



Novel Coronavirus (2019-nCoV) IgM/IgG Rapid Test Kit (Immunofluorescence)

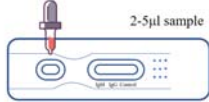
This reagent have been CE marked, for medical use only

Features

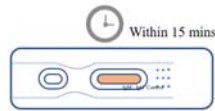
- ✧ Testing principle: Immunofluorescence assay, better sensitivity and specificity than colloidal gold assay.
- ✧ Specimen type: peripheral blood, whole blood, serum, plasma.
- ✧ Testing target: SARS-COV-2 antibodies IgM/IgG.
- ✧ Simple operation: cost only 15 minutes to report the results for large-scale specimen screening.
- ✧ Quantitative assay: equipped with a dry immunofluorescence analyzer which can display test value to assist in dynamic evaluation of antibody level.

Test Procedure & Interpretation of Results

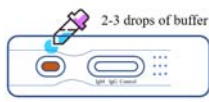
Step 1 Sample loading



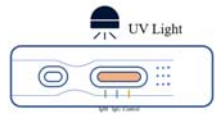
Step 3 Reaction period



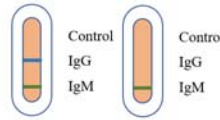
Step 2 Buffer loading



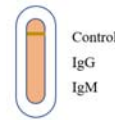
Step 4 Interpret Results



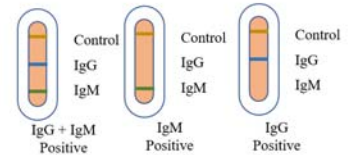
A. Invalid



B. Negative



C. Positive



A. **No band or only test band visible:** tests, which show no control band are not valid and shall **NOT** be evaluated

B. **Only Control band visible:** tests, which show only a control band are negatively valid.

C. **Control and test band visible:** tests, which show both a control band and a test band are positively valid.

Results of Clinical Trial

IgM	Clinical cases		Total
	Confirmed	Excluded	
Positive	61	6	67
Negative	18	194	212
Total	79	200	279

IgM Total consistent 91.4%

IgG	Clinical cases		Total
	Confirmed	Excluded	
Positive	70	4	74
Negative	9	196	205
Total	79	200	279

IgG Total consistent 95.3%

Product Application

- ✧ When a clinically suspected patient of COVID-19 with a negative result of nucleic acid test, IgM and IgG antibodies can be used to determine if infected.
- ✧ For clinically confirmed cases, dynamic monitoring antibodies levels of IgM and IgG.
- ✧ Combined detection of IgM and IgG to improve the detection rate, evaluate the clinical results and can be a marker for rehabilitative.

Product Info

Product Name	Specifications	Storage Condition
Novel Coronavirus (SARS-COV-2) IgM/IgG Test Kit (Immunofluorescence)	30 tests/kit	2~30°C