Yannovak - rapid test for the detection of post-vaccination and post-covid antibodies COVID-19 (whole blood / serum / plasma)

Package Leaflet

Yannovak is a rapid chromatographic immunoassay intended for the qualitative detection of IgG antibodies against the SARS-CoV-2 spike (S) protein receptor binding domain (RBD) in human serum, plasma or whole blood.

For professional in vitro diagnostics use only.

INTENDED USE
Yannovak is intended for use as an aid in the identification of individuals with an adaptive immune response to SARS-CoV-2. The results are used to detect IgG antibodies against SARS-CoV-2 S-RBD. Positive results indicate the presence of IgG antibodies against SARS-CoV-2.

SUMMARY AND EXPLANATION OF THE DISEASE
Coronaviruses infect many species of animals, including humans, and cause both acute and chronic diseases.[1] New coronaviruses belong to the genus β. COVID-19 is an acute respiratory infectious disease. People are generally prone to it. Currently, the main source of infection is patients infected with the new coronavirus. Infected people who do not show any symptoms can also be a source of infection. Based on the current epidemiological inquiry, the incubation period is 1 to 14 days, usually 3 to 7 days. The main symptoms include fever, fatigue and dry cough. In some cases, there is a stuffy nose, runny nose, sore throat, myalgia and diarrhea.
Upon infection with SARS-CoV-2 infection, the host usually begins to develop an immune response against the virus.

PRINCIPLE OF THE TEST
Yannovak is a membrane immunoassay test designed to detect IgG antibodies to the SARS-CoV-2 spike (S) protein receptor binding domain (RBD) in human serum, plasma or whole blood. The test is intended to aid in the evaluation of the adaptive humoral immune response to SARS-CoV-2 protein S.

Anti-human IgG antibodies are applied in the test area. During testing, SARS-CoV-2 IgG antibodies, if present in the sample, will react with SARS-CoV-2 S-RBD particles that have been pre-applied to the test strip. The mixture then proceeds upward to the membrane by capillary action and reacts with anti-human IgG antibodies in the area of the test lines. As a result, a pink / purple bar appears in the test line area, indicating a positive result. If the sample does not contain IgG antibodies to the SARS-CoV-2 spike (S) protein binding receptor domain (RBD), no pink / purple band will appear in the test line area, indicating a negative result. To check the whole procedure, a pink / purple band appears in the control line, which means that the correct sample volume has been added and the membrane has leaked.

REAGENTS
The test contains recombinant particles coated with the RBD fragment of SARS-CoV-2 as a detection reagent and anti-human IgG coated with a cellulose nitrate membrane as a capture reagent.

WARNINGS AND PRECAUTIONS
1. Read this package leaflet before performing the test. Failure to follow the instructions in the package leaflet may lead to inaccurate test results.
2. For professional in vitro diagnostics use only. Do not use after the expiration date.
3. Do not eat, drink or smoke while handling specimens or test kits.
4. Do not use the test if the bag is damaged.
5. Treat all specimens as potentially infectious. Follow established precautions against microbiological hazards during sample collection, handling, and storage, and follow standard procedures for proper sample disposal.
6. Wear protective clothing such as lab coats, disposable gloves, and eye protection when testing specimens.
7. Wash your hands thoroughly after testing.
8. Make sure to use an appropriate number of samples for testing. Too large or small amounts of sample may lead to deviation of results.
9. Dispose of the used test in accordance with local regulations.
10. The test results may be adversely affected by humidity and temperature.

STORAGE AND STABILITY OF THE KIT
Store packed test cards at room temperature or in a refrigerator (2-30 ° C). The test is stable until the expiration date, which is printed on a sealed bag. The test must remain in the sealed bag until it is used. **DO NOT FREEZE.** Do not use after the expiration date.

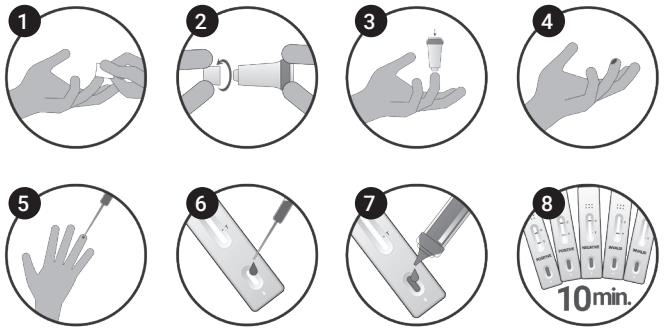
SPECIMEN COLLECTION AND PREPARATION
- The test is performed on a serum, plasma or whole blood sample.
- Testing should be performed immediately after sampling. Do not leave samples at room temperature for extended periods of time. Serum and plasma samples can be stored at 2-8 ° C for up to 7 days. For long-term storage, they should be stored below -20 ° C. Blood samples should be stored at 2-8 ° C and the test should be performed within 2 days of sampling. Do not freeze blood samples.
- Leave samples that have not been freshly taken at room temperature for 20 minutes. Frozen samples must be completely thawed and mixed thoroughly before testing. Samples should not be repeatedly frozen and thawed.
- If samples need to be shipped, they must be packaged in accordance with local regulations.
- EDTA K2, sodium heparin, sodium citrate and potassium oxalate can be used as anticoagulants for sampling.

PACKAGE CONTENTS
- Test Card
- Dropper
- Sterile Lancet
- Package Leafleft
- Extraction Buffer Tube
- Alcohol Pad

NOT INCLUDED
- Centrifuge • Pipette
- Timer

INSTRUCTIONS FOR USE
Leave the test kit at room temperature (15-30°C) for 20 minutes before testing.
1. Remove the test card from the bag and use it as soon as possible. The most accurate results are obtained if the test is performed within one hour.
2. Place the test on a flat and clean surface and do not handle it throughout the process.

For fingerstick whole blood sample:
1. Clean the fingertip with an alcohol pad at the injection site.
2. Carefully rotate and remove the sterile lancet cap.
3. Push the lancet firmly into your fingertip.
4. Wipe the first drop of blood. To increase blood flow, gently push your fingers around the injection site.
5. Hold the dropper vertically, aspirate the sample about 1 cm above the narrowed part.
6. Transfer 1 full drop of blood (approximately 20 µl) to the sample hole (S).
7. Add 2 drops of extraction buffer (approximately 80 µl) and turn on the timer.
8. Read the results in 10 minutes. Do not evaluate the result after more than 20 minutes.



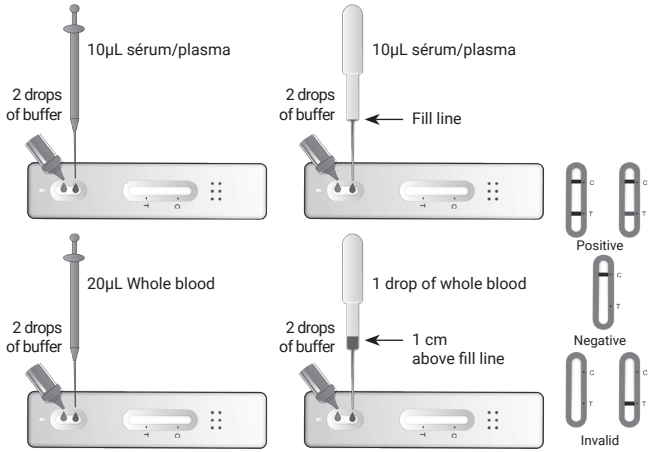
For venous whole blood, serum and plasma samples:
For serum or plasma samples:
- When using the dropper: Hold the dropper vertically, aspirate the serum or plasma sample into the constricted area (approximately 10 µl), transfer the sample to the sample hole (S), then add 2 drops of extraction buffer (approximately 80 µl) and turn on the timer.

When using a pipette: Transfer 10 µl of serum or plasma sample to the sample hole (S), then add 2 drops of extraction buffer (approximately 80 µl) and turn on the timer.

For venous whole blood samples:

- When using the dropper: Hold the dropper vertically, aspirate the sample about 1 cm above the constricted area and transfer 1 full drop of whole blood (approximately 20 µl) to the sample hole (S). Then add 2 drops of extraction buffer(approximately 80 µl) and turn on the timer.
- When using a pipette: Transfer 20 µl of the blood sample to the sample hole (S), then add 2 drops of extraction buffer (approximately 80 µl) and turn on the timer.

Wait for the pink / purple stripe (S) to appear. Read the results in 10 minutes. Do not evaluate the result after more than 20 minutes.



INTERPRETATION OF RESULTS

POSITIVE: * Two pink / purple stripes are displayed. A band should always appear in the control zone (C) and another band in the test zone (T). A positive result in the test area means that IgG samples against SARS-CoV-2 S-RBD are present in the sample.

*** NOTE:** The intensity of the color of the strip in the test zone (T) may vary depending on the concentration of IgG antibodies to SARS-CoV-2 S-RBD in the sample. Any shade of the strip in the test zone (T) should be evaluated as positive.

NEGATIVE: One colored strip appears in the control zone (C). No strip appears in the test zone (T).

INVALID: No stripe appears in the control zone. Probable reason is insufficient sample volume or incorrect procedural technique. Check the workflow and repeat with a new test. If the problem persists, contact your local distributor.

INTERNAL CONTROL

Internal procedural control is part of the test. The pink / purple stripe that appears in the test control zone (C) is the internal procedural control. This confirms a sufficient amount of sample and the correct technique. Control standards are not provided with the kit, however, it is recommended to perform positive and negative controls as a part of good laboratory practice to confirm the correctness of the test procedure and to verify that the test was performed correctly.

TEST LIMITS

1. When testing for the presence of specific IgG antibodies to SARS-CoV-2 in serum, plasma or whole blood samples from individual subjects, the test procedure and interpretation of test results should be followed carefully. Proper sampling is essential for optimal test performance. Failure to follow the procedure may result in an inaccurate result.
2. Yannovak is for in vitro diagnostics use only. This test should be used to detect IgG antibodies and against the SARS-CoV-2 spike (S) receptor binding domain (RBD) in whole blood, serum or plasma samples. This qualitative rapid test does not determine the quantitative values of IgG antibodies against the SARS-CoV-2 spike (S) receptor binding domain (RBD) or the level of increase in their concentration.
3. Yannovak only indicates the presence of IgG antibodies against the SARS-CoV-2 spike (S) receptor binding domain (RBD).
4. The level of hematocrit in the blood may affect the test result. For accurate results, the hematocrit level must be between 25% and 65%.
5. The test shows negative results under the following conditions: the antibody titre against the new coronavirus in the sample is below the minimum detection limit of the test or the antibodies against the new coronavirus were not present in the sample at the time of collection. It is recommended to re-sample the patient a few days later and perform the test again.
6. The persistent presence or absence of antibodies cannot be used to determine the success or failure of a particular therapy.
7. Results of immunosuppressed patients should be interpreted with caution.
8. Positive results may be due to past or current infection with coronavirus strains other than SARS-CoV-2 or other interference factors.
9. Not intended for screening of donated blood.

PERFORMANCE CHARACTERISTICS

Sensitivity and specificity

Yannovak was compared with ELISA; the results are shown in the table below.

Method		ELISA		Total Results
	Results	Positive	Negative	
Yannovak	Negative	87	2	89
	Positive	2	128	130
Total Results		89	130	219

Sensitivity 97.8% (95% CI *: 92.1-99.7%) * Confidence interval
Specificity: 98.5% (95% CI *: 94.6% -99.8%)
Accuracy: 98.2% (95% CI *: 95.4% –99.5%)

PRECISION

Intra-Assay

The accuracy within the series was determined by 3 replicates of three samples: negative, IgG positive-1 and IgG positive-2. Negative, IgG positive-1 and IgG positive-2 values were correctly identified in> 99% of cases.

Inter-Assay

The precision between the series was determined by three independent tests on the same three samples: negative, IgG positive-1 and IgG positive-2. 3 different batches of the Yannovak rapid test were tested for 3 days using negative, IgG positive-1 and IgG positive-2 samples. Samples were correctly identified in> 99% of cases.

Cross-Reactivity

Yannovak has been tested for anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-Adenovirus, anti-Measles, HAMA, RF, non-specific IgG, anti-EV71, anti-pParainfluenza virus, HBsAg, anti-Syphilis, anti-H.Pylori, anti-HIV and anti-HCV positive specimens. The results showed no cross-reactivity.

Interfering substances

The following substances have been tested using Yannovak and no interference was observed.

Triglyceride: 100mg / dl Ascorbic Acid: 20mg / dl Hemoglobin: 1000mg / dl Bilirubin: 60mg / dl Total cholesterol: 15mmol / l

LITERATURE

1. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011; 81: 85-164. PMID: 22094080 DOI: 10.1016 / B978-0-12-385885-6.00009-2

IVD Medical product in vitro
Tests per kit
Do not reuse
Store between 2-30°C
Expiration date
Compliance with European rules
Do not use if package is damaged
LOT Lot Number
Follow the Package Leaflet
Manufacturer
Warning
EC REP Authorized Representative

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