BAG DIAGNOSTICS EN IVD CE

SARS-CoV-2 Antigen Rapid Test
(Colloidal Goldimmunochromatography)

Product name

REF 728290 SARS-CoV-2 Antigen Rapid Test (25 Tests)

Intended use

The product is intended for the qualitative detection of antigen from SARS-CoV-2 in clinical samples (nasal swab).

Introduction

Coronavirus, as a large virus family, is a single positive stranded RNA virus with envelope. The virus is known to cause major illnesses such as colds, Middle East Respiratory Syndrome (MERS), and Severe Acute Respiratory Syndrome (SARS). The core protein of SARS-CoV-2 is the N protein (Nucleocapsid), which is a protein located inside the virus. It is relatively conserved among β-coronaviruses and is often used as a tool for the diagnosis of coronaviruses.

Test principle

The current test card is based on the specific antibody-antigen reaction and the sandwich immunocapture method.. The test card contains colloidal gold labeled SARS-CoV-2 N protein monoclonal antibody which is pre-coated on the combination pad, matched SARS-CoV-2 N protein monoclonal antibody immobilized on the Test area (T) and a goat anti-mouse antibody specific for the gold labeled SARS-CoV-2 N protein monoclonal antibody in the quality control area (C).

During testing, the N protein in the sample combines with the colloidal gold labeled SARS-CoV-2 N protein monoclonal antibody which is pre-coated on the combination pad. The antigen-antibody-complexes migrate upward under capillary effect, and subsequently is captured by the N protein monoclonal antibody immobilized in the test area (T). The higher the content of N protein in the sample, the more antigen-antibody-complexes are captured and the darker the color in the test area. If there is no virus in the sample or the virus content is lower than the detection limit, then there is no color demonstrated in the test area (T). Regardless of the presence or absence of the virus in the sample, a purple stripe will appear in the quality control area (C). The purple stripe in the quality control area (C) is a criterion for the judgment of whether or not there is enough sample and whether or not the chromatography procedure is functional.

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Content of the kit

The product consists of test cards, instructions for use and sample treatment solution. Each test card bag contains one SARS-CoV-2 antigen detection card and one package of desiccant.

REF	Test card	Instructions for use	Sample treatment solution
728290	25 tests	1	2x 3 ml
Each test card bag contains one test card and one package of desiccant.			

The test card consists of gold standard mat (coated with colloidal gold labelled SARS-CoV-2 N protein monoclonal antibody), sample mat, nitrocellulose membrane (Test area (T) is coated with a SARS-CoV-2 N protein monoclonal antibody; the quality control area (C) is coated with goat anti-mouse antibody specific for the gold labeled SARS-CoV-2 N protein monoclonal antibody), absorbing paper, and hydrophobic stiff card.

Storage and stability

The test must be stored at 4°C~ 30°C, kept dry and away from sunlight. The shelf life is 12 months. For per test card, it should be used within 1 hour after unsealing.
Production Date and Expiration date are shown in the package label.

Material required but not provided with the kit

Nasal swabs for sampling.

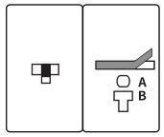
Sample requirements

The product is used to test the human nasal swab sample.
Sample collection: During the collection procedures for samples, take care to make proper protection, and avoid direct contact with the sample. In case of accidental contact, disinfection treatment should be carried out in time and necessary measures should be taken.
Nasal swab sample: During sampling, the swab head should be completely inserted into the nasal cavity and gently rotated 5 times. After removal, the swab head should be sampled in the other nasal cavity in the same way to ensure that enough samples are taken.
Sample preservation: After sample collection, please complete the test within 1 hour.
The sample should come to room temperature before testing.

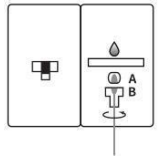
Test method

1. Please read the instruction for use carefully before performing the test. Before testing, restore the reagents and sample to room temperature.
2. During sampling, the swab head should be completely inserted into the nasal cavity and gently rotated 5 times. After removal, the swab head should be sampled in the other nasal cavity in the same way to ensure that enough samples are taken.
3. Before the test, the double-sided adhesive protective layer should be removed in advance to prevent liquid splashing. If the double-sided adhesive protective layer is torn off after adding diluent, it is easy to cause liquid splashing.
4. Thread the swab sample through the bottom of well B into well A. Add 6 drops of the sample treatment solution into well A. Do not drop the solution into the other wells. Rotate the shaft, two rounds each direction.
5. During the test, the test card should be placed on the horizontal desktop. The test card should be fixed and do not remove the test card.
6. After covering the left side, gently press the adhesive position to make the two sides completely fit and start timing. Wait until the purple band appears. The test result should be read within 15-20 minutes.

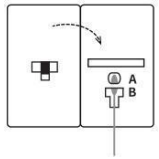
Remove the protective cover of the fixing glue



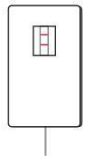
Thread the swab sample through the bottom of well B into well A. Drip the sample treatment solution to well A. Rotate the shaft, two rounds each direction



Stick the left and the right side together.



The test result will be shown after 15 min



Explanation of the test results

- Positive (+): There appear purple stripes in both, the quality control area (C) and in the test area (T).

Control line
Test line

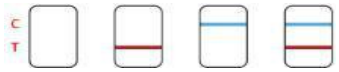
Positive

- Negative (-): There is only one purple stripe visible in the control area (C) and no stripe in the test area (T).

Control line
Test line

Negative

- Invalid: There is no stripe in the quality control area (C), or there is a blue stripe in the control area (C), indicating incorrect operating procedures or the test card has already deteriorated. Under this condition, the instruction for use must be read again carefully, and then a new test card has to be used to test again. If the problem still exists, stop using the products with the same lot number and contact BAG Diagnostics GmbH or your local supplier immediately.



Control line
Test line

Invalid Invalid Invalid Invalid

Limitations of the test

1. The test results of this product should be comprehensively judged by the physician in combination with other clinical information, and should not be used as the only criterion;
2. The product is used to detect the SARS-CoV-2 antigen of the clinical sample.

Product-performance index

1 Physical Property

1.1 Appearance

The test card must be clean and integral, no burrs, no damage, no pollution; the material must be firmly attached; the label must be clear and not damaged. The sample dilution must be clear without impurities and flocs.

1.2 Liquid migration speed

The liquid migration speed must be no less than 10 mm/min.

1.3 Membrane Strip Width

The membrane strip width of the testing card must be ≥ 2.5mm.

1.4 Volume of the sample treatment solution for the samples

The volume of the sample treatment solution for the sample is no less than the indicated value.

2 Detection Limit

For the detection of sensitivity reference material, the positive detection rate must be no less than 90%.

3 Negative reference products compliance rate

For the detection of negative reference material, the negative detection rate must be 100%.

4 Positive reference products compliance rate

For the detection of positive reference material, the positive detection rate must be 100%.

5 Repeatability

For the detection of enterprise reference material P2 and P4, the results must be positive and the color rendering should be uniform.

6 Cross-reactivity

This test device has no cross reactivity with endemicity human coronavirus OC43, human coronavirus 229E, human coronavirus HKU1, human coronavirus NL63, influenza A virus, influenza B virus, adenovirus 1/2/3/4/5/7, EB virus, measles virus, cytomegalovirus, rotavirus, norovirus, mumps virus, varicella zoster virus, mycoplasma pneumoniae, human metapneumovirus, parainfluenza virus 1/2/3/4, enterovirus, rhinovirus, HBV, HIV, HCV, Staphylococcos aureus, Staphylococcus epidermis, Pseudomonas aeruginosa, Streptococcus pneumoniae, Chlamydia, pneumoniae, Haemophilus influenza, Legionella pneumophila, Mycobacterium tuberculosis, Staphylococcus salivarius, Streptococcus pyogenes, Bordetella pertussis, Pneumocyctis jiroveci, Candida albicans.

7. Interfering subtances: (1) no interfering reaction with the following drugs: Quinine, Zanamivir, Ribavirin, Oseltamivir, Peramivir, Lopinavir, Ritonavir, Arbidol, Paracetamol, Acetaminophen,Acetylsalicylate, Ibuprofen, Levofloxacin, Azithromycin, Ceftriaxone, Meropenem, Tobramycin, Histamine hydrochloride, Phenylephrine, Oxymetazoline, Sodium chloride (including preservatives), Beclomethason, Dexamethason, Flunisolid, Triamcinolon acetonid, Budesonid, Mometason, Fluticasone, Strepsils (Flurbiprofen 8.75 mg)

8 Clinical performance

415 clinical samples tested with the nucleic acid detection method (PCR) test were obtained for testing, including 150 positive and 265 negative samples. The results with the SARS-CoV-2 Antigen Rapid Test Kit were compared with the nucleic acid method (PCR) used for the collected clinical samples. The results are summarized in the table below:

	Nucleic acid detection method (PCR)	
SARS-CoV-2-Rapid Antigen-Kit	positive	negative
Positive: total / Ct ≤ 32 / Ct ≤ 25	138 /134/109	1
Negative: total / Ct ≤ 32 / Ct ≤ 25	12 / 8 / 3	264
Diagnostic sensitivity total	**92,00%** (95%CI:83,63%-96,28%)	
Ct ≤ 32	**94,73%** (95%CI:89,28%-97,12%)	
Ct ≤ 25	**97,32%** (95%CI:89,99%-99,93%)	
Diagnostic specificity		**99.62%** (95%CI: 95,92%-99,87%)

Precautions

1. The test is only suitable for professionals to use in vitro auxiliary diagnosis. Do not use expired products.
2. Do not freeze or use after the expiration date (see the packaging for the expiration date).
3. Avoid excessive temperature and humidity in the experimental environment. The reaction temperature must be 15-30 ° C and the humidity must be below 70%.
4. The test card bag contains desiccant, and it must not be taken orally.
5. When testing, please wear protective clothing, medical mask, gloves and goggles.
6. Do not use the test card with broken single packaging, unreadable labelling, and past the expiration date.
7. Dispose of used specimens, test cards and other waste in accordance with relevant local laws and regulations.
8. The test card must be used within 1 hour after being taken out of the aluminum foil bag.
9. The users must take samples according to the requirements of the IFU
10. Before the test the double-sided adhesive protective layer must be removed in advance to prevent liquid splashing. If the double-sided adhesive protective layer is torn off after adding diluent, it is easy to cause liquid splashing.
11. Do not drop the sample treatment solution into the wrong well.
12. During the test, the test card should be placed on the horizontal desktop. The test card must be fixed and do not move the test card

Literature

Olsen DA, Bernstein D, Colloidal gold particle concentration immunoassay, US Patent 4,853,335, 1989

Dinnes J, Deeks JJ, Adriano A, Berhane S, Davenport C, Dittrich S, Emperador D, Takwoingi Y, Cunningham J, Beese S, Dretzke J, Ferrante di Ruffano L, Harris IM, Price MJ, Taylor-Phillips S, Hooft L, Leeflang MMG, Spijker R, Van den Bruel A. Rapid, point-of-care antigen and molecular-based tests for diagnosis of SARS-CoV-2 infection. Cochrane Database of Systematic Reviews 2020, Issue 8. Art. No.: CD013705. DOI: 10.1002/14651858.CD013705. Accessed 08 December 2020.

Lambert-Niclot S, Cuffel A, Le Pape S, Vauloup-Fellous C, Morand-Joubert L, Roque-Afonso AM, Le Goff J, Delaugerre C, McAdam AJ, Editor Evaluation of a Rapid Diagnostic Assay for Detection of SARS-CoV-2 Antigen in Nasopharyngeal Swabs, Journal of Clinical Microbiology Jul 2020, 58 (8) e00977-20,DOI: 10.1128/JCM.00977-20

Explanation of the symbols

	Do not use if damaged		Consult instructions for use
	Do not re-use		Manufacturing date
	Keep away from sunlight		Manufacturer
	Keep dry	Σ	Sufficient for n tests
	Use by	IFU	Instructions for use
IVD	In-Vitro- Diagnosticum	LOT	Batch Code
CONT	Content	TEST CARD	Test card
SOLN | SAMPLE	Sample Treatment solution	CE	CE mark
		REF	Catalogue number
Ag | DETECTION	Intended use: Qualitative detection of antigen from SARS-CoV-2 in clinical samples	4℃ 30℃	Temperature limit

Basic information

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Changes from Version 1/2020 in yellow.