金标英文说明书（COVID-19 Flu Combo）CE
尺寸：285x210mm、70g双胶纸、双面黑白印刷（对折）
01.05.14.109-221101

InTec PRODUCTS, INC.

REF ITP16050-TC1
ITP16050-TC5
ITP16050-TC25
01.05.14.109-221101

AQ+ Rapid COVID-19/Flu Combo Test

For in vitro diagnostic use only. IVD
Please read the instructions for use carefully prior to use and strictly follow the instructions.
Reliability of the assay cannot be guaranteed if there are any deviations from the instructions for use. Strict personal protection is required throughout the test!

Intended use

The AQ+ Rapid COVID-19/Flu Combo Test is a colloidal gold enhanced, rapid immunochromatographic assay for qualitative detection of antigens to SARS-CoV-2 and Influenza A and influenza B present in human nasopharyngeal/nasal specimens. The test is used as an aid in the diagnosis of COVID-19 infection and/or Influenza A and Influenza B.

Summary

COVID-19 and Influenza (Flu) are both contagious respiratory illnesses, but they are caused by different viruses. People can be infected with both flu and the virus that causes COVID-19 at the same time and have symptoms of both influenza and COVID-19. Because some of the symptoms of flu, COVID-19, and other respiratory illnesses are similar, the difference between them cannot be made based on symptoms alone. Testing is needed to tell what the illness is and to confirm a diagnosis. The AQ+ Rapid COVID-19/Flu Combo Test can distinguish SARS-CoV-2 viral antigens from Influenza A or Influenza B viral antigens from a single specimen using a single device. It is simple, visual qualitative and presents the result within 20 minutes.

Test principle

Gold conjugated mouse anti-SARS-CoV-2 N-protein IgG, gold conjugated mouse anti- influenza A nucleoprotein IgG and gold conjugated mouse anti- influenza B nucleoprotein IgG are pre-coated on the sample pad. Target antigen (SARS-CoV-2 antigen or Influenza A / Influenza B nucleoprotein antigens) can react with the gold conjugated mouse specific IgG and form an immune complex. The specimen will move forward along the test strip.
If the specimen contains target antigen and the concentration is above the minimum detection limit, the complex will be separately captured by the mouse anti-SARS-CoV-2 N-protein IgG, mouse anti- influenza A nucleoprotein IgG and mouse anti- influenza B nucleoprotein IgG pre-coated in different areas of the test band region, and form a color band. If the specimen does not contain target 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, gold conjugated mouse anti- influenza A nucleoprotein IgG and gold conjugated mouse anti- influenza B nucleoprotein IgG will be captured by the goat anti- mouse IgG. A color 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+ Rapid COVID-19/Flu Combo 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. The buffer should be stored capped at 2-30°C and used within 8 weeks after opening.

Warnings and precautions

The warnings and precautions are included, but not limited tothe following:
[Warnings]
• This product is for in vitro diagnosis of the infection of SARS-CoV-2 only; other diseases cannot be analyzed with any 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 (GMPP) should be followed.
· Wear disposable gloves at all times when handling specimens. Avoid contact of gloved hands with the face. Gloves should always 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 from different batch numbers or 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).
· Decontaminate and dispose of all specimens, reagents, and other potentially contaminated materials as infectious wastes in a biohazard container.

Reagent and materials provided

Table 1 Reagent and materials provided

Component	1 test (ITP16050-TC1)	5 tests (ITP16050-TC5)	25 tests (ITP16050-TC25)	
			Equipped with buffer tube (containing buffer solution)	Equipped with buffer tube and buffer bottle
Buffer tube	1×1 piece	1×5 pieces	1×25 pieces	1×25 pieces (without buffer solution)
Buffer bottle	\	\	\	10mL × 1 bottle
Cassette	1×1 piece	1×5 pieces	1×25 pieces	1×25 pieces
Disposable swab	1×1 piece	1×5 pieces	1×25 pieces	1×25 pieces
Instructions for use	1×1 piece	1×1 piece	1×1 piece	1×1 piece
Tube rack (optional)	On the package	1×1 piece	1×1 piece	1×1 piece

Note: Information of the disposable swab			
Accessory	Manufacturer	Authorized Representative	CE
Disposable Swab	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
	Medico Technology Co., Ltd. Room 201 of Builing 14th and Builing 17th, Hengyi Lane, Yuanhu Road, Zhangbei Industrial Park, Longcheng Street, Longgang District, Shenzhen, Guangdong, China	Intertek Semko AB, Box 1103 SE-164 22 Krista, Sweden	CE 0413 STERILE EO

Materials required but not provided

• Disposable gloves • Timer or stop watch • Biohazard waste container • Equipment or reagents fordisinfection

Specimen collection and storage

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 slowly.

Nasal specimen:
IInsert 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 three 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.

After the specimen is collected, it should be processed with the buffer provided as soon as possible (refer to section specimen treatment).

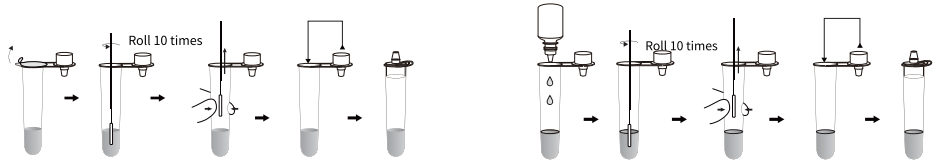
Test procedure

•After the test card is taken out of the sealed pouch, the test device must be performed within 1 hour. Please use immediately in high humidity environment (⩾80%RH).
• Equilibrate all reagents and specimens to room temperature (10-30°C) before use.

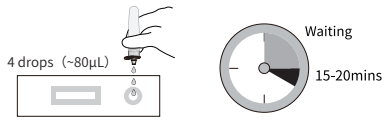
Specimen treatment

A. Equipped with buffer tube (containing buffer solution)
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.

B. Equipped with buffer tube and buffer bottle
1. Add the buffer into the buffer tube until reaching the mark.
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.



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. Equilibrate all the reagents to room temperature (10-30 °C) before use.
2. Add 4 drops (~80μL) of treated specimen into sample 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 Influenza A and Influenza B and SARS-CoV-2.

Result interpretation

Negative: Color band only appears on control band (C) area indicating a negative result.

Positive 1: Color bands appear at the Flu A, Flu B and CoV19 areas (even though very weak) and the control band (C) area indicating a positive result of infection of Influenza A and Influenza B and SARS-CoV-2.

Positive 2: Color bands appear at the Flu A and CoV19 areas (even though very weak) and the control band (C) area indicating a positive result of infection of Influenza A and SARS-CoV-2.

Positive 3: Color bands appear at the Flu A and Flu B areas (even though very weak) and the control band (C) area indicating a positive result of infection of Influenza A and Influenza B.

Positive 4: Color bands appear at the Flu B and CoV19 areas (even though very weak) and the control band (C) area indicating a positive result of infection of Influenza B and SARS-CoV-2.

Positive 5: Color bands appear at the Flu A area (even though very weak) and the control band (C) area indicating a positive result of infection of Influenza A.

Positive 6: Color bands appear at the Flu B area (even though very weak) and the control band (C) area indicating a positive result of infection of Influenza B.

Positive 7: Color bands appear at the CoV19 area (even though very weak) and the control band (C) area indicating a positive result of infection of SARS-CoV-2.

Invalid 1: Color band(s) appear only at the test band areas (Flu A, Flu B and/or CoV19) of the cassette. Repeat the test. Contact the supplier if the control band (C) remains invisible.

Invalid 2: A color 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 (C) remains invisible.

Note: CoV19 refers to COVID-19. The test is used as an aid in the diagnosis of SARS-CoV-2, the antigen of COVID-19. The color band appear s at the CoV19 area indicating the positive result of infection of SARS-CoV-2.

Performance Characteristics

Clinical Evaluation of antigen to SARS-CoV-2

Clinical performance of AQ+ Rapid COVID-19/Flu Combo Test (Nasopharyngeal swab) was determined by testing 209 positive and 211 negative specimens for SARS-CoV-2 antigen to have a sensitivity of 94.26% and specificity of 98.58%. Clinical specimens were confirmed to be positive or negative using an RT-PCR reference method.

		PCR		
		Positive	Negative	Total
AQ+ Rapid COVID-19/Flu Combo Test (Nasopharyngeal swab)	Positive	197	3	200
	Negative	12	208	220
	Total	209	211	420

Results analysis:
Sensitivity: 197/209=94.26% (90.23%-96.69%)
Specificity: 208/211=98.58% (95.90%-99.52%)
Total consistent: 405/420=96.43% (94.19%~97.82%)

Clinical performance of AQ+ Rapid COVID-19/Flu Combo Test (Nasal swab) was determined by testing 209 positive and 211 negative specimens for SARS-CoV-2 antigen to have a sensitivity of 92.82% and specificity of 98.58%. Clinical specimens were confirmed to be positive or negative using an RT-PCR reference method.

		PCR		
		Positive	Negative	Total
AQ+ Rapid COVID-19/Flu Combo Test (Nasal swab)	Positive	194	3	197
	Negative	15	208	223
	Total	209	211	420

Results analysis:
Sensitivity: 194/209=92.82% (88.50%-95.60%)
Specificity: 208/211=98.58% (95.90%-99.52%)
Total consistent: 402/420=95.71% (93.33%~97.27%)

Clinical Evaluation of antigen to Influenza A

Clinical performance of AQ+ Rapid COVID-19/Flu Combo Test (Nasopharyngeal swab) was determined by testing 226 positive and 204 negative specimens for Influenza A antigen to have a sensitivity of 93.36% and specificity of 98.53%. Clinical specimens were confirmed to be positive or negative using an RT-PCR reference method.

		PCR		
		Positive	Negative	Total
AQ+ Rapid COVID-19/Flu Combo Test (Nasopharyngeal swab)	Positive	211	3	214
	Negative	15	201	216
	Total	226	204	430

Results analysis:
Sensitivity: 211/226=93.36% (89.34%-95.94%)
Specificity: 201/204=98.53% (95.77%-99.50%)
Total consistent: 412/430=95.81% (93.48%~97.34%)

Clinical performance of AQ+ Rapid COVID-19/Flu Combo Test (Nasal swab) was determined by testing 226 positive and 204 negative specimens for Influenza A antigen to have a sensitivity of 92.04% and specificity of 99.02%. Clinical specimens were confirmed to be positive or negative using an RT-PCR reference method.

		PCR		
		Positive	Negative	Total
AQ+ Rapid COVID-19/Flu Combo Test (Nasal swab)	Positive	208	2	210
	Negative	18	202	220
	Total	226	204	430

Results analysis:
Sensitivity: 208/226=92.04% (87.76%-94.90%)
Specificity: 202/204=99.02% (96.50%-99.73%)
Total consistent: 410/430=95.35% (92.93%~96.97%)

Clinical Evaluation of antigen to Influenza B

Clinical performance of AQ+ Rapid COVID-19/Flu Combo Test (Nasopharyngeal swab) was determined by testing 218 positive and 204 negative specimens for Influenza B antigen to have a sensitivity of 94.04% and specificity of 99.02%. Clinical specimens were confirmed to be positive or negative using an RT-PCR reference method.

		PCR		
		Positive	Negative	Total
AQ+ Rapid COVID-19/Flu Combo Test (Nasopharyngeal swab)	Positive	205	2	207
	Negative	13	202	215
	Total	218	204	422

Results analysis:
Sensitivity: 205/218=94.04% (90.07%-96.48%)
Specificity: 202/204=99.02% (96.50%-99.73%)
Total consistent: 407/422=96.45% (94.22%~97.83%)

Clinical performance of AQ+ Rapid COVID-19/Flu Combo Test (Nasal swab) was determined by testing 218 positive and 204 negative specimens for Influenza B antigen to have a sensitivity of 92.66% and specificity of 98.53%. Clinical specimens were confirmed to be positive or negative using an RT-PCR reference method.

		PCR		
		Positive	Negative	Total
AQ+ Rapid COVID-19/Flu Combo Test (Nasal swab)	Positive	202	3	205
	Negative	16	201	217
	Total	218	204	422

Results analysis:
Sensitivity: 202/218=92.66% (88.41%-95.43%)
Specificity: 201/204=98.53% (95.77%-99.50%)
Total consistent: 403/422=95.50% (93.08%~97.10%)

Limit of Detection (LoD)

The LoD for Antigen to SARS-CoV-2 is 1.6 x10^2 $TCID_{50}$/mL. The LoD was established using limiting dilutions of heat-inactivated SARS-CoV-2 antigen.

Cross-Reactivity

AQ+ Rapid COVID-19/Flu Combo Test does not cross with the following common respiratory pathogens.

S.N.	Potential Cross-Reactant	Species	Concentration
1	Coronavirus229E	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	Mycoplasmapneumoniae	39505	10^7cfu/mL
6	Chlamydia pneumoniae	VR-2282	10^7cfu/mL
7	Coronavirus MERS	MERS	10^8pfu/mL
8	Parainfluenza virus type 1	HPIVs-1	10^6pfu/mL

S.N.	Potential Cross-Reactant	Species	Concentration
9	Mycobacterium tuberculosis	25177	10^7cfu/mL
10	Respiratory syncytial virus	RSV-A2	10^6pfu/mL
11	Legionella	33152	10^7cfu/mL
12	Streptococcus pneumoniae	CGMCC 1.8722	10^7cfu/mL
13	Enterovirus A	CV-A10	10^6pfu/mL
14	Enterovirus B	Echovirus 6	10^6pfu/mL
15	Staphylococcus aureus	CGMCC 1.2910	10^7cfu/mL
16	Human metapneumovirus	HMPV	10^6pfu/mL

Interfering Substances

The following potentially interfering substances have no impact on AQ+ Rapid COVID-19/Flu Combo Test. The final test concentrations of the interfering substances are documented in the Table below.

S.N.	Substance Name	Concentration
1	Hemoglobin	2g/L
2	Mucoprotein	20mg/mL
3	Zanamivir	50mg/mL
4	Ribavirin	2g/mL
5	Oseltamivir	200mg/mL
6	Peramivir	1g/mL
7	Lopinavir	1g/mL
8	Ritonavir	250mg/mL
9	Levofloxacin	2mg/mL
10	Azithromycin	500mg/mL

S.N.	Substance Name	Concentration
11	Ceftriaxone	1g/mL
12	Tobramycin	2g/mL
13	Oxymetazoline	1g/mL
14	Beclazone	0.5mg/mL
15	Dexamethasone	20mg/mL
16	Flunisolide	5mg/mL
17	Triamcinolone acetonide	100mg/mL
18	Budesonide	2mg/mL
19	Mometasone	1mg/mL
20	Fluticasone	10mg/mL

Hook Effect

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

Limitations

- The kit is designed to detect antigens of SARS-CoV-2 and Influenza A and Influenza B in nasopharyngeal and nasal specimens.
- 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.
- Clinical diagnosis on COVID-19/Flu infection should not be made only based on the results of the product.
- A negative result should not exclude the possibility of infection. A negative result can also occur in thefollowing circumstances:

-Recently acquired infection.
-Low levels of antigen below the detection limit of the test.
-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.

- For reasons above, care should be taken in interpreting negative results. Other clinical data (e.g., symptoms or risk factors) should be introduced inconjunction 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.

Key to symbols used

	CAUTION		KEEP DRY		DO NOT REUSE		USE-BY DATE
	KEEP AWAY FROM SUNLIGHT		CONSULT INSTRUCTIONS FOR USE	Σ N	CONTAINS SUFFICIENT FOR (N) TESTS	STERILE EO	STERILIZED USING ETHYLENE OXIDE
	TEMPERATURE LIMITATION	IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE		DO NOT USE IF PACKAGE IS DAMAGED	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
LOT	BATCH CODE	REF	CATALOGUE NUMBER	CE	EUROPEAN CONFORMITY		MANUFACTURER

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