COVISURE™ COVID-19

IgM/IgG Antibody Test

(Whole Blood / Serum / Plasma)

For In Vitro Diagnostic Use Only / For Professional Use Only

INTENDED USE

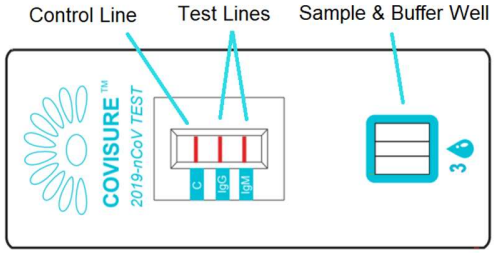
The COVISURE™ COVID-19 IgM/IgG Antibody Test is a lateral flow immunoassay test device for the rapid presumptive qualitative simultaneous detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in human whole blood, serum or plasma specimens from patients suspected of having a SARS-CoV-2 infection by a healthcare provider. Results from the COVISURE™ COVID-19 IgM/IgG Antibody Test should not be used as the sole basis for diagnosis. Results for this device must be considered in combination with clinical observations, patient history, epidemiological information, and other relevant diagnostic test results. Testing is limited to Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests. Since negative results do not preclude SARS-CoV-2 infection they should not be used as the sole basis for patient management decisions. IgM antibodies may not be detected in the first few days of infection. IgG antibodies to SARS-CoV-2 become detectable later following infection. Positive results for both IgG and IgM could occur after infection and can be indicative of acute or recent infection however levels over the course of infection are not well characterized. The sensitivity of the COVISURE™ COVID-19 IgM/IgG Antibody Test used in early stages after infection is unknown. The test device may yield false positive results for IgM and IgG antibodies due to cross-reactivity from pre-existing antibodies or other possible causes. Within the United States and its territories laboratories are required to report all positive results to the appropriate public health authorities. At this time, it is unknown for how long IgM or IgG antibodies may persist following infection. The COVISURE™ COVID-19 IgM/IgG Antibody Test HAS NOT BEEN REVIEWED BY FDA. For prescription use only. For in vitro diagnostic use only.

SUMMARY

Coronavirus (CoV) belongs to the Coronaviridae family. CoV is mainly transmitted through direct contact with secretions or through aerosols and droplets. There is also evidence that it can be transmitted through the fecal-oral route as well. There are seven known types of human coronavirus (HCoV) that cause human respiratory diseases: HCoV-229E, HCoV-NL63, HCoV-OC43, HCoV-HKU1, SARS-CoV, MERS-CoV and SARS-CoV-2. SARS-CoV-2 was first reported in 2019 in Wuhan, China with viral pneumonia cases and clinical manifestations of fever, fatigue, cough, and other symptoms which can rapidly develop into severe pneumonia, respiratory failure, septic shock, multiple organ failure, severe acid-base metabolism disorders, etc. The disease caused by SARS-CoV-2 infection in humans is formally known as COVID-19. COVID-19 can develop into a serious illness requiring hospitalization and even leading to patient death.

TEST PRINCIPLE

The COVISURE™ COVID-19 IgM/IgG Antibody Test is a lateral flow immunoassay qualitative Antibody Test that employs a unique combination of SARS-CoV-2 antigen-coated colored particles (colloidal gold dye particles) for the rapid presumptive qualitative simultaneous detection and differentiation of IgG and IgM antibodies to SARS-CoV-2 in human whole blood, serum or plasma. In the IgG component of the COVISURE™ COVID-19 IgM/IgG Antibody Test, anti-human IgG is coated in the IgG test line region. During testing, the specimen reacts with SARS-CoV-2 antigen-coated particles in the Test Cassette. The mixture then migrates upward on the membrane by capillary action and reacts with the anti-human IgG in the IgG test line region. If the specimen contains IgG antibodies to SARS-CoV-2, a colored line will appear in IgG test line region. In the IgM component of the COVISURE™ COVID-19 IgM/IgG Antibody Test, anti-human IgM is coated in the IgM test line region.



During testing the anti-SARS-CoV-2 IgM antibodies, if present in the specimen, react with the SARS-CoV-2 antigen-coated particles in the Test Cassette, and this complex is captured by the anti-human IgM, forming a colored line in the IgM test line region. Therefore, if the specimen contains anti-SARS-CoV-2 IgG antibodies, a colored line will appear in the IgG test line region. If the specimen contains anti-SARS-CoV-2 IgM antibodies, a colored line will appear in the IgM test line region. If the specimen does not contain anti-SARS-CoV-2 antibodies, 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.

CONTENTS OF KIT

KIT CONTENTS:

PART NUMBER:	CV19-CK25
Kit Size (# of Tests)	25
COVISURE™ COVID-19 IgM/IgG Test Cassette (PART# CV19-CK)	25 Cassettes (Individually sealed in pouch with 1-gram desiccant)
COVID-19 Test Buffer (PART# CV19-B)	1 Bottle (5mL)
Plastic Pipette (dropper)(20μL)	25 Pipettes
Product Insert	1 Copy

Composition:

Conjugate pad: Monoclonal Anti-SARS-CoV-2 antigen conjugated on the membrane.

G Line: Anti-human IgG

M Line: Anti-human IgM

C Line: Goat anti-rabbit IgG

Sample Buffer: 0.01M PBS; PH 7.4

MATERIALS REQUIRED BUT NOT PROVIDED

1.Personal protective equipment such as gloves, lab coat or gown. 2. Appropriate biohazard waste containers. 4. Timer. 5. Fingerstick Lancet. 6. Alcohol swab.

FOR VENIPUNCTURE BLOOD COLLECTION AND PLASMA SPECIMENS:

Venipuncture apparatus if collecting blood specimens. 2. Appropriate blood collection tubes. 3. Precision pipette capable of delivering 10-50μl of specimen. 4. Appropriate shipping containers. 5. Personal protective equipment. 6. Appropriate biohazard waste containers and disinfectants. 7. Centrifuge to process a plasma specimen.

STORAGE AND STABILITY

- The COVISURE™ COVID-19 IgM/IgG Antibody Test Kit contents are stable prior to the expiration date printed on the test cassette foil pouch.

- The test cassette is to be stored at 4℃~30℃ and should be kept dry and away from direct sunlight.

- Do not freeze.

- This reagent is to be used within 1 hour once the foil pouch is unsealed. If the temperature is higher than 30℃ or in a high humidity environment this reagent should be used immediately after opening.

SPECIMEN COLLECTION

Proper specimen collection and handling is critical to the performance of this test. Specimens should be tested as soon as possible after specimen collection.

Consider any materials of human origin as infectious and handle using standard biosafety procedures.

Plasma

1. Collect blood specimen into a lavender or blue top collection tube (containing EDTA or citrate, respectively, in a Vacutainer) by venipuncture.
2. Separate the plasma by centrifugation
3. Carefully withdraw the plasma into a new pre-labeled tube.

Serum

1. Collect blood specimen into a red top collection tub (containing no anticoagulants in a Vacutainer) by venipuncture.
2. Allow the blood to clot.
3. Separate the serum by centrifugation

Whole Blood:

For Fingerstick Whole Blood: Following laboratory procedures, clean the finger of the person being tested with an alcohol swab. Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad. Use a lancet to puncture the skin just slightly off the center of the finger and allow blood drop to form. Use 20μL dropper provided to collect fingerstick whole blood sample.

For Venous Whole Blood: Draw blood following laboratory procedure for obtaining venous blood. Depending on use, collect sample in a tube containing heparin or EDTA. Be sure the tube of blood is well mixed before sampling. If the specimen to be tested is refrigerated, remove it from the refrigerator and allow it to come to a temperature of 18 to 30°C (64 to 86°F).

Serum and Plasma Stability

Test specimens as soon as possible after collection. If specimens are not tested immediately, store at 2-8℃ for up to 3 days. The specimens should be frozen at -20℃ for longer storage.

For frozen samples avoid more than 4 freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature 18 to 30°C (64 to 86°F) and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing. Do not use

samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

TEST PROCEDURE

SAMPLE PREPARATION

1. Prior to beginning the test, ensure that all clinical specimens and test materials are at room temperature.

2. Check the expiration on each individual reagent and outer kit box before using the test. Do not use any tests past the expiration date on the label.

3. Use Universal Biological Precautions when handling any clinical specimen.

TEST PROCEDURE

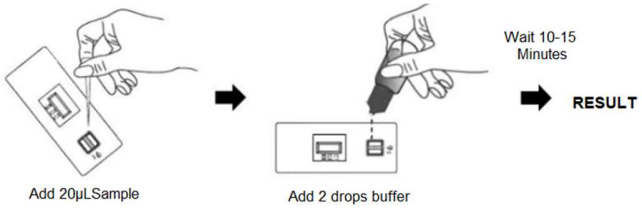
1. For fresh samples, begin with Step 2. For frozen samples, brings the specimens and test components to room temperature, and mix the specimen well once thawed.

2. When ready to test, open the pouch and remove the test device. Place the test device on a clean, flat surface.

3. Label the device with specimen ID #.

4. Using a transfer pipette, transfer serum, plasma, or whole blood, careful not to exceed the sample well.

TABLE 1: TEST PROCEDURE



WHOLE BLOOD (VENIPUNCTURE/FINGERSTICK) SPECIMEN

- To use a dropper: Hold the dropper vertically, draw the specimen into the dropper and transfer 1 drop of whole blood (approximately 20μL) to the SAMPLE WELL of the Test Cassette, then add 2~3 drops of BUFFER and start the timer.

- To use a micropipette: Pipette and dispense 20μL of whole blood to the SAMPLE WELL of the Test Cassette, then add 2~3 drops of BUFFER and start the timer.

SERUM OR PLASMA SPECIMEN

-To use a dropper: Hold the dropper vertically, draw the specimen up into the dropper and transfer one small drop (approximately 20μL) of the specimen to the SAMPLE WELL of the Test Cassette, then add 2~3 drops of BUFFER and start the timer. Avoid trapping air bubbles in the SAMPLE WELL.

-To use a micropipette: Pipette and dispense 20μL of serum or plasma to the SAMPLE WELL of the Test Cassette, then add 2~3 drops of BUFFER and start the timer.

QUALITY CONTROL

Each COVISURE™ COVID-19 IgM/IgG Antibody Test Kit contains a built-in procedural control feature. When running the test, the appearance of a red Control Line **(C)** in each test indicates proper functioning of the buffer reagents, capillary flow, and functional integrity of the test strip within the cassette. If the Control Line does not appear, the test is considered Invalid.

1. Internal Control: this test contains a built in control feature, the C Line. The C Line develops after addition of the specimen and sample diluent. If the C Line does not develop, the test is invalid. Review the procedure and repeat the test with a new device.
2. Positive and Negative Control: External positive and negative controls should be used in accordance with local, state, federal accrediting organizations, or your lab's standard Quality Control procedures, as applicable.

LIMITATIONS

1. The Assay Procedure and the Interpretation of Assay Result must be followed closely when testing for the presence of SARS-CoV-2 virus specific antibodies in the serum, plasma or whole blood specimen from individual subjects. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
2. The SARS-CoV-2 IgM/IgG Antibody Test is limited to the qualitative detection of antibodies specific for the SARS-CoV-2 virus. The intensity of the test line does not necessarily correlate to SARS-CoV-2 antibody titer in the specimen.
3. A negative or non-reactive result can occur if the quantity of antibodies for the SARS-CoV-2 virus present in the specimen is below the detection limit of the assay, or the virus has undergone minor amino acid mutation(s) in the epitope recognized by the antibody utilized in the test.
4. If symptoms persist and the result from the SARS-CoV-2 Antibody Test is negative or non-reactive, it is recommended to re-sample the patient a few days later or test with an alternative test device.
5. The results obtained with this test should only be interpreted in conjunction with clinical findings, and the results from other laboratory tests and evaluations.

INTERPRETATION OF RESULTS

READ TIME: Read the results at 10 to 15 minutes, do not interpret the results after 15 minutes.

LINE VISIBILITY: Any IgM or IgG line regardless of the intensity is considered a line. The intensity of the IgM and IgG should NOT be compared to the control line.

ANY LINE IS A LINE

Negative results do not rule out SARS-CoV-2 infection, particularly for patients who have been in contact with known infected persons or in areas with high prevalence of active infection.

NEGATIVE: Test is **NEGATIVE** for COVID-19 if: Only control line (C) is visible.

A negative result is a presumptive negative. Negative result does not exclude possible infection with SARS-CoV-2 virus. As with any test, providers must consider the patient's likelihood of exposure and the possibility of false laboratory results when making treatment or other patient management decisions. Professional Health Care Providers should follow all relevant CDC guidance, as well as local and state regulations to determine the appropriate course of action for result confirmation and prescribed treatment.

WARNING: Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.

POSITIVE: Test is **POSITIVE** for COVID-19 if:

A. Control line (C), IgM (Line 1), and IgG (Line 2), are visible.

B. Control line (C) and IgM (Line 1) are visible.

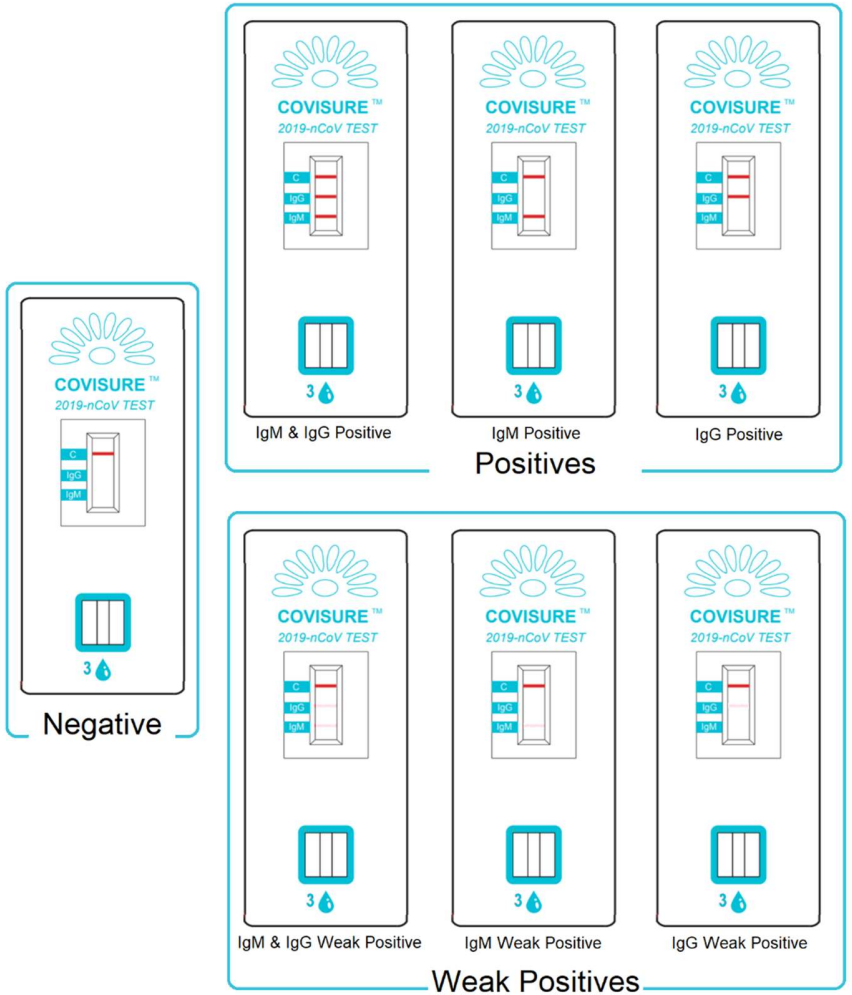
C. Control line (C) and IgG (Line 2) are visible.

A Positive result is a presumptive positive. Healthcare providers who have obtained a presumptive positive patient for COVID-19 should contact their local or national health department immediately for consultation and guidance.

WARNING: Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a diagnostic determination is made.

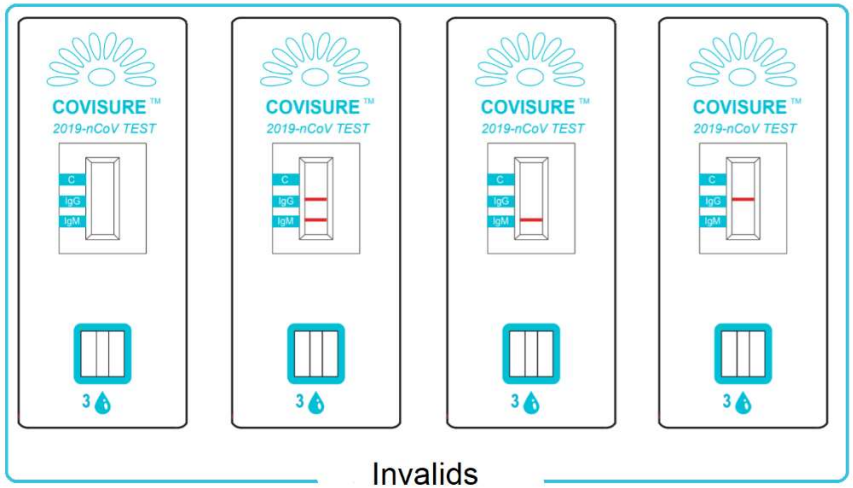
TABLE 2: RESULT INTERPRETATION



INVALID: Test is **INVALID** if: Control line (C) is **NOT VISIBLE** regardless of the IgM (Line 1), and IgG (Line 2) result.

An INVALID test result indicated that there may be a problem with the testing procedure of the COVISURE™ COVID-19 IgM/IgG Antibody Test. In the event of an INVALID result it is recommended that the Health Care Provider conduct the test again using a new COVISURE™

COVID-19 IgM/IgG Antibody Test cassette. If issues persist, please contact laboratory administrators and/or customer service.



WARNING: Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.

WARNING: THIS TEST HAS NOT BEEN REVIEWED BY FDA.

PERFORMANCE CHARACTERISTICS

SENSITIVITY, SPECIFICITY, AND ACCURACY

Comparison results of the clinical application performance of the COVISURE™ COVID-19 IgM/IgG Antibody Test was confirmed with specimens collected from healthy individuals as well as from confirmed COVID-19 patient specimens.

COVISURE™ COVID-19 IgM/IgG Antibody Test		Confirmed COVID-19 Patient Serum		
		Positive	Negative	Total
IgM/IgG	Positive	43	0	43
	Negative	3	0	3
Total		46	0	46

(1) The specimens of 100 healthy individuals were collected and tested. The test results of the COVISURE™ COVID-19 IgM/IgG Antibody Test were all negative. The IgM/IgG antibody negative coincidence rate was 100%. Demonstrating a clinical specificity of 100%.

(2) The specimens of 46 clinically confirmed COVID-19 patients with an infection timeline of 4-24 days were tested. The IgM/IgG antibody combined positive coincidence rate was 43/46, demonstrating a clinical sensitivity of 93.5%.

(3) A total of 146 specimens were tested. The comparison results of the clinical application performance of the COVISURE™ COVID-19 IgM/IgG Antibody Test with the expected results of the known negative and confirmed positive specimens was 143/146, demonstrating a relative accuracy of 97.9%.

CLINICAL SENSITIVITY, SPECIFICITY, AND RELATIVE ACCURACY

COVISURE™ COVID-19 IgM/IgG Antibody Test *(95% CI)*	
Sensitivity	93.5% (83.5% - 96.7%)
Specificity	100% (96.2%-100%)
Relative Accuracy	97.9%

CROSS-REACTIVITY - METHOD

The cross-reactivity study for the COVISURE™ COVID-19 IgM/IgG Rapid Test was designed to evaluate potential interference from antibodies against other viruses whose infection produces symptoms similar to those observed during SAR-CoV-2 virus infection. Five seropositive sample specimens for each cross reactant listed in below. No cross-reactivity was observed.

CROSS-REACTANTS

Cross-reactants	Sample Volume
anti-influenza A (IgM & IgG)	100uL
anti- influenza B (IgM & IgG)	100uL
anti-HCV (IgM & IgG)	100uL
anti-HBV (IgM & IgG)	100uL
ANA	100uL
anti-respiratory syncytial virus (IgM & IgG)	100uL
anti-Haemophilus influenzae IgG	100uL
anti-Haemophilus influenzae IgM	100uL

INTERFERING SUBSTANCES

The following compounds of potentially interfering substances have been tested using the COVID-19 IgM/IgG Rapid Test. The tests were performed on 3 negative and 2 confirmed positive COVID-19 serum samples. The substances and concentration for each substance is listed below. All results were concordant with expected results. No interference was observed.

INTERFERENCE

Potentially Interfering Substance	Concentration
Mucin	14mg/g
Bilirubin	200mg/L
Cholesterol	2500mg/L
Triglyceride	2500mg
Hemoglobin	25g/L
Human Haemoglobin	30mg/g
Human Blood	200μL/g
Interferon-alpha	2mg/g
Zanamivir	2mg/g
Ribavirin	2mg/g
Oseltamivir	2mg/g
Peramivir	2mg/g
Lopinavir	2mg/g
Ritonvir:	2mg/g
Arbidol	2mg/g

WARNINGS AND PRECAUTIONS

-For In Vitro Diagnostic Use Only.

-Local and national public health agencies should be notified of any patient suspected to have COVID-19.

-Confirmatory testing is necessary for positive detection results and may be necessary for negative detection results. Laboratories should consult with local or national public health officials on any positive detection OR no detection (negative) COVID-19 test result on the need for additional testing and appropriate transportation of specimens.

-Use of this assay should be limited to designated, trained personnel.

-All personnel who are involved in collecting, processing, handling, or transporting specimens from a patient with suspected COVID-19 should take appropriate precautions following the procedures recommended by local or national public health officials.

-Do not eat, drink or smoke in the area where specimens and kit reagents are handled. Avoid any contact between hands, eyes or mouth during specimen collection and testing.

-Dispose of all specimens and materials used in the test procedure in a biohazard waste container.

-Do not use any device if the pouch has been perforated.

-Each device is for single use only.

-Always check expiration date prior to testing. Do not use the test beyond the expiration date printed on the pouch.

-If desiccant packet is missing, do not use, discard and use a new test device.

-Adequate lighting is required to read the test results.

-Not for the screening of donated blood.

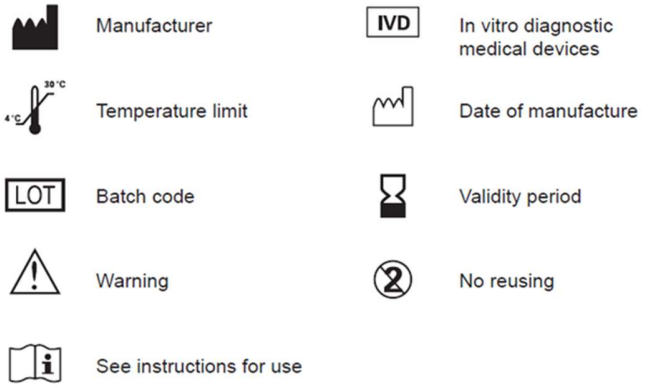
INQUIRIES AND GENERAL INFORMATION

Please visit our website at www.whpm.com

TECHNICAL

Via email: info@whpm.com

INTERPRETATION OF SYMBOLS



REFERENCES

1. Li, etc., Early Transmission Dynamics in Wuhan, China of Novel Coronavirus– Infected Pneumonia,DOI: 10.1056/NEJMoa2001316.
2. Li Taisheng, Peking Union Medical College Hospital's Proposal for Diagnosis and Treatment of "Novel Coronavirus Infected Pneumonia" (V2.0), Union Medical Journal, 2020.1.27.
3. Wei Qiuhua, Disinfection measures for pneumonia epidemic sources of novel coronavirus infection in 2019, Chinese Journal of Disinfection, 2020 (37) 1,59-62.

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