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COVID-19 Ab Kit (GICA, Rapid Card)

Package Information

Kit bag: desiccant, aluminum foil bag and package insert;

buffer solution: 3 mL;

Kit: COVID-9 N protein, COVID-9 S protein, nitrocellulose membrane, conjugate pad; sample pad; absorbent paper.

Package size:

20 kits/bag.

Intended Use

For in vitro test use, COVID-9 antibody can be detected.

Method

God Immunochromatographic Assay (GICA).

Principle

This assay is a one-step lateral flow chromatographic immunoassay. The test strip in the device includes: 1) a conjugate pad containing COVID-9 N protein , COVID-9 S protein, Rabbit IgG antibody, all of which are conjugated to a colloidal gold, and 2) nitrocellulose membrane containing a test line (T line) and a control line (C line). T line is coated with anti-Human IgG antibody, anti-Human IgM antibody, While C line is coated with mouse anti-rabbit IgG antibody. During the test, COVID-9 antibody and COVID-9 N or S protein labeled with colloidal gold formed antigen antibody complexes. If the specimen does not contain COVID-9 antibody or the COVID-9 antibody level is below the lower level, the T line will not appear. The C line is coated with mouse anti-rabbit antibody, which should bind to the gold-antibody conjugate and forms a burgundy colored line regardless of the presence of COVID-9 antibody.

Storage and validity

1. Sealed in aluminum foil bag at 2-30°C. Valid for 12 months.
2. Protect from light and don't freeze.

Specimen collection

Type: venous whole blood, plasma or serum.

Plasma/serum: stable for 72h at 2-8°C, and 9 days at -20±5°C. Recover it to room temperature before use, avoid thawing and refreezing frequently.

Venous whole blood: EDTA, heparin and sodium citrate is suggested to be employed; detect in 8 hours once sampling; stable for 7 days at 2-8°C.

Hemolysis may affect results. Do not test hemolyzed samples.

Test method

Refer to the kit instructions.

1. The kit, specimen and buffer solution should be recovered to room temperature (15-30°C) before tesing.
2. Tear aluminum foil bag out, take reagent strip out and place it on flat table, please use it immediately, and avoid long time exposure resulting in moisture absorption.
3. Extract 10 μl specimen form the piper and add it into sample hole of the kit, then 80 μl buffer solution add into immediately.
4. Read the result until 15 min.
5. Warning: the result after 20 min is invalid.

Interpretation of results

Invalid: If C line does not appear, the result is invalid

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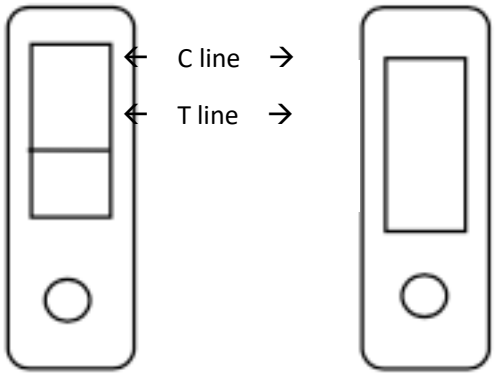
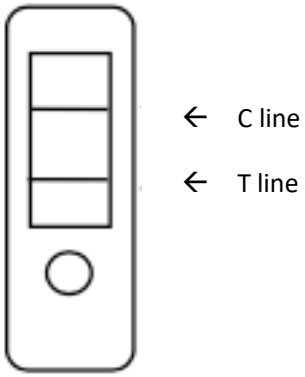
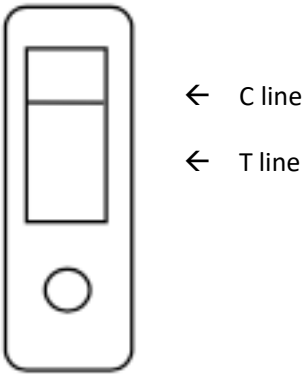
whether the T line appear or not, as shown in the figure. Prepare another package to test again. *Tips: please analysis the volume of sample addition.*



Positive: Both of T line and C line appear, as shown in the figure.



Negative: T line does not appear, while C line appear, as shown in the figure.



Limitation of Test Methods

1. The kit is only for testing human venous whole blood, plasma, serum.
2. The kit is mainly used for qualitative detection, the concentration of the COVID-9 in sample can not be supply.
3. Test result may be wrong due to technical reasons, operational errors and other specimen factors.
4. The kit is mainly used to assist clinical diagnosis. Clinical diagnosis judgments need to combine patient's history, clinical manifestation and other test examination.
5. If the result is negative, nucleic acid testing or virus culture identification is suggested to be employed to review.

Performance characteristics

1. **Positive coincidence rate:**

   The positive reference products of manufacturer coincidence was 5/5.

2. **Negative coincidence rate:**

   The negative reference products of manufacturer coincidence was 10/10.

3. **Sensitivity:**

   The ***S1*** reference of manufacturer with the minimum detection limit was negative, and ***S2, S3*** reference were positive.

4. **Precision:**

   2 precise reference products of manufacturer (*J1~J2*) was test 10 times individually, and each result was positive.

5. **Specificity Assay:**

   5.1 There is no interaction with specimen which

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contain *Parainfluenza antibody, Influenza A antibody, Influenza B antibody, Chlamydia pneumoniae antibody , Mycoplasma pneumoniae antibody , Adenovirus antibody,Rrespiratory syncytial virus antibody, HBsAg antibody, HCV antibody, TP antibody, HIV antibody, EB virus antibody, Measles virus antibody, Cytomegalovirus antibody, EV71 antibody, or Mumps virus antibody.*

5.2 Interfering substances:

1) There is no interference to test results if the concentrations of the following substances are at or below the given values.

Substances	**Concentrations**
Bilirubin	250 μmol/L
Hemoglobin	9 g/L
Triglyceride	15 mmol/L
RF	80 IU/mL
ANA	1:240
AMA	80 U/mL
Mouse IgG	1 000 μg/mL

2) There is no interference to test results if the following medicines exist in the specimen: *Histamine hydrochloride, IFN-α, Zanamivir, Oseltamivir, Ribavirin, Peramivir, Lopinavir, Ritonavir, Arbidol, Levofloxacin, Azithromycin, Ceftriaxone, Meropenem, Toramycin.*

6. Clinical studies:

596 clinical specimen (361 clinical diagnosed positive, and 235 clinical diagnosed negative) were tested, the sensitivity rate was 86.43% (95% CI: 82.51%, 89.58%), and specificity rate was 99.57% (95% CI: 97.63%, 99.92%).

Precautions

1. For in vitro diagnostic use only.
2. Do not use package when damaged, unclear label or even expired.
3. The test shall be operated in strict accordance with the instructions.
4. The results must be interpreted within 15 minutes.
5. Do not use highly hemolytic and lipid blood samples.
6. The disposable kit is referred to biological waste when used.

References

1. Pneumonia diagnosis and treatment for novel coronavirus infection (trial version sixth).

Basic information

Manufacturer: Xiamen Green Stone Swiss Co ., Ltd.

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