



MICROPROFIT
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fluorecare[®]



SARS-CoV-2 & Influenza A/B Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)



The fluorecare[®] SARS-CoV-2 & Influenza A/B Antigen Combo Test Kit is an easy-to-use chromatographic immunoassay for the qualitative detection of SARS-CoV-2, Influenza A and/or influenza B proteins from individuals with suspected SARS-CoV-2 and/or Influenza infection. The kit demonstrates reliable results in 15 minutes with 60uL of sample. No complicated process or device is required.

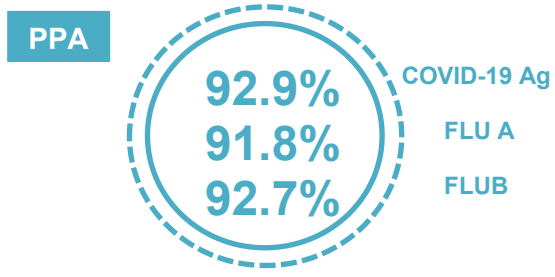
Fast



Easy



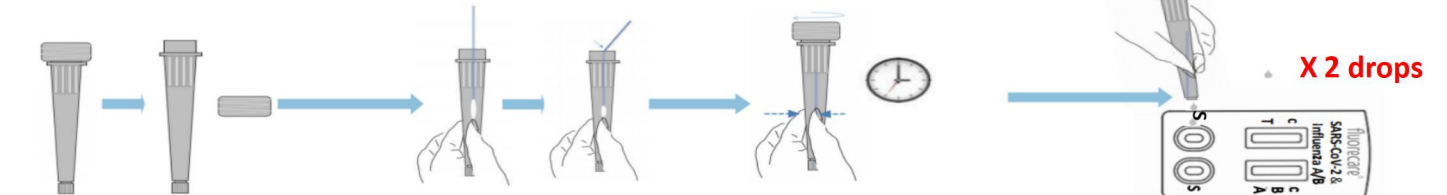
Reliable



1 Procedure



Collect specimen (Oropharyngeal swab/nasal swab) with sterile swab



1 Packing with prepack sample treatment solution: open the treatment tube cap.

Packing without pre-pack sample treatment solution: Add about 12 drops (300µL) sample treatment solution to the extraction tube.

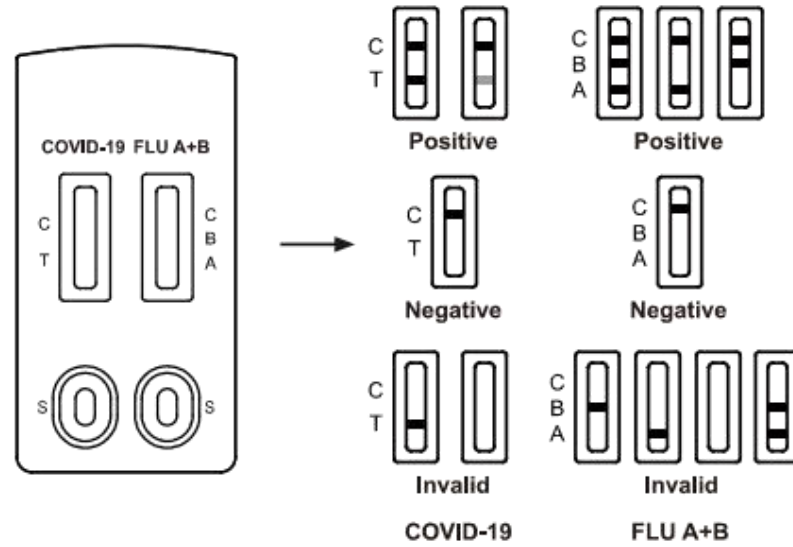
2 Place the swab sample in the tube, then break the swab at the swab node, and leave the lower half in the treatment tube.

3 Cover treatment tube cap, squeeze the swab in the tube for 10 times. Then wait for 5 minutes of reaction.

4 Open the bottom cap, add 2 drops (about 60µL) of sample to the sample hole, then wait for 15 minutes of reaction at room temperature.

Shenzhen Microprofit Biotech Co., Ltd.

2 Interpretation



3 Clinical Performance Evaluation

SARS-CoV-2 & Influenza A/B Antigen Combo Test Kit has been evaluated with specimens obtained from patients. RT-PCR is used as the reference method. Specimens were considered positive if RT-PCR indicated a positive result. Specimens were considered negative if RT-PCR indicated a negative result.

Virus	Number of samples	Test Result				Agreement Statistics		
		Concordant Positive	Discordant Positive	Concordant Negative	Discordant Negative	Agreement Parameter	Percent Agreement(%)	95% CI*
SARS-CoV-2 Antigen	668	64	0	300	26	PPA*	92.9%	(89.8%,95.3%)
						NPA*	100.0%	(98.8%,100.0%)
Influenza A	315	56	1	253	5	PPA	91.8%	(81.9%,97.3%)
						NPA	99.6%	(97.8%,99.9%)
Influenza B	316	51	0	261	4	PPA	92.7%	(82.4%, 98.0%)
						NPA	100%	(98.6%,100.0%)

* Confidence Intervals(CI), Positive Percent Agreement (PPA), Negative Percent Agreement (NPA)

4 Specification

- Intended Use:** Detection of SARS-CoV-2, Influenza virus type A&B antigen
- Package:** 25 Tests/Box
- Storage condition:** 2-30 °C for 12 months
- Speciem Type:** Oropharyngeal, nasal or nasopharyngeal swab
- Time to result:** 15 minutes

Options:

- Prepack sample treatment solution (0.3mL/tube)
- Positive control swabs (SARS-CoV-2, Influenza A & B)



5 Ordering Information

Product Code	Test Name	Sample Type	Reaction Time (min)	Package Size
MF-69	SARS-CoV-2 & Influenza A/B Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)	Oropharyngeal, Nasopharyngeal, Nasal	15	25T/5T/1T