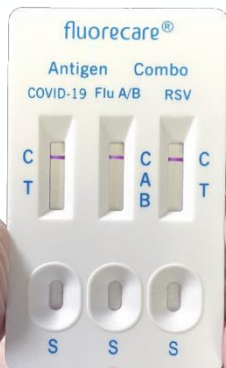


SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit (Self-Test)

Product Brochure

Version: V1.1-2022.07.05



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 everywhere and everytime 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

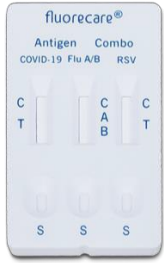


Simple Storage: Room temperature (2-30°C)



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

Components



Test card



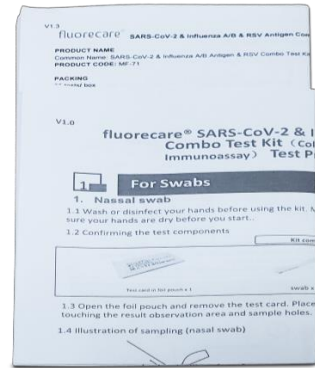
Tube



Test card bag



Swab



Introduction

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

CeCert.

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

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

Shenzhen Microprofit Biotech Co.,Ltd.

Add: Haowei Building, No. 8 Langshan 2nd Road,
Songpingshan, Songpingshan Community, Xili
Street, Nanshan District, Shenzhen, P.R. China

Tel: +86-755-86325154, +86-755-61688835

Fax: +86-755-61688111

Websit: www.microprofit-bio.com

E- mail: bio@microprofit-bio.com



Warsaw, 12.10.2022

CeCert Sp. z o.o.
ul. Warecka 11A
00-034 Warszawa

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

Ref: CeCert/337/2022

Dear Sirs,

With reference to the application 63B/2022 and 64A/2022 regarding the assessment of the documentations of an IVD medical devices for self-testing:

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

manufactured by Shenzhen Microprofit Biotech Co., Ltd. due to the change, I would like to inform that we have completed the assessment of the reported change with a positive result.

The multilingual IFUs and labels for both dVICES as well as the IFUs and labels with the new additional brand "SOLMIRA" have been approved.

EC certificates of conformity no. CeCert/091/W/E.1 and CeCert/092/W/E.2 remain in force and valid.

Sincerely,

**Director of in Vitro Diagnostic Medical
Devices Certification Department**



NIP: 1231429092
REGON: 382803094
KRS: 0000776156



CeCert Sp. z o.o.
ul. Warecka 11A
00-034 Warszawa

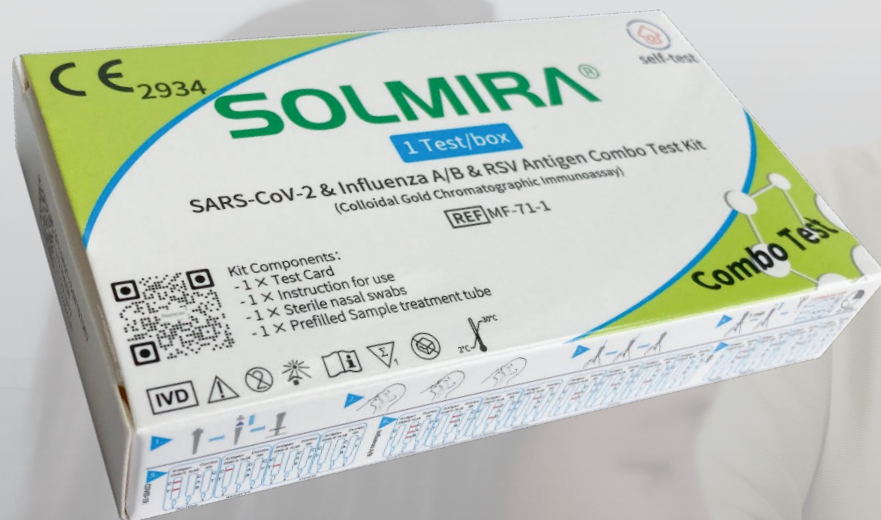


Telefon: 721 721 526
E-mail: biuro@cecercert.pl
Web: www.cecercert.pl

SOLMIRA®

CE 2934 IVD

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



4 IN 1

Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2, influenza A/B and RSV can be similar. It is hard to make an accurate diagnosis based on symptoms alone.

Differentiates between respiratory diseases
Reduce the risk of a misdiagnosis
Helps identify cases of co-infection

Cost-Effective

1 sample, 4 test results, 15 minutes to diagnosis

CE Mark for Self-Testing

CE self-testing certificated, Belgium AFMPS & Spain AEMPS Listed

Comprehensive

Effective for mutants Alpha, Beta, Gamma, Delta and Omicron of SARS-CoV-2 ; strains h3n2 and h1n1 of influenza A ; strains victoria and yamagata of influenza B; types A and B of RSV

Self-Testing

Suitable for non-medical staff, no need for extra equipment.

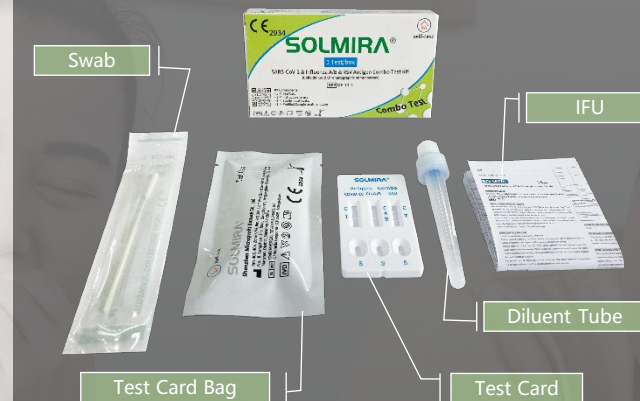
Room Temperature

Transport, store and operate at room temperature

High Performance

	Sensitivity	Specificity
SARS-CoV-2	92.93%	100.00%
Influenza A	92.04%	100.00%
Influenza B	90.91%	100.00%
RSV	95.45%	100.00%

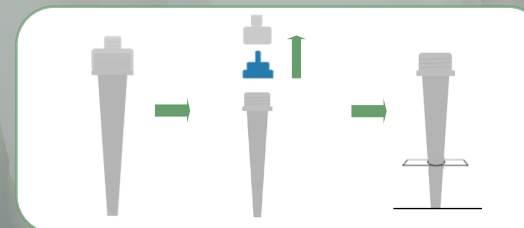
Components of 1 test



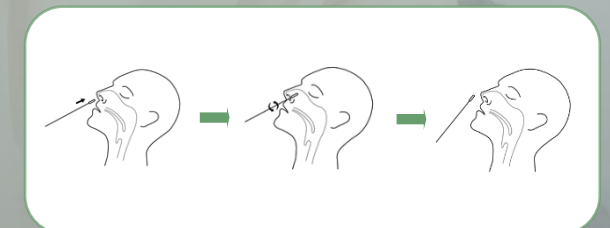
Characteristics

Method	Colloidal Gold Chromatographic Immunoassay
Reaction Time	15 mins
Shelf Life	18 months
Storage Temperature	2-30°C (Room temperature)
Sample Types	Nasal swab
Specification	1 Test/box, 2 Tests/box, 5 Tests/box

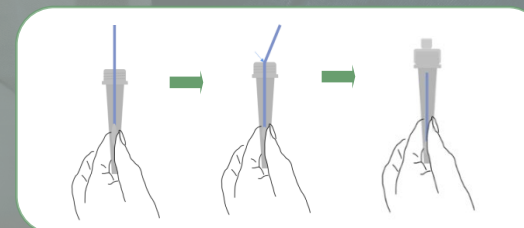
Brief Operation Procedure



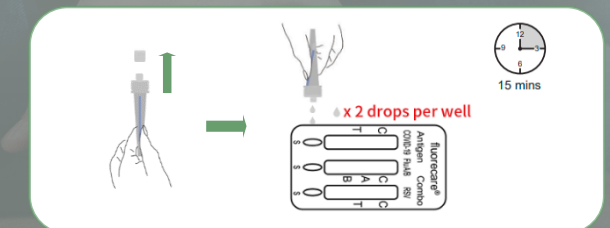
1 Twist off the cap of the diluent tube and remove the inner blue stopper. Insert the diluent tube into the hole of the kit or use other items to hold the diluent tube in place.



2 Insert the nasal swab into the left nostril to a depth of 2.5 cm (1 inch) from the edge of the nostril. Rotate the nasal swab on the nostril wall (mucous membrane) 5 times to ensure adequate sampling. Repeat the process in the right nostril with the same nasal swab.



3 Place the swab sample into the tube, then break the swab at the swab node and leave the lower half in the tube. Close the cap. Squeeze the swab 10 times in the test tube.



4 Unscrew the terminal at the top of the cap. Each sample well of the test card requires 2 drops (about 60 µL) of the treated sample solution. Keep the test card at room temperature for 15 minutes to observe the test results.



Shenzhen Microprofit Biotech Co., Ltd.

Tel: +86-755-61688835

Fax: +86-755-61688111

E-mail: bio@microprofit-bio.com

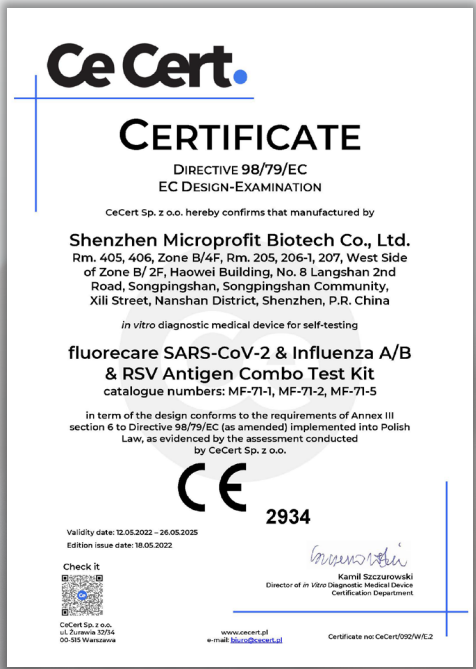
Website: www.microprofit-bio.com



Shenzhen Microprofit Biotech Co., Ltd.

Add: 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

CE Certificate



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.

Belgium AFMPS & Spain AEMPS Listed

Belgium



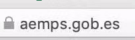
Lijst van aanbevolen SARS-CoV-2 antigen zelftesten
 Liste des autotests antigéniques du SARS-CoV-2 recommandés
 List of recommended SARS-CoV-2 antigen self-tests
 versie/version 29.07.2022

11 MAI 2021 - Arrêté royal portant exécution de l'article 3, § 2, de la loi du 22 décembre 2020 portant diverses mesures relatives aux tests antigéniques rapides et concernant l'enregistrement et le traitement de données relatives aux vaccinations dans le cadre de la loi du 11 mai 2021 - Koninklijk besluit tot uitvoering van artikel 3, § 2, van de wet van 22 december 2020 houdende diverse maatregelen met betrekking tot snelle antiegentesten en de registratie en verwerking van gegevens betreffende vaccinaties in het kader van de wet van 11 mei 2021

Fabrikant/Fabricant/Manufacturer	gemachtigde/représentant autorisé/authorised representative	Naam van de test/Nom du test/Name of the test	Referentie/Référence/Reference (marques commerciales/handelsmerken/trademarks)
Shenzhen Microprofit Biotech Co., Ltd. (CN)	CMC MEDICAL DEVICES & DRUGS, S.L. (ES)	SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)	MF-71 (MF71-1; MF71-2; MF71-5) (Fluorecare)

Les versions de ces documents sont les plus récentes reçues par l'AFMPS (des mises à jours ont pu être réalisées)
 Deze versies van de documenten zijn de meest recente die het FAGG ontvangen heeft (het zou kunnen dat er updates zijn geweest)
 The versions of these documents are the most recent received by the FAMHP (updates may have been made)

Spain



Fluorecare Kit de Prueba Combinada para el Antígeno del SARS-CoV-2, la Gripe A/B y el VSR	Shenzhen Microprofit Biotech Co., Ltd. (China)	MF-71-1 (1 test); MF-71-2 (2 test); MF-71-5 (5 test)	Nº 2934	NASAL
---	--	--	---------	-------

