# NUEVO

## COVID-19 IgM/IgG / IgM/IgG SOLO / IgM/IgG DUET

Detection of SARS-CoV-2 IgM/IgG Ab

## INTENDED USE

NUEVO COVID-19 IgM/IgG Kit is an immunochromatographic assay kit for the qualitative detection of IgM and IgG antibodies in human whole blood, serum and plasma.

## EXPLANATION OF THE TEST

NUEVO COVID-19 IgM/IgG Kit is a chromatographic immunoassay kit for rapid, qualitative and convenient detection of SARS-CoV-2 antibodies in human serum, plasma or whole blood. This test is for in vitro professional diagnostic use of patient with clinical symptoms with SARS-CoV-2 infection.
The nitrocellulose membrane is coated with two test lines (G and M) and a control line. Both the control line and test lines in the result window are not visible before applying any specimens. Monoclonal anti-COVID-19 antibody is coated on the control line region and Monoclonal anti-human IgG is coated on the test line region in IgG device and Monoclonal anti-human IgM is coated on the test line region in IgM device. And also, human IgM/IgG-specific antibody is conjugated to the colloidal gold particles. This conjugate is placed on a polyester or glass fiber as conjugate pad. When the sample is dropped into the sample well on the device, the solubilized conjugate migrates with the sample by passive diffusion and both the conjugate and sample come into contact with the antibody that immobilized onto the nitrocellulose. If the sample contains COVID-19 IgM/IgG antibodies, the result is visible as red line within ~10 minutes in the test line on the membrane. The solution continues to migrate to encounter a control reagent that binds a control conjugate, thereby producing another red control line.

## MATERIALS PROVIDED

1. Test Device (individually in a foil pouch with desiccant)
2. Buffer (individual in a airtight container)
3. Alcohol Swab (individual foil wrapped)
4. Safety Lancet
5. Capillary Tube (10㎕)
6. Instructions for Use

## MATERIALS REQUIRED BUT NOT PROVIDED

1. Medical Mask and Medical Latex Gloves
2. Watch or Timer

## STORAGE AND STABILITY

| COMPONENT | CONDITION | EXPIRATION |
|---|---|---|
| TEST DEVICE | 2~30°C | 12 months after its manufacture date |
| BUFFER | | |

## PRECAUTIONS

1. For professional and in vitro diagnostic use only.
2. Do not reuse the test kit.
3. Do not use the test kit if the pouch is damaged or the seal is broken.
4. Do not use the extraction buffer tube of another lot.
5. Do not smoke, drink or eat while handling specimen.
6. Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly after the tests are done.
7. Clean up spills thoroughly using an appropriate disinfectant.
8. Handle all specimens as if they contain infectious agents.
9. Observe established precautions against microbiological hazards throughout testing procedures.
10. Dispose of all specimens and materials used to perform the test as bio-hazard waste. Laboratory chemical and biohazard wastes must be handled and discarded in accordance with all local, state, and national regulations.
11. Desiccant in foil pouch is to absorb moisture and keep humidity from affecting products. If the moisture indicating desiccant beads change from yellow to green, the test device in the pouch should be discarded.

## SAMPLE TYPE

Whole blood, serum and plazma (EDTA, sodium citrate and Heparin) of human blood.

## SAMPLE STORAGE

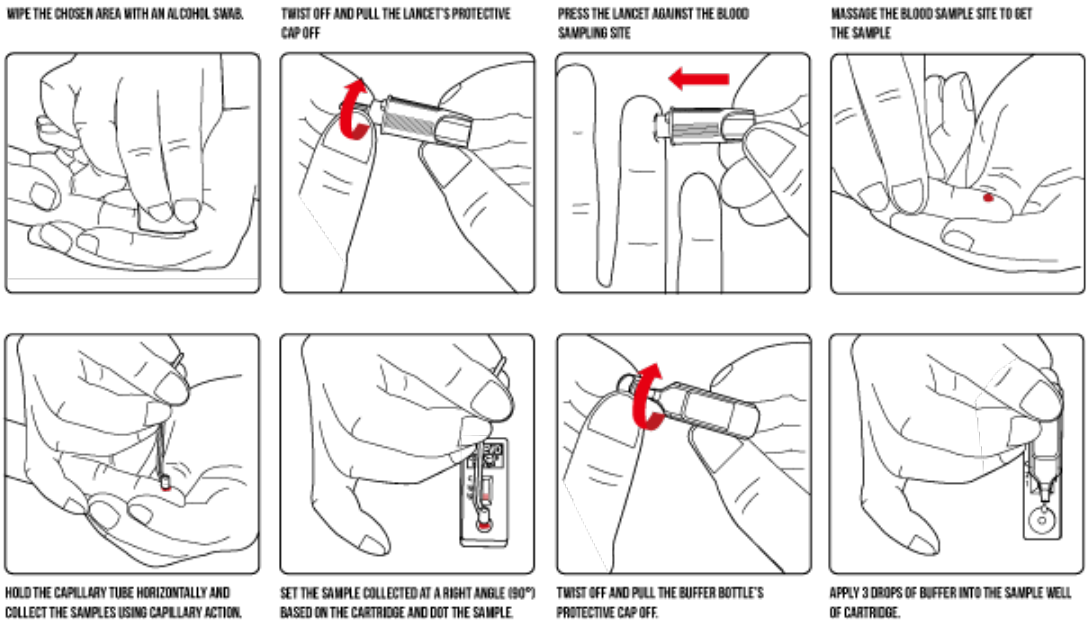
All specimens should be tested immediately.

## LIMITATION OF THE TEST PROCEDURE

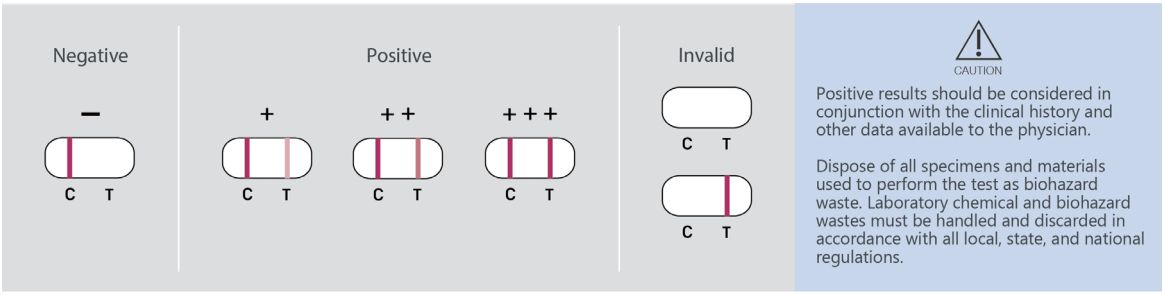
1. NUEVO IgM/IgG Test Kit is designed for the qualitative detection of IgG and IgM antibodies to COVID-19 in human whole blood, serum, or plasma. This kit can provide a fast and easy way to get a very accurate result, but do not completely exclude the possibility of false positive or false negative results caused by various factors. So, refer to the result of this kit, please make a final decision with clinical manifestation and other test results, collectively.

2. False positive results due to cross-reactivity with antibodies to other coronaviruses, (e.g., HKU1, 229E, NL63, OC43) can occur.

## TEST PROCEDURE




## INTERPRETATION OF TEST RESULT




1. A colored band of control line (C) will appear in the left section of the result window to show that the test is working properly.
2. A colored band of test line (T) will appear in the right section of the result window to show the test result.
3. Even if the control line is faint, and or the test line isn't uniform, the test should be considered to be performed properly and the test result should be interpreted as a positive result.

## PERFORMANCE CHARACTERISTICS

| RESULT | | Allplex™ 2019-nCoV Assay | | TOTAL |
|---|---|---|---|---|
| | | POSITIVE | NEGATIVE | |
| NEUVO COVID-19 IgM/IgG | POSITIVE | 33 | 0 | 33 |
| | NEGATIVE | 0 | 33 | 33 |
| TOTAL | | 33 | 33 | 66 |

NUEVO BIOLIFE

R&D
Manufacturing Requester

NUEVO BIOLIFE INC.
3F WINNER BD, 107-9 BANPO-DONG, SEOCHO-GU, SEOUL, REP OF KOREA 06575
TEL / +82 2 567 9949 FAX / +82 2 567 9960
WWW.NUEVOBIOLIFE.COM

Z BIOTECH INC.
#1409, 134 GONGDAN-ROHEUNGDEOK-GU CHEONGJU-SI, REP OF KOREA 28576
TEL / +82 43 278 0075 FAX / +82 43 278 0074
WWW.ZETBIO.COM