REF Catalog No. Covid-Ag-20
IVD In Vitro Diagnostic

INTENDED USE:

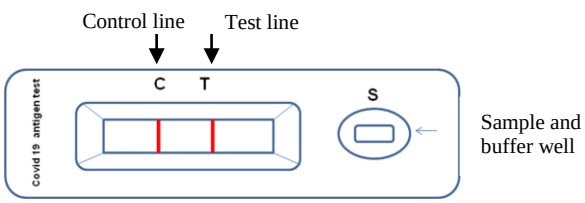
Assay+ COVID-19 antigen rapid test is a lateral flow immunochromatographic assay intended for the qualitative detection of the nucleocapsid protein of SARS-CoV-2 from the nasopharyngeal swab from the suspected COVID-19 patients within five days of symptom onset. This test is an aid to differentiate Covid 19 virus infection from other respiratory tract infection caused by coronavirus 229E, NL63, OC43 and HKU1, or severe acute respiratory syndrome caused by SARS-CoV and MERS-CoV. The test should be performed in doctor office, pharmacy, clinical laboratory or health provider. This test can also perform for the Point of Care (POC) purpose.

SARS-CoV-2 antigen is generally detectable in nasopharyngeal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but the clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Negative results are presumptive, and confirmation with a molecular assay may need if necessary.

Assay+ COVID-19 antigen is intended for use by medical professionals or trained operators who are proficient in performing tests and trained clinical laboratory personnel or individuals trained in point of care settings.

TEST PRINCIPLE:

Assay+ COVID-19 antigen test is a lateral flow immunochromatographic assay to detect the specific SARS-CoV-2 nucleocapsid protein in nasal oropharyngeal swab specimens collected from the individuals suspected with COVID-19 infection by their healthcare provider within the first five days of symptom after onset. Nasopharyngeal swabs require a sample preparation step in which the sample is eluted into the extract buffer. Extracted swab sample is added to the sample well of the test device for testing. When the swab sample migrates on the test strip, SARS-CoV-2 viral antigen binds to the conjugated SARS-CoV-2 nucleocapsid protein antibody forming an immune complex. The immune complex is then captured by the test line on the nitrocellulose membrane forming a visible red line within 20 minutes.



KIT COMPONENTS:

Contents	Quantity / kit	Description
Test device	20	Foil pouch contains one test cassette.
Extraction buffer	2	The extract buffer bottle contains 5ml extract buffer.
Nasopharynx swab	20	swabs for nasal oropharyngeal specimen collection
Extraction tube	20	Extract specimen and load sample
Package insert	1	Instructions for use

COMPONENTS REQUIRED BUT NOT PROVIDED

Timer

PRECAUTIONS:

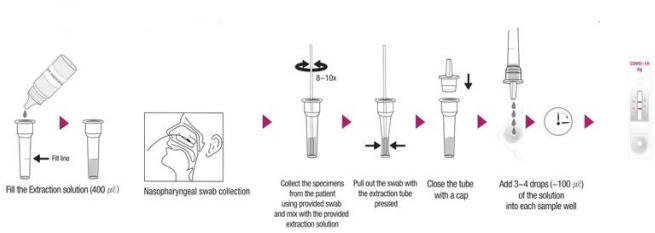
- For in vitro diagnostic use only.
- This test can be used in patient care settings.
- This test is only used to detect the proteins from SARS-CoV-2, not for any other viruses or pathogens.
- The results must be interpreted together with other clinical information.
- Use immediately after opening the pouch.
- Follow this package insert. to obtain accurate results
- Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false-positive result. Avoid touching any bleeding areas on the nasopharynx when collecting specimens.
- Do not interpret the test result before 15 minutes after starting the test.
- Inadequate or inappropriate sample collection, storage, and transport can result in incorrect results. If specimen storage is needed, swabs can be placed into extraction buffer for up to four hours. Specimens should not be stored dry.
- Do not use if the test device package is damaged.
- Do not use the kit contents beyond the expiration date.
- Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.
- Dispose of used contents as biohazardous wastes in accordance with federal, state, and local requirements.
- Mask, nitrile/latex gloves should be worn when performing this test.
- Reagents contain sodium azide, which is harmful if inhaled, swallowed, or exposed to skin. If there is contact with skin, wash with plenty of water. Sodium azide may react with lead and copper plumbing to form highly explosive metal azide. On disposal, flush with a large volume of water to prevent azide build-up.
- Do not interchange kit contents from different lots.
- Do not re-use any contents in the kit.

STABILITY AND STORAGE CONDITIONS:

● Store the test kit as packaged between 2 ~ 30°C.
● The reagents and materials in Assay+ COVID-19 antigen is stable till the expiration date printed on the package. Do not use beyond the expiration date.
● The test device must remain in the sealed pouch until use.
● Do not freeze any contents of the kit.

SPECIMEN COLLECTION:

● Specimens may be stable for 4 hours in extraction buffer.
● Add 400ul (about 16 drops extract buffer into extract tube
● Insert swab into nostril, slowly reach to the surface of the posterior nasopharynx.
● Swab the posterior nasopharynx surface.
● Slowly take out the swab and insert into extract buffer
● Vigorously rotate and twist the swab against the tube wall at least 10 times.
● Squeeze the tube wall to obtain as much liquid as possible.
● Dispose of swab properly.
● Cap to the tubes, hold the tube vertically, add 4 drop (about 100 µl) specimen into the sample well.

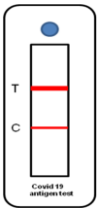


400ul

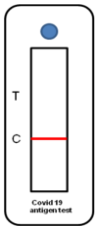
TEST PROCEDURES:

1. Remove test cards from the sealed pouch before testing, lay over a clean flat surface.
2. Label the device with patient name or control number, for the best result, the assay should be performed within one hour.
3. Add 4 drop (about 100 µl) specimen without air bubbles into the sample well. (See specimen collection)
4.Wait for 10 to 20 minutes to observe the result, do not interpret the result before 20 minutes.

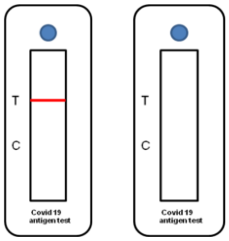
INTERPRETATION OF RESULT:



Positive test:
Both T and C show red lines indicating Covid19 infection.



Negative test:
Only C shows red line, indicating no Covid19 infection.



Invalid test

QUALITY CONTROL:

Internal Quality Control: Assay+ COVID-19 antigen test contains a built-in internal control that is included in the test device. A red-colored line appearing in the control region, "C" is designed as an internal control. The appearance of the control line indicates that sufficient flow and the functional integrity of the test device. If the control line does not develop in 10 minutes, the test result is considered invalid and retesting with a new device is recommended.

TEST LIMITATION:

● Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary.
● Failure to follow the instructions for use may adversely affect test performance and/or invalidate the test result.
● If the differentiation is needed for SARS virus infection, additional testing is needed, or in consultation with local public health departments.
● Clinical performance using virus transport medium is established on frozen specimens and performance may be different with fresh clinical specimens.
● Extracted specimens may be frozen at -80°C and used up to 5 days after freezing.
● Fresh samples are stable for 4 hours in extraction buffer at room temperature.
● Results from antigen testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to determine infection status.
●This test indicates the presence of SARS-CoV-2 nucleocapsid protein in the specimen from both viable and non-viable SARS-CoV-2 virus. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
● The detection of SARS-CoV-2 nucleocapsid antigen is dependent upon proper specimen collection, handling, storage, and preparation. Failure to observe proper procedures in any one of these steps can lead to incorrect results.

● Results from the device should be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient.
● This device has been evaluated for use with human specimen material only.
● False-negative results may occur if the concentration of the target antigen in the clinical specimen is below the detection limits of the device.
● This device is a qualitative test and does not provide information on the viral concentration present in the specimen.
● This test cannot rule out diseases caused by other bacterial or viral pathogens.
● The prevalence of infection will affect the test's predictive values.
● Positive and negative predictive values are highly dependent on prevalence. False-negative test results are more likely during peak activity when the prevalence of the disease is high. False-positive test results are more likely during the periods of low SARS-CoV-2 activity when prevalence is moderate to low.

CLINICAL PERFORMANCES:

1. Analytical Sensitivity:

Limit of Detection (LoD), The LoD for direct swab is established using heat-inactivated SARS-CoV-2 isolate. The strain is spiked into the pooled human nasal swab matrix obtained from multiple healthy volunteers eluted in viral transport medium to prepare positive samples. The confirmed LoD for direct swab is 6.6 x 10^3 TCID50/ml based on the supplier information.

2. Clinical agreement study:

A total of 233 people from different demographics in Nigeria randomly enrolled in this study in a clinical SARS-CoV2 test laboratory. Fresh swab taken from the posterior nasopharynx surface was used for both RT-PCR COVID 19 tests and Assay+ COVID 19 antigen test, the results from RT-PCR test and Bioassay COVID 19 antigen test kits were recorded for the further analysis.

Presence and absence of symptoms such as fever, chill, sore throat, cough, shortness of breath, coryza, altered sense of smell, general malaise, abdominal pain, vomiting, diarrhoea, headache, eye infection, muscle ache, joint ache, and tiredness were also recorded.

Assay+ Covid 19 antigen test	**RT-PCR**		
	Positive	Negative	Total
Positive	143	1	144
Negative	23	66	89
Total	166	67	233

Positive percent agreement (PPA)	86.14% (95% CI: 80.15% - 90.52%)
Negative percent agreement (NPA)	98.51%(95% CI: 92.02 - 99.74 %)

3. Patient Demographics

Age group	Assay+ Covid 19 antigen test		
	PCR +	Assay+ rapid test	Prevalence
≤ 5	3	2	67%
6 to 21	27	23	85.19%
22 - 59	133	113	84.96.%
≥ 60	4	3	75%
Unknown	2	2	100%
Total	166	143	

4. Cross-reactivity study

Cross-reactivity of the COVID-19 antigen Rapid Test was evaluated by using following recombinant viral nucleoproteins. No cross-reactive signal was found.

SARS nucleoprotein	Norovirus I nucleoprotein
Coronavirus NL63 nucleoprotein	Norovirus II nucleoprotein
Coronavirus 229E nucleoprotein	HPV 6 capsid
Coronavirus HKU1 nucleoprotein	HPV 11 capsid
Coronavirus OC43 nucleoprotein	HPV 16 capsid
Ebola nucleoprotein	HPV 18 capsid
Lasa nucleoprotein	Mumps' nucleoprotein
Hanta virus nucleoprotein	M. pneumonia antigen
HBV core protein	
HCV core protein	

INQUIRES AND GENERAL INFORMATION:

Please visit: https://bioassayplus.com
Contact: marketing@bioassayplus.com

COMPANY ADDRESS:

Bioassayplus-Lab Inc.
Bioassayplus-Pharma Inc.
4510 Rhodes Drive
Windsor, Canada N8W 5K5