InTec PRODUCTS, INC.

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REF ITP16045-TC1
ITP16045-TC2
ITP16045-TC5
ITP16045-TC7
ITP16045-TC25

AQ+
COVID-19 Ag Rapid Self-Test

Please read the instructions carefully prior to use and strictly follow the instructions.
For Research & performance evaluation only.
User should not take any decision of medical relevance without first consulting his or her medical practitioner.
For use with nasal swab specimens.
For self-testing use.

REAGENTS AND MATERIALS PROVIDED

Test Cassette

Buffer tube

Disposable swab

Tube holder

Instructions for use

Component	25 tests (ITP16045- TC25)	7 tests (ITP16045- TC7)	5 tests (ITP16045- TC5)	2 tests (ITP16045- TC2)	1 test (ITP16045- TC1)
Buffer tube	350μL×25 pieces	350μL×7 pieces	350μL×5 pieces	350μL×2 pieces	350μL×1 piece
Cassette	1×25 pieces	1×7 pieces	1×5 pieces	1×2 pieces	1×1 piece
Disposable swab	1×25 pieces	1×7 pieces	1×5 pieces	1×2 pieces	1×1 piece
Instructions for use	1×1 piece	1×1 piece	1×1 piece	1×1 piece	1×1 piece
Tube holder	1×1 piece	1×1 piece	1×1 piece	On the package	On the package

Note: Information of the disposable swab

Accessory	Manufacturer	Authorized Representative	CE mark
Disposable Swabs	Jiangsu Changfeng Medical Industry Co., Ltd. Touqiao Town, Guangling District Yangzhou, 225109 Jiangsu,P.R. China	Llins Service & Consulting GmbH Obere Seegasse 34/2, 69124 Heidelberg, Germany	CE 0197 STERILE EO

MATERIALS REQUIRED BUT NOT PROVIDED

- Disposable gloves
- Biohazard waste container
- Timer or stopwatch
- Equipment or reagents for disinfection.

TEST PROCEDURE

Preparation

1. Carefully read the instructions for use prior to use AQ+ COVID-19 Ag Rapid Self-Test.
2. Check the expiry date on the foil pouch. Do not use the kit if expiry date has passed.
3. Allow all reagents and specimens to reach room temperature (10-30°C) before use.

Collection

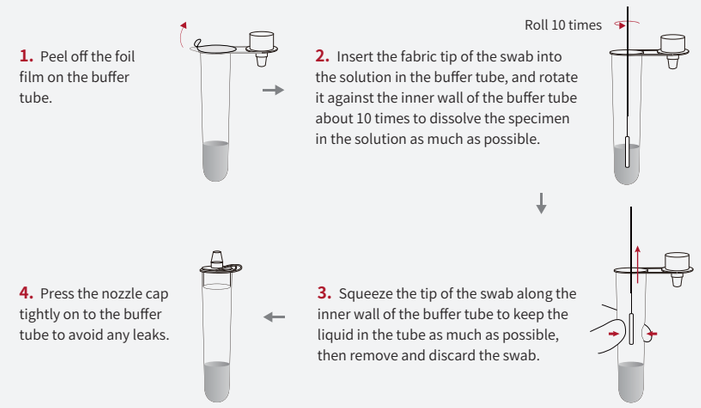
Very important! Specimens should be collected under strict personal protection.
• Collect the specimen with the provided swab by the method as below:

Nasal specimen:

Insert the swab into the nasal cavity, gently turn and push the swab into the nasal cavity until it is blocked at the turbinate (about 2.0cm- 2.5cm from the nostril). Rotate the swab 5 times against the wall of the nasal cavity and remove the swab. Use the same swab to sample the other nostril in the same way to ensure that you get enough samples.

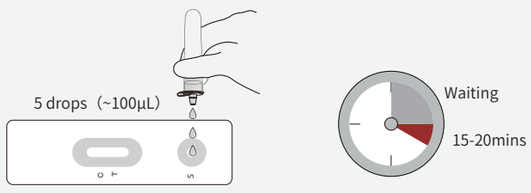
If you experience pain when taking a sample, pull the swab out immediately, otherwise injury may result.
If bleeding occurs, it may affect the test results. If blood is seen on the nasal swab, stop collecting the specimen and repeat the test after the bleeding has stopped.

Specimen treatment



Specimen addition

1. Unseal the foil pouch and put the cassette on a clean, dry and level surface; Do not open the pouch until ready to perform a test. Use the test under low environment humidity within 1 hour. Bring all the reagents to room temperature(10-30 °C) before use.
2. Add 5 drops (~100μL) of treated specimen into "S" well of the cassette.
3. Wait at least 15 minutes (and 20 minutes at most) to interpret the result.



CAUTION Negative results cannot rule out the possibility of exposure to or infection of SARS-CoV-2.

RESULT INTERPRETATION

Negative: Colored band only appears on control band area indicates a negative result.
Positive: Colored bands appear at both the test band area (even though very weak) and the control band area indicates a positive result.
Invalid 1: A colored band appears only at the test band area of the cassette. Repeat the test. Contact the supplier if the control band remains invisible.
Invalid 2: Colored band appears at neither the control band area nor the test band area of the cassette. Repeat the test. Contact the supplier if the control band remains invisible.

Caution:

In the event of a positive result, you are advised to immediately contact the local health department or a doctor for further diagnosis and treatment. It is essential that you comply with all local regulations on self-isolation.
If the test result is negative, a COVID-19 infection cannot be ruled out. Continue to comply with all applicable rules regarding contact with others and protective measures. Should you experience any of the typical COVID-19 symptoms such as fever, cough, body aches, tiredness, runny nose or diarrhea or have had direct contact with a person who tested positive, you should immediately consult a doctor for further diagnosis and treatment and contact the local one adhere to the rules of conduct recommended by local health authorities.

If the test did not work and is considered Invalid. This may be the result of an incorrect test procedure and the test should be repeated. Please perform a new test with a new sample and a new test.

INTENDED USE

The AQ+ COVID-19 Ag Rapid Self-Test is a colloidal gold enhanced, rapid immunochromatographic assay for qualitative detection of SARS-CoV-2 antigens in the nasopharyngeal/nasal specimen collected by swabs from individuals who are suspected of having COVID-19. The test is used as an aid in the diagnosis of SARS-CoV-2 infection. The test is suitable for use under healthcare professional supervision. Individuals should have appropriate training in how to administer the test correctly. Remote healthcare professional supervision can be used with appropriate clinical governance, once training has been completed and verified.
The test is for self-test with self-collected anterior nasal (nares) swab samples from individuals aged 15 years or older with symptoms of COVID-19 within the first seven (7) days of symptom onset. Or self-test with adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first seven (7) days of symptom onset.

SUMMARY

COVID-19 is a SARS-CoV-2 (also known as 2019-nCoV) associated pneumonia. A portion of patients have developed severe pneumonia, pulmonary oedema, ARDS, or multiple organ failure and have died. The AQ+ COVID-19 Ag Rapid Self-Test is based on immunochromatography for detection of SARS-CoV-2 antigen in the specimen collected by the swab. It is a visual qualitative test and presents the result within 20 minutes.

TEST PRINCIPLE

Gold conjugated mouse anti-SARS-CoV-2 N-protein IgG is pre-coated on the conjugate pad. SARS-CoV-2 antigen (N protein) can react with the gold conjugated mouse SARS-CoV-2 specific IgG and form an immune complex. The specimen will move forward along the test strip. If the specimen contains SARS-CoV-2 antigen (N protein) and the concentration is above the minimum detection limit, the complex will be captured by the mouse anti-SARS-CoV-2 N-protein IgG pre-coated at the test band region, and form a colored band. If the specimen does not contain SARS-CoV-2 antigen or the concentration is below the minimum detection limit, there will be no band shown at the test band region.
Regardless of whether the analyte exists in the specimen, the gold conjugated mouse anti-SARS-CoV-2 N-protein IgG will be captured by the goat anti-mouse IgG. A colored band will appear at the control band region.
Only when the control band appears, the correlated result is valid.

STORAGE CONDITIONS AND STABILITY

The AQ+ COVID-19 Ag Rapid Self-Test shall be stored at 2-30°C. The shelf life of the kit is as indicated on the outer package. Test cassette should be used within 1 hour upon opening the foil pouch.

PERFORMANCE CHARACTERISTICS

Clinical Evaluation

Clinical performance of AQ+ COVID-19 Ag Rapid Self-Test was determined by testing 223 positive and 247 negative specimens for SARS-CoV-2 antigen to have a sensitivity of 96.41% and specificity of 99.60%. Clinical specimens were confirmed to be positive or negative using an RT-PCR reference method.

		PCR		
		Positive	Negative	Total
AQ+ COVID-19 Ag Rapid Self-Test (Nasal swab)	Positive	215	1	216
	Negative	8	246	254
	Total	223	247	470

Results analysis:
Sensitivity: 215/223=96.41% (95%CI：93.08%-98.17%)
Specificity: 246/247=99.60% (95%CI：97.74%-99.93%)
Total coincidence rate: 461/470=98.09% (95%CI：96.40%~98.99%)

Usability Study

50 lay users, including self-collection (n=30) and collection for other lay user (n=20), participated in the study, and were instructed to self-collect or collect a sample from others, complete the required procedural steps, and interpret the test results unassisted in a simulated home setting. After the simulated test, about 80% (n = 41) of the participants can basically and accurately state the relevant test process requirements after reading the product specification, including applicable sample type, sample collection, performing the test, reading and understanding the result and some precautions. About 90% (n = 46) of the participants can accurately complete the test according to the instructions in one operation after reading the product specification.

Limit Of Detection (LoD)

The LoD for AQ+ COVID-19 Ag Rapid Self-Test is 1.60 x10^2 $TCID_{50}$/mL. The LoD is established using limiting dilutions of heat-inactivated SARS-CoV-2 antigen.

Cross-reactivity

AQ+ COVID-19 Ag Rapid Self-Test does not cross with the following common respiratory pathogens.

S.N.	Potential Cross-Reactant	Species	Concentration
1	Coronavirus 229E	VR -740	10^6pfu/mL
2	Coronavirus NL63	COV-NL63	10^6pfu/mL
3	Coronavirus OC43	VR -1558	10^6pfu/mL
4	Coronavirus HKU1	COV-HKU1	10^6pfu/mL
5	Seasonal H1N1 influenza	A-H1N1	10^6pfu/mL
6	H3N2 influenza virus	A-H3N2	10^6pfu/mL
7	H7N9 avian influenza virus	A-H7N9	10^6pfu/mL
8	Influenza B Yamagata	B-Yamagata	10^6pfu/mL
9	Mycoplasma pneumoniae	39505	10^7cfu/mL
10	Chlamydia pneumoniae	VR-2282	10^7cfu/mL
11	Coronavirus MERS	MERS	10^6pfu/mL
12	Parainfluenza virus type 1	HPIVs-1	10^6pfu/mL
13	Mycobacterium tuberculosis	25177	10^7cfu/mL
14	Respiratory syncytial virus	RSV-A2	10^6pfu/mL
15	Legionella	33152	10^7cfu/mL
16	Streptococcus pneumoniae	CGMCC 1.8722	10^7cfu/mL
17	Enterovirus A	CV-A10	10^6pfu/mL
18	Enterovirus B	Echovirus 6	10^6pfu/mL
19	Staphylococcus aureus	CGMCC 1.2910	10^7cfu/mL
20	Human metapneumovirus	HMPV	10^6pfu/mL

Interfering Substances

The following potentially interfering substances have no impact on AQ+ COVID-19 Ag Rapid Self-Test. The final test concentrations of the interfering substances are documented in the table below.

S.N.	Substance Name	Concentration	S.N.	Substance Name	Concentration
1	Hemoglobin	2 g/L	1	Ceftriaxone	1 g/mL
2	Mucoprotein	20 mg/mL	2	Tobramycin	2 g/mL
3	Zanamivir	50 mg/mL	3	Oxymetazoline	1 g/mL
4	Ribavirin	2 g/mL	4	Beclazone	0.5 mg/mL
5	Oseltamivir	200 mg/mL	5	Dexamethasone	20 mg/mL
6	Peramivir	1 g/mL	6	Flunisolide	5 mg/mL
7	lopinavir	1 g/mL	7	Triamcinolone acetonide	100 mg/mL
8	Ritonavir	250 mg/mL	8	Budesonide	2 mg/mL
9	Levofloxacin	2 mg/mL	9	Mometasone	1 mg/mL
10	Azithromycin	500 mg/mL	10	Fluticasone	10 mg/mL

Hook Effect

There is no Hook effect under concentration of 3.40 x10^5 $TCID_{50}$/mL. The Hook effect is established using limiting dilutions of heat-inactivated SARS-CoV-2 antigen.

Precision of Measurement

The precision of AQ+ COVID-19 Ag Rapid Self-Test is very good and stable.
Three lots of products were tested for 3 repeatable references respectively, and the parallel test for 80 times. Test results of positive specimen were all positive, and intensity value was consist, test results of negative specimen were all negative.

Clinical specimens were tested by three lots of products respectively, for parallel test 20 times. Test results of positive specimen were all positive, and intensity value was consist, test results of negative specimen were all negative.

Two experimental groups: different operators, different instruments and equipment, three lots of products were tested for clinical specimens, each swab specimen was tested for 60 times. Test results of positive specimen were all positive, and intensity value was consist, test results of negative specimen were all negative.

WARNINGS AND PRECAUTIONS

The warmings and precautions are included, but not limited to the following.

Warmings

- This product is for in vitro diagnosis of the infection of COVID-19 only, other diseases cannot be analyzed with component of this kit.
- All specimens with positive results must be confirmed using an appropriate test such as RT-PCR or equivalent.

Precautions

- Do not use expired reagents or test cassettes.
- Do not use the kit if any of the components is damaged or missing.
- Do not reuse the cassette, swab or buffer tube.
- Do not eat or smoke while handling specimens.
- Do not touch or drink the liquid inside the buffer tube. Do not allow it to come into contact with your skin, your eyes or any external surface.
- If the solution makes contact with your skin, immediately wash your skin with water.
- If the solution gets into your eyes, immediately wash them with water.
- If you experience any symptoms after contact with the liquid, seek medical help immediately.
- If the liquid inside the buffer tube is spilled, clean it using gloves and absorbent tissue.
- Do not store the specimen in buffer tube; it is only used for specimen processing.
- Do not use pooled specimens or specimens other than specified(i.e.urine, blood).
- Do not interchange reagents among kits of different batch number or even products.
- Do not perform the test under environment which leads to rapid evaporation(e.g.＞40℃ and ＜40% RH,close to a running fan or air conditioner).
- Clean and disinfect all the areas that may be contaminated by spills of specimens or reagents with appropriate disinfectant to control infectious risks.
- Keep out of the reach of children. Any child under age of 15 shouldn’ t perform the test without parental guidance, or professional aid.
- Refer to the local regulations in force regarding the disposal of the testing materials.
- If you experience pain when taking a sample, pull the swab out immediately, otherwise injury may result.
- If bleeding occurs, it may affect the test results. If blood is seen on the nasal swab, stop collecting the specimen and repeat the test after the bleeding has stopped.
- Children and adolescents under the age of 15 or people who cannot understand the instructions of use correctly should only take the test under the supervision of an adult or someone who can fully understands the instructions of use correctly.

FREQUENTLY ASKED QUESTIONS (FAQ)

1. What is the AQ+ COVID-19 Ag Rapid Self-Test used for?
Rapid antigen tests are commonly used in the diagnosis of respiratory illnesses. In this case, the rapid antigen detection test looks for proteins produced by the SARS-CoV-2 virus, which is the virus that causes the disease called COVID-19. Antigen tests are immunoassays that detect the presence of a specific viral antigen, which means they identify people who currently have a viral infection.
2. Where can I get AQ+ COVID-19 Ag Rapid Self-Test?
Self-testing COVID-19 test kits are available either by prescription or over the counter in a pharmacy or retail store without a prescription.
3. How quickly are results for COVID-19 Antigen tests available?
Turnaround time for results is usually very quick. In this case, you can get the result within 15-20 minutes.
4. How does the test kit work?
The N protein of the SARS-CoV-2 virus reacts with the stripe-like coating of the test line and if present, results in a color change colored line appears. Therefore, if the sample does not contain any viral proteins or antigens, there will be no colored appearing on test (T) line.
5. When should/can I test myself ?
You can test yourself whether you have symptoms or not. Antigen rapid tests are most likely to perform well in patients with high viral loads which usually appear in the pre-symptomatic (1-3 days before symptom onset) and early symptomatic phases of their illness (within the first 5-7 days of illness).
6. What can affect my test result? What should I pay attention to?
Be sure to visibly collect sample material (nasal secretions).
Perform the test immediately after taking the sample.
Follow the instructions for use carefully.
Apply the drops of extraction buffer only to the sample well (S).
Too many or too few drops of extraction solution can lead to an invalid or incorrect test result.
7. What should I do, if there is no C (Control) line appearing?
Your test result is invalid. Repeat the test according to the instructions for use.
8. How to interpret the results?
Colored bands appearing at both test band area (even though very weak) and control band area indicates a positive result.
Colored band only appearing on control band area indicates a negative result.
If you are still unsure about the results, contact the nearest health facility according to the recommendations of your local authorities.
9. What should I do with the positive or negative results?
If your result is positive, you should contact the medical facility as recommended by your local authorities. Your test result may be double-checked and the authority or facility will explain the appropriate next steps.
If your result is negative, this may mean that no virus is detected or the viral load is too low to be detected. If you experience symptoms (headache, fever, migraine, loss of sense of smell or taste, etc.), please consult your primary care physician in the nearest health care facility as recommended by your local authorities.If you are not sure, you can repeat the test.
10. How can I dispose of the testing materials?
Please refer to the local regulations in force regarding the disposal of the testing materials.

Limitations

- The kit is designed to detect SARS-CoV-2 antigen in nasal specimen collected by the provided swab. Other types of specimens may not supply accurate results and the device will not notify this kind of misuse to the user.
- The intensity of test band does not necessarily correlate to the titer of antigen in specimen.
- The presence of the control band only indicates the flow of the conjugate.
- This product is intended to detect SARS-CoV-2 antigen from individuals, clinical diagnosis on SARS-CoV-2 infection should not be made only based on the results of the product.
- A negative result should not exclude the possibility of infection caused by SARS-CoV-2. A negative result can also occur in the following circumstances:
  - Recently acquired SARS-CoV-2 infection.
  - Low levels of antigen below the detection limit of the test.
  - SARS-CoV-2 antigen in the patient failed to react with specific antibody utilized in the assay configuration, in exceptional cases this may lead to observation of negative results.
  - Specimens are not properly stored.
  - Extremely high concentration of a particular analyte.
  - Recently discovered type or subtype of SARS-CoV-2.
- For reasons above, care should be taken in interpreting negative results. Other clinical data (e.g., symptoms or risk factors) should be introduced in conjunction with the test results.
- Specimen with positive results should be retested with other technological method such as PCR under the guidance of local regulations before the clinical diagnosis is made.
- Positive test results do not rule out co-infections with other pathogens.
- The product is not validated on specimens from infants, children, or patients on anti-retroviral treatment.
- Use of hemolytic specimens, rheumatoid factors-contained specimens, hyperlipemia specimens or icteric specimens may lead to impairment to the test result.

GLOSSARY OF SYMBOLS

	CAUTION		KEEP DRY		DO NOT REUSE
	KEEP AWAY FROM SUNLIGHT	2℃ 30℃	TEMPERATURE LIMITATION (2-30℃)		CONSULT INSTRUCTIONS FOR USE
	MANUFACTURER	IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE	Σ N	CONTAINS SUFFICIENT FOR $_{(N)}$ TESTS
LOT	BATCH CODE	REF	CATALOGUE NUMBER	CE	EUROPEAN CONFORMITY
	DATE OF MANUFACTURE		DO NOT USE IF PACKAGE IS DAMAGED		USE-BY DATE
EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY				

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Shuo Su, Gary Wong, Weifeng Shi, et al. Epidemiology, Genetic recombination, and pathogenesis of coronaviruses. Trends in Microbiology, Juni 2016, Band 24, Nr. 6: 490-502

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