Abbexa COVID-19 Antigen Rapid Test Kit

Instructions For Use
Revision Date: 17/12/2020
Version: 1.0.0

REF Catalog No: abx294181b

IVD In Vitro Diagnostic

UK CA

INTENDED USE

The COVID-19 Antigen Rapid Test Kit is a single- use in vitro diagnostic device used for laboratory and hospital testing. It is a lateral flow immunoassay which detects SARS-CoV-2 antigen, the virus that causes COVID-19, in oropharyngeal swab, nasal swab, and nasopharyngeal swab samples. The presence of such antigen indicates potential COVID-19 infection.

SUMMARY

Results are for the detection of SARS-CoV-2 antigen. SARS-CoV-2 antigens are generally detectable several days after initial infection. The levels of antigen will be higher during early infection, and decline as the infection progresses. The test is best used as soon as symptoms, if any, appear.

Positive results are indicative of acute or recent infection.

Negative results do not preclude COVID-19 infection and should not be used as the sole basis for patient management decisions.

For in vitro diagnostic use only.

BACKGROUND

The Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) is an emergent virus responsible for the respiratory illness Coronavirus Disease 2019 (COVID-19). First documented in the city of Wuhan (China), it has spread to most countries across the globe.

The original source of SARS-CoV-2 is unknown. It has been reported to have high similarity to coronaviruses found in bats and pangolins, however, neither of these animals are thought to have been sold in the meat market that the earliest patients visited, suggesting an intermediate host.

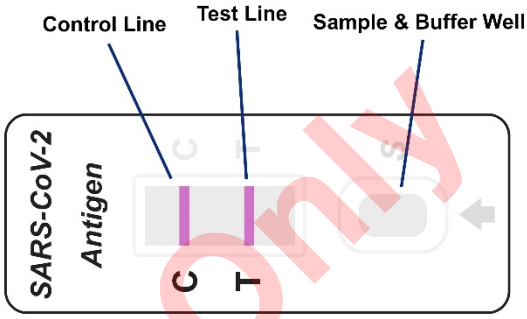
The virus is easily transmitted from person to person, primarily via droplets. Infected individuals can reduce transmission rates by wearing a face mask or covering the mouth when coughing/ sneezing, by sanitizing their hands regularly, and by self-isolating. People who have not yet been infected can wear a face mask and use eye protection to block droplets, not touch their face or food without sanitizing first, and avoid crowded areas.

The mortality rate for COVID-19 has been difficult to calculate due to the number of undiagnosed cases. Estimates range from 0.02% to 14%; most center at approximately 2-4%. The threat to the average healthy adult is low, however immunodeficiencies or respiratory illnesses can increase the mortality risk substantially.

TEST PRINCIPLE

The Abbexa COVID-19 Antigen Rapid Test Kit is a lateral flow immunoassay which can detect SARS-CoV-2/COVID-19 virus antigen. The sample pad inside the cassette contains gold nanoparticles coated with anti-SARS-CoV-2 antibody and mouse IgG. Anti-SARS-CoV-2 antibody is coated in the respective test region on a nitrocellulose membrane, creating the test line, and Goat anti-Mouse IgG antibodies are coated on the control line. The control region on the upper end of the cassette confirms if the test has been successful.

The test comes with a cassette, swab, and extraction buffer tube. When a correct volume of test sample and buffer is dispensed into the sample well of the test cassette, the sample migrates by capillary action along the test strip. If there is any SARS-CoV-2 virus antigen in the sample, it will bind to the SARS-CoV-2 antibody conjugates. The immunocomplex will then be captured by the SARS-CoV-2 antibody in the test line, forming a purple-colored T Line, indicating a SARS-CoV-2 virus antigen positive test result.



Information regarding the immune response to SARS-CoV-2 is limited and still evolving. At this time, it is unknown how long the antigen may persist following infection.

The test contains an internal control (C Line) which exhibits a purple-colored band of goat anti-mouse IgG / mouse IgG-gold conjugate immunocomplex regardless of the color development on any of the test bands (T Line). If no control band is observed, the test result is invalid and the sample must be retested.

REAGENTS AND MATERIALS

The kit is provided in a 25 test size. The number of components are as follows:

	Catalogue #	abx294181b
	Kit size (tests)	25
Components	Cassette (unit)	25
	Extraction Buffer Tube (unit)	25
	Sample Swab (unit)	25
	Buffer Tube Cap (unit)	25
	IFU (unit)	1

Composition

Conjugate Pad	Gold nanoparticles coated with SARS-CoV-2 antibody, and mouse IgG.
T Line	SARS-CoV-2 antibody.
C Line	Goat polyclonal antibody to mouse IgG.

Other Material Required But Not Provided

Timer

STORAGE AND STABILITY

1. Store the buffer and cassette at 2-30°C (36-86°F). These components are stable for a minimum of 12 months.
3. If stored at 2-8˚C, ensure that the test device is brought to 15-25˚C before opening.
4. Do not freeze the kit or store the kit over 30˚C.

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SAMPLE COLLECTION AND PREPARATION

Consider any materials of human origin as infectious and handle using the appropriate standard biosafety procedures. The World Health Organisation currently recommends testing samples potentially carrying the SARS-CoV-2 virus in Biosafety Level 2 facilities.

Oropharyngeal Swab: Tilt the head back and open the mouth wide, exposing the pharyngeal tonsils on both sides. Use the swab to gently wipe the tonsils on both sides at least 3 times each, then wipe the posterior pharyngeal wall (the mouth roof above the tonsils) at least 3 times.

Nasal Swab: Prior to collecting the sample, the patient should blow their nose. Carefully insert the swab into the nostril and push until resistance is met (less than one inch into the nostril), rotate the swab against the nasal wall several times and then remove it from the nostril.

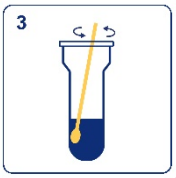
Nasopharyngeal swab: Carefully insert the swab into the nostril, keep the swab near the floor of the nasal cavity while gently pushing the swab into the posterior nasopharynx (back of the throat). Rotate the swab several times then remove it gently.

TEST PROCEDURE

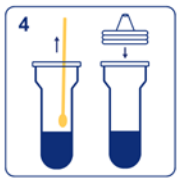
Instructions for use with swab.

Place the cassette on a level surface at room temperature (15-25°C, 59-77°F).

Remove the seal on the extraction buffer tube.



Place the swab in the extraction buffer tube and rotate 10 times, squeezing against the tube walls to extract the most sample.



Remove the swab and cover the tube with the buffer tube cap.

Add 3 drops of the extracted sample into the sample well.

Wait 10 minutes

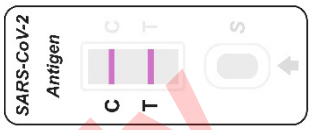
Read the results (see interpretation of results section).

QUALITY CONTROL

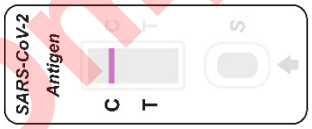
Internal Control: This test contains a built-in control feature, the C Line. The C Line develops after addition of the Extraction Buffer. If the C Line does not develop, the test is invalid. Review the procedure and repeat the test with a new device.

INTERPRETATION OF ASSAY RESULTS

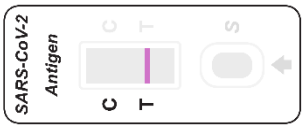
#1
Positive



#2
Negative



#3
Test Failure



#4
Test Failure

1. Valid Assay
The readout should show 1 line in the C (control) region. A line may appear next to the T region depending on the presence of SARS-CoV-2 antigen. Faint lines are treated as a positive result.

1.1 C and T regions are positive: patient has acute or recent infection with SARS-CoV-2.

1.2 C region positive, T region negative: patient does not have acute infection with SARS-CoV-2.

2. Invalid Assay

C region negative, T region either positive or negative: test did not function correctly.

Negative results do not rule out SARS-CoV-2 infection, particularly for patients who have been in contact with known infected persons or in areas with high prevalence of active infection. Follow-up testing with a molecular diagnostic test is necessary to rule out infection in these individuals.

Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection.

False positive results may occur due to cross-reacting antigens from other infections, such as other coronaviruses, or from other causes.

Samples with positive results should be confirmed with alternative testing method(s) and clinical findings.

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PERFORMANCE CHARACTERISTICS

1. Clinical Performance

1.1 Study of: Testing of RT-PCR positive clinical samples

Thirty one (31) positive swab samples collected from individuals who tested positive with a RT-PCR method for SARS-CoV-2 infection. These samples, along with one hundred and twenty seven (127) negative swab samples were coded and tested together with the abx294181b COVID-19 Antigen Rapid Test Kit. Of the 31 PCR positive samples, twenty eight (28) tested positive with abx294181b. Of the 127 PCR negative samples, one hundred and twenty-six (126) tested negative with abx294181b.

Taken together, the abx294181b COVID-19 Antigen Rapid Test Kit had a sensitivity and specificity of 90.32% and 99.21%, respectively.

		PCR result		
		Positive	**Negative**	**Total**
Kit result	**Positive**	28	1	29
	Negative	3	126	129
	Total	31	127	158

Sensitivity / Percentage Positive Agreement (PPA) = 28/31 (90.32%), 95% CI: 79.92% to 100%.
Specificity / Negative Percentage Agreement (NPA) = 126/127 (99.21%), 95% CI: 97.68% to 100%.

1.2 Study of: Comparison of sample types

Eight (8) positive patients had oropharyngeal, nasal and nasopharyngeal swabs taken consecutively. Another forty-two (42) negative patients had oropharyngeal, nasal and nasopharyngeal swabs taken consecutively. These samples were coded and tested with the abx294181b COVID-19 Antigen Rapid Test Kit. Of the 8 positive patients tested, all 8 equivalent oropharyngeal, nasal and nasopharyngeal swab samples tested positive. Of the 42 negative patients tested, all 42 equivalent oropharyngeal, nasal and nasopharyngeal swab samples tested negative. Pearson's Rank Correlation Coefficient (ρ) was calculated to be 1.0.

2. Assay Cross Reactivity

Cross-reactivity of the COVID-19 Antigen Rapid Test Kit was evaluated using the pathogens listed below. This test had no observable cross-reactivity with the following pathogen antigens in their respective concentrations:

Staphylococcus aureus	5 x 10^4 PFU/mL
Streptococcus pneumoniae	5 x 10^4 PFU/mL
Measles Virus	1 x 10^5 $TCID_{50}$/mL
Mumps Virus	1 x 10^5 $TCID_{50}$/mL
Adenovirus type 3	5 x 10^5 $TCID_{50}$/mL
Mycoplasma pneumoniae	5 x 10^4 PFU/mL
Parainfluenza virus type 2	1 x 10^5 $TCID_{50}$/mL
Metapneumovirus	1 x 10^6 $TCID_{50}$/mL
Coronavirus OC43	2 x 10^4 $TCID_{50}$/mL
Coronavirus 229E	1 x 10^4 $TCID_{50}$/mL
Bordetella parapertussis	5 x 10^4 PFU/mL
Influenza B, Victoria line	2 x 10^5 $TCID_{50}$/mL
Influenza B, Y line	2 x 10^5 $TCID_{50}$/mL
Influenza A, H1N1	5 x 10^5 $TCID_{50}$/mL
Influenza A, H3N2	1 x 10^6 $TCID_{50}$/mL
Avian Influenza, H7N9	1 x 10^6 $TCID_{50}$/mL
Avian Influenza, H5N1	1 x 10^6 $TCID_{50}$/mL
Epstein-Barr virus (EBV)	1 x 10^5 $TCID_{50}$/mL
Enterovirus CA16	1 x 10^5 $TCID_{50}$/mL
Rhinovirus	1 x 10^5 $TCID_{50}$/mL

3. Substance Interference

This test had no observable interference with the following substances at or below the listed concentrations.

Anti-mitochondrial antibodies	80U/ml
Anti-nuclear antibodies	1:240
Bilirubin	250 µMol/L
Hemoglobin	9 g/L
Mouse IgG	1 mg/ml
Rheumatoid factor (anti-IgG autoantibodies)	80 IU/ml
Triglycerides	15 mMol/L

4. Therapeutic Interference

This test had no observable interference with the following therapeutic agents at or below the listed concentrations.

Azithromycin	100 µg/mL
Ceftriaxone	1 mg/mL
Histamine dihydrochloride	100 µg/mL
Interferon alfa (IFN-α)	200 µg/mL
Levofloxacin	200 µg/mL
Lopinavir	10 µg/mL
Meropenem	10 µg/mL
Oseltamivir	300 µg/mL
Ribavirin (tribavirin)	1 µg/mL
Ritonavir	1 mg/mL
Tobramycin	10 µg/mL
Zanamivir	40 µg/mL
Peramivir	300 µg/mL
Umifenovir	500 ng/mL

WARNINGS

1. This package insert must be read completely before performing the test. Failure to follow directions in insert may yield inaccurate test results.
2. Keep out of reach of children.
3. Dispose of the kit after use or expiry. Dispose of used test in a biohazards bin.
4. Avoid exposure of test to high temperatures, humidity, and/or strong odors.
5. Do not eat any components of the test, including the buffer. If buffer is swallowed, take plenty of water and seek medical attention. Do not induce vomiting.
6. Do not use the components of any other type of test kit as a substitute for the components in this kit.
7. Wear protective clothing and disposable gloves while handling the kit reagents and clinical samples. Wash hands thoroughly after performing the test.
8. Do not remove outer packaging of components until ready to use.
9. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.
10. Do not exceed 20 minutes when waiting for results.

LIMITATIONS OF THE PROCEDURE

1. The C region confirms that appropriate levels of capillary action (i.e. wicking) have taken place for the test to have worked.
2. The COVID-19 Antigen Rapid Test Kit is intended for in vitro diagnostic use only. The kit is suitable only for the qualitative detection of SARS-CoV-2 antibodies in oropharyngeal swab, nasal swab and nasopharyngeal swab samples. Other sample types have not been tested.
3. There may be some cross-reactivity of this kit to other coronaviruses. A positive test is not proof that the causative agent is SARS-CoV-2 / COVID-19.
4. The test detects SARS-CoV-2 antigen; it does not directly confirm if the patient is an active carrier of the virus. Conversely, active carriers of the virus may show a negative antibody result. Other

tests (such as qPCR) may be required in combination for diagnosis, particularly for negative results.
5. A negative test does not necessarily preclude the patient from being infectious.
6. Lines may appear darker or fainter according to the relative antigen concentration in the sample.
7. If using a nasal swab sample, it is recommended to use the nostril with the most secretion under visual inspection.
8. This is a qualitative test; it is not suitable for quantitative or semi-quantitative determination of antigen.
9. No hook effect was observed with clinically-relevant positive samples.

INQUIRIES AND GENERAL INFORMATION
Please visit website www.abbexa.com

ORDERING
Contact Abbexa via email: orders@abbexa.com

TECHNICAL
Via email: support@abbexa.com

Store between 2-30°C

For in vitro diagnostic use

REF Catalog number

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