

Novel Coronavirus 2019-nCoV Antigen Test(Colloidal Gold)

Specimen Requirements

- Sample collection**
Gently insert the entire soft tip of the swab into one nostril for 1.5cm until you feel a bit of resistance.
Using medium pressure, rub the swab sticks slowly in a circular motion around the inside wall of your nostril 4 times for a total time of 15 seconds.
Repeat the same process with the same swab in the other nostril.
- Sample treatment**
The swabs after sampling is soaked below the liquid level of the sample extraction buffer. Rotate and press 3 times. The swab soaking time is not less than 15s.
The swab head is squeezed, then take out the swab and tighten the sampling tube.
- Sample preservation**
The treated sample should be tested within 1h.

Test Procedure

- Place the test cassette, sample extraction buffer at room temperature for 15-30 minutes, and equilibrate to room temperature (10-30°C).
- Open the aluminum foil pouch of the test cassette, place the test cassette on a flat surface.
- Add 4 drops of the treated sample into the sample well of the test cassette. (In case of chromatographic abnormalities, extra add 1-2 drops of the treated sample accordingly.) incubate at 10-30°C for 15 minutes.
- Observe the results after incubate at 10-30°C for 15 minutes. The result after 30 minutes is invalid.

Interpretation of result



Clinical Performance

This study enrolled a total of 223 human anterior nasal swab specimens, of which 108 were positives for RT-PCR Test, 115 negatives for RT-PCR Test; As for data collection of the corresponding RT-PCR Test results.

Assessment system Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)	Reference system (clinical diagnostic results)		
	Positive(+)	Negative(-)	Total
Positive(+)	104	1	105
Negative(-)	4	114	118
Total	108	115	223

Sensitivity: 96.30%; Specificity: 99.13%; Accuracy: 97.76%.

Product information

Product name	Test samples	Specifications	Storage conditions
Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)	Human Anterior Nares Swab	1T/kit, 5T/kit, 20T/kit, 40T/kit	4-30°C

Beijing Hotgen Biotech Co., Ltd.
Add: 9 building, No.9 Tianfu Street, Daxing District, Beijing, 102600, P.R. China
Website: www.hotgen.com.cn

Zugelassen für Laintestungen



Stock Code: 688068.SH

Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) Summary Data



Beijing Hotgen Biotech Co., Ltd.

Declaration of Conformity

Manufacturer:

Name: Beijing Hotgen Biotech Co., Ltd
Address: 9th building, No.9 Tianfu Street, Biomedical Base, Daxing District, Beijing, 102600, P.R.China

European Representative:

MedNet GmbH Borkstrasse 10, 48163 Muenster, Germany

Product Name:

Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)
Novel Coronavirus 2019-nCoV Antigen Test (Up-converting Phosphor Immunochromatographic Technology)

Classification: Others of ANNEX II of IVDD

Conformity Assessment Route: Annex III

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

General applicable directives:

In Vitro Diagnostic Medical Devices DIRECTIVE 98/79/EC

Harmonized standards:

EN ISO 13485:2016, EN ISO 15223-1:2016, EN ISO 14971:2012, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002, EN ISO 17511:2003, EN ISO 23640:2015, EN 13641:2002, EN 13975:2003, EN 62366:2008



Signature: Lin Changqing

Name: Lin Changqing
Title: General manager
Place: Beijing, China.
Date of Issue: Aug 27, 2020

Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)



Product Features

- High Accuracy, Specificity and Sensitivity
- No need instrument, get results in 15 minutes
- Room temperature storage
- Sample: Human Anterior Nares Swab
- Detect the presence of viral proteins
- Identify acute or early infection

Clinical Performance

(Disease Course 5-7 Days)

Sensitivity: 96.30%; Specificity: 99.13%; Accuracy: 97.76%.



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