

Novel Coronavirus IgM/IgG Combo Rapid Test-Cassette(Serum/Plasma/Whole blood)



Novel Coronavirus (2019-nCoV)

IgM/IgG Rapid Test Kit

This reagent have been CE marked, for medical and scientific

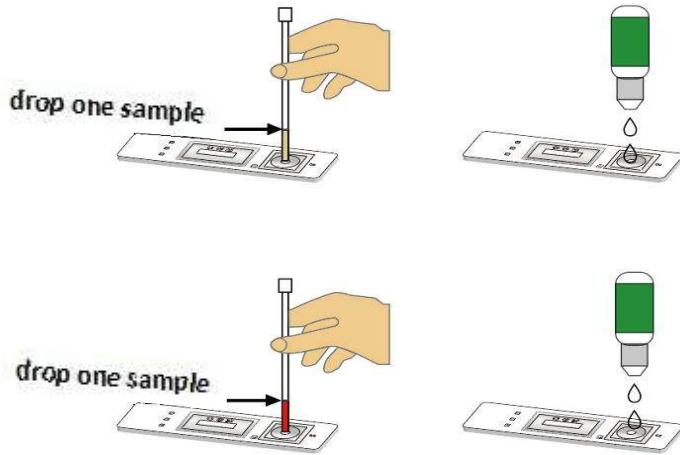
Features

- ✧ **Testing principle: colloidal gold assay Specimen**
- ✧ **Type: peripheral blood, whole blood, serum, plasma.**
- ✧ **Testing target: COVID 19/SARS-COV-2 antibodies IgM/IgG.**
- ✧ **Simple operation: cost only 15 minutes to report the results for large-scale specimen**
- ✧ **test value to assist in dynamic evaluation of antibody level.**
- ✧ **Fast and easy operation for high risk suspicious case**

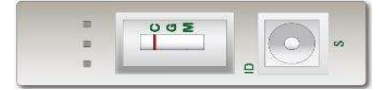


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Test Procedure & Interpretation of Results



1. **NEGATIVE RESULT:** If only the C line is present, the absence of any burgundy color in both test lines (G and M) indicates that no anti-novel coronavirus antibodies are detected. The result is negative or non-reactive.



2. **POSITIVE RESULT:**

2.1 In addition to the presence of C line, if only the M line develops, the test result indicates that IgM anti-novel coronavirus is detected. The result is IgM anti-novel coronavirus positive or reactive.



2.2 In addition to the

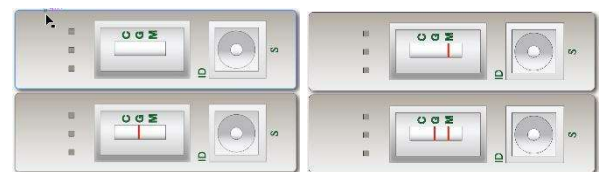
presence of C line, if only the M line develops, the test result indicates that IgG anti-novel coronavirus is detected. The result is IgG anti-novel coronavirus positive or reactive.



2.3 In addition to the presence of C line, if both G and M lines develop, the test result indicates that IgG and IgM anti-novel coronavirus are detected. The result is IgG and IgM anti-novel coronavirus positive or reactive.

Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a diagnosis is made.

3. **INVALID:** If no C line develops, the assay is invalid regardless of any burgundy color in the test lines (G and M) as indicated below. Repeat the assay with a new device.



Results of Clinical Trial

IgM	Clinical cases		Total
	Confirmed	Excluded	
Positive	33	3	36
Negative	3	261	364
Total	36	264	400

IgG	Clinical cases		Total
	Confirmed	Excluded	
Positive	29	2	31
Negative	3	234	237
Total	32	236	268

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
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.
- ✧ Can be assessment tool for Vaccine results

Product Info

Product Name	Specifications	Storage Condition
Novel Coronavirus (COVID19 RT-19) IgM/IgG Test Kit	20 tests/box	2~30°C

Index of CE Symbols

 Consult instructions for use	 For <i>in vitro</i> diagnostic use only	 Use by
 Catalog #	 Lot Number	 Tests per kit
 Store between 2-30°C	 Authorized Representative	 Do not reuse
 Manufacturer	 Date of manufacture	

1. Zhu N, Zhang D, Wang W, Li X, Yang B, Song J, et al. A Novel Coronavirus from Patients with Pneumonia in China, 2019. 24 January 2020. New England Journal of Medicine.
2. Wu P, Hao X, Lau EHY, Wong JY, Leung KSM, Wu JT, et al. Real-time tentative assessment of the epidemiological characteristics of novel coronavirus infections in Wuhan, China, as at 22 January 2020. Eurosurveillance. 2020;25(3):2000044.
3. Lamarre A, Talbot PJ. Effect of pH and temperature on the infectivity of human coronavirus 229E. Canadian Journal of Microbiology. 1989;35(10):972-4.
4. Bucknall RA, King LM, Kapikian AZ, Chanock RM. Studies with human coronaviruses II. Some properties of strains 229E and OC43. Proceedings of the Society for Experimental Biology and Medicine. 1972;139(3):722-7.
5. John RKS, King A, De Jong D, Bodie-Collins M, Squires SG, Tam TW. Border screening for SARS. Emerging Infectious Diseases. 2005;11(1):6.
6. Gunaratnam PJ, Tobin S, Seale H, Marich A, McAnulty J. Airport arrivals screening during pandemic (H1N1) 2009 influenza in New South Wales, Australia. Medical Journal of Australia. 2014;200(5):290-2.
7. Shu P-Y, Chien L-J, Chang S-F, Su C-L, Kuo Y-C, Liao T-L, et al. Fever screening at airports and imported dengue. Emerging Infectious Diseases. 2005;11(3):460.
8. Huizer Y, Swaan C, Leitmeyer K, Timen A. Usefulness and applicability of infectious disease control measures in air travel: a review. Travel Medicine and Infectious Disease. 2015;13(1):19-30.
9. Tran K, Cimon K, Severn M, Pessoa-Silva CL, Conly J. Aerosol generating procedures and risk of transmission of acute respiratory infections to healthcare workers: a systematic review. PLoS One. 2012;7(4):e35797-e.
10. Wang C, Horby PW, Hayden FG, Gao GF. A novel coronavirus outbreak of global health concern. The Lancet. 24 January 2020.

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