

Composition and Description of the Device

a. Formulation and composition

| Item | Ingredients | Material | Technical Data | Function |
|---|---|---|----------------|---|
| Novel Coronavirus Antigen Test Cassette | Encloser | HIPS | / | As a carrier for the chromatography process |
| | Chemical substance of Novel Coronavirus Antigen Test Cassette | Novel Coronavirus(2019-nCoV) antibody (for coating) | 2.0 mg/mL | T-line coating antibody |
| | | Novel Coronavirus(2019-nCoV) antibody (for labeling) | 0.02 mg/mL | Labelling antibody |
| | | Goat anti-mouse Antibody (for Coating) | 2.0 mg/mL | C line coating antibody |
| | | Chloroauric acid | 0.04% | For the preparation of colloidal gold |
| Sample extraction buffer | Chemical substance of sample extraction buffer | NaCl | 1.7% | Used for sample extraction and dilution |
| | | Na ₂ HPO ₄ ·12H ₂ O | 0.7% | |
| | | KH ₂ PO ₄ | 0.1% | |
| | | Tween-20 | 0.5% | |
| | | KV300 | 0.1% | |
| | Tube | PE | / | |
| | Tube cap | PP | / | |

b. Capture antibodies

- Which Capture antibodies and antigens were used. Whether monoclonal or polyclonal antibodies used. What species they are derived from.

Mouse monoclonal anti-SARS-CoV-2 antibody is coated on the test line region and goat anti-mouse monoclonal antibody is coated on the control line region. The binding pad is bound with a mouse monoclonal anti-SARS-CoV-2 antibody conjugated with colloidal gold.

- What epitope is targeted by the antibodies used in an assay.

Nucleocapsid protein of SARS-CoV-2 Antigen

- Provide the components of the conjugates used (antigen or antibody and colour probe) and conjugation method.

Colloidal gold labelled with mouse monoclonal anti-SARS-CoV-2 antibody was coated on the glass fiber binding pad.

- Indicate if the test uses biotin-streptavidin/avidin chemistry in any of the steps for coupling reagents.

NA.

Colloidal gold labelled with mouse monoclonal anti-SARS-CoV-2 antibody was coated on the glass fiber binding pad.

Labeling process: Add 20 μ L of 2% potassium carbonate into 1mL of colloidal gold prepared from 0.04% chloroauric acid. Antibody concentration shall be labelled as 20 μ g/mL, and the labelling time is 10min. Block with 0.1% BSA for 5min. The amount of preparation needs to be adjusted according to production requirements.

The labelled binding pad and the coated PVC board are combined into a semi-finished product, and the quality of the semi-finished product is inspected.

C. Product description

➤ Legal manufacturer.

Manufacturer: Beijing Hotgen Biotech Co., Ltd.

➤ Product name

Product name: Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)

➤ Overview and intended use of the IVD.

- Type of IVD

Lateral flow antigen rapid diagnostic test.

- What the product detects.

Qualitative detection of Nucleocapsid protein of SARS-CoV-2.

- The function of the product.

Aid to diagnosis.

- The clinical indication for the IVD (i.e. specific disorder, condition or risk factor of interest that the product is intended to detect, define or differentiate.)

Rapid investigation for suspected cases of novel coronavirus, reconfirmation method for nucleic acid detection in discharged cases.

- Whether the product is automated or manually operated.

Manually operated

- Whether the test is qualitative or quantitative.

Qualitative.

- The type of specimen(s) required.

Human anterior nasal swab samples.

- The target population.

Suspected cases of novel coronavirus.

➤ **A general description of the principle of the assay method or instrument principles of operation.**

This kit is based on the colloidal gold immunochromatographic technology, and uses double antibody sandwich method to detect the novel coronavirus antigen in human nasal swabs or throat swabs samples. The detection line (T line) of the novel coronavirus antigen test cassette was coated with novel coronavirus antibody, and the quality control line (C line) was coated with goat anti-mouse antibody.

During the test, the sample is dropped into the sample well of the test cassette. The novel coronavirus antigen in the sample is first combined with the novel coronavirus antibody labelled with colloidal gold to form a novel coronavirus antigen - labelled novel coronavirus antibody - colloidal gold complex. This

complex migrates on the membrane via capillary action, to form a solid phase novel coronavirus antibody - novel coronavirus antigen - labelled novel coronavirus antibody - colloidal gold complex at the T line position. As the chromatography continues, a solid phase goat anti-mouse antibody - labelled novel coronavirus antibody - colloidal gold complex is formed at the position of line C. After the test is completed, observe the colloidal gold color reaction of T line and C line to determine results of novel coronavirus antigen in nasal swab or throat swabs samples.

➤ **How they are expected to work.**

Positive: Two color bands appear in the observation window, that is, a red or magenta line appears at the position of the quality control line (C line) and the detection line (T line) , which indicates the test result of novel coronavirus antigen in the sample was positive.

Negative: A red or magenta line appears at the position of the quality control line (C line) in the observation window, and no line appears at the position of the test line (T line), indicating the test results of the novel coronavirus antigen in the sample were negative or the antigen concentration in the sample was below the limit of detection of the kit.

Invalid: No line appears in the position of the quality control line (line C) in the observation window, which indicates that the test is invalid, should collect sample again and retest.