The COVID-2019 ANTIGEN RAPID TEST KIT (Colloid Gold Immunochromatography) Instruction Manual

【Product Name】

The COVID-2019 ANTIGEN RAPID TEST KIT (Colloid Gold Immunochromalography)

【Packaging Specifcafion】

20 T/box, 1T/box

【Intended Use】

This kit is used for the quaitative detection of the COVID-2019-NP antigen in human nasopharyngeal swab and oropharyngeal swab samples. It is mainly used for clinical reference, but cannot be used as the basis of diagnosis of the COVID-2019.

【Detection Principle】

This kit uses the principle of highly specifc antibody-antigen reaction and clloidal gold labeling immunochromalographic analysis technology. The reagent contains COVID-2019-NP antigen monoclonal anibody prefixed in the lest area (m on the membrane and the COVID-2019-NP Antigen monoclonal anbody coated on the label pad-olloidail gold mixlure.The sample is drpped into the sample well and reacts wth the COVID-2019.NP antigen monoconal antibody which is bound to the pre-coated clloidal gold particles when testing.Then the mixture is chromatographed upwards wilh callaly efeets. i is posive. The antibody labeled by clloidal gold particles will first bind to the COVID-2019-NP antigen virus in the sample during chromatography Then the conjugates are bound by the COVID-2019-NP anigen monoclonal antibody fxed on the memBrane, and a red line appears in the test area (T),fi is negaive, there's no red line in the test area(T).Whether the sample contains COVID-2019 or not,

a red line wil appear in the qualty control area (C) The red line appearing in the qualy control area (C) is the standard tor Judging whether there are enough samples and whether the chromalographic process is normal, and it also serves as the internal control standard for the reagent.

【Packing Components】

1 Test cassette: 20tests, 1 test

2 Sample soluton (0.9% Sodlum chloride solution : 20 tubes,1tube

3 Swabs; 20 pieces, 1 piece

4 Dropper tips: 20 pleces, 1 piece

【Storage Conditions And Validiy】

The test kit should be stored at4 °C - 30 °C，and cannot be frozen. The valdity period is 12 months.The test cassette shall be used within 1 hour after opening.

【Specimen Requirements】

Polyester sponge swabs with PP (polypropylene) rods are recommended for aseptic swabs when collecting samples.

1. Nasal secretions collection:

Insert the swab into the nasal cavily where secretions are most when collect nasal screions Gently rolate and push the swab into the nasal cavity until the nasal turbinate is blocked (about 2.0-2.5cm from the nostril), then press the swab against the nasal wall for three times and remove the swab.

2.Throat secretions collection:

Insert the swab completely from the mouth into the throal, centering on the red part of the throat wall and maxillary tonsils, and rub the bilateral throat tonsils and throat wall moderately. Avoid touching the tongue and remnove the swab.

3.The samples should be treated wilth the wirus sampling solution or the sample extraction solution provided with this kit as soon as possible after collecion. And complete the test in 5 minutes.

【Test Methods】

Please read the instrucion manual carefully before testing. Place the test kit and conduct the testing at room temperature.

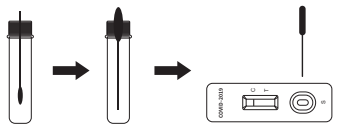


Figure I

1 Specimen extraction

(See Figure 1)

(1) Put the swab into the sampling tube and rotate it about 10 times to make the sample dissolve in the souton as much as pssile.

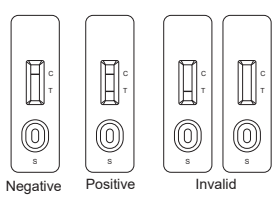
2 Detection operations:

(I)Open the aluminum foil bag along the tear mouth and take the test cassette out, and put it in flat.

(2)Add 100ul (about 4 drops) of sample solution extract to the sample well of the test cssette.

(3)Observe the results showed within 10-20 minutes, and the results showed after 30 minutes have no clinical significance.

【Interpretation Of Test Results】



Positive (+) : Two red lines appear. One is in the test area (T) and the other is in the quality control area (C).

Negative (-) : Only a red line appears in the quality control area (C), and no line appears in the test area (T).

Invalid: No red line displays in the quality control area (C). This indicates that the incorrect operation or the test cassette has deteriorated or damaged.

【Limitations Of Test Methods】

1.This kit is only for the detection of respiratory secretions; from nasopharyngeal swabs andoropharyngeal swabs.

2.The acracy of the test depends on the sample clecion po. mproper samplecllection, improper storage of samples, unfresh samples,。or repeated freeze-thaw cycles ofsamples will affect the test results.

3.The presence of idividual drugs in the sample clcte, such as high cocenrations of over-the-counter drugs and prescription drugs (nasal sprays), can iterere with the rsuts lf the results are suspicious, please retest.

4.The test cssete only provides qultative delection of the SARS-COV-2 in the sample. If you need to detect the specific content of an indicator, please use the relevant poessional instruments.

5.The test result of this kit is for cinial reference only and should not be used as the sole basisfor cinical diagnosis and treatment. The cinial management of patients should be considered in combination with their symptoms 1 signs, medical history, other laboratory tests, andtreatment responses.

6.Due to the limitation of the method of antigen detection reagents, its analyical sitivityis generally lower than that of nucleic acid reagents. Therefore, the experimenters should pay more attention to the negative results and need to make a comprehensive judgment in combination with other test results. It is recommended to review the suspicious negative results by using nucleic acid detection or virus culture identification methods.

7.Analysis of the possibility of false negative results:

①Unreasonable sample collection, transportation and processing, and too low concentration of tested substances in samples may lead to false negative results.

②Genetic variations of virus can cause changes in antigenic determinants, which can lead to false negative results. This is more likely to occur by using monoclonal antibody reagents.

③The optimal sample type and sampling time (peak virus titer) after infection have not been verified, so collecting samples fractinally, in multiple parts on the same patient may avoid false negative results.

【Product Performance Index】

1、Physical performance

1.1.1 Appearance

1) The test kit and its components should be complete;

2)The packaging bag should be sealed well, with no breakage and with clear label;

3) The material is firmly attached, and the strip width is suitable for the cassette.

1.1.2Film strip width: ⩾3.0mm.

1.1.3Liquid migration velocity: The liquid moving speed should not be less than 10 mm/min.

1.2Accuracy and repeatability Repeat the test 10 times with negative quality control solution (0 ng/mL) and 10 ng/mL, 20ng/mL, and 40 ng/mL COVID-2019-NP recombinant antigen control solutions. Positive quality control solution must not show negative results, and negative quality control solution cannot have positive results.

1.3 lnter-batch difference Testing 10ng/mL, 40ng/mL samples 10 times for each by using threebatches test kits. 10 ng/mL samples should be shown weakly positive results, and no positive or strongly positive results should appear. 40 ng/mL sample should be shown strongly positive results,and no positive or weakly positive results should appear.Negative results should be negative.

1.4HOOK effect: Test the 100ng/mL COVID-2019-NP recombinant antigen sample, the result should be strongly positive.

Specificity: Test the 100 ng/mL canine coronavirus, feline coronavirus, and porcine coronavirus positive samples, the result should be negative.

【Matters Needing Attention】

1.This kit is single-use for in vitro diagnosis. Do not use if expired.

2.It indicates an error if no line appears in the quality control area(C) and test area (T). Please retest.

3.The high temperature of the experimental environment should be avoided. The test kit which was stored at low temperature needs to be restored to room temperature before opening to prevent moisture absorption.

4.It is recommended to use fresh samples, do not use repeatedly freeze-thaw samples.

5.Please use the swab and sample extraction solution provided in this kit when sampling. Do not mix test cassettes and sample extraction solutions from different batches.

6.If the virus sampling solution is used to treat the specimen, then it can be directly detected without using sample extraction solution.

7.The laboratory requires bio-safety level II or operation in a bio-safety cabinet.

8.Pay attention to safety measures during operation, such as wearing protective clothes and gloves. Used swabs, test cassettes, extraction tubes, etc. should be decontaminated before disposal. High-pressure steam disinfection is recommended.

9.There is desiccant inside the aluminum foil bag. Do not eat.

【Interpretations Of Identification】

IVD	In vitro diagnostic medical device	EC REP	Authorized representative in the European Community	LOT	Production batch code
CE	CE Mark		Consult instructions For use		Temperature limit
	Manufacturer		Do not re-use		Use-by date

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