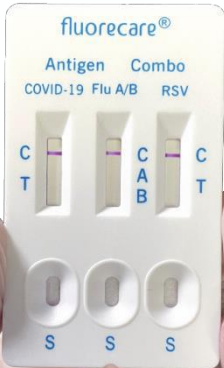




SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit (Self-Test)

Product Brochure

Version: V1.2-2022.07.06



Introduction

During the first few days of a Covid-19 illness, symptoms tend to be nonspecific and may include cough, fever and sore throat. These symptoms can be indistinguishable from other viral infections, such as influenza, respiratory syncytial virus (RSV), or viruses associated with the common cold. Because of this, combo diagnostic testing is needed and important, not only to determine the cause of the illness, but also to determine whether treatment is appropriate.

fluorecare[®] SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit is an easy and rapid way to identify which infections cause the symptoms. It can be used anywhere and anytime by yourself.



Efficiency: 4 in 1 test



Rapid: Results in 15 mins



Non-invasive diagnosis: Nasal swab sample



Convenient: Easy operation and no need for extra Equipment



Simple Storage: Room temperature (2-30°C)



Comprehensive: Effective for mutants of SARS-CoV-2 Alpha, Beta, Gamma, Delta and Omicron

Components



Characteristics

Method	Colloidal Gold
Test Time	15 mins
Shelf Life	18 months
Sample Type	Nasal swab
Specification	Kits for 1T, 2T, 5T
Storage	Room temperature (2-30°C)

CE Certificate

Ce Cert.

CERTIFICATE

DIRECTIVE 98/79/EC
EC DESIGN-EXAMINATION

CeCert Sp. z o.o. hereby confirms that manufactured by

Shenzhen Microprofit Biotech Co., Ltd.

Rm. 405, 406, Zone B/4F, Rm. 205, 206-1, 207, West Side
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Xili Street, Nanshan District, Shenzhen, P.R. China

in vitro diagnostic medical device for self-testing

**fluorecare SARS-CoV-2 & Influenza A/B
& RSV Antigen Combo Test Kit**
catalogue numbers: MF-71-1, MF-71-2, MF-71-5

in term of the design conforms to the requirements of Annex III
section 6 to Directive 98/79/EC (as amended) implemented into Polish
Law, as evidenced by the assessment conducted
by CeCert Sp. z o.o.

CE 2934

Validity date: 12.05.2022 – 26.05.2025

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Check it



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Certificate no: CeCert/092/W/E.2


Kamil Szczurowski
Director of *in Vitro* Diagnostic Medical Device
Certification Department

Clinical Accuracy

SARS-CoV-2

Method		RT-PCR		Total Results
fluorecare [®] SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit	Results	Positive	Negative	
	Positive	342	0	342
	Negative	26	450	476
Total Results		368	450	818

Positive correct rate (Clinical sensitivity)at Ct<38=92.93%(95%CI:89.82%~95.33%)

Negative correct rate (Clinical specificity) = 100% (95%CI:99.18% ~100%)

Method		RT-PCR		Total Results
By Lay Person	Results	Positive	Negative	
	Positive	30	0	30
	Negative	2	87	89
Total Results		32	87	119

Clinical Accuracy

Influenza A

Method		Reference Product		Total Results
fluorecare [®] SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit	Results	Positive	Negative	
	Positive	104	0	104
	Negative	9	555	564
Total Results		113	555	668

Clinical sensitivity =92.04% (95%CI:85.42% ~96.29%)

Clinical specificity =100.00% (95%CI:99.34%~100.00%)

Method		Reference Product Professional Test		Total Results
Self-Test	Results	Positive	Negative	
	Positive	17	0	17
	Negative	0	102	102
Total Results		17	102	119

Clinical Accuracy

Influenza B

Method		Reference Product		Total Results
fluorecare [®] SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit	Results	Positive	Negative	
	Positive	80	0	80
	Negative	8	580	588
Total Results		88	580	668

Clinical sensitivity =90.91% (95%CI:82.87% ~95.99%)

Clinical specificity =100.00% (95%CI:99.37%~100.00%)

Method		Reference Product Professional Test		Total Results
Self-Test	Results	Positive	Negative	
	Positive	11	0	11
	Negative	1	107	108
Total Results		12	107	119

Clinical Accuracy

RSV

Method		Reference Product		Total Results
fluorecare [®] SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit	Results	Positive	Negative	
	Positive	63	0	63
	Negative	3	602	605
Total Results		66	602	668

Clinical sensitivity =95.45% (95%CI:87.45% ~99.05%)
Clinical specificity =100.00% (95%CI:99.39%~100.00%)

Method		Reference Product Professional Test		Total Results
Self-Test	Results	Positive	Negative	
	Positive	31	0	31
	Negative	1	87	88
Total Results		32	87	119

About us

Founded in 2009, Microprofit Biotech is a national high-tech enterprise from China, which is specialized in medical devices and reagents in the field of in-vitro diagnosis (IVD) with the idea of POCT (point-of-care-testing). fluorecare®, the official brand of Microprofit Biotech, dedicated to entire products of point-of-care (POC) tests based on immunofluorescence quantitative assay platform.



With professional R&D, manufacture, marketing, sales and service team, Microprofit Biotech sold products to nearly 100 countries&areas and has won a good reputation around the world. Microprofit Biotech strictly complies with national and international regulations and standards and got many certification,such as CE certificates, FDA certificates, FSC certificates and ISO 13485:2016 quality system certification.



Microprofit Biotech

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