InTec PRODUCTS, INC.

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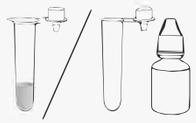
REF ITP16044-TC25
ITP16044-TC25-

AQ+
COVID-19 Ag Rapid Test

Please read the instructions carefully prior to use and strictly follow the instructions.

REAGENTS AND MATERIALS PROVIDED

Test Cassette



Buffer tube or Buffer bottle +Test tube

Disposable swab

Control swab

Tube holder

Instructions for use

Buffer bottle type (ITP16044-TC25-)

Component			
Buffer bottle	10mL×1 piece	**Tube holder**	1×1 piece
Cassette	1×25 pieces	**Test tube**	1×25 pieces
Disposable swab	1×25 pieces	**Positive control swab**	1×1 piece
Instructions for use	1×1 piece	**Negative control swab**	1×1 piece

Buffer tube type (ITP16044-TC25)

Component			
Buffer tube	350μL×25 pieces	**Tube holder**	1×1 piece
Cassette	1×25 pieces	**Positive control swab**	1×1 piece
Disposable swab	1×25 pieces	**Negative control swab**	1×1 piece
Instructions for use	1×1 piece		

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

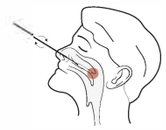
Preparation

1. Carefully read the instructions for use prior to using AQ+ COVID-19 Ag Rapid 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:

Nasopharyngeal specimen:
Insert the swab through one nostril parallel to the palate (not upwards) until resistance is encountered, indicating contact with the nasopharynx.
Gently rub and roll the swab over surface of the nasopharynx for 10 times to absorb secretions. Withdraw the swab from the nasal cavity.

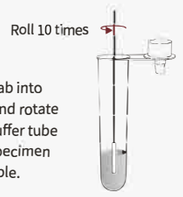


Nasal specimen:
Insert the swab into the nasal cavity, gently turn and push the swab into the nasal cavity until it is blocked at the turbinate (about 2.0cm- 2.5cm from the nostril). Rotate the swab 5 times against the wall of the nasal cavity and remove the swab. Use the same swab to sample the other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

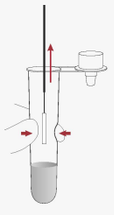
Specimen treatment

For Buffer bottle type

1. Add buffer to the test tube until the liquid reaches mark on test tube.



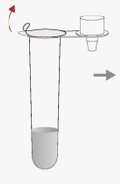
2. Insert the fabric tip of the swab into the solution in the buffer tube, and rotate it against the inner wall of the buffer tube about 10 times to dissolve the specimen in the solution as much as possible.



3. Squeeze the tip of the swab along the inner wall of the buffer tube to keep the liquid in the tube as much as possible, then remove and discard the swab.

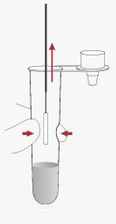
4. Press the nozzle cap tightly on to the buffer tube to avoid any leaks.

For Buffer tube type

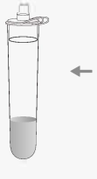


1. Peel off the foil film on the buffer tube.

2. Insert the fabric tip of the swab into the solution in the buffer tube, and rotate it against the inner wall of the buffer tube about 10 times to dissolve the specimen in the solution as much as possible.



3. Squeeze the tip of the swab along the inner wall of the buffer tube to keep the liquid in the tube as much as possible, then remove and discard the swab.



4. Press the nozzle cap tightly on to the buffer tube to avoid any leaks.

POSITVE / NEGATIVE CONTROL SWAB

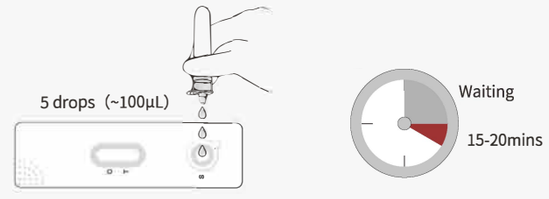
The controls are specifically formulated and manufactured to ensure performance of AQ+ COVID-19 Ag Rapid Test and are used to verify the user's ability to properly perform the test and interpret the results. The Positive Control will produce a positive test result and has been manufactured to produce a visible test line (T). The Negative Control will produce a negative test result.

CAUTION The control swabs are control use only, do not use for specimen collection.

1. Peel off the foil film on the buffer tube.
2. Insert the control swab into the solution in the buffer tube, and rotate it against the inner wall of the buffer tube about 10 times to dissolve the specimen in the solution as much as possible.
3. Press the nozzle cap tightly on to the buffer tube to avoid any leaks.
4. Squeeze the tip of the swab along the inner wall of the buffer tube to keep the liquid in the tube as much as possible, then remove and discard the swab.
5. Follow the below RESULT INTERPRETATION

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.



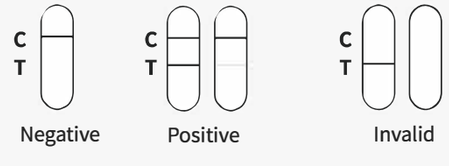
Alternative procedure for specimens stored in Viral Transport Medium (VTM):

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 300μL of the VTM specimen into the buffer tube and mix well. Press the nozzle cap tightly on to the buffer tube to avoid any leaks.
3. Add 5 drops (~100μL) of treated specimen into "S" well of the cassette.
4. 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.



INTENDED USE

The AQ+ COVID-19 Ag Rapid 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.

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 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 sample 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 bandShown 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 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 Test (Nasopharyngeal) was determined by testing 223 positive and 247 negative specimen for COVID-19 antigen to have a sensitivity of 97.31% and specificity of 100%. Clinical specimens were confirmed to be positive or negative using an RT-PCR reference method.

		PCR		
		Positive	Negative	Total
AQ+ COVID-19 Ag Rapid Test (Nasopharyngeal swab)	POSITIVE	217	0	217
	NEGATIVE	6	247	253
	TOTAL	223	247	470

Results analysis:
Sensitivity: 217/223=97.31% (94.26%-98.76%)
Specificity: 247/247=100% (98.47%-100%)
Total coincidence rate: 464/470=98.72% (97.24%~99.41%)
Clinical performance of AQ+ COVID-19 Ag Rapid 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 Test (Nasal swab)	Positive	215	1	216
	Negative	8	246	254
	Total	223	247	470

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

Limit Of Detection (LoD)

The LoD for AQ+ COVID-19 Ag Rapid 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 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	10^8pfu/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 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.

WARMINGS 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

- Very important! When handling and processing specimens, laboratory practices and procedures that are basic to good microbiological practices and procedures should be followed.
- Wear disposable gloves at all times when handling specimens. Avoid contact of gloved hands with the face. Gloves should be inspected before use to check they are intact.
- Do not use expired reagents or test cassettes.
- Do not use the swab if the package is damaged or the seal is broken.
- Do not use the test cassette if the foil pouch is damaged or the seal is broken.
- Do not reuse the cassette, swab or buffer tube.
- Do not eat or smoke while handling specimens.
- 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°C 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.
- Decontaminate and dispose of all specimens, reagents, and other potentially contaminated materials as infectious wastes in a biohazard container.

Limitations

- The kit is designed to detect SARS-CoV-2 antigen in nasopharyngeal/nasal specimencollected 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 configura tion, 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°C 30°C	TEMPERATURE LIMITATION (2-30°C)		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				

BIBLIOGRARHY

Susan R. Weiss, Julian L. Leibowitz, Coronavirus Pathogenesis, Advances in Virus Research, Band 81: 85-164
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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