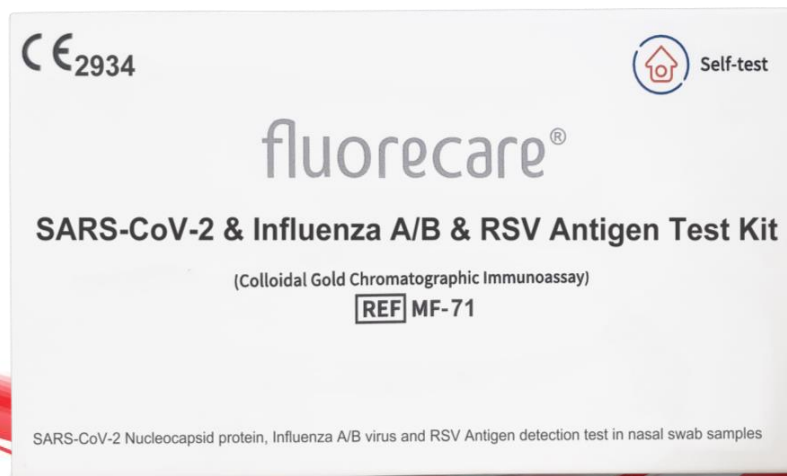


fluorecare[®]

CE 2934

pH-20



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

MF-71

Product Brochure



**Microprofit
Biotech**



SARS-CoV-2

Influenza A/B

RSV

Combo Test Kit

Advantages

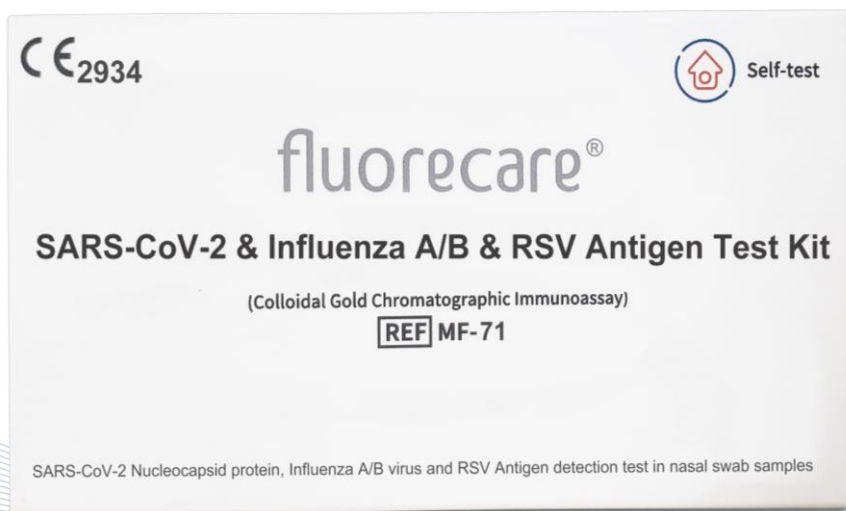
1. Rapid : Results in 15 mins
2. Non-invasive diagnosis : Nasal swab sample
3. Efficiency : Rapidly differentiate 4 infections in 1 test
4. Convenient : Easy operation and no need for extra Equipment
5. Storage: No need refrigerated transportation and store at room temperature
6. It is effective for Alpha, Beta, Gamma, Delta and Omicron

Characteristics

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

fluorecare®

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Test Kit



Test card Tube Test card bag Swab Introduction

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
of Zone B/ 2F, Haowei Building, No. 8 Langshan 2nd
Road, Songpingshan, Songpingshan Community,
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

Edition issue date: 18.05.2022

Check it



CeCert Sp. z o.o.
ul. Żurawia 32/34
00-515 Warszawa

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

www.cecet.pl
e-mail: biuro@cecet.pl

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

Clinical Accuracy

1. Results and Analysis of SARS-CoV-2

Method		RT-PCR		Total Results
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

2. Results and Analysis of Influenza A:

Method		Reference product		Total Results
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

3. Results and Analysis of Influenza B:

Method		Reference product		Total Results
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	58-	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

4. Results and Analysis of RSV:

Method		Reference product		Total Results
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

CONTACT INFO

pH-20 bv

Coupure Links 279
9000 Gent

Joke Dewaele
Tel. 0472 55 55 07
info@ph-20.com