

COVID-19 Vaccine IgG Rapid Test (Colloidal Gold)

COVID-19 comprehensive screening and monitoring

Intended Use

The COVID-19 Vaccine IgG Rapid Test is a lateral flow immunoassay test intended for qualitative detection of antibodies to the Receptor Binding Domain (RBD) of the SARS-CoV-2 virus spike protein. The test is designed for human blood serum, blood plasma or the whole blood.

Works For: whole blood, serum or plasma

High Accuracy

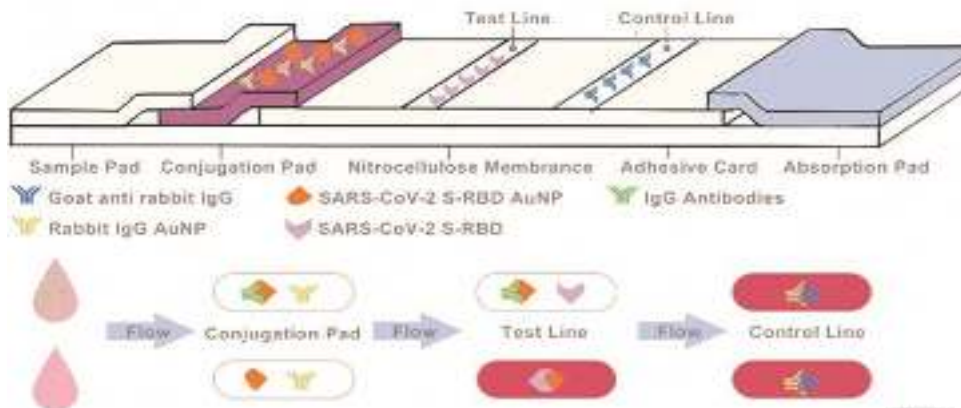
Fast Detection: Results in 15 minutes

Easy to Use

The test is useful for assessment of adaptive immune response of individuals to SARS-CoV-2 after exposure to the virus or after the vaccination.

Principle of the Test

The COVID-19 Vaccine IgG Rapid Test is a lateral flow immunoassay type test for detection of antibodies to the SARS-CoV-2 virus in blood samples.



The test cartridge contains colloidal gold labeled SARS CoV-2 recombinant RBD protein, that binds to the SARS-CoV-2 IgG antibodies forming a complex. Test (T) line of the membrane is coated with the SARS-CoV-2 recombinant RBD protein and captures this complex during sample migration. The purple red color will develop after this capture indicating the presence of SARS-Cov-2 antibodies in the sample and positive result.

Sample Collection and Testing

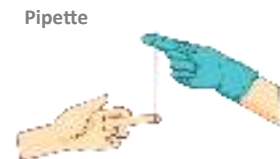
Lancet



1. Clean and disinfect the hand with alcohol wipe



2. Using a lancet, penetrate the skin



3. Collect the blood using pipette



4. Place the test cartridge flat on the desk and transfer one drop (approx. 10 ul) of blood to the sample well



5. Add 2 drops of the sample buffer (approx. 100 ul) to the sample well immediately



6. Let the sample to soak in, read the results in 10-15 minutes

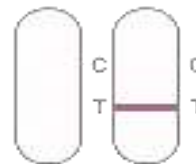
Results Interpretation:



Positive



Negative



Invalid

Product Information



Packing size:
1 test/kit
20 tests/kit



Specimen type:
blood/serum/plasma



Storage:
2-30°C
in a dry place

Content of the Kit

- Cartridge
- Sample Buffer
- Pipette
- Instructions for Use (IFU)

Specificity and Sensitivity Study

Rapid Test Results	VNT test Results Comparison		Total
	Positive	Negative	
Positive	98	0	98
Negative	2	400	402
Total	100	400	500

Positive Percent Agreement (PPA): 98% (98/100)

Negative Percent Agreement (NPA): 100% (400/400)



LABEXCANADA Inc.

Add: 1091 GorhamSt,Newmarket,ON,L3Y 8X7

Tel: + (905) 392-7200

Fax :+(905) 853-4548

Email: info@labexcanada.com

CE

