%-99.92% | |
| >21 days | 28 | 2 | 93% | - | 77.93%-99.18% | |
| PCR Negative | 1 | 59 | - | 98% | 91.06%-99.96% | |

In addition, the performance of the assaya SN-Ab Dual Antibody Test for COVID-19 was compared to the results of an FDA Emergency Use Authorized serology test by 346 blood specimens. The test results are as follows.

| assaya SN-Ab Dual Antibody Test for COVID-19 | US FDA approved SARS-CoV-2 Antibody Test | | | |
|--|--|----------|----------|-------|
| | | Positive | Negative | Total |
| | Positive | 198 | 15 | 213 |
| Negative | 15 | 125 | 141 | |
| Total | 213 | 141 | 346 | |

Interference

The performance of the assaya SN-Ab Dual Antibody Test for COVID-19 was not affected by potentially interfering substances. The item and concentration of interfering substances are listed as follows.

| No. | Interference Substances | Testing Conc. |
|-----|-------------------------|---------------|
| 1 | Hemoglobin | 1 mg/dL |
| 2 | Bilirubin | 1 mg/dL |
| 3 | Triglyceride | 150 mg/dL |
| 4 | Albumin | 20 mg/dL |

Cross Reactivity

The cross-reactivity of the assaya SN-Ab Dual Antibody Test for COVID-19 was performed on 84 blood specimens which had been confirmed containing other high-risk pathogen antibodies by commercial serology test, including Influenza A/B, Adenovirus, Parainfluenza, Respiratory syncytial virus, Rhinovirus, HCoV-OC43, and SARS-CoV-2. Test result are shown in the table below.

| Negative Group (without COVID-19 Antibody) | | |
|--|-----------------------|----------------------------|
| No. of assaya negative results | Total specimen number | Accuracy % (Correct/Total) |
| 78 | 79 | 98.7% (78/79) |
| Positive Group (without COVID-19 Antibody) | | |
| No. of assaya positive results | Total specimen number | Accuracy % (Correct/Total) |
| 5 | 5 | 100.0% (5/5) |

References

1. The Clinical Virology Laboratory, Department of Laboratory Medicine at Yale: <http://info.med.yale.edu/labmed/virology/booklet.html> (http://info.med.yale.edu/labmed/virology/booklet.html). Chen N, Zhou M, Dor Y, et al. (15 February 2020). "Epidemiological and clinical characteristics of 99 coronavirus pneumonia in Wuhan, China: a descriptive study". The Lancet. 395
2. 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 met Pharmaceutica Sinica B. doi:10.1016.
3. Yannick Galipeau. (2020 Dec 18). "Humoral Responses and Serological Assays in Infections". doi: 10.3389/ fimmu. 2020.610688.
4. "How to Protect Yourself & Others". Centers for Disease Control and Prevention 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).
6. Henretig F.M. MD, King C. MD, Textbook of Pediatric Procedures, Chapter 123 - Specimens Williams and Williams (April 1997).

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-SN-AB-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

Do not use if and consi

Manufacturers

IVD



Panion & BF Biotech Inc. Xizhi Factory
8F, No.308-8, Sec. 1, Datong Rd., Xizhi Dist., New Taipei City 22146 Taiwan
Web: [vstriptechnology.com/](http://www.vstriptechnology.com/) (http://www.vstriptechnology.com/)

Spacket



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