COVID 19 Ag CARD

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Rapid Visual Test for the Qualitative Detection of Covid-19 (SARS-COV-2) antigen in Human nasopharyngeal and nasal swab specimens

INTRODUCTION

Novel corona virus infection SARS CoV-2 [COVID-19] has spread to more than 203 countries of various regions including Africa, America, Europe, South East Asia and Western Pacific. The WHO had declared COVID-19 as the global public health emergency and subsequently as pandemic because of its worldwide spread. It is now one of the top-priority pathogens to be dealt with, because of high transmissibility, severe illness and associated mortality, wide geographical spread, lack of control measures with knowledge gaps in veterinary and human epidemiology, immunity and pathogenesis. The quick detection of cases and isolating them has become critical to contain it. Whereas molecular diagnostic tests were rapidly developed antigen based tests are of utmost requirement for early diagnosis of infection. Antigen is generally detectable in upper respiratory specimen during acute phase of infection.

INTENDED USE

Covid 19 Ag Card Test is designed for in vitro qualitative detection of Covid 19 antigen in human nasopharyngeal, nasal swab specimens. The kit is intended for professional use and as a screening test and is an aid in early diagnosis of SARS COV-2 infection in patients with clinical symptoms.

Caution: The laboratory results alone should not form the basis of medical report for individual patient. The clinical history and any other test performed must be taken into account. The presumptive diagnosis by Covid 19 Ag Card test may be confirmed by PCR.

PRINCIPLE

Covid 19 Ag Card is an immunoassay based on "Sandwich" principle. The test contains two pre-coated lines, "C" Control line and "T" test line. SARS-CoV-2 specific Antibody is immobilized on nitrocellulose membrane at "T" Line. Colloidal gold is conjugated to another antibody specific for SARS-CoV-2 Antigen. The test sample treated with extraction buffer when added to the device, interacts with the Colloidal gold Conjugate. If the specimen contains a novel Coronaviruses antigen, it will form a complex with the Colloidal gold-labelled with SARS-CoV-2 antibody. The complex migrates through the nitrocellulose strip by capillary action. When the complex meets the line of corresponding immobilized antibody, the complex is trapped forming a pink purple band which confirms a reactive test result. Absence of a colored band in the test region indicates a non-reactive test result. A red procedural control line should always develop at "C" region to indicate that the test has been performed properly.

KIT CONTENTS (25 TESTS)

1.	COVID 19 Ag Test Cards	:	25 Nos.
2.	Sample Extraction Buffer	:	1 Vial
3.	Sample Extraction Tube	:	25 Nos.
4.	Sample Dropper	:	25 Nos.
5.	Sterile nasopharyngeal Swabs	:	25 Nos.
6.	Sample Extraction Tube Stand	:	1 No.
7.	Instruction Manual	:	1 No.

KIT STORAGE AND STABILITY

The kit should be stored at 2-30ºC in the cool and driest area available. Expiry date on the kit indicates the date beyond which kit and its components should not be used. Covid 19 Ag Card should not be frozen and must be protected from exposure to humidity.

KIT PRESENTATION (PACK SIZE)

10 Test Pack, 25 Test Pack. 50 Test Pack, 100 Test Pack & 200 Test Pack

MATERIAL REQUIRED BUT NOT PROVIDED

The kit contains all the items required to perform this test. However, a timer or stop watch is required.

DESCRIPTION OF SYMBOLS USED

The following are graphical symbols used in or found on J. Mitra diagnostic products and packing. These symbols are the most common ones appearing on medical devices and their packing. They are explained in more detail in the European Standard EN ISO 15223-1:2016.

	Manufactured By	IVD	*In vitro* diagnostic medical device
Σ	No. of tests		See Instruction for use
LOT	Lot Number / Batch Number	2°C 30°C	Temperature Limitation
	Manufacturing Date		Caution, see instruction for use
	Expiry Date	REF	Catalogue Number
	Do not use if package is damaged	EC REP	Authorized Representative in the European Community
2	Single use only		Keep away from sunlight
	Keep Dry		

WARNING FOR USERS

CAUTION: ALL THE SAMPLES TO BE TESTED SHOULD BE HANDLED AS THOUGH CAPABLE OF TRANSMITTING INFECTION.

1. The use of Disposable Gloves, glasses and proper portecting clothing is STRONGLY RECOMMENDED while running the test.
2. This test detects the presence of covid 19 antigen in the human nasopharyngeal / nasal swab specimens only. **Do not use Human Whole blood (EDTA Anticoagulated), plasma sera, urine and saliva as specimen for this test.**
3. Deviation in the test procedure may adversely affect test performance and/or produce invalid results and hence adherence to test procedure and precautions given in the product insert shall be strictly followed.
4. In case there is a cut or wound in hand, DO NOT PERFORM THE TEST.
5. Deviation in the test procedure may adversely affect test performance and/or produce invalid results and hence adherence to test procedure and precautions given in the product insert shall be strictly followed.
6. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
7. Do not pipette by mouth.
8. Tests are for in vitro diagnostic use only and should be run by competent trained person only.
9. All specimens to be tested should be handled in accordance with the laboratory practice for infectious diseases.
10. Spills should be decontaminated promptly with Sodium Hypochlorite or any other suitable disinfectant.
11. Wash hands thoroughly with soap or any suitable detergent, after the use of the kit. In case of needle prick or other skin puncture or wounds, wash the hands with excess of water and soap.
12. Do not perform the test in area with strong air flow i.e. under fan or strong air conditioning.
13. Observe established precautions against microbiological hazards throughout sample collection and testing procedures.
14. Dispose off all specimens and materials used to perform the test as bio-hazard waste. Laboratory chemical and biohazard wastes must be handled and discarded in accordance with all local, state, and national regulations for Covid 19.

PRECAUTION

Optimal assay performance requires strict adherence to the assay procedure described in the manual.

1. Do not use kit components beyond the expiration date, which is printed on the kit.
2. Do not re-use the test kit.
3. Do not use the test kit if the pouch is damaged or the seal is broken.
4. Do not use the sample extraction buffer of another lot.
5. Do not smoke, drink or eat while handling specimen.
6. Avoid microbial and cross contamination of reagents.
7. Bring all the reagents to room temperature (20-30ºC) before use.
9. Use a separate swab and sample extraction tube for each specimen and then discard it as biohazardous waste.
10. **Ensure that the sample extraction buffer is added in the tube upto the mark provided (0.4).**

BEFORE YOU START

The sample extraction buffer vial provided in the kit has closed nozzle and screw cap with pin (outside). Before using sample extraction buffer, keep the vial vertically straight and tap down gently on the working platform, so that sample extraction buffer comes down at the bottom of the vial. To orifice/puncture the closed nozzle, follow the instruction as illustrated on back side of the manual.

SPECIMEN COLLECTION, SAMPLE PREPARATION AND STORAGE

Human nasopharyngeal swab specimens should be used for the test.

1. Take out required no. of Sample Extraction Tube from the pouch and place in the Sample Extraction Tube Stand provided with the kit.
2. Label the sample extraction tube with patient's name or identification number. Improper identification may lead to wrong result reporting.
3. Add Sample Extraction Buffer from the vial in Sample Extraction Tube upto the mark provided (0.4 ml).
4. **Nasopharyngeal Swab specimen collection:** Take the nasopharyngeal swab provided in the kit and carefully insert into the nostril presenting the most secretion on visual inspection. Keep the swab near the septum floor of the nose by gently pushing the swab into the posterior nasopharynx. Gently rotate the swab several times against the nasal wall and remove it from the nasopharynx.

Care should be taken to collect mucus free swab specimen.

5. Sample preparation:

i) Insert the collected specimen swab (as mentioned above) into the Sample Extraction tube containing Sample Extraction Buffer.

ii) Swirl the swab 10 times, and squeeze the swab head against the tube wall of the extraction tube to release the antigen in the buffer to remove as much liquid as possible from the swab. **Dispose off swab according to biohazard waste disposal method.**

iii) Tightly close the cap of the tube and mix the contents by gentle shaking (5 times).

6. **Sample Storage:** It is recommended to test the patient specimens immediately after collection.

Specimens collected in Sample extraction buffer may be stored at 2-8ºC for upto 4 hours or at room temperature upto 1 hour.

TEST PROCEDURE

1. Take out the COVID 19 Ag test card from the foil pouch prior to use and place it on a flat and dry surface and mark the test card with patient's name or identification number. Improper identification may lead to wrong result reporting.
2. Transfer 5 drops (150 μl) of the extracted sample (from step 2 "Sample Preparation") using sample dropper provided into the sample well of the test card. Dispose off the sample dropper immediately considering it to be potential biohazardous.
3. Allow the reaction to occur for 20 minutes.

Read the result at 20 minutes. Do not read the results after 30 minutes. Results beyond 30 minutes may give false results.

NOTE: Discard the device immediately after reading the results, considering it to be infectious.

INTERPRETATION OF TEST RESULTS

POSITIVE

Appearance of two distinct pink line in the control region 'C' and test region 'T' indicates that the specimen is positive for Covid 19 antigen. Any pink line observed in test are (T) - whether faint or dark, along with Control line shall be considered as positive and result to be interpreted as Covid antigen positive.

NEGATIVE

Appearance of one distinct pink line in the control region 'C' only and no line in the test region 'T' indicates that the specimen is negative for Covid 19 antigen.

INVALID

If no "C" Control line appears after the test is completed, with/ without "T" test line; the test indicates ERROR. **The left over collected specimen (from sample collection and preparation step) shall be Centrifuged at 10,000 rpm for 15 minutes and re-run the test using fresh new device.** The invalid result may be obtained due to following reasons:

(a) Improper storage at temperature other than the recommended temperature.

(b) Wrong sample collection and / or test procedure.

(c) Long atmospheric exposure of the test device after opening the pouch.

PERFORMANCE CHARACTERISTICS

The performance of 3 different lots of Covid 19 Ag Card has been evaluated and validated by ICMR validation centre; Govt. Institute of Medical Sciences, Greater Noida using RT-PCR confirmed positive (112) and negative samples (106). The results obtained on are as follows:

Sensitivity (in samples ≤ 30 ct) = **91.51%**

Specificity = **100%**

Positive Predictive Value: 100%

Negative Predictive Value : 92.17%

LIMITATIONS OF THE TEST

1. The kit works best when used with fresh specimens. Specimens containing mucus/ particulates can result in improper flow of extracted sample & hence making the interpretation of results difficult.
2. Potentially interfering substances like Nasal Sprays, nasal drops , Homeopathic allergic release medicines, anti inflammatory medicines ,anti- viral drugs ,Biotin etc. may lead to False positive results .
3. Any deviation from test procedure may lead to erratic results.
4. This is only a screening test and should not be used as the sole criteria for the diagnosis of Covid- 19 infection.
5. All samples detected non -reactive must be confirmed by using RT-PCR. Therefore for a definitive diagnosis & more accuracy of immune status, the patient's clinical history and symptomatology should be considered in order to obtain a confirmation of Covid-19 infection. A negative result at any time does not preclude the possibility of an early infection of Covid-19 infection .The results should be reported only after complying with above procedure.
5. This is a Qualitative test and therefore neither determine Covid 19 Antigen quantitative value nor the rate of SARS-CoV-2 antigen concentration.
6. For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended.
7. The test result must always be evaluated with other data available to the physician.
8. A negative result may occur if the concentration of antigen in a specimen is below the detection limit of the test or if the specimen was collected or transported improperly. Therefore a negative test result does not eliminate the possibility of SARS-CoV-2 infection, and should be conrmed by RT-PCR.
9 Positive test results do not rule out co-infections with other pathogens.

LIMITED EXPRESSED WARRANTY DISCLAIMER

The manufacturer limits the warranty to the test kit, as much as that the test kit will function as an *in vitro* diagnostic assay within the limitations and specifications as described in the product instruction manual, when used strictly in accordance with the instructions contained therein. The manufacturer disclaims any warranty expressed or implied including such expressed or implied warranty with respect to merchantability, fitness for use or implied utility for any purpose. The manufacturer's liability is limited to either replacement of the product or refund of the purchase price of the product and in no case liable to claim of any kind for an amount greater than the purchase price of the goods in respect of which damages are likely to be claimed. The manufacturer shall not be liable to the purchaser or third parties for any injury, damage or economic loss, howsoever caused by the product in the use or in the application there of.

BIBLIOGRAPHY

1. Scohy A., Anantharajah A., Bodeus M., Kabamba-Mukadi B., Verroken A., Rodriguez-Villalobos H.: Low performance of rapid antigen detection test as frontline testing for COVID-19 diagnosis. J. Clin Virol. 2020 Aug; 129: 104455. doi:10.1016/j.jcv.2020.104455
2. Nicholas C.G., Pons-Salort M., White P.J., N., Ferguson N. M.: Comparison of molecular testing strategies a mathematical modeling study. THE LANCET Infectious Diseases. DOI: http://doi.org/10.1016
3. Patterson E.I., Prince T., Anderson E.R., Casas-Sanchez A., Smith S.L., Cansado-Utrilla C., Turtle L., Hughes G.L.: Method of inactivation of SARS-CoV-2 for downstream biological assays.
4. Che Xi-Y., Hao W., Wang Y., Di B., Xu Yin-C., Feng Ch-S., Wan Zh-Y., Cheng V.C.C., Yuen Kw-Y.: Nucleocapsid Protein as Early Diagnostic Marker for SARS; Emerg Infect Dis.2004 Nov;10(11):1947-1949. doi:10.3201/eid1011.040516

REFER THE BACK PAGE OF THE INSTRUCTION MANUAL FOR PICTORIAL REPRESENTATION & BETTER CLARITY OF THE TEST PROCEDURE AND RESULT INTERPRETATION.

in vitro diagnostic reagent, not for medicinal use

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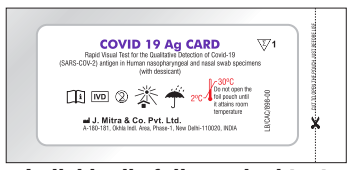
COVID 19 Ag CARD

Rapid Visual Test for the Qualitative Detection of Covid-19 (SARS-COV-2) antigen in Human nasopharyngeal and nasal swab specimens

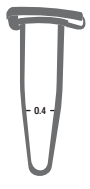
MATERIAL PROVIDED



Individually foil pouched test device with a dessicant. Lot No., Mfg. & Exp. date are printed on back of the pouch.

Sample Extraction Buffer Vial

Sample Extraction Tube



Sample Dropper

Nasopharyngeal Swab

Sample Extraction Tube Stand

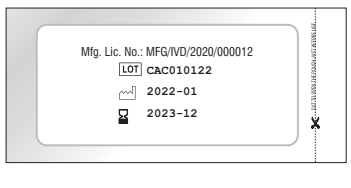
PREPARATION FOR THE TEST

1) Carefully read the instruction manual for using the Covid 19 Ag Card Test

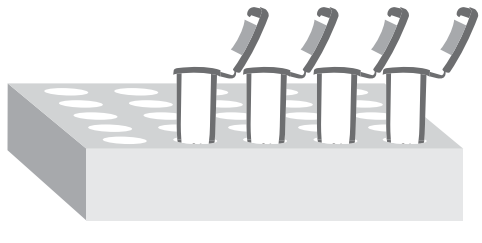
2) Bring the required number of test devices, Sample Extraction Tubes and Sample Extraction Buffer vial to room temperature prior to testing.

RT 20-30°C

3) Check the expiry date at the back of test device foil pouch and Sample Extraction Buffer vial label. **Use fresh kit if expiry date has passed**.



4) Take out required no. of Sample Extraction Tube from the pouch, label it with patient ID and place in the Sample Extraction Tube Stand.



5) Make Sample Extraction Buffer vial ready to use

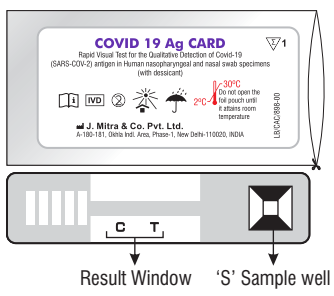
I) Open the cap

ii) Invert the cap & press on the closed nozzle

iii) Give a half turn twist to puncture the nozzle

iv) Screw the cap tightly after use

6) Cut open the device foil pouch and check the color of the dessicant pouch, it should be blue in color. **Do not use the device if dessicant is pink in color.**

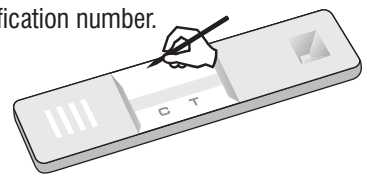


Dessicant in good condition

Pink color dessicant

⚠ Do not use the device if dessicant is pink in color

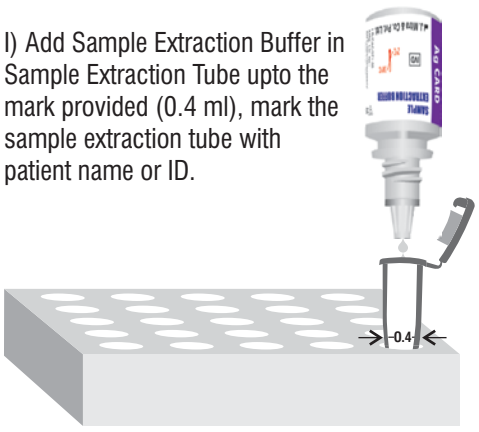
7) Label the test device with patient's name or identification number.



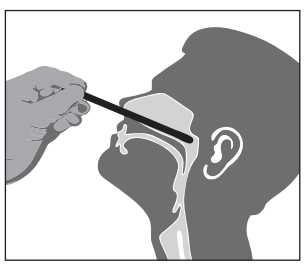
TEST PROCEDURE

1) SPECIMEN COLLECTION & PREPARATION:

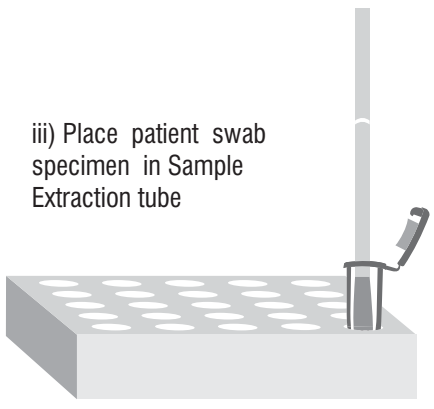
I) Add Sample Extraction Buffer in Sample Extraction Tube upto the mark provided (0.4 ml), mark the sample extraction tube with patient name or ID.



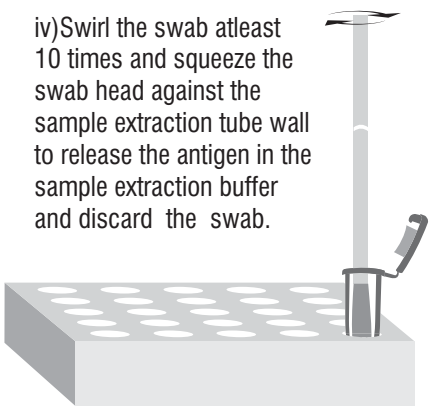
ii) Take nasopharyngeal swab sample



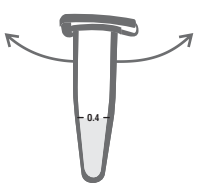
iii) Place patient swab specimen in Sample Extraction tube



iv)Swirl the swab atleast 10 times and squeeze the swab head against the sample extraction tube wall to release the antigen in the sample extraction buffer and discard the swab.



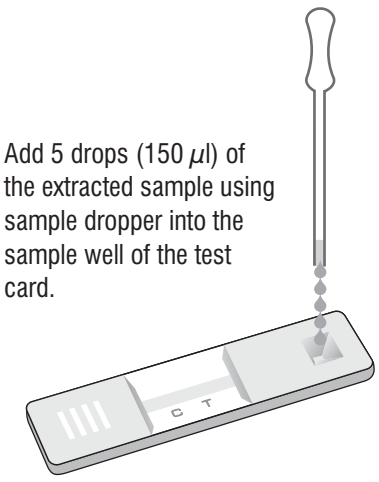
v) Close the cap tightly and mix the contents of the vial by gentle shaking (5 times).



2) RUNNING THE TEST ON THE DEVICE

Take the specimen reagent mixture from the sample extraction tube using sample dropper provided with the kit.

Add 5 drops (150 μl) of the extracted sample using sample dropper into the sample well of the test card.



3) READING TIME

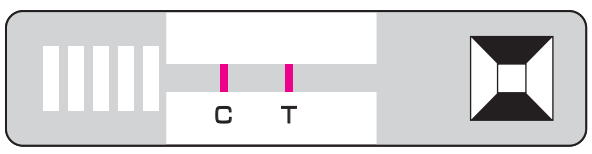
Read result at 20 Minutes

20 minutes

⚠ Do not read results after 30 minutes

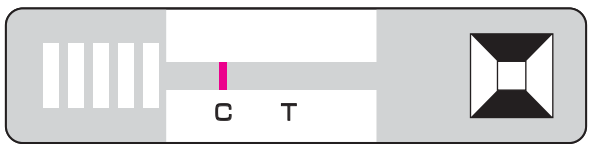
RESULT INTERPRETATION

POSITIVE for Covid 19 Antigen



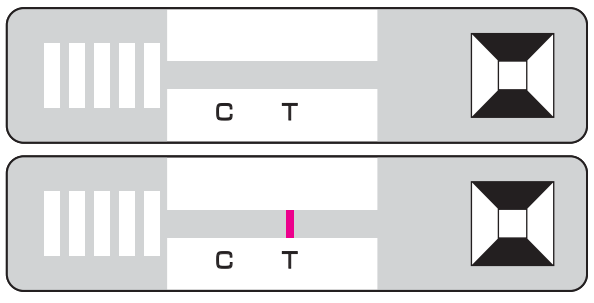
Appearance of red coloured line in the control region 'C' and Test region 'T' indicates that the specimen is positive for Covid 19 Antigen.

NEGATIVE



Appearance of one red coloured line in the control region 'C' indicates that the specimen is negative for Covid 19 Antigen.

INVALID



If neither control line nor test line appears or only test line appears, the test should be treated as Invalid. Repeat the test again.