Covid 19 Rapid Antigen Test,Clongene Covid 19 Antigen Rapid Test Diagnostic Colloidal Gold Antigen Test

Our Product Introduction

Basic Information

- Place of Origin: China
- Brand Name: DVOT
- Certification: CE/BfArM/ PEI /TGA
- Model Number: Swab / Saliva
- Minimum Order Quantity: Negotiable
- Price: Negotiable
- Packaging Details: Each boxes 25tests packing /17.5 kg per carton. 64*34*55cm 1250 test per Carton.
- Delivery Time: 5-8 Working days
- Payment Terms: T/T, Western Union
- Supply Ability: 5000000Test

Product Specification

- Product Name: Diagnostic Kit For COVID-19 Antigen Rapaid Test
- Format: Cassette
- Safety Standard: EN149-2001+A1-2009
- Warranty: 12months
- Keyword: Antigen Rapid Test
- Specimen: Whole Blood/ Serum/ Plasma
- Result Time: Read In 15 Minutes
- Accuracy: Over 99.4%
- After Sale Service: Online Technical Support
- Storage: 1~30° Normal Temperature
- Highlight: **Clongene Covid 19 Antigen Rapid Test**, **Colloidal Gold Covid 19 Antigen Rapid Test**, **Diagnostic Colloidal Gold Antigen Test Kit**

More Images

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Product Description

Immunochromatography Lateral Flow Test Kit ,SARS-CoV-2 Lateral Flow Test Kit

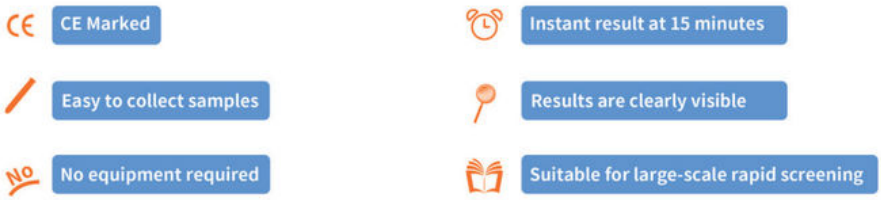
Professional Use

Intend Use

This rapid test kit is intended for the qualitative detection of SARS-CoV-2 infection from patients. It is for professional use only. It is an aid in the diagnosis of the patients with suspected SARS-CoV-2 infection in conjunction with clinical presentation and results of other laboratory tests. Results from this test kit should not be used as the sole basis for diagnosis.

Product Advantage

- Simplicity: It is extremely easy to use with simple to understand instructions.
- Fast: After the extraction of the sample, it will take just 10-15 mins for the result to be reflected on the testing device.
- Reliable: CE, ISO13485 ,TGA Certificated, Stric quality control, High quality
- Extraction tube is fully enclosed for disposal



Main Components

- 25 Test Cassettes
- 25 Sample tubes
- 1 Sample extraction buffers
- 25 Swabs
- 1 Package Insert

PERFORMANCE CHARACTERISTIC

1. Clinical Verification

The performance of Test Card was established with 243 sample collected from symptomatic patients, who with symptoms onset within 7 days.

Performance Characteristics

Clinical Performance

Nasopharyngeal Swab

770 nasopharyngeal swabs were collected from individual symptomatic patients by using CLUNGENE® COVID-19 Antigen Rapid Test. The RT-PCR cycle threshold (Ct) is the relevant signal value. Lower Ct value indicate higher viral load. The sensitivity was calculated for the different Ct value range (Ct value≤33 and Ct value≤37).

Summary data as below:

COVID-19 Antigen		RT-PCR (Ct value ≤ 33)		Total
		Positive	Negative	
CLUNGENE®	Positive	145	2	147
	Negative	3	593	596
Total		148	595	743

PPA (Ct ≤ 33): 98.0% (145/148), (95%CI: 94.2%~99.3%)
NPA: 99.7% (593/595), (95%CI: 98.8%~99.9%)

COVID-19 Antigen		RT-PCR (Ct value ≤ 37)		Total
		Positive	Negative	
CLUNGENE®	Positive	161	2	163
	Negative	14	593	607
Total		175	595	770

PPA (Ct ≤ 37): 92.0% (161/175), (95%CI: 87.0%~95.2%)
NPA: 99.7% (593/595), (95%CI: 98.8%~99.9%)

PPA - Positive Percent Agreement (Sensitivity) NPA - Negative Percent Agreement (Specificity)

Nasal Swab

617 nasal swabs were collected from individual symptomatic patients by using CLUNGENE® COVID-19 Antigen Rapid Test. The sensitivity was calculated for the different Ct value range (Ct value≤33 and Ct value≤37).

Summary data as below:

COVID-19 Antigen		RT-PCR (Ct value ≤ 33)		Total
		Positive	Negative	
CLUNGENE®	Positive	132	3	135
	Negative	4	462	466
Total		136	465	601

PPA (Ct ≤ 33): 97.1% (132/136), (95%CI: 92.7%~98.9%)
NPA: 99.4% (462/465), (95%CI: 98.1%~99.8%)

COVID-19 Antigen		RT-PCR (Ct value ≤ 37)		Total
		Positive	Negative	
CLUNGENE®	Positive	139	3	142
	Negative	13	462	475
Total		152	465	617

PPA (Ct ≤ 37): 91.4% (139/152), (95%CI: 85.9%~94.9%)
NPA: 99.4% (462/465), (95%CI: 98.1%~99.8%)

PPA - Positive Percent Agreement (Sensitivity) NPA - Negative Percent Agreement (Specificity)

Limit of Detection (Analytical Sensitivity)

The study used cultured SARS-CoV-2 virus which is heat inactivated and spiked into nasopharyngeal swab specimen. The Limit of Detection (LoD) is 5.7×10^2 $TCID_{50}$/mL.

Cross Reactivity (Analytical Specificity)

32 commensal and pathogenic microorganisms that may be present in the nasal cavity have been evaluted and no cross-reactivity was observed.

Interference

17 potential interference substances with different concentration were evaluated and found no affect to the test performance.

High-dose Hook Effect

The COVID-19 Antigen Rapid Test was tested up to $1.0 \times 10^{5.67}$ $TCID_{50}$/mL of inactivated SARS-CoV-2 and no high-dose hook effect was observed.

Certificates

Our Certifications

LAB

Factory Workshop

Why Choose Us?

10

FACTORY DIRECT SUPPLY, Professional manufacturer

We have many certificates CE ,ISO,TUV,TGA

Industry and trade integration,more discount!

Overseas Warehouse in Europe,Fast shipment

Packing & Delivery

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