

# Istruzioni per l'uso

Ver. NLM 8453 del 02/03/2020

Immunoenzimatica

## Test per dosaggio anticorpale IgG/IgM per Coronavirus (2019-nCoV) in immunocromatografia a fluorescenza

2019-nCoV IgG/IgM Antibody Determination Kit: Fluorescence Immunochromatography

**Cod. NLM AD593/25**

REF

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CE



25 TEST

CND

W0105040619

IVD



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Organizzazione con Sistema di gestione qualità certificata ISO 9001 e Sistema di gestione qualità settore medicale certificato ISO 13485 (organismo di certificazione IMQ - Certificazione CSQ).

# 2019-nCoV IgG/IgM Antibody Determination Kit

## Fluorescence Immunochromatography

Time	15 minutes	Sample Volume	10ul
Sample	Whole blood/plasma/serum/Peripheral blood	Stability	In the original package, the reagents are valid for 18 months under 2°C to 30°C.
Accurate	The positive rate of IgG/IgM detection is more than 90%	Operation	Used with portable POCT analyzer Easy operation.



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## 01. Intended Use

- Used for qualitative determination of IgG and IgM antibodies of novel coronavirus in human serum, plasma or whole blood in vitro.

## 02. Clinical Application

- Current evidence suggests that the novel coronavirus is transmitted mainly through droplets, aerosols, and direct contact with secretions.
- In humans infected with a novel coronavirus (2019-ncov), the body's immune system produces an immune response to the virus, producing specific antibodies. The determination of relevant antibodies can be used to screen for infection with novel coronaviruses.

## 3. Applicable Department

- Emergency Department
- ICU
- Pneumology Department
- Cardio-Pulmonary Function Department



Test kit

# 2019-nCoV IgG/2019-nCoV IgM Antibody Determination Kit Operation



## Comparison of Fluorescence Immunochromatography with Nucleic acid amplification method

2019-nCoV IgG/IgM (Fluorescence Immunochromatography )		2019-nCoV Nucleic acid amplification method
<b>Testing Time</b>	15 mins, Point of care test	Long time detection time (More than 2 hours)
<b>Operation</b>	1, Peripheral blood, plasma, serum and whole blood sample are all available	1, Requires specific laboratory (Physical Partition) and expensive equipment
	2, One Step Test, Detection at all times, Easy Operation	2, Complicated operation, Detection in batches
<b>Storage</b>	Room temperature, common transportation	2-8° C storage, cold chain transportation needed
<b>Accuracy</b>	High accuracy, The positive rate of IgG/IgM detection is more than 90%.	Test results are affected by other factors, high false negative rate.