CARLO DE GIORGI

THE EXCELLENCE OF CHOICE

DETAILS & TECHNICAL INFORMATION

Rapid diagnostic is important: the fast timing in obtaining a test result may slow new infections »

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Rapid diagnostic is essential to reduce the spread of SARS-CoV-2. Which to choose and why?

	ANTIGENIC NASOPHARYNGEAL	ANTIGENIC SALIVARY	SEROLOGICAL
What is the test for?	The antigen test is used for the qualitative search for viral proteins (antigens) that are identified when the virus is actively replicating.	The salivary test serves for the qualitative search of viral proteins (antigens) that are identified when the virus is actively replicating.	The serological test is used for the qualitative detection of specific antibodies present in the blood (IgM and IgG) in response to infection caused by SARS-CoV-2.
What biological material is used?	Nasopharyngeal swab performed by healthcare personnel.	Expectoration (sputum) collected with the help of healthcare personnel.	Drop of blood collected by a lancing device with the help of healthcare personnel.
How can the test help?	Diagnose an ongoing infection	Diagnose an ongoing infection	Diagnose a recent or past infection
What to do after reading the test results?	For a complete diagnosis it is necessary to proceed with the molecular test, whatever is the result.	For a complete diagnosis it is necessary to proceed with the molecular test, whatever is the result.	Molecular testing must be proceed to evaluate the possible active presence of the virus.

Rapid antigen test: COVID-19 Antigen Rapid Test Cassette (CLUNGENE®)

15 minutes

180/180
The results for the sample **MEDIUM POSITIVE** the detection rate is 100%.

179/180
The results for the sample **LOW POSITIVE** the detection rate is above 95%

180/180
The results for the sample **NEGATIVE** the detection rate is 100%.

COVID-19 Antigen Rapid Test Cassette (CLUNGENE®) is useful for the early detection of an ongoing infection caused by SARS-CoV-2.

The evaluation of the performance of COVID-19 Antigen Rapid Test Cassette has been realized by analyzing 285 nasopharyngeal swabs and comparing the results obtained with RT-PCR molecular test.

COVID-19 Test		RT-PCR		Total
		Positive	Negative	
Covid-19 Antigen Rapid Test Cassette	Positive	64	0	64
	Negative	6*	215	221
Total		70	215	285

*Positive Percent Agreement (PPA)= 91.4% (64/70), (95%CI: 82.5%~96.0%); Negative Percent Agreement (NPA) =100% (215/215), (95%CI: 98.2%~100%); *The 6 discordant specimens (CLUNGENE Device Negative/ Comparator RT-PCR assay Positive) had Ct Values of 34, 36, 35.5, 34, 35 and 33. The PPA is 98.5% (64/65) (95%CI: 91.8%~99.7%) with specimens of a Ct count ≤33.*

High precision

The accuracy during the rapid test analysis was determined by three batches, using the following samples panel: negative, positive and positive medium low.

Two CLUNGENE® researchers performed analyzes for five nonconsecutive days with three batches of COVID-19 rapid tests, including two runs per day and two replicates of each sample of analysis.

Each sample was tested 180 times (2 replicates × 2 operators × 3 lots × 5 days × 3 laboratories).

Clinical case extract | Sensitivity and Specificity Report & Precision Report | Company: Hangzhou Clongene Biotech Co.

Technical details

The rapid antigen test

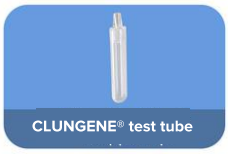
COVID-19 Antigen Rapid Test Cassette is produced by the Hangzhou International Clongene Biotech Co., Ltd. specializes in vitro diagnostics.

COVID-19 Antigen Rapid Test Cassette is a diagnostic test for professional use based on the rapid lateral flow immunochromatographic method for the qualitative detection of SARS-CoV-2 antigen at the nasopharyngeal level.

Important: Rapid antigen tests can only be performed by qualified healthcare personnel.

Product code	Box dimensions
543/00	268 mm x 124 mm x 65 mm

Covid-19 Antigen Rapid Test Cassette includes:

	Cassette COVID-19 Ag	x 25
	Test tube with dropper cap	x 25
	Reagent liquid	x 25
	Sterile swabs for nasopharyngeal sampling	x 25
	Workstation	x 1

How it works

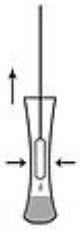
1

Collect sample by using the nasopharyngeal swab.

2

Insert the swab with the sample into the diluent tube and shake the swab 5-10 times.

3

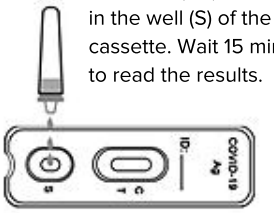


Remove the swab by gently pressing the bottom of the tube.

4

Close the tube carefully, using the cap provided

5



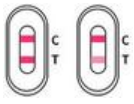
Add 3 drops (about 100 uL) in the well (S) of the cassette. Wait 15 minutes to read the results.

6

NEGATIVE

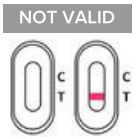
A colored line on the letter C (Control)

POSITIVE



Two lines: a colored line on the C (Control) and a colored line on the T (Test).

NOT VALID



No lines or a single line on the T: the swab must be performed again using another package.

Rapid salivary antigenic test: Novel Coronavirus Antigen Detection Kit (Colloidal Gold) NEWGENE

15 minutes

90,00%
Sensibility

95,00%
Specificity

93,30%
Indicator for the rate of agreement

Novel Coronavirus Antigen Detection Kit (Colloidal Gold) manufactured by Bioengineering NEWGENE is used to evaluate the presence of active infection caused by SARS-CoV-2, identifying the antigens in sputum samples.

COVID-19 test*		Gold standard reagent		Total
		Positive	Negative	
Novel Coronavirus Antigen Detection Kit	Positive	36	4	40
	Negative	4	76	80
Total		40	80	120

**Clinical sensitivity (%) = [36 / (36 + 4)] x 100% = 90.0% ; Clinical specifcity (%) = [76 / (4 + 76)] x 100% = 95.0%*
Total agreement rate (%) = [(36 + 76) / (36 + 4 +4 + 76)] x 100% = 93.3%

NEWGENE Bioengineering identifies the presence of Sars-CoV-2 nucleocapsid proteins

The data were obtained from a comparison between the gold standard reference test (RT-PCR) and Novel Coronavirus Antigen Detection Kit (Colloidal Gold) NEWGENE to estimate their sensitivity, specificity and rate of agreement. There were 120 samples tested. Novel Coronavirus Antigen Detection Kit developed by NEW GENE (Hangzhou) Bioengineering Co., Ltd. can be used for rapid and qualitative detection of SARS-COV-2 in sputum samples.

Clinical case extract | Sensitivity and Specificity Report & Precision Report | Company: New Gene (Hangzhou) Bioengineering Co., Ltd.

Technical details

Salivary antigen test

Novel Coronavirus Antigen Detection Kit (Colloidal Gold) is a rapid test based on the lateral flow immunochromatographic method for the qualitative detection of Sars-Cov-2 antigen (nucleocapsid) in sputum samples.

Sputum is the mucus that is expelled from the lower respiratory tract (bronchi and lungs), through a deep cough; it is not pure saliva.

The rapid saliva test helps to make a first level screening population.

Novel Coronavirus Antigen Detection Kit (Colloidal Gold) is a rapid test that allows to identify the positive subjects, which will be further confirmed by a thorough diagnosis with the molecular test (RT-PCR).

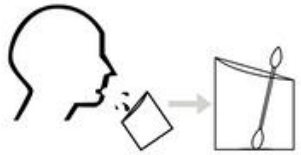
Important: rapid salivary tests can only be performed by qualified healthcare professionals.

Product code	Box dimensions
574/00	268 mm x 124 mm x 65 mm

Novel Coronavirus Antigen Detection kit includes:	
Cassette Covid-19	x 25
Sample extraction tube	x 25
Disposable paper cone	x 25
Alcohol wipe	x 25
Sterile swabs for sample collection	x 25

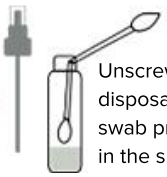
How it works

1



Collect the sputum (10-50 mg) after a cough, using a disposable paper cone provided in the kit.

2



Unscrew the cap of the disposable tube, insert the swab previously immersed in the sputum sample and break the swab shaft inside the tube.

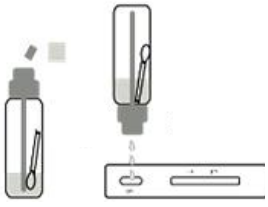
3

Screw the cap of the disposable tube and shake to completely mix the sample.

4

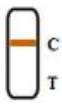
After mixing the contents of the tube, leave to incubate for 1 minute.

5



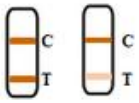
Cut the end of the tube cap and pour 3 drops of solution into the well (S) of the cassette.

NEGATIVE



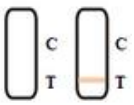
A colored line on the letter C (Control)

POSITIVE



Two lines: a colored line on the C (Control) and a colored line on the T (Test).

NOT VALID



No lines or a single line on the T: the swab must be performed again using another package.

Rapid Serological Test: COVID-19 IgG / IgM Rapid Test Cassette (WB / S / P) CLUNGENE®

15 minuti

97,40%
Sensitivity for IgG antibodies

87,01%
Sensitivity for IgM antibodies

98,89%
Specificity for IgM antibodies

93,41%
Precision indicator for IgM and IgG antibodies

COVID-19 IgG / IgM Rapid Test Cassette (WB / S / P) CLUNGENE® is useful for detecting the presence of antibodies developed by the immune system in case of infection with SARS-CoV-2.

IgM are the first antibodies that are produced by the body in case of infection

The sensitivity and specificity of the test COVID-19 IgG / IgM Rapid Test Cassette (WB / S / P) CLUNGENE® were analyzed, comparing 167 clinical samples confirmed with the molecular test (RT-PCR) for IgM antibodies.

COVID-19 IgM*		RT-PCR		Total
		Positive	Negative	
COVID-19 IgG/IgM Rapid Test Cassette CLUNGENE®	Positive	67	1	68
	Negative	10	89	99
Total		77	90	167

**A statistical comparison was made between the results yielding a sensitivity of 87,01%, a specificity of 98,89% and an accuracy of 93,41%.*

IgG are antibodies that appear later and remain for a longer period.

For identifing the presence of IgG the test measured the positivity rate of the 77 patients during the recovery period.

COVID-19 IgG*		Number of patients during the recovery period	Total
COVID-19 IgG/IgM Rapid Test Cassette CLUNGENE®	Positive	75	75
	Negative	2	2
Total		77	77

**The results had a sensitivity of 97.40%.*

Clinical case extract | Sensitivity and Specificity Report & Precision Report | Company: Hangzhou Clongene Biotech Co.

Technical details

Lancing serological test

COVID-19 IgG / IgM Rapid Test Cassette (WB / S / P) CLUNGENE® is a rapid serological test, for professional use, based on the rapid lateral flow immunochromatographic method.

The test is used for the qualitative detection of antibodies developed by the immune system in case of infection with the SARS-CoV-2 virus.

The procedure is simple and follows a positive/negative logic, where a drop of blood is examined with the help of a CLUNGENE® disposable COVID-19 IgG / IgM Rapid Test Cassette (WB / S / P) test and within few minutes the result is available.

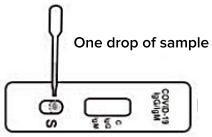
Important: rapid serological tests can only be performed by qualified healthcare personnel.

Product code	Box dimensions
544/00	210 mm x 122 mm x 65 mm

COVID-19 IgG/IgM Rapid Test Cassette (WB/S/P) CLUNGENE® includes:	
Rapid test COVID-19	x 25
Lancets device	x 25
Dropper pipette	x 25
Alcohol wipe	x 25
Reagent liquid	x 25

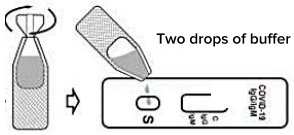
How it works

1



Using a dropper pipette, transfer 1 drop (about 10µl) of blood into the well (S) of the cassette.

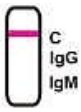
2



Immediately add 2 drops (approximately 70µl) of diluent to the well (S). Wait 15 minutes to read the results.

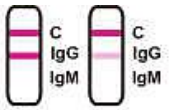
3

NEGATIVE

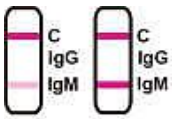


The presence of the control line: a colored line on the letter C (Control)

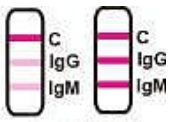
POSITIVE



A colored line on the letter C (Control) and a colored line on the IgG

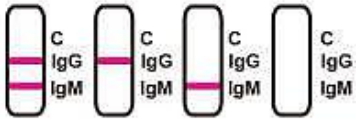


One colored line on the letter C (Control) and one colored line on the IgM



One colored line on the letter C (Control), one colored line for IgG and one colored line for IgM

NOT VALID



CLONGENE (HANGZHOU) BIOTECH CO., LTD.*

Clongene is a high-tech enterprise specializing in biological raw materials and in vitro diagnostic products. Founded in 2004, Clongene is recognised for its research facilities, development and production.

The main product lines: antibodies, antigens, enzymes, immunological diagnosis (colloidal gold immunoassay, CLIA chemiluminescence immunoassay, FIA fluorescence immunoassay, molecular diagnosis - PCR).

Clongene is a leading manufacturer in the technology and in vitro diagnostic products, with a solid reputation and diversified services in the global market.

NEW GENE (HANGZHOU) BIOENGINEERING CO., LTD.*

A high-tech company engaged in the research, development, production and distribution of biological materials, in vitro diagnostic tests and related devices, and also in the development of the industrial chain of artificial intelligence-assisted diagnosis system.

The company covers a full range of in vitro diagnostic products such as immunological diagnosis, molecular diagnosis and microbiological testing.

Among the unique technological advantages, the company devoped areas of early cancer screening, rapid detection of infectious diseases and rapid screening for geriatric diseases.

** Source information from Clongene Biotech and New Gene Bioengineering corporate websites*

In response to the growing pandemic and the difficulty of performing molecular testing laboratory in a short time, we are working with leading international manufacturers in the field of in vitro diagnostics.

THE RAPID TEST CAN NOT REPLACE THE DIAGNOSIS BY MOLECULAR ANLYSIS.

The effectiveness of the tests depends on several factors, including the time from onset of the disease, the concentration of virus in the sample, the quality of the sample collected, and how the test is processed.

We remain at your disposal for further information. We continue to offer the best quality at affordable prices and delivery short a period of time.

As a distributor of rapid tests for COVID-19, we would like to remind you the following important information:

- Manufacturers guarantee the reliability of the rapid tests available, as stated in their clinical studies. All documents are at customers disposition to view the results of the tests.
- The rapid tests must be carried out by taking the biological material, as indicated in the user manual of the product, and exclusively by healthcare personnel or doctors.
- The instructions for use of the rapid test kit provided by the manufacturer must be strictly followed in order not to compromise its effectiveness.
- The index of sensitivity of rapid tests is considered to be generally lower than the RT-PCR molecular test conducted in the laboratory by highly specialized personnel.
- Regardless of the outcome of the rapid test, medical specialists strongly recommend undergoing a molecular test.

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