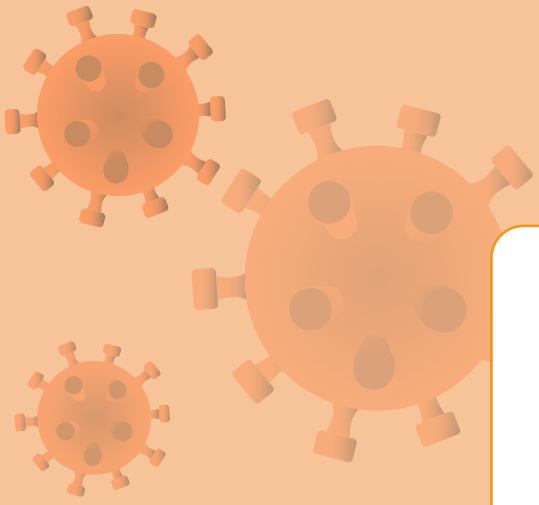
BERONI GROUP LIMITED

COVID-19 Antigen Rapid test

(Nasal and throat swab samples)



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BACKGROUND

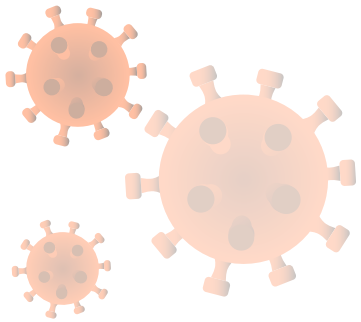
COVID-19 Antigen Rapid test

In response to the current global COVID crisis, Beroni Group has developed and validated the COVID-19 Antigen Rapid test. This detection kit is a rapid in vitro diagnostic based on immunochromatographic detection techniques (lateral flow) developed for the qualitative detection of COVID-19 (SARS-CoV-2) antigen in nasal or throat swab samples.

This product can be distributed in the EU, where it has received CE-IVD certification.

Advantages of our COVID-19 Antigen Rapid test

1.Quick - get results in 15 minutes.
2.Simple - reading the results directly.
3.Sampling – nasal or throat swab sampling.
4.Self-contained – no need for additional diagnostic equipment.
5.High sensitivity and specificity.



Coronavirus disease (COVID-19) and SARS-CoV-2

The novel coronavirus belongs to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigations, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestation include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

The COVID-19 virus spreads primarily through close contact with an infected person (within 6 feet) via droplets of saliva or discharge from the nose or mouth when an infected person coughs or sneezes and inhaled through the nose into the lungs.

INSTRUCTIONS FOR USE

COVID-19 Antigen Rapid test

(Nasal and throat swab samples)

INTRODUCTION

Before using the COVID-19 Antigen Rapid test, this package insert must be read carefully. All the instructions must be followed strictly. Assay reliability and results are not guaranteed in case of deviations from the instructions provided in this package insert.

INTENDED USE

COVID-19 Antigen Rapid Test Cassette is for in vitro qualitative detection of specific antigens to SARS-CoV-2 present in human throat or nasal cavity. It cannot be used as the basis for the diagnosis and exclusion of COVID-19.

This reagent is used to detect cases with suspected symptoms of COVID-19 within 7 days. If suspected symptoms are more than 7 days, it is recommended to test with COVID-19 antibodies or nucleic acid reagents.

The main clinical symptoms of COVID-19 are: Fever, dry cough, fatigue, a few patients will have stuffy nose, runny nose and diarrhea.

KIT CONTENTS

1. 20 individually sealed foil pouches each containing:
   - Disposable test cassette
   - Collection Tube
   - Sample extraction solution
   - Desiccant pouch
2. 1 Instructions for use

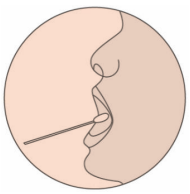
TECHNICAL PRINCIPLE

This kit uses double antibody sandwich immunoassay to detect specific antigens to SARS-CoV-2 in human throat or nasal cavity. The membrane was precoated with SARS-CoV-2 specific antibody on the test zone and goat-anti-mouse IgG antibody on the control zone. During the test, the specimen is allowed to react with SARS-CoV-2 specific antibody-colloidal gold particles conjugate, which was predried on the test. The conjugate binds to the SARS-CoV-2 forming an antibody-antigen complex. The complex migrates through the membrane by the capillary action, then the complex is captured by specific antibody to SARS-CoV-2 on the test zone to produce a visual red color line. The color of line is positive correlated with the amount of SARS-CoV-2 in specimen.
Regardless of the presence of SARS-CoV-2, as the mixture continues to move across the membrane to the control zone, the complex is captured by immobilized goat-anti-mouse IgG antibody to form a distinct red line.

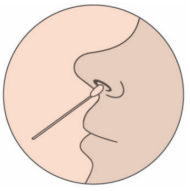
TEST PROCEDURE

SAMPLE COLLECTION

1. Throat Swab Sample
   Take a disposable sampling swab out, insert it into the throat of the patient. Use the swab to gently wipe the pharyngeal tonsils on both sides of the patient for at least 3 times, and then wipe them on the posterior pharyngeal wall for at least 3 times. Withdraw the swab from the throat.



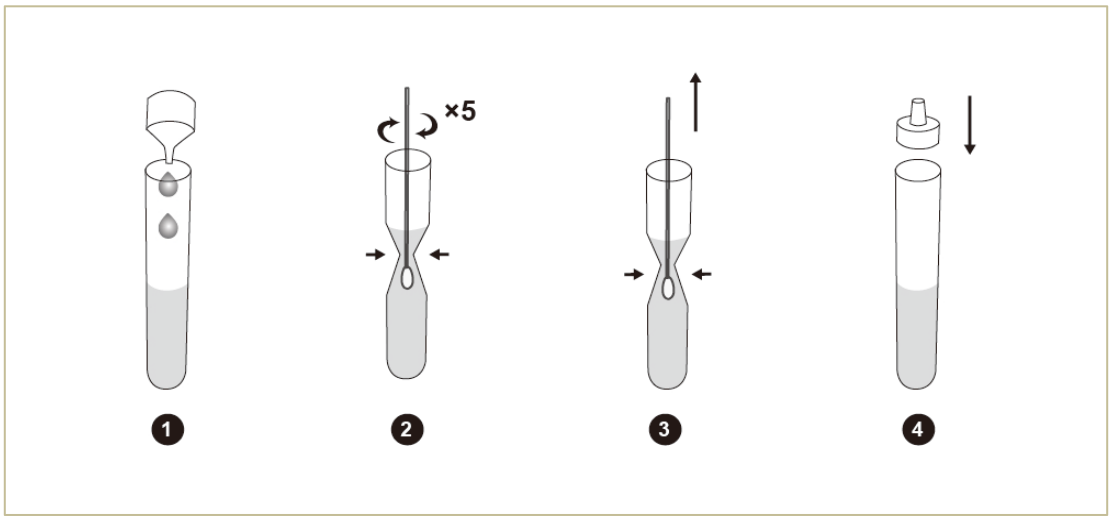
2. Nasal Swab Sample
   Take a disposable sampling swab out, insert it into the nostril of the patient. Carefully insert the swab into the nostril. Gently rotating, pushing the swab until meet resistance at the level of the turbinate bone (less than one inch into the nostril). Rotate the swab several times against the nasal wall then remove it from the nostril.



SAMPLE STORAGE

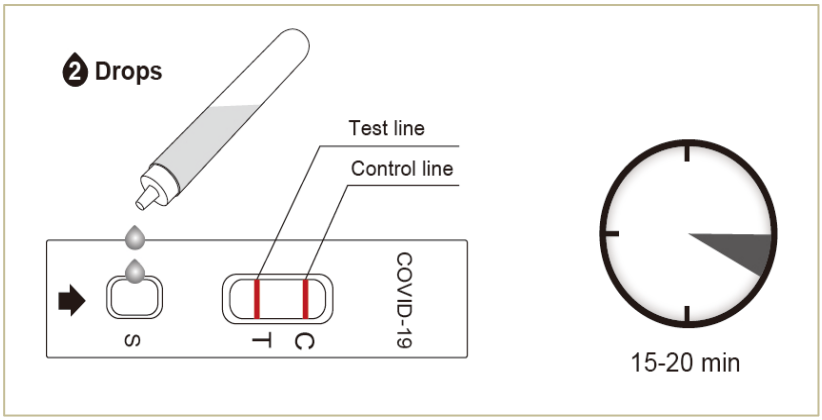
Samples should be tested as soon as possible after collection. Throat or nasal swabs are stable for up to 24 hours at 2~8°C.

SWAB PREPARATION (NASAL / THROAT)



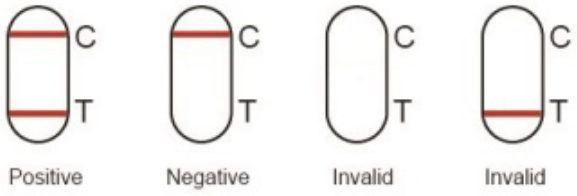
1. Remove the pointed nozzle cap out of the sample collection tube. Twist and open the sample preservation solution tube, then add the sample extraction solution into the sample collection tube.
2. Insert the patient swab into the sample collection tube. While squeezing the buffer tube, stir the swab more than 5 times.
3. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.
4. Press the pointed nozzle cap tightly onto the tube.

SWAB PREPARATION (NASAL / THROAT)



1. All clinical samples must be at room temperature before beginning the assay.
2. Open the package, the pouch should be sealed well. If the test reagent store in the refrigerator, it should be restored to room temperature. Then open the pouch and take out the test cassette, place it on the platform.
3. Add 2 drops of patient sample extraction solution which from the tube into S Well, Observe the result in 15～20 minutes, interpret the test result after 20 minutes may cause false result.

INTERPRETATION OF THE RESULTS



1. **Positive:** One color line in the control zone (C) and one color line in the test zone (T). This indicates that the sample contains SARS-CoV-2 antigen.
2. **Negative:** Only one color line in the control zone (C). This indicates that no SARS-CoV-2 antigen has been detected.
3. **Invalid:** If no color line appears in the control zone (C), the test is invalid. Discard the test cassette and perform with new cassette.

Built-In Control

COVID-19 Antigen Rapid Test Cassette has a built-in control that demonstrates assay validity. A color line appeared on the control zone (C) indicates that the test runs correctly.

Clinical Agreement

COVID-19 Antigen Rapid Test predictive agreement.

The clinical agreement of the COVID-19 Antigen Rapid Test was assessed against known COVID-19 negative and positive nasopharyngeal samples, as confirmed by RT-PCR (n=229).

COVID-19 Antigen Rapid Test	COVID-19 status by RT-PCR				Total	
	Positive (+)		Negative (-)			
Positive (+)	A	59	B	16	A+B	75
Negative (-)	C	8	D	146	C+D	154
Total	A+C	67	B+D	162	A+B+C+D	229

Sensitivity:
A/(A+C)% = 88.06% (95% credibility interval : 78.17%~93.82%)
Specificity:
D/(B+D)% = 90.12% (95% credibility interval : 84.56%~93.83%)
Total Accuracy:
(A+D)/(A+B+C+D)% = 89.52% (95% credibility interval : 84.88%~92.86%)

Performance Characteristics

1. **Negative reference sample coincidence rate:** 10 negative enterprise reference samples were tested and the results were all negative.
2. **Positive reference sample coincidence rate:** 5 antigen positive enterprise reference samples were tested and the results were all positive.
3. **Minimum detectability:**

3.1 3 limited detection of enterprise reference samples were used for testing, repeated 3 times, L1 should be negative, L2 and L3 should be positive.

3.2 The minimum detectability of this product for the SARS-CoV-2 virus strain is no more than 2000$TCID_{50}$ /mL.

4. **Intra-lot repeatability:** Parallel determination of enterprise repeatable reference samples, each repeated 10 times, R1 should be negative, R2 and R3 should be positive.
5. **Inter-lot repeatability:** Parallel determination of enterprise repeatable reference samples with 3 batches of reagents, each batch repeated 10 times. With 3 batches of reagents, R1 should be negative, R2 and R3 should be positive.
6. **Interfering substances:** α - interferon, zanamivir, ribavirin, ritonavir, pramivir, lopinavir, abidol, levofloxacin, azithromycin, ceftriaxone, meropenem, tobramycin have no effect on the test results of this product.
7. **Cross reaction:** There was no cross-reaction with potential cross-reactive substances.

Virus/Bacteria/Parasite	Strain	Concentration	Results
Coronavirus	OC43	1.0×10^5 $TCID_{50}$ /mL	NEG
	NL63	1.0×10^4 $TCID_{50}$ /mL	NEG
Adenovirus	Type 3	1.5×10^6 $TCID_{50}$ /mL	NEG
	Type 7	1.5×10^6 $TCID_{50}$ /mL	NEG
	Type 55	4.0×10^5 $TCID_{50}$ /mL	NEG
Influenza A	A/14160（H1N1）	3.0×10^5 $TCID_{50}$ /mL	NEG
	A/44045 (H3N2)	1.0×10^5 $TCID_{50}$ /mL	NEG
Influenza B	B/1704	2.5×10^5 $TCID_{50}$ /mL	NEG
	B/179	4.0×10^5 $TCID_{50}$ /mL	NEG
Respiratory syncytial virus	Type A	3.0×10^5 $TCID_{50}$ /mL	NEG
Mycoplasma pneumoniae	Mutant 22	5.0×10^4 cells/mL	NEG
Streptococcus pneumonia	178 [Poland 23F-16]	5.0×10^4 cells/mL	NEG
Legionella pneumophila	Bloomington-2	5.0×10^4 cells/mL	NEG
Mycobacterium tuberculosis	HN878	5.0×10^4 cells/mL	NEG
Rhinovirus	A16	1.0×10^5 $TCID_{50}$ /mL	NEG

KIT LIMITATIONS

1. The kit is only used to detect human throat swab or nasal swab.
2. The accuracy of the test depends on the process of sample collection. Improper sample collection, improper sample storage or repeated freezing and thawing of samples will affect the test results.
3. The test results of this reagent are for clinical reference only and should not be used as the sole basis for clinical diagnosis and treatment. The clinical management of the patient should be considered in combination with other laboratory tests of the patient's symptoms/signs history and treatment response.

STORAGE CONDITIONS AND SHELF LIFE

COVID-19 Antigen Rapid Test Cassette should be stored in dark place at 2~30°C for 24 months from the date of manufacture. Keep the test cassette in sealed pouch until use. Once you have taken the test cassette out of the pouch, use it immediately. Do not use the test beyond the indicated expiration date.

WARNINGS AND PRECAUTIONS

WARNING
For Medical Professional and In Vitro Diagnostic use ONLY

> Read the package insert completely before use. It is very important that the correct procedure is followed. Fail to add the patient sample may lead to a false result.

PRECAUTIONS

1. This product is an in vitro diagnostic reagent to qualitatively detect the SARS-CoV-2 antigen in human throat or nasal cavity.
2. The reagent may cause false negative results in COVID-19 patients with asymptomatic infection.
3. Do not use the test if the pouch is damaged or the seal is broken.
4. Do not modify the test procedure.
5. Do not touch the reaction zone of the reagent.
6. Each test is for single use only.
7. Make sure the test is not expired (EXP Date is indicated on the kit box).
8. All the waste and specimen should be treated in case of transmitting disease and must be properly disinfected (autoclaving is preferred) before disposal.
9. Always interpret the results under good light conditions to avoid misreading of the results.
10. Different batch of product components cannot be mixed.
11. If desiccant bag is not present in the pouch, DO NOT USE the test.
12. Always add accurate volume of specimen by following the instruction.
13. The test cassette must be used directly after unsealing. It is not allowed to divide it for use.
14. If the reagent is stored in refrigerator, it should be restored to room temperature before testing.
15. Observe the result in 15~20 minutes. Interpret the test result after 20 minutes may cause false result.

CONTACT INFORMATION

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