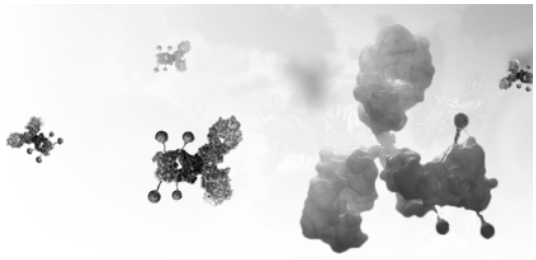


SARS-CoV-2 Antigen Rapid Test Kit (DTS922)

This product is for research use only and is not intended for diagnostic use.

PRODUCT INFORMATION

Size	20T
Intended Use	The SARS-COV-2 Antigen Rapid Test Kit is a rapid chromatographic immunoassay for the qualitative detection of SARS-COV-2 Antigen in human whole blood, serum or plasma, thus as an aid in the diagnosis of COVID-19 infections. The test is for research use only.
General Description	Coronavirus disease 2019 (COVID-19) is a respiratory disease caused by infection with the SARS-CoV-2 virus. Common signs of infection include respiratory symptoms, fever, cough, shortness of breath and breathing difficulties. In severe cases, infection can cause pneumonia, severe acute respiratory syndrome (SARS), kidney failure and death. Coronaviruses (CoV) are a large family of viruses that cause illness ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV). The 2019 Novel Coronavirus, formerly known as 2019-nCoV and now known as SARS-COV-2, is a new strain of coronavirus that was first identified during an outbreak in Wuhan, China which started in December 2019.
Reagents And Materials Provided	20xTest Cassettes | 20x Dropper | 1x Buffer Solution | 1xPackage Insert
Storage	The original packaging should be stored at 4-8°C. Avoid light, keep dry and do not freeze. The test kit is stable for 12 months in the sealed pouch.
Specimen Collection And Preparation	1. The SARS-COV-2 Antigen Rapid Test Kit is intended for use with human whole blood, serum or plasma specimens only. 2. Only clear, non-hemolyzed specimens are recommended for use with this test. Serum or plasma should be separated as soon as possible to avoid hemolysis. 3. Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, serum or plasma specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days after collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.

45-1 Ramsey Road, Shirley, NY 11967, USA
Email: info@creative-diagnostics.com
Tel: 1-631-624-4882 Fax: 1-631-938-8221

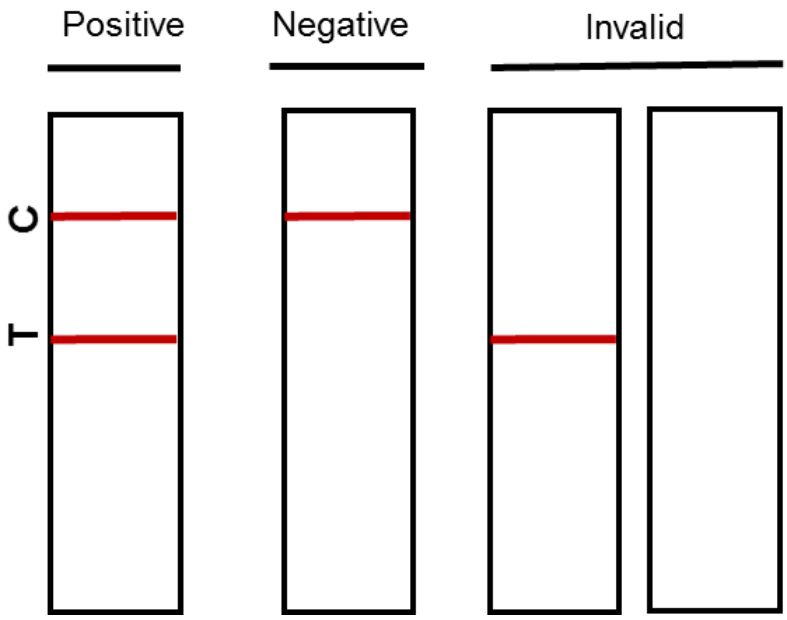
4. Containers containing anticoagulants such as EDTA, citrate, or heparin should be used for whole blood storage.
5. Bring specimens to room temperature before the testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.

Assay Procedure

Please note: Allow the test device, specimen, buffer, and/or controls to room temperature (15-30°C) before the testing.
1. Bring the pouch to room temperature before opening. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface.
For Serum or Plasma Specimens: using the provided disposable dropper, transfer 20uL (1 drop) serum/plasma to the specimen well of the test device, then add 2 drops of buffer solution and start the timer.
For Whole Blood (Venipuncture/Fingerstick) Specimens: Using the provided disposable dropper, and transfer 1 drop of whole blood (approximately 20 µL) to the specimen well of the test device, then add 2 drops of buffer solution and start the timer.
Note: Specimens can also be applied using a micropipette.
3. Read results at 8-10 minutes. Do not interpret the result after 20 minutes.

Interpretation Of Results

POSITIVE: *The colored line in the control line region (C) appears and a colored line appears in test line, which indicates that the SARS-COV-2 is positive and N protein has been detected.
NEGATIVE: The colored line in the control line region (C) appears. But no line appears in test line, which indicates that the SARS-COV-2 is negative and no N protein has been detected.
INVALID: There is no line appear in the (C) region.



Notices: Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and

45-1 Ramsey Road, Shirley, NY 11967, USA
Email: info@creative-diagnostics.com
Tel: 1-631-624-4882 Fax: 1-631-938-8221

	repeat the procedure with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.
Performance Characteristics	Physical appearance: 1. The components in this kit are neat and complete in appearance, no burrs, no damage, no pollution; the material is firmly attached; the label has clear writing and no damage. 2. Film strip width: Film strip width not less than 2.5 mm. 3. Travel speed: Not less than 10mm/min.
Precision	Extracted three batches of SARS-COV-2 Antigen Rapid Test Kit, each batch of at least 10 parts of people, repeat positive samples detected at least 10 times. 3 batches of test results should be consistent. Take any one of the negative samples for 10 times and the results are all negative.
Detection Limit	1:5 dilution of a N protein in 10ug/mL was diluted by 6 gradients then tested. The result showed the sensitivity was 3ng/mL.
Sensitivity	The test has tested 5 positive human serum samples, and the test results showed that all was positive; and 10 healthy human samples were tested, and the test results were negative.
Precautions	1. Do not use the kit beyond the expiration date. 2. Do not eat, drink or smoke in the area where the specimens or kits are handled. 3. Do not use the test if the pouch is damaged. 4. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens. 5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested. 6. The used test should be discarded according to local regulations.
Limitations	1. This test paper can only show the qualitative level of N protein produced by the human body after the new coronavirus (2019-ncov) infection in the sample and cannot be used as the only diagnostic criterion. 2. This product belongs to colloidal gold immunochromatographic test paper, which has the inherent limitations of colloidal gold immunochromatographic method.

45-1 Ramsey Road, Shirley, NY 11967, USA
Email: info@creative-diagnostics.com
Tel: 1-631-624-4882 Fax: 1-631-938-8221