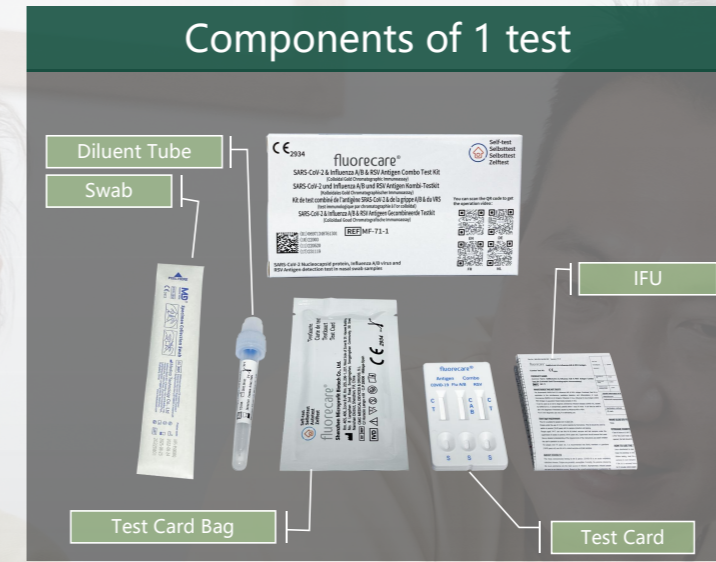
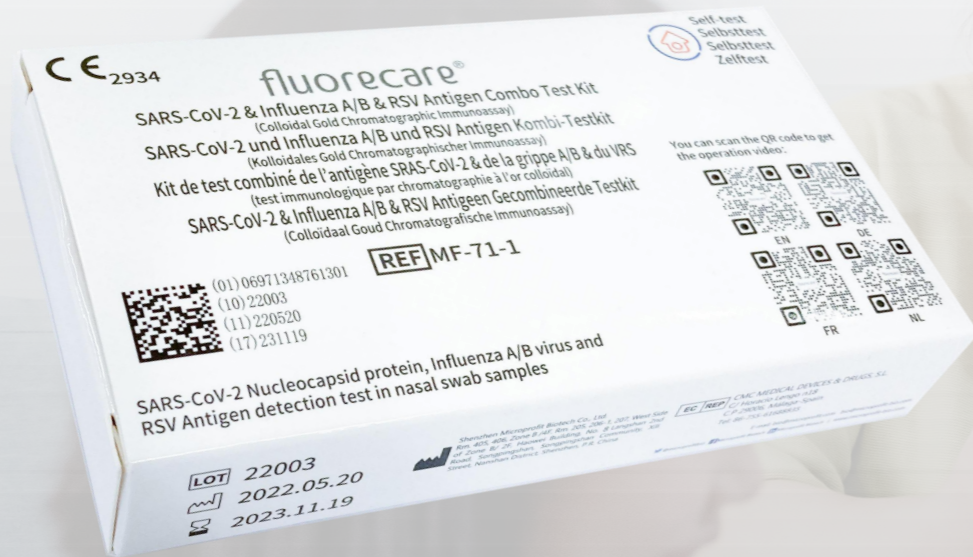


fluorecare®

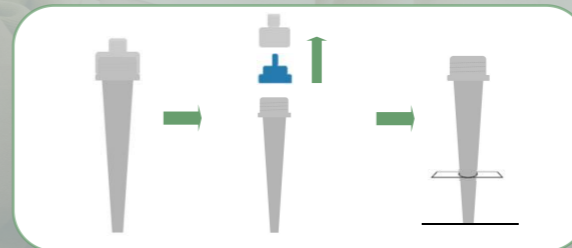
SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit (Self-Test)

CE 2934 IVD

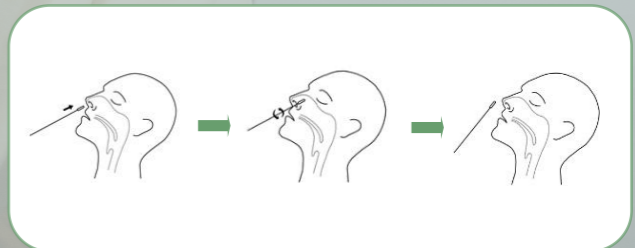


Characteristics	
Method	Colloidal Gold Chromatographic Immunoassay
Reaction Time	12 mins
Shelf Life	24 months
Storage Temperature	2-30°C (Room temperature)
Sample Types	Nasal swab
Specification	1 Test/box, 2 Tests/box, 5 Tests/box

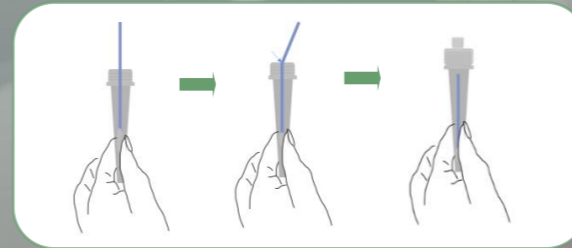
Brief Operation Procedure



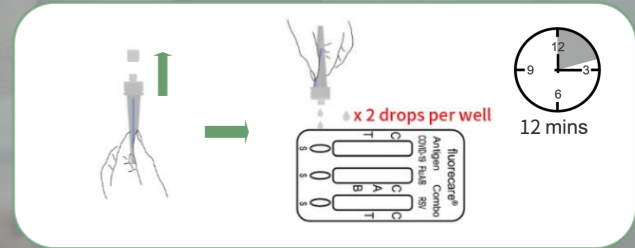
1 Twist off the cap of the diluent tube and remove the inner blue stopper. Insert the diluent tube into the hole of the kit or use other items to hold the diluent tube in place.



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 12 minutes to observe the test results.

4 IN 1 SARS-CoV-2 / RSV Influenza A / Influenza B

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

Cost-Effective

1 sample, 4 test results, 12 minutes to diagnosis

CE Mark for Self-Testing

CE self-testing certificated, Italy & Belgium AFMPS & Spain AEMPS Listed, marketing authorized in Saudi Arabia

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%



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CE Certificate



Marketing Authorization of Saudi Arabia



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 more than 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.

Listed in

Italy

Dispositivo	Numero	Categoria	Modello	Descrizione	Identificativo	Autodiagnostics	Data	FABBRICANTE	Paese
Dispositivo	229694	N	MF-71	FLUORECARE SARS-COV-2 & INFLUENZA A/B & RSV ANTIGEN COMBO TEST KIT.	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	D.L.vo 332/2000	23/09/2022	SHENZHEN MICROPROFIT BIOTECH CO., LTD.	CN
Dispositivo	233383	N	MF-71-1	SOLUBRA SARS-COV-2 & INFLUENZA A/B & RSV ANTIGEN COMBO TEST KIT.	W0105099099 - VIROLOGIA - TEST RAPIDI E "POINT OF CARE" - ALTRI	D.L.vo 332/2000	22/11/2022	SHENZHEN MICROPROFIT BIOTECH CO., LTD.	CN

Belgium AFMPS

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 pandémie de COVID-19.
 11 MEI 2021 - Koninklijk besluit tot uitvoering van artikel 3 § 2 van de wet van 22 december 2020 houdende diverse maatregelen met betrekking tot snelle antigeentesten en de registratie en verwerking van gegevens betreffende vaccinaties in het kader van de COVID-19-pandemie.

Fabrikant/Fabricant/Manufacturer	gsmachtigde/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 AEMPS

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

