NUEVO

COVID-19 Ag / Ag SOLO / Ag DUET

Detection of SARS-CoV-2 antigen

INTENDED USE

NUEVO COVID-19 Ag Test Kit is an immunochromatographic assay kit for the qualitative detection of SARS-CoV-2 antigen from nasopharyngeal and oropharyngeal swab taken from human.

EXPLANATION OF THE TEST

NUEVO COVID-19 Ag Test Kit is a chromatographic immunoassay kit for rapid, qualitative and convenient detection of SARS-CoV-2 antigen in nasopharyngeal swab sputum specimen from human. Test kit contains a membrane strip, which is immobilized with the anti-SARS-CoV-2 monoclonal anti-body on the test line (T) and Goat-anti mouse IgG on the control line (C) respectively.
When the sample and the extraction solution are applied to the sample well, the sample is moved to the gold conjugated pad and reacts with anti-SARS-CoV-2 monoclonal anti-body coupled gold conjugate followed by reaction with anti-SARS-CoV-2 monoclonal antibody immobilized in the test line.
When the sample contains SARS-CoV-2 antigens, a visible line appears in the test region on the membrane, The solution continues to migrate to encounter a control reagent that binds a control conjugage, thereby producing another band in the contol region.

MATERIALS PROVIDED

1. Test Device (individually in a foil pouch with desiccant)
2. Extraction Buffer Tube
3. Nozzle Cap
4. Sterile Swabs for Sample
5. Instructions for Use

MATERIALS REQUIRED BUT NOT PROVIDED

1. Medical Mask and Medical Latex Gloves
2. Specimen Collection Container
3. 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

Nasopharyngeal swab specimen from human.

SAMPLE STORAGE

All specimens should be tested immediately.

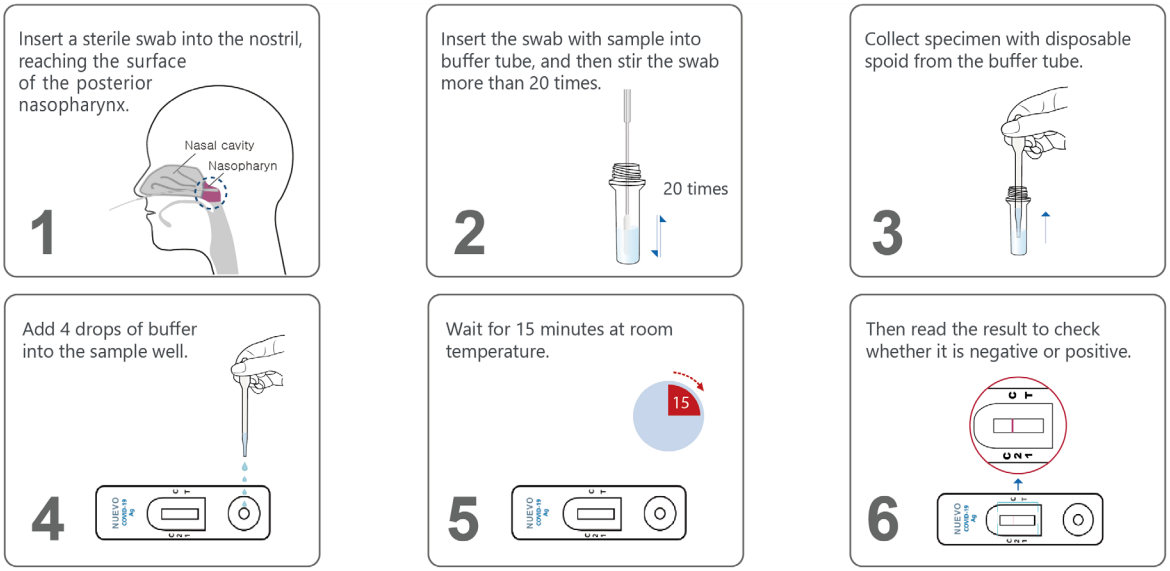
LIMITATION OF THE TEST PROCEDURE

NUEVO COVID-19 Ag is designed for primary screening test. This kit can provide a fast and easy way to get a result, but do not completely exclude the possibility of false positive or false negative result caused by various factors. So, after refering to the result of this kit, please make a final decision with clinical manifestation, other test results, and a doctor's opinion collectively.

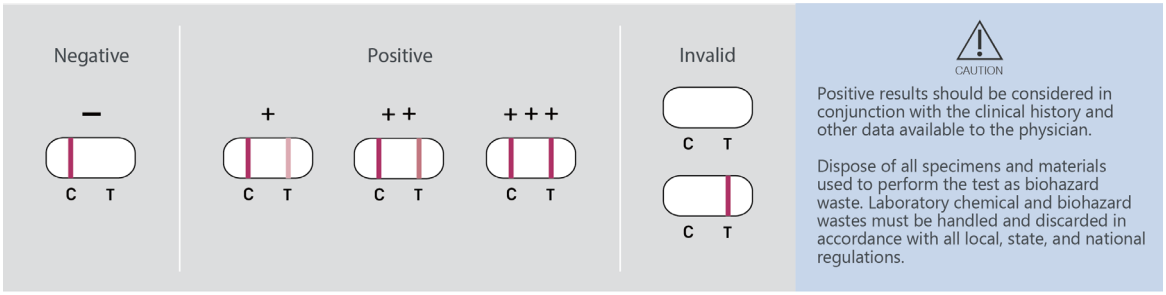
Positive test results do not rule out co-infections with other pathogens. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.

The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after day 5 of illness are more likely to be negative compared to a RT-PCR assay.

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		REAL-TIME PCR		TOTAL
		POSITIVE	NEGATIVE	
NEUVO COVID-19 Ag	POSITIVE	30	1	31
	NEGATIVE	3	32	35
TOTAL		33	33	66
CLINICAL SENSITIVITY 90.9%				
CLINICAL SPECIFICITY 96.9%				

ANALYTICAL SENSITIVITY

Limit of Detection (LoD) LoD of Heat-inactivated SARS-CoV-2 is 7.50×103 TCID50/ml.

ANALYTICAL SPECIFICITY

- Cross-Reactivity : No cross-reactivity was observed with influenza A virus, influenza B virus.
- No interference was observed with Albumin human, Salicylic Acid, Hemoglobin human, Ethanol, Acetaminophen, Caffeine, Aspirin and Ibuprofen

NUEVOBIOLIFE

R&D
Manufacturing
Requester

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