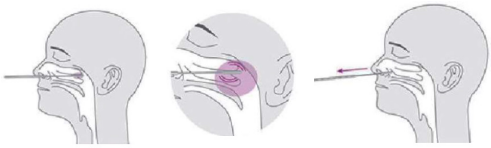
QuickTestCorona™ COVID-19 & Influenza A+B Antigen Rapid Test

(Nasopharyngeal Swab)



Package Insert

The QuickTestCorona™ COVID-19 & Influenza A+B Antigen Combo Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2, Influenza A and Influenza B virus antigens in the human nasopharynx.

For professional in-vitro-diagnostic use only!

INTENDED USE

The QuickTestCorona™ COVID-19 & Influenza A+B Antigen Combo Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2, Influenza A and Influenza B virus antigens in nasopharyngeal swab specimens. The results are intended for the detection of SARS-CoV-2 and Influenza A+B antigens. An antigen is generally detectable in upper respiratory tract samples 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 required to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The pathogen detected may not be the definite cause of the disease.

Negative results do not rule out SARS-CoV-2/ Influenza A+B infection and should not be used as the sole basis for treatment or patient management decisions. Negative results should be treated as suspected and confirmed by a molecular assay if necessary for patient management. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical symptoms consistent with COVID-19/Flu A+B. The QuickTestCorona™ COVID-19 & Influenza A+B Antigen Combo Rapid Test is intended for use by trained clinical laboratory personnel.

SUMMARY

The novel coronaviruses are part of the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

Influenza (commonly known as „flu") is a highly contagious, acute viral infection of the respiratory tract. It is a contagious disease that can be easily transmitted by coughing and sneezing of aerosolized droplets containing live viruses.[1] Influenza outbreaks occur every year in the autumn and winter months. Type A viruses are generally more prevalent than type B viruses and are associated with most severe influenza epidemics, while type B infections tend to be milder.

The gold standard of laboratory diagnostics is the 14-day cell culture with one of several cell lines that can support the growth of the influenza virus.[2] Cell cultures have limited clinical utility because the results are obtained too late in the clinical course for effective patient intervention. Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) is a newer method that is generally more sensitive than culture and has improved detection rates of 2-23% over culture.[2] However, RT-PCR is expensive, complex, and must be performed in specialized laboratories.

TEST PRINCIPLE

The QuickTestCorona™ COVID-19 Antigen Rapid Test is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 Antigens in human nasopharyngeal swab specimens. SARS-CoV-2 antibodies are coated in the test line region. During the test, the specimen reacts with SARS-CoV-2 antibody-coated particles. The mixture then migrates upward on the membrane by capillary action and reacts with the SARS-CoV-2 antibody in test line region. If the specimen contains SARS-CoV-2 Antigens, a colored line will appear in test line region as a result of this. If the specimen does not contain antigens to SARS-CoV-2, no colored line will appear in the test line region, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

The Influenza A+B Rapid Test (Nasopharyngeal Swab) is a qualitative lateral flow immunoassay for the detection of Influenza A and Influenza B antigens in human nasopharyngeal swab specimens. In this test, antibodies specific to influenza A and influenza B are separately applied to the test line regions of the test. During the test, the extracted sample reacts with the antibodies to Influenza A and/or Influenza B applied to the particles. The mixture migrates up the membrane to react with the antibodies to Influenza A and/or Influenza B on the membrane to produce one or two colored lines in the test regions. The appearance of these colored lines in one or both test regions indicates a positive result. To serve as a procedural control, one colored line always appears in the control region when the test is performed properly.

REAGENTS

The test contains Anti-SARS-COV-2, Anti-Influenza A and Anti-Influenza B as capture reagent, Anti-SARS-COV-2, Anti-Influenza A and Anti-Influenza B as detection reagent.

PRECAUTIONS

1. This package insert must be read completely before performing the test. Failure to follow the instructions in the package insert may result in inaccurate test results.
2. For professional in vitro diagnostic use only. Do not use after the expiration date!
3. Do not eat, drink or smoke in the area where the specimens or kits are handled.
4. Do not use the test if the pouch is damaged.
5. Handle all samples as if they contain infectious agents. Always follow established precautions against microbiological hazards when collecting, handling, storing and disposing of patient specimens and used kit contents.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
7. Wash hands thoroughly after handling.
8. Make sure that an appropriate amount of specimens is used for the assay Too large or too small a quantity of specimens may cause discrepancies in the results.
9. Viral transport media (VTM) may affect the test result, do not store samples in viral transport media; extracted samples for PCR tests cannot be used for the test
10. The used test should be disposed of according to local regulations.
11. Humidity and temperature may adversely affect the results.

STORAGE AND STABILITY

Store the test in the sealed original pouch at 2-30°C. The test device can be used until the expiration date printed on the sealed pouch and must remain in the sealed pouch until use.

If the test is stored at 2-8°C, the sealed pouch must be brought to room temperature before use.

The test should be kept away from direct sunlight, heat and moisture.

DO NOT FREEZE! Do not use after the expiration date.

MATERIALS

Materials Provided

• 20 sealed pouches, each containing one test cassette and one desiccant • 20 sterile swabs • 20 specimen collection containers with cap • 2 bottles with extraction buffer • 1 workstation • 1 package insert

Materials Required but not Provided

• clock or timer

SPECIMEN COLLECTION AND PREPARATION

Specimen Collection

1. Insert a sterile swab into the patient's nostril until it reaches the surface of the posterior nasopharynx
2. Swipe the surface of the posterior nasopharynx.
3. Remove the sterile swab from the nasal cavity

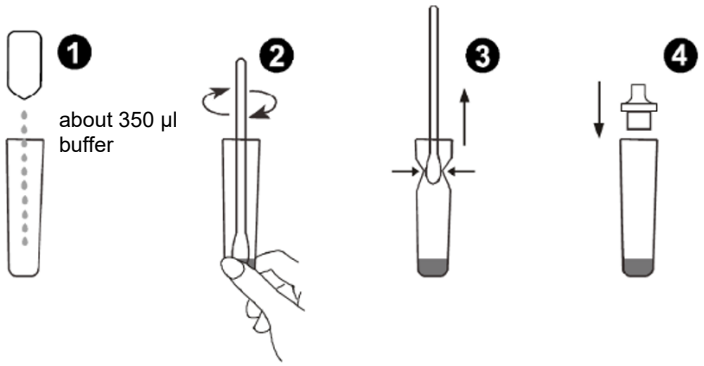
Specimen Preparation

NOTE: Swab specimens should be tested as soon as possible after collection. If the specimen is not processed immediately, it should be placed in a dry, sterile and closed plastic tube for storage. Based on data generated from the influenza virus, the swab specimen is stable for up to 8 hours at room temperature and 24 hours at 2-8 °C.

Use ONLY the sample collection tubes and extraction buffers included in the kit to prepare the swab samples!

1. Place the sample collection container in the workstation. Add approximately 350µl extraction buffer. (approx. 10 drops)
2. Insert the swab specimen into the specimen collection tube. Stir the head of the swab for approximately 10 seconds and press it against the inner wall of the tube to release the antigens in the collection tube.
3. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.
4. Place the cap on the collection tube.

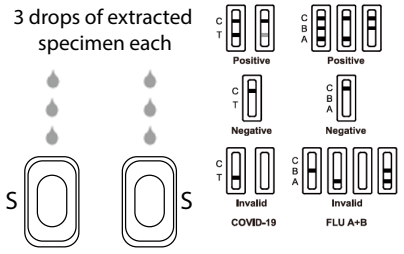
NOTE: Specimen storage after extraction is stable for 2 hours at room temperature or 24 hours at 2-8 °C



TEST PROCEDURE

Allow the test, reagents, swab specimen and/or controls to equilibrate to room temperature (15-30°C) before testing!

1. Remove the test device from the sealed pouch and use it within one hour. For best results, perform the test immediately after opening the pouch.
2. Invert the test tube, add 3 drops of the extracted sample (approximately 75 µl) to both sample wells (S) and then start the timer.
3. Wait until the colored line(s) appear(s). Read the result after 15 minutes. Do not interpret the result after 20 minutes or later.



INTERPRETATION OF RESULTS

(see illustration above)

POSITIVECOVID-19 Antigen:* In the left window two lines of different colors appear. One colored line should be in the control region (C) and another colored line should be in the test region (T). A positive result in the test region indicates the detection of COVID-19 antigens in the specimen.

POSITIVE Influenza A:* Two distinct colored lines appear in the right window. One colored line should be in the control region (C) and another colored line should be in the influenza A region (A). A positive result in the Influenza A region indicates that Influenza A antigen has been detected in the specimen.

POSITIVE Influenza B:* Two distinct colored lines appear in the right window. One colored line should be in the control region (C) and another colored line should be in the Influenza B region (B). A positive result in the Influenza B region indicates that Influenza B antigen has been detected in the specimen.

POSITIVE Influenza A and Influenza B:* Three clearly colored lines appear in the right window. One colored line should be in the control region (C) and two colored lines should be in the influenza A region (A) and the influenza B region (B). A positive result in the influenza A region and the influenza B region indicates that influenza A antigen and influenza B antigen were detected in the specimen.

***NOTE:** The intensity of the color in the test line region (T) varies depending on the amount of COVID 19 antigen present in the specimen. Therefore, any shade of color in the test line region (T/B/A) should be considered positive.

NEGATIVE: A colored line appears in the control region (C). No visible colored line appears in the test line region (T/B/A).

INVALID: The control line does not appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal Quality Control

Internal procedural controls are included in the test. A colored line that appears in the control region (C) is an internal positive procedural control. It confirms sufficient sample volume and correct procedural technique. A good background is an internal negative procedural control. If the test works properly, the background in the result region should be white to light pink and should not interfere with the readability of the test result.

External Quality Control

Controls are not included in this kit. However, in accordance with Good Laboratory Practice (GLP), positive/negative controls are recommended.

LIMITATIONS

1. The test procedure and interpretation of the test result must be followed closely when testing for the presence of SARS-CoV-2/Influenza A/Influenza B antigens in human nasopharyngeal swab specimens from suspected individuals. Proper specimen collection is critical for optimal test performance. Failure to follow the procedure may result in inaccurate results.
2. Performance of the QuickTestCorona™ COVID-19 & Influenza A+B Antigen Combo Rapid Test has been evaluated using only the procedures described in this package insert. Changes to these procedures may alter the performance of the test.
3. The QuickTestCorona™ COVID-19 & Influenza A+B Antigen Combo Rapid Test is for in vitro diagnostic use only. This test should be used to detect SARS-CoV-2/Influenza A/Influenza B antigens in human nasopharyngeal specimens as an aid in the diagnosis of patients suspected of being infected with SARS-CoV-2, Influenza A or Influenza B in conjunction with the clinical presentation and results of other laboratory tests. This qualitative test cannot be used to determine the quantitative value or rate of increase of SARS CoV-2/Influenza A/Influenza B antigen concentration.
4. The QuickTestCorona™ COVID-19 & Influenza A+B Antigen Combo Rapid Test indicates only the presence of SARS-CoV-2/Influenza A/Influenza B antigens in the specimen and should not be used as the sole criterion for diagnosis of SARS-CoV-2/Influenza A/Influenza B infection.
5. Results obtained with the test should be considered in conjunction with other clinical findings from other laboratory tests and evaluations.
6. If the test result is negative or non-reactive and clinical symptoms persist, it is recommended that a new specimen be collected from the patient a few days later and retested or tested with a molecular diagnostic device to rule out infection in these individuals.
7. The test will give negative results under the following conditions The titre of the novel coronavirus antigens, influenza A or influenza B virus in the sample is lower than the minimum detection limit of the test.
8. Negative results do not rule out infection with SARS-CoV-2, especially in individuals who have been exposed to the virus. Follow-up testing with molecular diagnostics should be considered to rule out infection in these individuals.
9. A negative result for influenza A or influenza B obtained with this kit should be confirmed by RT-PCR or culture.
10. Excess blood or mucin on the swab specimen may interfere with the test procedure and lead to a false positive result.
11. The accuracy of the test depends on the quality of the swab specimen. False negative results may occur due to improper specimen collection or storage.
12. Positive results of COVID-19 may be due to infection with non-SARS CoV-2 coronavirus strains or other interference factors. A positive result for Influenza A and/or B does not preclude an underlying co-infection with another pathogen, so the possibility of an underlying bacterial infection should be considered.

EXPECTED VALUES

The QuickTestCorona™ COVID-19 & Influenza A+B Antigen Combo Rapid Test was compared to a leading commercial RT-PCR test. The correlation between these two systems is no less than 95%.

PERFORMANCE CHARACTERISTICS

Sensitivity, Specificity and Accuracy

The QuickTestCorona™ COVID-19 & Influenza A+B Antigen Combo Rapid Test was evaluated using samples collected from patients. RT-PCR is the reference method for the QuickTestCorona™ COVID-19 & Influenza A+B Antigen Combo Test. Samples were considered positive if RT-PCR indicated a positive result. Samples were considered negative if the RT-PCR indicated a negative result.

Method		RT-PCR		Total
COVID-19 Antigen Rapid Test	Results	Positive	Negative	
	Positive	110	2	112
	Negative	5	319	324
Total		115	321	436

Sensitivity: 95.65% (91.9%-99.4%)* **Specificity:** 99.38% (98.5%->99.9%)*
Accuracy: 98.39% (97.2%-99.57%)* *95% Confidence Interval

Sensitivity based on Ct-value

For this purpose, QuickTestCorona™ conducted a comparative study in Austria with patient samples that were confirmed positive by RT-PCR (including determination of the Ct value). In this study the QuickTestCorona™ COVID-19 Antigen Rapid Test achieved the following results:

RT-PCR Ct-Values	Sensitivity of the QuickTestCorona™ COVID-19 Antigen Rapid Test
20-30	100 %
20-31	96.2 %
20-32	96.3 %
20-33	90.0 %
20-34	90.3 %

In the particularly important Ct range between 20 and 30, the QuickTestCorona™ rapid test with **100% sensitivity** achieved a perfect result. All samples confirmed as positive by RT-PCR were detected as positive here. This study clearly shows that the QuickTestCorona™ COVID-19 Antigen Rapid Test is a highly sensitive test for the detection of coronavirus.

Method		RT-PCR		Total
Influenza A Antigen Rapid Test	Results	Positive	Negative	
	Positive	16	1	17
	Negative	1	62	63
Gesamt		17	63	80

Sensitivity: 94.1% (71.3%-99.9%)* **Specificity:** 98.4% (91.5%-99.9%)*
Accuracy: 97.5% (91.3%-99.7%)* *95% Confidence Interval

Method		RT-PCR		Total
Influenza B Antigen Rapid Test	Results	Positive	Negative	
	Positive	11	0	11
	Negative	1	68	69
Total		12	68	80

Sensitivity: 91.7% (61.5%-99.8%)* **Specificity:** >99.9% (95.7%-100%)*
Accuracy: 98.8% (93,2%-99.9%)* *95% Confidence Interval

Specificity tests with different virus strains

The QuickTestCorona™ COVID-19 & Influenza A+B Antigen Combo Rapid Test was tested with the virus strains listed in the table below. For the following virus strains no detectable line was observed at the test line region at the concentrations given:

COVID-19

Beschreibung	Test Level
Adenovirus Type 3	3.16 x 10^4 TCID50/ml
Adenovirus Type 7	1.58 x 10^5 TCID50/ml
Human Coronavirus OC43	2.45 x 10^6 LD50/ml
Influenza A H1N1	3.16 x 10^5 TCID50/ml
Influenza A H3N2	1 x 10^5 TCID50/ml
Influenza B	3.16 x 10^6 TCID50/ml
Human. Rhinovirus 2	2.81 x 10^4 TCID50/ml
Human. Rhinovirus 14	1.58 x 10^6 TCID50/ml
Human. Rhinovirus 16	8.89 x 10^6 TCID50/ml
Measles	1.58 x 10^4 TCID50/ml
Mumps	1.58 x 10^4 TCID50/ml
Parainfluenza Virus 2	1.58 x 10^7 TCID50/ml
Parainfluenza Virus 3	1.58 x 10^8 TCID50/ml
RSV	8.89 x 10^4 TCID50/ml

Influenza A+B

Beschreibung	Test Level
Adenovirus Type 3	3.16 x 10^4 TCID50/ml
Adenovirus Type 7	1.58 x 10^5 TCID50/ml
Human. Coronavirus OC43	2.45 x 10^6 LD50/ml
Human. Rhinovirus 2	2.81 x 10^4 TCID50/ml
Human. Rhinovirus 14	1.58 x 10^6 TCID50/ml
Human. Rhinovirus 16	8.89 x 10^6 TCID50/ml
Measles	1.58 x 10^4 TCID50/ml
Mumps	1.58 x 10^4 TCID50/ml
Parainfluenza Virus 2	1.58 x 10^7 TCID50/ml
Parainfluenza Virus 3	1.58 x 10^8 TCID50/ml
RSV	8.89 x 10^4 TCID50/ml

TCID50 = Tissue Culture Infectious Dose: The dilution of the virus that can be expected to infect 50% of the inoculated culture vessels under the test conditions.

LD50 = Lethal Dose: The virus dilution that can be expected to kill 50% of the inoculated mice under the test conditions.

Precision

Intra-Assay and Inter-Assay

Precision within and between runs was determined using seven samples from the COVID-19 and Influenza A/B standard control. Three different batches of the The QuickTestCorona™ COVID-19 & Influenza A+B Antigen Combo Rapid Test were tested with negative results: SARS-COV-2 antigen weak, SARS-COV-2 antigen strong, influenza A weak, influenza B weak, influenza A strong and influenza B strong. Ten replicates of each level were tested daily for 3 consecutive days. The samples were correctly identified in >99% of cases.

Cross-Reactivity

The following organisms were tested at 1.0x10^8 org/ml and all were found negative when tested with the QuickTestCorona™ COVID-19 & Influenza A+B Antigen Combo Rapid Test

Arcanobacterium	Pseudomonas aeruginosa
Candida albicans	Staphylococcus aureus subspaureus
Corynebacterium	Staphylococcus epidermidis
Escherichia coli	Streptococcus pneumoniae
Moraxella catarrhalis	Streptococcus pygenes
Neisseria lactamica	Streptococcus salivarius
Nesseria subllava	Streptococcus sp group F

BIBLIOGRAPHY

1. Williams, KM, Jackson MA, Hamilton M. (2002) Rapid Diagnostic Testing for URIs in Children; Impact on Physician Decision Making and Cost. Infec. Med. 19(3): 109-111.
2. Betts, R.F. 1995. Influenza virus, p. 1546-1567. In G.L. Mandell, R.G. Douglas, Jr. and J.E. Bennett (ed.), Principle and practice of infectious diseases, 4th ed. Churchill Livingstone, Inc., New York, N.Y.
3. WHO recommendations on the use of rapid testing for influenza diagnosis, World Health Organisation, July 2005.
4. Westgard JO, Barry PL,Hunt MR, Groth T. A multi-rule Shewhart for quality control in clinical chemistry, Clinical Chemistry 1981;27:493-501

Consult instructions for use	Tests per kit	Do not use if package is damaged
For In vitro diagnostic use only	Use by	Do not reuse
Store between 2-30 °C	Lot number	Catalogue number

CE

Manufacturer
MEXACARE GmbH
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Version 1.5aENG, valid from 2020-10-30

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