ImmunoPass™

COVID-19 NEUTRALIZING ANTIBODY RAPID TEST FOR POINT OF CARE USE

For Emergency Use Authorization only
For prescription use only
For in vitro diagnostic use only

INTENDED USE

The ImmunoPass™ COVID-19 Neutralizing Antibody Rapid Test is a rapid lateral flow chromatographic immunoassay intended for the semiquantitative measurement of neutralizing antibodies (Nab) to SARS-COV-2 in human blood.

The ImmunoPass™ COVID-19 Neutralizing Antibody Rapid Test is a point of care test that measures relative levels of antibodies against SARS-CoV-2 Spike Receptor Binding Domain (RBD) protein and blocks it from binding to ACE2 cellular receptor. Antibodies, including neutralizing antibodies to SARS-CoV-2, are generally detectable in blood several days after initial infection or after a COVID-19 vaccine and have been shown to neutralize the virus. This test is intended for use as an aid in classifying individuals with an adaptive immune response to SARS-CoV-2.

The ImmunoPass™ COVID-19 Neutralizing Antibody Rapid Test should not be used to diagnose acute SARS-CoV-2 infection. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, to perform moderate or high complexity tests and as applicable and for Point of Care (POC) testing.

The ImmunoPass™ COVID-19 Neutralizing Antibody Rapid Test is only for use under the Food and Drug Administration's Emergency Use Authorization (EUA).

SUMMARY

SARS-CoV-2 is a β coronavirus and causes COVID-19, an acute respiratory infectious disease. Individuals infected with SARS-CoV-2 are the main source of infection, but infected people who are asymptomatic can also be a source of infection. Based on the current epidemiological investigation, the incubation period is 2 to 14 days, with a median of 5 days. The main manifestations of COVID-19 include fever, fatigue, and dry cough. Nasal congestion, runny nose, sore throat, myalgia, and diarrhea may also be present.

The ImmunoPass™ COVID-19 Neutralizing Antibody Rapid Test is a rapid test that utilizes a combination of SARS-COV-2 antigen coated colored particles and a modified human ACE2 protein receptor for the detection of antibodies to SARS-COV-2 that block interaction of the virus with human cells expressing ACE2.

Individuals may have detectable virus present for several weeks following seroconversion. It is likely, but not known, if neutralizing antibodies prevent transmission of infectious virus. Absence of neutralizing antibodies preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

PRINCIPLE

The ImmunoPass™ COVID-19 Neutralizing Antibody Rapid Test is a lateral flow immunochromatographic assay for semi-quantitative measurement of antibodies that prevent SARS-CoV-2 from binding to human cells expressing ACE2 receptor. The test leverages the interaction between RBD-modified dark green nanoparticles that bind ACE2 at the test line when neutralizing antibodies are absent or low. When concentration of NAb increases, they start competing with ACE2 for binding the RBD-modified nanoparticles and the test line decreases. As indicated by the competitive nature of this assay, test line density is inversely proportional to NAb present in the sample. Thus, an absent or faint test line indicates high levels of NAb, whereas a dark or strong test line suggests lack of NAb within a given blood sample. During testing, anti-RBD antibodies in blood bind to RBD-conjugated dark green gold nanoshells in the test cassette. When assay (chase) buffer is added to the sample port, the dried components on the strip interact with blood sample.

WARNINGS AND PRECAUTIONS

- For prescription use only. For in vitro diagnostic use only. Do not use after expiration date.
- This test has not been FDA cleared or approved; this test has been authorized by FDA under an EUA for use by laboratories certified under CLIA to perform moderate or high complexity tests and as applicable and for Point of Care (POC) testing.
- This test has been authorized only for the presence of neutralizing antibodies against SARS-CoV-2, not for any other viruses or pathogens.
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used tests, specimens, and potentially contaminated material should be discarded according to the local regulations.
- Humidity and temperature may adversely affect results.

MATERIALS

Materials provided

KIT COMPONENTS	AMOUNT PER KIT
Test cassettes	25
Chase buffer (2mL buffer vial)	25
Lancet (21-25 gauge)	25
Alcohol Wipes	25
Micro Capillary Pipettes	25
Instructions for Use	1

Materials required but not provided

- Timer

STORAGE AND STABILITY

The stability of the device is unknown at the time of writing. We recommend storing the rapid tests between 15-30°C. Do not freeze. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The ImmunoPass™ COVID-19 Neutralizing Antibody Rapid Test can be performed using human blood.
- Blood may be obtained by a finger stick using the lancet provided.
- The blood should be collected using the provided micro capillary pipette
- Testing should be performed immediately after specimen collection.

1 Clean finger with the Alcohol Wipe

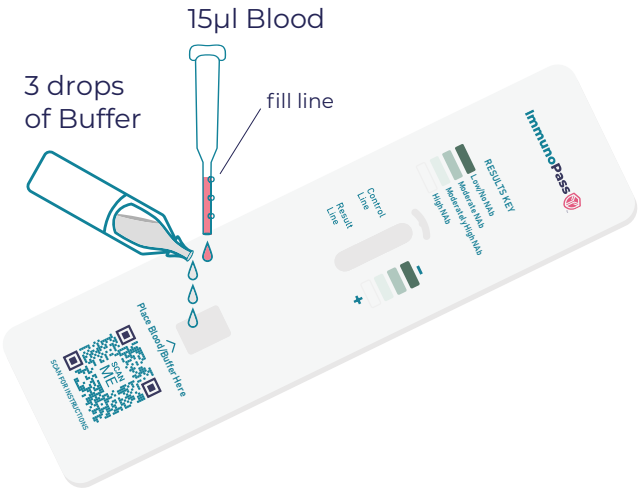
2 Pierce the side of a finger with the spring-loaded Lancet

3 Use Capillary Pipette to collect sample. Fill to the third tick mark.

DIRECTIONS FOR USE

Allow the kit components to reach room temperature (15-30°C) prior to testing.

1. Place the test cassette on a clean and level surface. Remove the top label. Use the micropipette to collect a 15µl sample, filling to the fill line, designated by the third plastic tick mark from the tip. Dispense 15µl of specimen to the sample port of the test cassette, then add 3 drops of buffer to the sample port and start the timer.
2. Wait for the colored line(s) to appear. The test result should be read at 10 minutes. Do not interpret the result after 30 minutes. If the test does not respond within 1-2 minutes, this may indicate that an air bubble has formed within the buffer solution. If this occurs, add 1 additional drop of buffer solution.

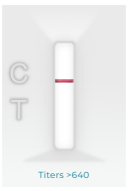


INTERPRETATION OF RESULTS

Each test result is a "snapshot" of COVID-19 Neutralizing Antibodies (NAb) levels at the time the finger-stick test is performed. Neutralizing antibody levels can increase or decrease over time. The purpose of this test is identify individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. This test can be used to track individual neutralizing antibody levels over time. Neutralizing antibody levels may be one of a number of factors to consider in personal decision making or patient management.

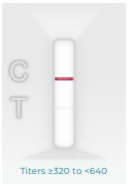
Clinical applicability of detection or correlation of neutralizing activity at different titer levels is currently unknown. Results should not be interpreted as an indication of degree of immunity or protection from infection. Research to assess the correlation between titer levels and immunity is ongoing. Because SARS-CoV-2 neutralizing antibody tests are not standardized, results from different tests cannot be compared.

TEST RESULTS SCORECARD



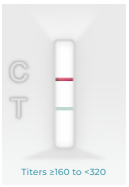
HIGH NAb

HIGH VIRUS-NEUTRALIZING ACTIVITY.
No visible line.



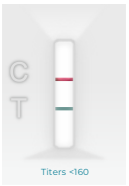
MODERATELY HIGH NAb

MODERATELY HIGH VIRUS-NEUTRALIZING ACTIVITY.
Faint line.



MODERATE NAb

MODERATE VIRUS-NEUTRALIZING ACTIVITY.
Medium line.



NOT DETECTABLE NAb

NO VIRUS-NEUTRALIZING ACTIVITY.
Strong green line.

The color intensity of the dark green line in the test (T) region will vary based on the concentration and potency of neutralizing antibodies present in the sample. Each ImmunoPass™ COVID-19 Neutralizing Antibody Rapid Test has a printed score card next to the observation window as shown in the figure below.

No visible line indicates high levels of neutralizing antibodies that correlate with those measured in VSV pseudotype neutralizing antibody assays as stronger neutralizing capacity at titer levels ≥ 640.

LIMITATIONS

For use under an Emergency Use Authorization Only

- Use of the ImmunoPass™ COVID-19 Neutralizing Antibody Rapid Test is limited to healthcare providers who have been trained. It is not for home use.
- The ImmunoPass™ COVID-19 Neutralizing Antibody Rapid Test is for *in vitro* diagnostic use only. The test should be used for the semi-quantitative detection of SARS-COV-2 neutralizing antibodies in blood.
- The Assay Procedure and the Interpretation of Assay Result must be followed closely when testing for the presence of SARS-CoV-2 virus specific neutralizing antibodies in the blood from individual subjects. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
- Reading test results earlier than 10 minutes after the addition of Buffer may yield erroneous results. Do not interpret the result after 30 minutes.
- The ImmunoPass™ COVID-19 Neutralizing Antibody Rapid Test will only indicate the presence of SARS-COV-2 neutralizing antibodies in the specimen and should not be used as the sole criteria for the diagnosis of SARS-COV-2.
- In the early onset of symptom, anti-SARS-COV-2 neutralizing antibody concentrations may be below detectable levels.
- Results from immunosuppressed patients should be interpreted with caution.
- As with all diagnostic tests, results must be interpreted together with other clinical information available to the physician.
- A negative result for a sample indicates absence of detectable anti-SARS-CoV-2 neutralizing antibodies. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions.
- False positive results for neutralizing antibodies may occur due to cross-reactivity from pre-existing antibodies or other unknown causes. Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a diagnostic determination is made.
- A negative result can occur if the quantity of the anti-SARS-CoV-2 neutralizing antibodies present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
- Some specimens containing unusually high titer of rheumatoid factor may affect expected results.
- Results from neutralizing antibody testing should not be used as the basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.

Conditions of Authorization for the Laboratory

The ImmunoPass™ COVID-19 Neutralizing Antibody Rapid Test Letter of Authorization and authorized labeling are available on the FDA website: **https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd.**

Health care providers using ImmunoPass COVID-19 Neutralizing Antibody Rapid Test Cassette ("your product" in the conditions below), must adhere to the Conditions of Authorization indicated in the Letter of Authorization as listed below:

- Health care providers using your product will use your product as outlined in the Instructions for Use. Deviations from the authorized procedures, including the authorized clinical specimen types, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
- Health care providers will collect information on the performance of your product and report to Empowered Diagnostics (info@empdx.net) any suspected occurrence of false reactive or false non-reactive results and significant deviations from the established performance characteristics of your product of which they become aware.
- Health care providers using your product must be appropriately trained in immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit and use your product in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the product.

PERFORMANCE CHARACTERISTICS

Clinical Performance on the Point of Care Testing of ImmunoPass

- On-site clinical testing for this study took place using 5 operators to test 130 subjects. The 130 subjects evaluated in this study provide a balanced mix of 65 females and 65 males.
- The following table summarizes the Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) for the ImmunoPass™ COVID-19 Neutralizing Antibody Rapid Test when compared with subjects that tested positive or negative for COVID-19 (using an EUA approved RT-PCR method).

ImmunoPass™ Neutralizing Antibody Rapid Test	**EUA Approved COVID-19 RT-PCR**	
	Positive	**Negative**
Positive	42	2
Negative	0	85
Total	42	87
Positive Percent Agreement (PPA)	100% (95% CI: 94% - 100%)	
Negative Percent Agreement (NPA)	97.7% (95% CI: 93% - 100%)	

Assay Cross Reactivity

- Cross-reactivity of the ImmunoPass™ COVID-19 Neutralizing Antibody Rapid Test Cassette was evaluated using serum/plasma samples which contain antibodies to the pathogens listed below.
- A total of 28 specimens from 12 different categories were tested. No false Positives were found in this set.
- influenza A .....NL63 (alpha coronavirus)
- influenza B.....OC43 (beta coronavirus)
- Rhinovirus.....HKU1 (beta coronavirus)
- Parainfluenza .....Respiratory Syncytial Virus (RSV)
- Adenovirus.....Coccidioidomycosis
- 229E (alpha coronavirus) .....

Antibody Class Specificity

ImmunoPass COVID-19 Neutralizing Antibody Rapid Test Cassette is agnostic to antibody isotype.

Interferences

ImmunoPass COVID-19 Neutralizing Antibody Rapid Test Cassette was tested in the presence of highest possible concentrations of lipids (lipemia), conjugated and unconjugated bilirubin (icterus), hemoglobin (hemolysis) and human serum albumin and was shown to be impervious to these potential interferents commonly present in human blood samples.

Technical Support

For questions, or to report a problem, please call Empowered Diagnostics at 954-354-2768.

Manufactured by:
EMPOWERED DIAGNOSTICS
3341 West McNab Road, Pompano Beach, FL 33069

www.empdx.net
info@empdx.net
Contact: **954-354-2768**