

1. Product Box Design & Packaging



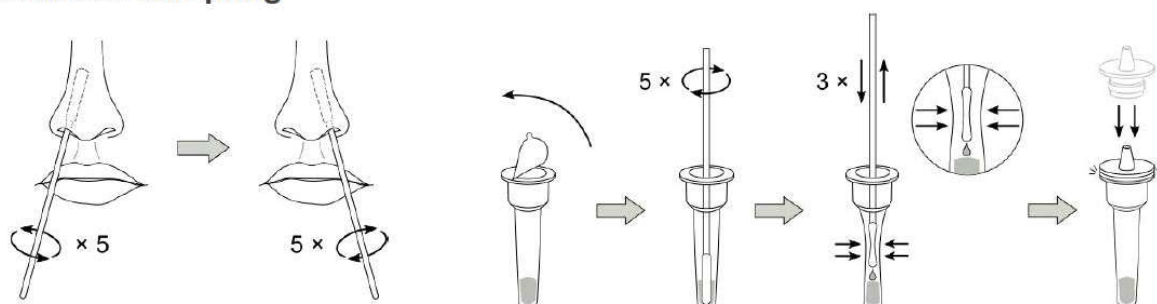
1 test packing



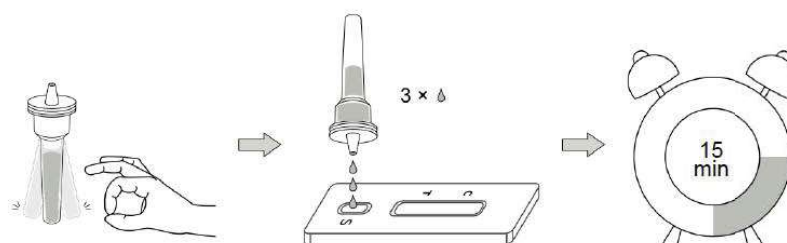
Product intro

Nasal Swab

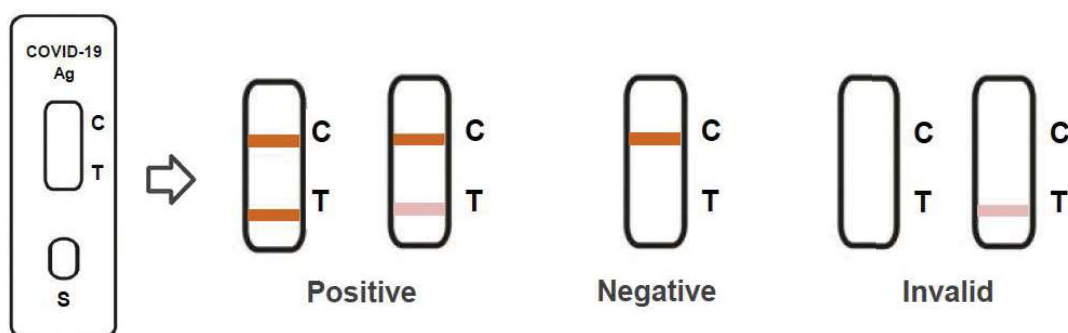
Test Procedures: Sampling



Test Procedures: Detection



Interpretation of Results



Positive(+): Red bands appear at both of T and C line in 15 to 30 minutes. A white band at the T line should be considered as a negative result.

Negative(-): A red band appears at C line while no red band appears at T line in 15 to 30 minutes after sample loading.

Invalid: As long as no red band appears at C line, it indicates that the test result is invalid, and should retest the sample with another test card.

Performance

Sensitivity	Specificity
97.1%	99.2%

2. Declaration of Conformity



DECLARATION OF CONFORMITY
Regarding In Vitro Diagnostic Directive (98/79/EC)

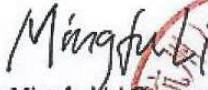
Manufacturer: New Gene (Hangzhou) Bioengineering Co., Ltd.
Address: Room 1606, Floor 16, Building 5, 688 Bin'an Road, Changhe Street, Binjiang District, Hangzhou City, Zhejiang Province, P. R. China

EC Representative: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product Name: COVID-19 Antigen Detection Kit
Product Code: COVID-19-NG08
Specification: 25Tests/Box 1Test/Box
Classification: Others (IVDD)
Conformity Assessment Procedure: Annex III of In Vitro Diagnostic Directive (98/79/EC)

We herewith declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

EN 23640:2015	EN 13640:2002
EN 980:2016	EN 13641:2002
EN ISO 14971:2019	EN ISO 18113-1:2011
EN 13612:2002	EN ISO 18113-4:2011

Signature:   
Name/ Position: Mingfu Li / General Manager
Date: 29/09/2020
Place: Hangzhou, Zhejiang, China

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Authorized Signature (S)