YRLG22301025/YRLG22301050/YRLG22301100

BIOEASY™
2019-Novel Coronavirus (2019-nCoV) IgG/IgM GICA Rapid Test (Colloidal Gold) (Serum / Plasma/ Whole Blood)

FOR IN VITRO DIAGNOSTIC USE

This instruction for use (IFU) must be read carefully prior to use. Instruction for use must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions for use.

PACKING SPECIFICATION

25 Tests/ Kit(YRLG22301025), 50 Tests/ Kit(YRLG22301050),
100 Tests/ Kit(YRLG22301100)

INTENDED USE

BIOEASY™ 2019-Novel Coronavirous (2019-nCoV) Ab GICA Rapid Test is a colloidal gold enhanced, rapid immunoassay for the qualitative detection of 2019-nCoV IgG and IgM antibody in serum, plasma and whole blood samples from patients with suspected 2019-nCoV infection, patients with suspected clustering cases, and others who need to diagnose or differentially diagnose 2019-Novel Coronavirous (2019-nCoV).

This product is for in vitro emergency use only during the pneumonia epidemic of the 2019-nCoV infection since December 2019. The test kit should be complied with the relevant requirements of the "Pneumonitis Diagnosis and Treatment Scheme for 2019-Novel Coronavirous Infection" and "Pneumonitis Prevention and Control Scheme for 2019-Novel Coronavirous Infection" in use.

The 2019-Novel Coronavirou is a new type of coronavirus belonging to the genus β. It has a capsule, and its particles are round or oval, often polymorphous, with a diameter of 60-140nm. Its genetic characteristics are significantly different from SARSr-CoV and MERSr-CoV. Current research shows that it has more than 85% homology with bat SARS-like coronavirus (bat-SL-CoVZC45). In vitro isolation and culture, 2019-nCoV can be found in human respiratory epithelial cells in about 96 hours, while it takes about 6 days to isolate and culture in Vero E6 and Huh-7 cell lines.

PRINCIPLE OF THE PROCEDURE

The 2019-Novel Coronavirous (2019-nCoV) Ab GICA Rapid Test is a colloidal gold enhanced indirect immunoassay for the qualitative determination of 2019-nCoV IgG and IgM antibody in human serum, plasma and whole blood samples.

The product is pre-embedded with recombined 2019-nCoV antigen and chicken IgY antibody on the nitrocellulose membrane, and coated with anti-human IgG, anti-human IgM and goat anti-chicken IgY antibody respectively on the T1 line, T2 line and C line on the nitrocellulose membrane. When a positive sample is tested, the 2019-nCoV IgM and/or IgG antibody combines with the colloidal gold labeled 2019-nCoV antigen to form a complex. Under the action of chromatography, the complex flows along the membrane, when it passes T1 line and/or T2 line it combines with the anti-human IgG and/or IgM to form a colloidal gold complex to show color, and the gold colloidal labeled chicken IgY antibody combines with goat anti-chicken IgY antibody at C lint to show color. Negative samples only show color on C line.

REAGENTS AND MATERIALS SUPPLIED

The test kit consists of test card, a Sample diluent,dropper , an instruction for use, etc.

1. The test card is packed in individual foil pouches. It contains a desiccant and consists of a test strip and a plastic cassette. The main components on the test strip are:

a) 2019-nCoV antigen (immobilized in the T area of nitrocellulose membrane);
b) goat anti-chicken IgY polyclonal antibody (immobilized in the C area of nitrocellulose membrane);
c) 2019-nCoV antigen labeled with colloidal gold conjugate, chicken IgY antibody (embedded on conjugate pad);
d) Other test strip supports.

2. The main component of the sample diluent is phosphate solution.
3. Main components:

Specifications / Ingredients	25 tests/kit	50 tests/kit	100 tests/kit
Test card with desiccant in a sealed foil pouch	25	50	100
Sample Diluent	2	4	8
Dropper	25	50	100
Instruction for use	1	1	1

Note: The components in different batches of the kit cannot be mixed.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch
- Pipette

STORAGE AND STABILITY

1. Storage conditions: Store in a dry place at 2-30°C; do not freeze.
2. Shelf life: 24 months;
3. The test device should be used as soon as possible after being removed from the aluminum foil bag;
4. MFD date and EXP date: mark on label.

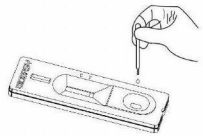
SPECIMEN REQUIEMENTS

1. It is suitable for serum, plasma or whole blood samples. The commonly used anticoagulants (heparin, EDTA or sodium citrate) have no effect on the results of this kit.
2. Samples should be collected according to routine clinical methods and avoid hemolysis.
3. If serum or plasma specimens are to be tested in 5 days, they should be refrigerated at 2° C~8° C. Storage at -20℃ should not exceed 3 months. For long time storage, they should be -70° C cryopreservation and avoid repeated freezing and thawing (no more than 3 times).
4. Whole blood samples can be stored at 2° C~8° C kept in refrigerator for 3 days with no cryopreservation.
5. Restore the sample to room temperature before test.
6. Obvious hemolysis, lipohemia and jaundice samples should not be used.
7. Transportation of the samples should be sealed ice cup with ice or sealed foam box with ice.

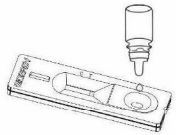
TEST PROCEDURE

1. Return the reagent or sample to room temperature.
2. Open the aluminum foil bag, take out the test card, and lay it flat on a flat operating table and number it.

Add 10μL pre-handled sample extraction into the sample well.

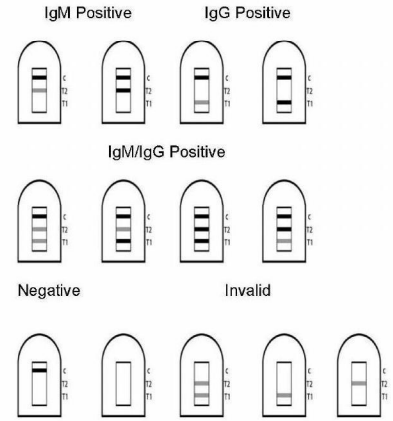


Add 60 μL sample dilution into the sample well.



The result should be read at 15-20 minutes. Results after 20 minutes are invalid.

INTERPRETATION OF TEST RESULTS



LIMITATIONS

1. The test results of this product cannot be used as a basis for diagnosis. Comprehensive judgment should be made in combination with clinical symptoms, epidemiological conditions and further clinical data.
2. In the early stage of infection, the test result may be negative because the 2019-nCoV antibody or low antibody level has not yet appeared in the sample.
3. Due to the limitation of the detection method, the negative test result of this reagent cannot exclude the possibility of infection.
4. This reagent can only qualitatively detect 2019-nCoV antibody in human serum, plasma and whole blood samples. It cannot determine the certain antibody content in the samples.

PERFORMANCE CHARACTERISTIC

1. Serum sample results:

The trial has tested 317 serum samples. The results are as followed:

PCR results / Bioeasy results	Positive	Negative	Total
Positive	136	1	137
Negative	16	164	180
Total	152	165	317

Positive coincidence rate(Sensitivity)=136/（136+16）×100%=89.47%;

Negative coincidence rate(Specificity)=164/（1+164）×100%=99.39%;

Total coincidence rate=（136+164）/（136+1+16+164）×100%=94.64%。

According to follow-up analysis, 2 PCR results are negative, while our product shows positive results to these 2 cases. Later the patients of the 2 samples have been confirmed to be infected by the novel coronavirus;

2. Plasma sample results:

The trial has tested 306 plasma samples. The results are as followed:

PCR results / Bioeasy results	Positive	Negative	Total
Positive	121	0	121
Negative	13	172	185
Total	134	172	306

Positive coincidence rate(Sensitivity)=121/（121+13）×100%=90.30%;

Negative coincidence rate(Specificity)=172/（0+172）×100%=100.00%;

Total coincidence rate=（121+172）/（121+0+13+172）×100%=95.75%.

3. Whole blood sample results:

The trial has tested 304 whole blood samples. The results are as followed:

PCR results / Bioeasy results	Positive	Negative	Total
Positive	112	0	112
Negative	14	178	192
Total	126	178	304

Positive coincidence rate(Sensitivity)=112/（112+14）×100%=88.89%;

Negative coincidence rate(Sepecificity)=178/（0+178）×100%=100.00%;

Total coincidence rate=（112+178）/（112+0+14+178）×100%=95.39%

4. Repeatability

The test was repeated 10 times with 1 enterprise replicate reference product, and the results should all be positive, and the reaction results should be consistent, and the color rendering should be uniform.

5. Minimum detection limit

Tested 3 times with 1 enterprise's minimum detection limit reference product, the results should all be positive.

6. Difference between batches

Take three different batches of kits and test with 1 enterprise replicate reference product. The results should all be positive, and the reaction results should be consistent. There is no difference and in chromaticity and even.

7. Through the test kit to the reference product testing analysis, when the samples containing hemoglobin (≤6 mg/mL), bilirubin (≤12 mg/dL), triglycerides (≤15 mg/mL), cholesterol (10 mg/mL) or rheumatoid factor (≤80 IU/mL)in different concentrations, decision does not affect the test result, test results are no interference.

8. This product does not cross-react with IgM positive samples of influenza A virus, influenza B virus, respiratory syncytial virus, human parainfluenza virus, Mycoplasma pneumoniae and Chlamydia pneumoniae.

WARNINGS AND PRECAUTIONS

1. The reagent is a disposable in vitro diagnostic reagent, which is only used for the detection of human serum, plasma and whole blood samples. All samples that test positive with this test card must be further validated. The operation should be carried out strictly in accordance with the instructions. Do not use it out of date and damaged product.
2. This reagent can be stored at room temperature. Reagents or samples stored at low temperature should be return to room temperature before use.
3. If the clinical samples need to be frozen at -20 ℃ or below, it is recommended that the frozen samples should not be frozen for more than three months and repeatedly frozen and thawed not more than three times.
4. The reagent should be used as soon as possible after being taken out of the aluminum foil bag, to avoid being exposed to the air for a long time, which will affect the test results due to moisture.
5. Do not use samples that have been left for too long, grow bacteria, or have odors for experiments.
6. Please follow the laboratory testing procedures for infectious diseases. The waste after use should be treated as infectious materials, and do not be discarded randomly.
7. There should be appropriate biosafety assurance procedures for those substances containing and suspected sources of infection. The following are relevant considerations:

(1) Handle samples and reagents with gloves;
(2) Do not suck samples with your mouth;
(3) Do not smoke, eat, drink, cosmetic or touch contact lenses while handling these items;
(4) Disinfect the spilled sample or reagent with disinfectant;
(5) Disinfect and treat all samples, reagents and potential pollutants in accordance with relevant local regulations;
(6) Each component of the reagent remains stable until the expiry date under proper handling and storage conditions. Do not use the expired reagent kit.

BIBLIOGRAPHY

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Key to symbols used:

TEST CARD	**Test Card with Desiccant in a Sealed Foil Pouch**		
COMPONENT	**Materials Included**	DROPPER	**Dropper**
DILUENT	**Sample Diluent**	IFU	**Instruction for Use**
	Consult Instructions For Use		**Date of Manufacturer**
	Store at 2°C~30°C		**Do Not Reuse**
	Expiration Date	REF	**Catalogue Number**
	Manufacturer		**Keep away from Sunlight**
LOT	**Lot Number**	Σ	**Tests per Kit**
EC REP	**Authorized Representative**		**Keep Dry**
IVD	**In Vitro Diagnostic Medical Device**		
SUBSIDIARY	**Subsidiary of Shenzhen Bioeasy Biotechnology Co., Ltd.**		

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