Rapidan® Tester

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INSTRUCTION FOR USE
SARS-CoV-2 IgM/IgG Ab Test
For IgG and IgM antibodies of corona virus disease
Detection in Whole Blood / Serum / Plasma

in vitro diagnostic test

Only for professional *in vitro* diagnostic use

Product Code: RTCV01

SARS-CoV-2 IgM/IgG Antibody Test detects IgG and IgM antibodies of corona virus disease in human serum, plasma or whole blood

BACKGROUND INFORMATION

SARS-CoV-2 belongs to the broad family of viruses known as coronaviruses. It is a positive-sense single-stranded RNA (+ssRNA) virus. Other coronaviruses are capable of causing illnesses ranging from the common cold to more severe diseases such as Middle East respiratory syndrome(MERS). It is the seventh known coronavirus to infect people, after 229E, NL63, OC43, HKU1, MERS-CoV, and the original SARS-CoV. Protein modeling experiments on the spike (S) protein of the virus suggest that it has sufficient affinity to the angiotensin converting enzyme 2 (ACE2) receptors of human cells to use them as a mechanism of cell entry. Studies have shown that SARS-CoV-2 has a higher affinity to human ACE2 than the original SARS virus strain. An atomic-level image of the S protein has been created using cryogenic electron microscopy. SARS-CoV-2 infections cause COVID-19 disease. People who have confirmed COVID-19 have a range of symptoms, from people with little to no symptoms to people being severely sick and dying. Most people (about 80%) recover from the disease without needing special treatment. Around 1 out of every 6 people who gets COVID-19 becomes seriously ill and develops difficulty breathing.
SARS-COV-2 IgG/IgM Ab rapid test is used to qualitatively detect IgG and IgM antibodies of corona virus disease in human serum, plasma or whole blood. This device is intended to be used by professionals as a screening test and as an aid in the diagnosis of infection with 2019 Corona Virus. Any reactive specimen with the SARS-COV-2 IgG/IgM Ab rapid test must be confirmed with alternative testing method(s).

INTENDED USE

SARS-CoV-2 IgM/IgG Antibody Test is a rapid immunochromatographic assay is used to qualitatively detect IgG and IgM antibodies of corona virus disease in human serum, plasma or whole blood.

REAGENTS

This test included anti-human IgG and anti-human IgM and, coronavirus antigen-coated particles.

METHOD

SARS-CoV-2 IgM/IgG Antibody Test is a rapid, qualitative, immunochromatographic assay for the detection of IgG and IgM antibodies of corona virus disease in human serum, plasma or whole blood. This test consists of two components, an IgG component and an IgM component. In the IgG component, anti-human IgG is coated in IgG test line region. During testing, the specimen reacts with coronavirus antigen-coated particles in the test cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG in IgG test line region. If the specimen contains IgG antibodies to coronavirus at detectable level, a colored line will appear in IgG test line region. In the IgM component, anti-human IgM is coated in IgM test line region. During testing, the specimen reacts with anti-human IgM. IgM antibodies to coronavirus, if present in the specimen at detectable level, reacts with the anti-human IgM and the coronavirus antigen-coated particles in the test cassette, and this complex is captured by the anti-human IgM, forming a colored line in IgM test line region. Therefore, if the specimen contains IgG antibodies to coronavirus at detectable level, a colored line will appear in IgG test line region. If the specimen contains IgM antibodies to coronavirus at detectable level, a colored line will appear in IgM test line region. If the specimen does not contain antibodies to coronavirus, no colored line will appear in either of the test line regions, 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.

PRECAUTIONS AND LIMITATIONS

1. For professional and *in vitro* diagnostic use only.
2. Read this insert completely and carefully prior to use of the test. Test must be performed in strict accordance with these instructions to obtain accurate results.
3. Do not use test kit beyond expiry date. The test device is single use. Do not reuse.
4. The test device should remain in its original sealed pouch until usage. Do not use the test if the seal is broken or the pouch is damaged.
5. Wear disposable gloves while performing the test.
6. Use a new pipette for each sample.
7. The test device should be discarded in a proper biohazard container after testing.
8. This test kit should be handled only by adequately qualified personnel trained in laboratory procedures and familiar with their potential hazards. Wear appropriate protective clothing, gloves and eye/face protection and handle appropriately with the requisite Good Laboratory Practices.
9. All patient samples should be handled as taking capable of transmitting disease into consideration. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of samples.
10. Do not perform the test in a room with strong air flow, i.e. electric fan or strong air-conditioning. Users must strictly follow the instructions for the operation and result interpretation.
11. Do not use hemolized blood for testing.
12. Do not use serum samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.
13. This test will indicate only the selectively total IgG and IgM antibodies in the sample, and should not be used as the only basis for the diagnosis of coronavirus. As with all diagnostic tests, it should be kept in mind that an identification diagnosis can't be based on a single test result. Diagnosis can only be reached by an expert after the evaluation of all clinical and laboratory findings.
14. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of coronavirus.

STORAGE

Test device should be kept away from direct sunlight, moisture, heat and radiation sources. Store at 4 - 30°C (39 - 86°F). Do not freeze.
The test in the original packaging retains stable until expiry date at storage conditions. The test device should be used maximum one hour after the foil is opened.
Kit components : Test cassettes, 10 µl pipettes, diluent and instructions for use.
Additional materials required but not provided : Sample collection tube, centrifuge and timer.
Additional materials recommended but not provided : Micropipettes to deliver mentioned amount of sample in the test procedure, negative and positive control materials.

SAMPLE COLLECTION AND PREPARATION

The test can be performed using whole blood, serum or plasma. To avoid hemolysis, serum or plasma should be separated from blood as soon as possible.
For Whole Blood Samples: Test should be performed immediately with whole blood samples. Otherwise, whole blood samples should be stored at 2 - 8 °C with anticoagulants (EDTA, heparin, citrate should be used) to avoid coagulation until they are being tested in a period of 2 days after collection.
For Serum Samples: Collect blood into a collection tube without anticoagulant, leave to settle for 30 minutes for blood coagulation and then centrifuge the blood. At the end of centrifuge period remaining supernatant is used as serum.
For Plasma Samples: Collect blood into a collection tube with anticoagulants (EDTA, heparin, citrate should be used) to avoid coagulation of blood sample and then centrifuge the blood. At the end of centrifuge period supernatant is used as plasma.

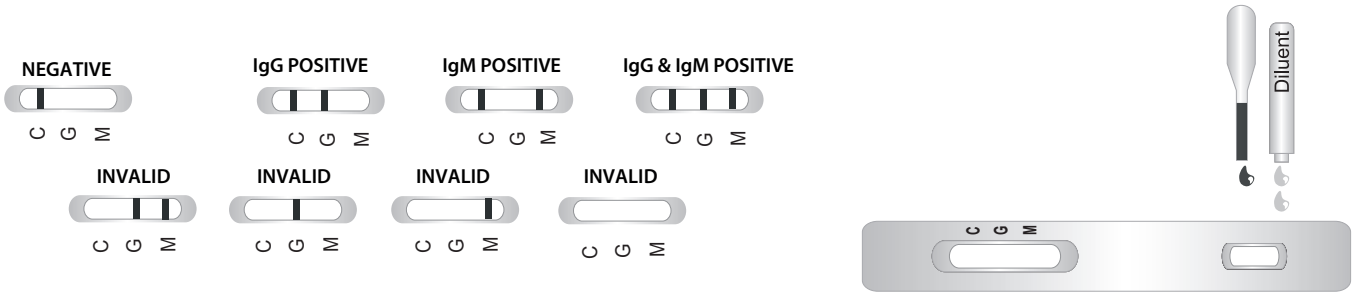
Do not use turbid, hemolyzed samples. If the sample cannot be tested on the day of collection, store the serum, plasma samples in a refrigerator or freezer. Do not freeze and thaw the serum, plasma samples repeatedly. Do not freeze whole blood sample. Bring the samples to room temperature before testing. Frozen samples must be completely thawed and mixed well prior to testing. Turbid test samples should be centrifuged. Using of frozen and thawed samples should be avoided whenever possible, due to the blocking of the membrane by the debris. Do not use serum samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

TEST PROCEDURE

1. Bring the tests and whole blood / serum / plasma samples to room temperature. Take the test out of its pouch.
2. Draw whole blood / serum / plasma samples into pipette and put 10 µl into the sample well of the cassette. Immediately after, 2 drops (about 70- 100 µL) of diluent is added into the sample well and allowed to soak in. Avoid the formation of any air bubbles.
3. Results should be read at 15 minutes as shown below. Results forming after 20 minutes should be regarded as invalid.

INTERPRETATION OF RESULTS

Negative : Only one colored line is visible in "C" area.
IgG and IgM POSITIVE: Three lines appear. One colored line should be in "C" area, and two colored lines should appear in IgG test line region and IgM test line region. The color intensities of the lines do not have to match. The result is positive for IgG and IgM antibodies.
IgG POSITIVE: Two lines appear. One colored line should be in "C" area and a colored line appears in IgG test line region.
IgM POSITIVE: Two lines appear. One colored line should be in "C" area and a colored line appears in IgM test line region.
* NOTE: Low concentration of IgG/IgM may cause a faint line in "T" area. Even such a faint line in "T" area should be regarded as "positive".
Samples with reactive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.
Invalid : No colored line is visible or only one colored line is visible in "T" area; test should be repeated using a new test device.



QUALITY CONTROL

Tests have built in procedural quality control features. When the test is complete, the user will see a colored line in the "C" area of the test on negative samples and a colored line in the "T" and "C" area on positive samples. The appearance of the control "C" line is considered as an internal procedural control. This line indicates that sufficient volume of sample was added as well as valid test result. It is recommended that a negative control and a positive control be used to verify proper test performance as an external control. Users should follow appropriate federal, state and local guidelines concerning the external quality controls.

PERFORMANCE EVALUATION

SARS-CoV-2 IgM/IgG Ab Test has been evaluated using clinical samples. PCR methods are used to compare SARS-CoV-2 IgM/IgG Ab Test and following results are obtained.

SARS-CoV-2 IgM

		PCR Test		Total
		+	-	
Turklab SARS-CoV-2 IgM Ab Test	+	246	40	286
	-	54	960	1014
Total		300	1000	1300

Analysis of coincidence rate of SARS-CoV-2 IgM Ab Test and PCR Test in serum samples:
Positive coincidence rate=246 / (246+54) × 100% = 82%,
Negative coincidence rate=960 / (40+960) × 100% = 96%,
Total coincidence rate=(246+960) / (246+54+40+960) × 100% = 92.8%.

SARS-CoV-2 IgG

		PCR Test		Total
		+	-	
Turklab SARS-CoV-2 IgG Ab Test	+	279	25	304
	-	21	975	996
Total		300	1000	1300

Analysis of coincidence rate of SARS-CoV-2 IgG Ab Test and PCR Test in serum samples:
Positive coincidence rate=279 / (279+21) × 100% = 93%,
Negative coincidence rate=975 / (25+975) × 100% = 97.5%,
Total coincidence rate=(279+975) / (279+21+25+975) × 100% = 96.5%.

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Instruction For Use Preparation Date: 23.03.2020 • Rev.0
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