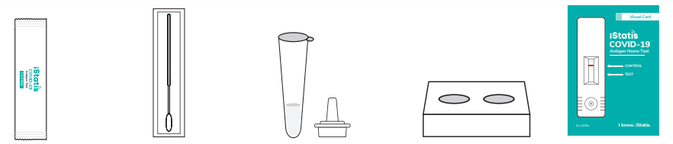
iStatis ENGLISH

COVID-19 ANTIGEN HOME TEST

INSTRUCTIONS FOR USE

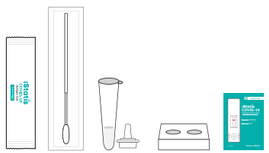
COMPONENTS



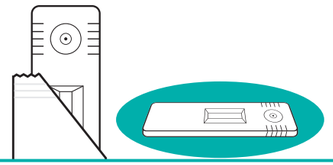
TEST SET UP

1. Wash your hands thoroughly for at least 30 seconds before the test.

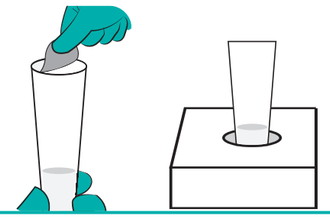
2. Unpack the components from kit pouch.



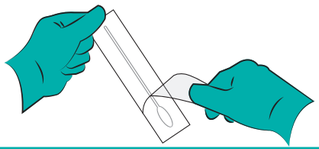
3. Remove the cartridge from its packaging and lay flat on the table.



4. Tear off the foil seal of the Buffer Vial and place the vial into the vial holder.

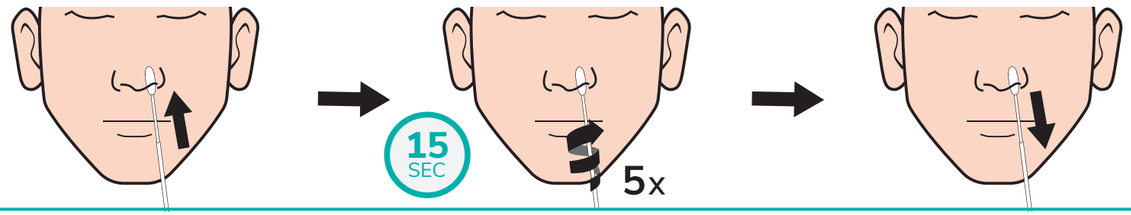


5. Remove the swab from the sterile packaging, being mindful not to touch the soft pad with your hand.

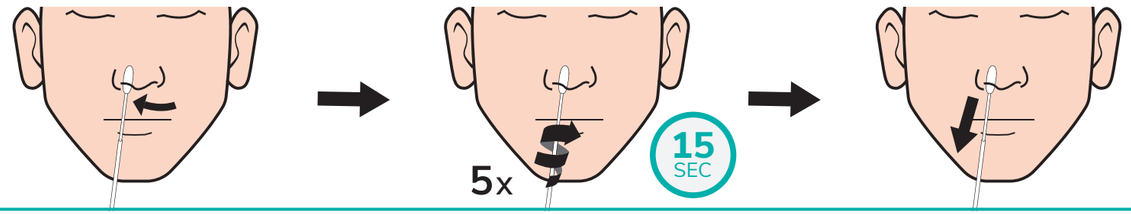


NASAL SAMPLE COLLECTION

6. Gently insert the swab with soft pad no more than 3/4 inch into the **LEFT nostril**. Then, slowly rotate the swab at least **5 times** in a circular path for **15 seconds**. Once complete carefully remove the swab from the LEFT nostril.

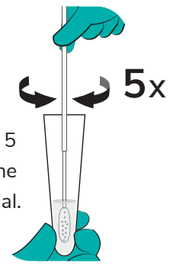


7. Place the swab directly into the **RIGHT nostril**, repeating the process of rotating at least **5 times** in a circular path for **15 seconds.**

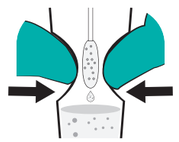


TEST PROCEDURE AFTER NASAL SAMPLE COLLECTION

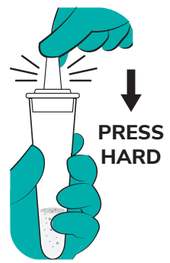
8. Place the swab into the extraction vial. Rotate the swab vigorously atleast 5 times. Further rotate the swab another 5 times while squeezing the sides of the extraction vial.



9. Remove the swab by rotating against the Buffer Vial while squeezing the sides of the vial to release the liquid from the swab.



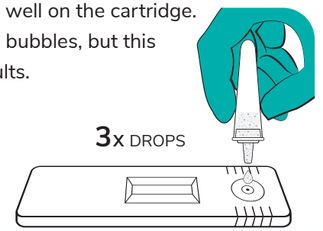
10. Insert the Buffer Vial Cap to the vial containing the sample and push firmly to close onto the vial.



11. While holding the top of the vial with one hand flick the bottom of the vial with the other to thoroughly mix the solution.

12. Slowly turn the vial vertically upside down, pinch the vial, and add 3 drops to the sample well on the cartridge. The first drop may contain bubbles, but this will not affect the test results.

IMPORTANT:
Do not move or lift the test cartridge during this time.



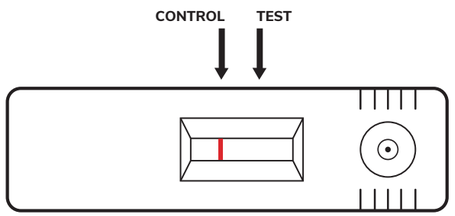
15 Mins

Start a Timer!

The results of the test CAN be read at **15 minutes.**

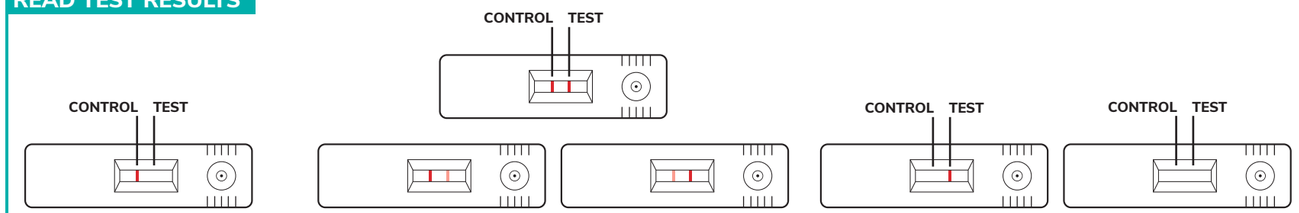
The test result should NOT be read after **30 minutes.**

13. Place the cartridge here or hold visual card next to the cartridge to read the results.



I know. iStatis.

READ TEST RESULTS



NEGATIVE

Your result is negative if only control line is present. This means virus that causes COVID-19 was not found in your sample.

POSITIVE

Your result is positive if both control line and test line are present. This means the virus that causes COVID-19 was found in your sample.
If positive, please immediately reach out to your healthcare provider for additional testing and follow local self-isolation guidelines.

INVALID

Your result is invalid, if no control line is present. Even if a test line is present but no control line, the result is considered invalid. Control line must appear to indicate that the test has been performed correctly.

DISPOSAL

Discard all the test kit components in to the trash bin.

iStatis

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COVID-19 Antigen Home Test

Single-use lateral flow immunoassay for the detection of nucleocapsid proteins from SARS-CoV-2

REF **90-1117**

For *in vitro* Diagnostic Use only.
Store at 2°C to 30°C (35.6° to 86°F).

Read this Package Insert (Instructions for use) completely before using the product. Although the assay is designed to be simple to use, conformance with the test procedure is necessary to ensure accurate results.

INTENDED USE

The **iStatis COVID-19 Antigen Home Test** is a single use, visually read, lateral-flow *in vitro* qualitative immunoassay intended for the detection of nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal swab specimens collected by untrained lay users who are suspected of COVID-19 infection within the first seven days of symptom onset or without symptoms or other epidemiological reasons to suspect COVID-19. The iStatis COVID-19 Antigen test is intended for self-testing and suitable for users who are 2 to 65+ years or older for collection of nasal swabs and performance of testing. For children under 14 years old, adults shall perform the iStatis COVID-19 Antigen Home Test and interpret the results.

BACKGROUND

Coronaviruses (CoV) are a large family of viruses that can infect humans and animals.[1] In humans, coronaviruses cause illnesses ranging from the common cold to more severe diseases such as severe acute respiratory syndrome (SARS). SARS-CoV-2, is a new strain of coronavirus that was first identified during an outbreak in Wuhan, China in 2019 and causes Coronavirus Disease 2019 (COVID-19), a respiratory disease characterized by fever, cough, and shortness of breath.[2] In more severe cases, infection can cause pneumonia, SARS, kidney failure, and death.[3]

PRINCIPLES OF THE TEST

The **iStatis COVID-19 Antigen Home Test** is a manual, visually read, lateral flow immunoassay for the qualitative detection of SARS-CoV-2 nucleocapsid proteins in anterior nasal swab specimens collected from individuals who are suspected of COVID-19. The assay is packaged as a kit containing a single-use cartridge unit along with a single-use buffer vial to be used with nasal swabs. The test consists of a set of sample absorption pads, a conjugate reagent pad with specific SARS-CoV-2 antibodies, and a test membrane where a secondary SARS-CoV-2 antibody as well as a control antibody have been striped on two distinct lines to form the entire test strip. Results are visualized in 15 minutes following addition of the buffer solution to the cartridge in the form of visible control and test lines. Results should not be read after 30 minutes.

KIT COMPONENTS AND STORAGE

Store iStatis COVID-19 Antigen Home Test unopened at 2 to 30°C (35.6°to 86°F).

All kit components are packaged for single use only.

Each test contains the following materials:

1. **Test Cartridge**: Individually packaged, prepared with control (antibody capture) and test (SARS-CoV-2 nucleocapsid antibody) lines. For single use with anterior nasal swab samples.
2. **Nasal Swab** STERILE EO CE0123**:** A sterile nasal swab for sample collection from the patient. COPAN Italia S.p.A; Via F.Perotti, 10, 25125 Brescia, Italy.
3. **Vial Holder:** Cardboard holder to hold buffer vial during sample collection process.
4. **Buffer Vial:** A vial that contains buffer for extraction of the sample from the included nasal swab.
5. **Buffer Vial Cap:** A dispensing nozzle to dispense the collected sample onto the cartridge.
6. **Visual Card:** A supplemental guide card to help user interpret test result accurately.

MATERIALS REQUIRED BUT NOT PROVIDED

- Personal protective equipment such as gloves, lab coat, or gown
- Biohazard waste containers
- Timer

WARNINGS AND PRECAUTIONS

For *in vitro* diagnostic use only.

1. Do not use test cartridge if packaging has been damaged.
2. Do not use the kit beyond the expiry date.
3. Do not interchange kit contents from different lots.
4. Avoid touching any bleeding areas of the nostril area during specimen collection, as excess blood or mucus on the swab may interfere with test results.
5. Freshly collected sample should be processed immediately after collection.
6. Testing should be performed under normal room lighting conditions.
7. Avoid microbial contamination and exercise care in handling the kit components.
8. Use of disposable gloves while handling kit reagents or specimens is recommended.
9. All specimens should be handled carefully as it is capable of transmitting infectious agents.
10. If extraction buffer makes contact with skin and eyes, wash affected areas with water. If skin irritation, rash or other abnormal reaction occurs, please get medical advice/attention.
11. Failure to use the provided buffer solution and vial may result in leakage and/or overflow of liquids from the test cartridge.
12. If the kit is refrigerated, ensure it is brought to room temperature before performing the test.
13. ⚠ Sodium azide is present at 0.1% in all assay reagents and are harmful if swallowed.
14. Spills should be cleaned up with household bleach or disinfecting wipes.
15. Please consult with medical practitioner to make any decision of medical relevance.

LIMITATIONS OF THE TEST

- The iStatis COVID-19 Antigen Home Test must be used in accordance with the instructions in this package insert to obtain accurate results.
- Clinical significance of the test results needs to be analyzed in combination with other test indicators and clinical manifestations.
- Results from antigen testing should not be used to diagnose or exclude SARS-COV-2 infection.
- Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.
- A negative result may be obtained if the specimen is inadequate, or antigen concentration is below the sensitivity/detection limit of the test. Therefore, it is recommended that all negative test results undergo confirmatory testing using other method and/or qualified assays.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

RESTRICTIONS ON USE

- Suitable for users who are 2 to 65+ years or older for collection of nasal swabs and performance of testing. For children under 14 years old, their guardians shall perform the iStatis COVID-19 Antigen Home Test and interpret the results.

STORAGE

- Store in the original packaging in a cool, dry location between 2 to 30°C. DO NOT FREEZE.
- Do not store near a heat source or in direct sunlight.
- The test should be performed at room temperature (15 to 30°C).
- Do not open the test cartridge pouch until you are ready to perform the test.

DISPOSAL

Put all components back into the outer packaging after use. Throw away into waste bin. Dispose in accordance with local regulations.

FREQUENTLY ASKED QUESTIONS

What is COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus which is a new virus in humans causing a contagious respiratory illness. COVID-19 can present with a mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Older adults and people of any age who have underlying medical conditions have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 include hospitalization and death. The SARS-CoV-2 virus can be spread to others not just while one is sick, but even before a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.).

What are the symptoms of COVID-19?

Many individuals with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea), although some individuals experience only mild symptoms or no symptoms at all. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that, when present, symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat or new loss of taste or smell, nausea or vomiting or diarrhea. COVID-19 can present with a mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Signs and symptoms may appear any time from 2 to 14 days after exposure to the virus, and the median time to symptom onset is approximately 5 days.

Will this test hurt?

The nasal swab provided with iStatis test is not sharp, however the swab can feel slightly uncomfortable when collecting sample from the nostril. If you feel pain, please do not use the test and consult your health care provider.

What if I have a negative test result?

A negative test result means that proteins from the virus that causes COVID-19 was not found in your sample. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means you could possibly still have COVID-19 even though the test is negative. The amount of antigen in a sample may decrease the longer you have symptoms of infection. In symptomatic people, specimens collected after you have had symptoms for more than five days may be more likely to be negative compared to a molecular assay. If you test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath you should seek follow up care with your healthcare provider.

What if I have a positive test result?

A reactive test result means proteins from the virus that causes COVID-19 were found in your sample. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. There is an exceedingly small chance that this test can give a positive result that is wrong (a false positive result). If you test positive with the iStatis COVID-19 Antigen Home Test you should self-isolate and seek follow-up care with your healthcare provider as additional testing may be necessary.

What if I have an invalid test result?

An invalid test result means that the test was run incorrectly, or insufficient specimen was added. Invalid test results cannot be interpreted. Repeat the test with a fresh specimen using a new cartridge, kit components and support materials.

How will I know if my test was done correctly?

The iStatis COVID-19 Antigen Home Test has a built-in control line to show that the test has been performed correctly and that you have added the proper sample type and the amount of nasal sample. If the control line does not appear (invalid test result), your test has not worked. It is not possible to draw conclusions from this result and you will need to perform another test. In the event of repeated invalid results, consult a doctor.

Is the solution in the vial harmful?

The solution in the vial contains potentially harmful chemical Sodium Azide at 0.1% and is harmful if swallowed. The buffer vial should only be used as directed; do not ingest; keep out of the reach of children; avoid contact with skin and eyes. If the solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, consult a doctor.

How accurate is this test?

Based on a clinical evaluation study conducted in Europe, iStatis COVID-19 Antigen Home Test has demonstrated a diagnostic sensitivity of 100% confirmed positive by a RT-PCR test authorized by the US FDA for emergency use and a diagnostic specificity of 100% confirmed negative by Healthcare professional observers.

In addition, the following retrospective clinical study conducted in Europe with intended Professional users and iStatis COVID-19 Antigen Test demonstrated the following:

- Diagnostic sensitivity of 100% was achieved with 103 retrospectively collected COVID-19 Positive samples on iStatis COVID-19 Antigen Test. All 103 samples tested positive with the iStatis COVID-19 Antigen Test, resulting in a diagnostic sensitivity of 100% (103/103) with confidence interval of 96.4% to 100%.
- Diagnostic specificity of 99.7% was achieved with 300 retrospectively collected COVID-19 Negative samples on iStatis COVID-19 Antigen Test. Out of the 300 confirmed COVID-19 negative samples, 299 samples were accurately tested negative on iStatis, resulting in a diagnostic specificity of 99.7% (299/300) with a confidence interval of 98.1% to 99.9%.
- In addition, iStatis COVID-19 Antigen Test achieved a diagnostic specificity of 98.0% when 100 nasal swab specimens collected from COVID-19 negative hospitalized patients were tested. Out of 100 confirmed COVID-19 Negative samples, 98 samples tested accurately negative on the iStatis COVID-19 Antigen Test. This resulted in a diagnostic specificity of 98.0% (98/100) with confidence interval of 93.0% to 99.4%.

What is the Detection Limit?

The iStatis COVID-19 Antigen Test Limit of detection (LoD) was determined by testing limiting dilutions of UV-inactivated SARS-CoV-2 virus (Delta Variant) in pooled human nasal matrix from confirmed negative donors. The iStatis COVID-19 Antigen Test Limit of Detection (LoD) in nasal matrix was confirmed to be 377.5 $TCID_{50}$ per swab.

Whether cross-reactivities can occur?

No cross-reactivity was observed with these pathogens when tested with the iStatis COVID-19 Antigen Test: Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, Human coronavirus MERS-CoV, Human coronavirus SARS-CoV,, Adenovirus, Human Metapneumovirus, Parainfluenza Virus type 1,Parainfluenza Virus type 2, Parainfluenza Virus type 3, Parainfluenza Virus, type 4, Influenza A, Influenza B, Enterovirus, Respiratory syncytial virus, Rhinovirus, Haemophilus influenzae, Streptococcus pneumoniae, Streptococcus pyogenes, Candida albicans, Pooled human nasal wash, Bordetella pertussis, Mycoplasma pneumoniae, Chlamydophila pneumoniae, Legionella pneumophila, Staphylococcus aureus, Staphylococcus epidermis

Whether interferences can occur?

The following potentially interfering substances had no impact on the performance of the iStatis COVID-19 Antigen Test: Whole Blood, Mucin, Chloraseptic (Menthol/Benzocaine), Naso GEL (NeilMed) Phenylephrine Hydrochloride (Phenylephrine Nasal Drops), Oxymetazoline (Nasal Drops), Cromolyn Sodium Salt (Cromolyn Nasal Spray), Homeopathic (Zicam), Homeopathic (Alkalol), Sore Throat Phenol Spray, Tobramycin (antibiotic), Mupirocin (antibacterial), Fluticasone Propionate (Flonase), Oseltamivir Phosphate (Tamiflu) (antiviral).

BIBLIOGRAPHY

1. Fehr AR, Perlman S. Coronaviruses: an overview of their replication and pathogenesis. Methods Mol Biol. 2015; 1282:1-23. doi:10.1007/978-1-4939-2438-7_1
2. https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html
3. Wadman M, Couzin-Frankel J, Kaiser J, Maticic C. How does coronavirus kill? Clinicians trace a ferocious rampage through the body, from brain to toes. doi:10.1126/science.abc3208

TECHNICAL INFORMATION

For further information or assistance, contact the Technical Support +1-866-674-6784 or customercare@biolytical.com.

Reference herein to any specific third party by name, trade name, trademark, manufacturer or otherwise does not constitute or imply an endorsement or recommendation of this Kit by such third party, or of the products or services of such third party by bioLytical or that such products or services are necessarily best suited for the intended purpose.

GLOSSARY OF SYMBOLS

2°C 30°C	Store at 2°C to 30°C		Manufacturer
IVD	*In Vitro* diagnostic medical device	⚠	Caution Harmful if swallowed
	Consult Package Insert	STERILE EO	Sterilization by Ethylene Oxide
	Do not reuse	Σ N	Contains sufficient for "N" tests
LOT	Lot number	CE	CE Mark
	Do not use if damaged		Keep dry
REF	Catalogue Number		Keep away from direct sunlight
	Use By Date		This side up
EC REP	European Authorized Representative		

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