

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) Technical File (I)	Document No	Version	Page
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I General Description

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1. Manufacturer Information:

- 1) Name: Atlas Link (Beijing) Technology Co., Ltd
- 2) Registered trademark: NOVA Test®
- 3) Description: Manufacturer of *in vitro* diagnostic test kit since 2004.
- 4) Technology Profile: Atlas Link Technology Co., Ltd has targeted its research and development resources on technological discoveries and applications in immunology, primarily in the area of *in vitro* diagnostics.
- 5) Location 1:
 Address: Room 811 Zeyang Plaza, No.166 Fushi Road, Shijingshan Dist., Beijing, P.R.China
 Tel: [REDACTED] 5.1.2e Fax: [REDACTED] 5.1.2e
<http://www.atlas-link.com/english>

- Location 2:
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Fax: + 5.1.2e

2. European Representative Information:

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66386 St. Ingbert
Germany

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3. Product Introduction

This kit is used for in vitro rapid qualitative detection of novel coronavirus (SARS-CoV-2) antigens in nasopharyngeal and nasal swab samples. The product is designed to be used for population screening early phase for disease outbreaks. Testing is limited to laboratories certified and self-testing. Results are for the identification of SARS-CoV-2 nucleocapsid antigen. This antigen is generally detectable in upper respiratory samples during the acute phase of infection.

4. Classification

Product: SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)

Classification: Self-testing IVD Test Device
EDMA code: 15 70 90 90 00

5. Characteristic

- 5-1 Easy to use, no additional instrument or reagent is needed;
- 5-2 High specificity and sensitivity
- 5-3 Each test is enclosed in a moisture proof aluminum pouch with a Silicon Gel for long time storage.

6. Intended Use

NOVA Test@SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) is an immunochromatographic membrane assay that uses the double-antibody sandwich method to detect the novel coronavirus (SARS-CoV-2) nucleocapsid protein from Anterior nasal swab (NS) and Nasopharyngeal swab (NPS) specimens from suspected patients may infected COVID-19. Performance of the test is limited to professional use and self-testing use.

SARS-CoV-2 Antigen Rapid Test Kit provides preliminary test results, with negative results don't preclude SARS-CoV-2 infection. The test kit cannot be used as the sole basis for treatment or other management decision. For in vitro diagnostic use only.

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7. List of Components

Catalog No.	Product Name	Package	Storage Condition
nCov-500	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)	1pcs/box	2°C-30°C
Package Contents:			
1) Pouch contents: Test cassette, desiccant. 2) Assay Diluent 3) Disposable Specimen Swab 4) Disposable Extraction Dropper 5) Biohazard Waste Bag 6) Instruction for Use/Quick guide			

7-1 Composition

The SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing Monoclonal antibodies conjugated with colloid gold, 2) a nitrocellulose membrane strip containing test band (T band) and a control band (C band). The T band is pre-coated with Monoclonal antibodies specifically against SARS-COV-2 antigen for the detection of SARS-COV-2 antigen, and the C band is pre-coated with quality control antibody.

Test Device Assembly:

The coated membrane, the labeling conjugate, and an absorbent pad are assembled onto an adhesive plastic sheet. Two waterproof labels are taped over the conjugate pad and the absorbent pad along with other supportive fiber cloths, the assembled sheet is cut into strips.

As for the cassette, the strip component is then assembled into a plastic cassette casing. The device is then sealed in an aluminum pouch with desiccant. The product name, lot number and expiration date are printed onto the aluminum pouch and packed for shipping.

7-2 Biological action

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. SARS-CoV-2 antigens if present in the specimen will bind to the Monoclonal antibodies conjugates. The immunocomplex is then captured on the membrane by the pre-coated Monoclonal antibodies, forming a burgundy colored T band, indicating a SARS-CoV-2 positive test result.

Absence of test band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band regardless of the color

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development on the test band. Otherwise, the test result is invalid and the specimen must be retested with another device.

7-3 Appearance

The SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) has a letter of T and C as "T Line" and "Control Line" on the surface of the case. Both the "T Line" and "Control Line" is used for test procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working. A purple "T Line" will be visible in the result window if there is enough SARS-CoV-2 antigens in the sample.

8. Storage and Stability

The test kit can be stored at room temperature (2°C to 30°C) in the sealed pouch for 18 months. The test kits should be kept away from direct sunlight, moisture and heat.

9. Warnings & Precautions

1. For in vitro diagnostic use.
2. To avoid erroneous results, specimens must be processed as indicated in the assay procedure section.
3. When collecting a nasopharyngeal swab/nasal swab sample, use the specimen swab supplied in the kit. Use of alternative swabs may result in false negative results.
4. Do not touch the reaction area of test strip.
5. Do not use test kit beyond the expiration date.
6. Do not use the kit if the pouch is punctured or sealed not well.
7. Package content should discard as medical waste accord with local legislation.
8. Poor vision and/or improper lighting may affect interpretation of the results.
9. This test is intended for single use only. DO NOT REUSE.
10. Do not freeze the cassette or any other material.
11. Do not eat, drink or smoke in the area where the specimens or kits are handled.
12. Keep out of children's reach.