EGENS® COVID-19 Antigen Rapid Test Kit

English

EGENS®

Please read this package insert carefully prior to use and strictly follow the instructions.

INTENDED USE

EGENS® SARS-CoV-2 Ag Duo is a solid phase immunochromatographic assay intended for the *in vitro* qualitative detection of specific severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antigens in human oral saliva and nasal swab specimen. The test kit is applicable in healthcare system and the scientific field of research and for professional use only. Results are for the identification of SARS-CoV-2 nucleocapsid antigen. Antigen is generally detectable in oral saliva or nasal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status.
Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19 and confirmed with a molecular assay, if necessary.

INTRODUCTION

Coronaviruses are enveloped RNA viruses that are distributed broadly among humans and cause respiratory, enteric, hepatic, and neurologic diseases. Seven coronavirus species are known to cause human diseases. Four of these viruses - 229E, OC43, NL63, and HKU1 - are prevalent and typically cause common cold symptoms in immunocompetent individuals. The three other strains - severe acute respiratory syndrome coronavirus (SARS-CoV), Middle East respiratory syndrome coronavirus (MERS-CoV) and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) - are zoonotic in origin and have been linked to sometimes fatal illness. Coronavirus disease 2019 (COVID-19) is a respiratory infectious disease caused by SARS-CoV-2. The most common symptoms include fever, cough, fatigue, shortness of breath, and loss of smell and taste. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.
Currently, persons infected by SARS-CoV-2 are the main source of transmission. Asymptomatic infected people can also spread the virus. Based on the current epidemiological investigation, the incubation period is 2 to 14 days (median incubation time around 5 days).

PRINCIPLE

The **EGENS® SARS-CoV-2** Ag Duo is a lateral flow immunochromatographic assay. The test uses SARS-CoV 2 antibodies (test line T) and goat anti-mouse IgG (control line C) immobilized on a nitrocellulose strip. The burgundy colored conjugate pad contains colloidal gold conjugated to SARS-CoV-2 antibodies (SARS-CoV-2 conjugates) and mouse IgG-gold conjugates. When a specimen followed by assay diluent is added to the sample well, SARS-CoV-2 antigen, if present, will bind to SARS-CoV-2 conjugates forming antigen antibodies complex. This complex migrates through nitrocellulose membrane by capillary action. When the complex meets the line of the corresponding immobilized antibodies, the complex will be combined forming a burgundy colored band which confirms a reactive test result. Absence of a colored band in the test region indicates a non-reactive test result.
In addition, the test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex goat anti-mouse IgG/mouse IgG-gold conjugate regardless of the color development on any of the test bands. Otherwise, the test result is invalid and the specimen must be retested with another device.

MATERIALS SUPPLIED

Each sealed pouch contains a test device and a desiccant.
Sterile and single use specimen collection swab(s) | Extraction tube(s) with buffer | Package insert

MATERIAL REQUIRED BUT NOT PROVIDED

Materials not supplied but recommended for the performance are personal protection, as gloves and mouth protection. Standard microbiological supplies and equipment such as timer are not provided.
External positive and negative controls can be purchased separately from **EGENS** GmbH. These should be tested periodically consistent with good laboratory practice.

STORAGE AND STABILITY

The test kit should be stored in a dry place protected from direct sunlight at 2-30 °C. The test device should be used within 1 hour after opening of the sealed pouch. If in a high humidity environment, use it immediately. DO NOT FREEZE. Do not use after the expiry date.

WARNINGS AND PRECAUTIONS

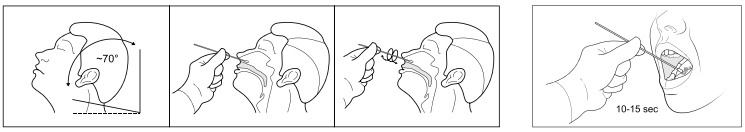
1. For *in vitro* diagnostic use only.
2. The test is for single use only. Do not reuse.
3. Do not perform the test in a room with strong air flow and in environment that is too hot, too humid, or too dry.
4. The test device should be used as soon as possible after opening the pouch. Avoid keeping it in the air for a long time, which may result in failure due to damp. Do not use it if the pouch is damaged or broken.
5. This test is only validated using the material provided with this kit.
6. Do not mix components from different lots.
7. Handle all specimens as if infectious by using safe laboratory procedures.
8. When testing many samples of specimens, please mark well to avoid confusion.
9. After the test is completed, used materials as test device, extraction tube and swabs should be discarded into medical waste garbage bags, which will be specially disposed by the qualified unit to handle medical waste.
10. This test has been authorized only for the detection of SARS-CoV-2 proteins, not for any other viruses or pathogens.

SPECIMEN COLLECTION

Standard precautions should always be followed whenever samples are obtained from patients: use protective gown, pair of nonsterile gloves, face mask and visor for face and eye protection.
Use the supplied sterile, single use specimen collection swabs.

Nasal specimen collection

1. Ask the patient to take off the mask and to blow their nose to clear nasal passage of excessive mucus.
2. Tilt the patient's head back 70 degrees.
3. Carefully insert swab into the nostril until resistance is met at turbinates.
4. Gently rotate the swab several times against the nasal wall to absorb secretions. Repeat in other nostril using the same swab.
5. Place the swab into extraction tube containing the buffer solution.
6. Ask the patient to reapply the mask.



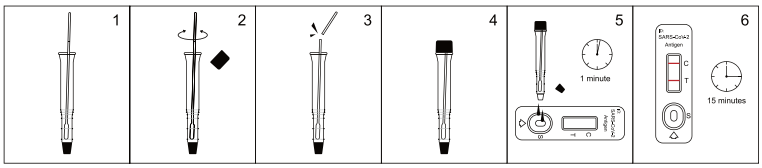
Oral saliva specimen collection

1. Ask the patient to take off the mask.
2. Ask the patient to rinse the mouth with clean water before sampling.
3. Ask the patient to cough up secretions deep in the throat and accumulate it in the oral cavity above the tongue.
4. Insert the specimen collection swab in the mouth and place over the tongue.
5. Rotate the swab to absorb the sample for 10-15 seconds and remove it.
6. Place the swab into extraction tube containing the buffer solution.
7. Ask the patient to reapply the mask.

TEST PROCEDURE

This test procedure has to be read completely before performing the test.
Allow test device, specimen, buffer and/or controls to equilibrate to room temperature (15-30 °C) prior to testing and use it as soon as possible.

1. Open the extraction tube and insert the swab after specimen collection (refer to section 'Specimen Collection') into the extraction tube containing the buffer solution.
2. Rotate the swab constantly and repeat several times.
3. Break the swab at the predetermined breaking point.
4. Cover the extraction tube and incubate for at least 1 minute.
5. Remove the test device from the sealed foil pouch and place it on a clean and even surface. Remove the lower cap of the tube and add 2 drops of the sample solution vertically into the sample well of the test device.
6. Wait 15 minutes to interpret and record the test result. The result is invalid after 20 minutes.

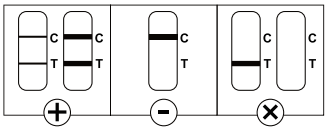


INTERPRETATION OF RESULT

⊕ POSITIVE
If the C band and T band are both present, then the test indicates the presence of SARS-CoV-2 antigens in the specimen. The test result is positive. The purple red test line may vary in shade and intensity depending on the detected antigen concentration. Also, a light or faint test line must be interpreted as a positive result.

⊖ NEGATIVE
If only the C band is present, the absence of any burgundy color in the T band indicates that no SARS-CoV-2 antigens are detected in the specimen. The test result is negative.

⊗ INVALID
Control line C is missing, or control line C and test line T are missing. Incorrect specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Read the instructions carefully again and repeat the test with a new test device. If the problem persists, discontinue using the test device immediately and contact your local distributor.



LIMITATIONS

1. This test is suitable for testing human oral saliva and nasal swab secretion. This test kit is not intended to be used for other body fluids and samples.
2. The test results should be used in combination with the clinical examination, medical history, and other examination results.
3. A negative result for an individual subject indicates absence of detectable SARS-CoV-2 antigens. A negative test result does not preclude the possibility of exposure to or infection with SARS-CoV-2.
4. A negative result may occur if the quantity of the SARS-CoV-2 antigens present in the specimen is below the detection limits of the assay.
5. Positive test results do not rule out co-infections with other pathogens.
6. Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
7. Negative test results are not intended to rule out other non-SARS viral or bacterial infections.
8. Optimal test performance requires strict compliance with the test procedure described in this instructions for use. Deviations may lead to aberrant results. Incorrect specimen volume may lead to invalid test results.
9. Do not keep your prepared sample solution longer than for 60 minutes. This may lead to false test results.

PERFORMANCE CHARACTERISTICS

1. Clinical Studies
Antigen detection in the samples of COVID-19 patients has a high consistency with nucleic acid detection samples. The relative sensitivity for nasal specimen samples is 96.7%. The relative specificity rate is 100% and the accuracy of the product is 99.4%. For oral saliva specimens the relative sensitivity is 92.5%, the relative specificity is 99.8% and the accuracy is 98.4%

Performance of the EGENS® SARS-CoV-2 Ag Duo **vs FDA Authorized (comparator) RT PCR Test**

Nasal specimen samples		RT PCR Comparator		
		Positive	Negative	Total
EGENS® SARS-CoV-2 Ag Duo	Positive	116	0	116
	Negative	4	500	504
	Total	120	500	620
Positive Percent Agreement		96.7% [95% CI: 91.7%, 98.7%]		
Negative Percent Agreement		100% [95% CI: 99.2%, 100%]		
Overall Agreement		99.4% [95% CI: 98.4%, 99.8%]		

Oral saliva specimen samples		RT PCR Comparator		
		Positive	Negative	Total
EGENS® SARS-CoV-2 Ag Duo	Positive	111	1	112
	Negative	9	499	508
	Total	120	500	620
Positive Percent Agreement		92.5% [95% CI: 86.4%, 96.0%]		
Negative Percent Agreement		99.8% [95% CI: 98.9%, 100%]		
Overall Agreement		98.4% [95% CI: 97.1%, 99.1%]		

2. Limit of Detection (LoD)
Limit of detection (LoD) of the **EGENS® SARS-CoV-2** Ag Duo was determined by evaluation of different concentrations of heat inactivated SARS-CoV-2. The **EGENS® SARS-CoV-2** Ag Duo is confirmed with a LoD of 14.4 $TCID_{50}$/mL.

3. Analytical Specificity/Cross Reactivity/Microbial Interference
Analytical specificity of the **EGENS® SARS-CoV-2** Ag Duo has been evaluated to other pathogens. No antigen false positive results or microbial interferences were observed with the following potential cross reactants: Human Coronavirus (229E, OC43, NL63, HKU1), MERS-CoV, Adenovirus, Human Metapneumovirus (hMPV), Parainfluenza virus 1-4, Influenza A, Influenza B, Influenza C, Enterovirus, Respiratory syncytial virus, Rhinovirus, *Haemophilus influenzae, Streptococcus pneumoniae, Staphylococcus aureus, Staphylococcus epidermis, Streptococcus pyogenes, Candida albicans, Bordetella pertussis, Mycoplasma pneumoniae, Chlamydia pneumoniae, Legionella pneumophila*, and a pooled human nasal wash – representative of normal respiratory microbial flora (healthy donors). The minimum concentration of viruses tested for the cross-reactivity studies was 1 x 10^5 $TCID_{50}$/mL, and that for bacteria was 1 x 10^6 CFU/mL.

4.Interference Substances Studies
Potential interference of the **EGENS® SARS-CoV-2** Ag Duo was evaluated using natural clinical samples. No antigen false negative or false positive results have been observed with the following potential interference substances at the stated concentrations: human blood (1% v/v), mucosal protein (1 mg/mL), menthol (50 mg/mL), dyclonine/menthol (2 mg/mL), phenylephrine (1% v/v), oxymetazoline (1% v/v), triamcinolone (50 mg/L), ribavirin (50 mg/L), alkalol (10% v/v), benzocaine and menthol (50 mg/mL), fluticasone propionate (5% v/v), tobramycin (8 µg/mL), mupirocin (10 mg/mL), and biotin (0.15 mg/mL).

REFERENCES

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5. „Naming the Coronavirus disease (COVID-19) and the virus that causes it". World Health Organization. Archived from the original on 28 February 2020. Retrieved 28 February 2020.
6. Hessen MT (27 January 2020). „Novel Coronavirus Information Center: Expert guidance and commentary". Elsevier Connect. Archived from the original on 30 January 2020. Retrieved 31 January 2020.
7. CDC Interim Guidelines for Collecting, Handing, and Testing Clinical Specimens for COVID-19. https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html

INDEX OF SYMBOLS

	See instructions for use		Expiry date
IVD	For *in vitro* diagnostic use only	LOT	Batch number
	Store between 2 °C - 30°C		Manufacturer
	Tests per kit		Keep dry
REF	Catalog number		Do not reuse
	Keep away from sunlight		

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