SARS-CoV-2 IgM/IgG Antibody Rapid Test

REF	502090	**Specimen:** whole blood, serum or plasma
Language: English		**Version:** 01
Effective Date: 2020-02		

For professional *in vitro* diagnostic use only.

INTENDED USE

The *StrongStep*® SARS-CoV-2 IgM/IgG Test is a rapid immunochromatographic assay for the simultaneous detection of IgM and IgG antibodies to SARS-CoV-2 virus in human whole blood, serum or plasma. The assay is used as an aid in the diagnosis of COVID-19.

INTRODUCTION

Coronavirues are enveloped RNA virus that are distributed broadly among humans, other mammals and birds, that cause respiratory, enteric, hepatic and neurologic diseases. Seven coronavirus species are known to cause human disease. Four virus - 229E, OC43, NL63 and HKU1 – are prevalent and typically cause common cold symptoms in immunocompetent individuals. The three other strains – severe acute respiratory syndrome coronavirus (SARS-CoV), Middle East respiratory syndrome coronavirus (MERS-CoV) and 2019 Novel Coronavirus (COVID-19) – are zoonotic in origin and have been linked to sometimes fatal illness, IgM and IgG antibodies to 2019 Novel Coronavirus can be detected with 1-2 weeks after exposure. IgG remains positive , but the antibody level drops overtime.

PRINCIPLE

The *StrongStep*® SARS-CoV-2 IgM/IgG Test utilizes the principle of Immuno-chromatography. Mouse anti-human IgM and human IgG antibodies are immobilized on the nitrocellulose membrane respectively, as two individual test lines (IgM line and IgG line) in the test window of the test device. As the test sample flows through the membrane within the test device, the colored–SARS-CoV-2 specific recombinant antigen-colloidal gold conjugate complexes with specific antibodies (IgM and/or IgG) of SARS-CoV-2 virus, if present in the sample. This complex moves further on the membrane to the test region where it is captured by the anti-human IgM and/or human IgG antibodies coated on the membrane leading to formation of a colored band, which indicates a positive test results. Absence of this colored band in the test window indicates a negative test result. A built-in control line will always appear in the test window when the test has performed properly, regardless of the presence or absence of anti- SARS-CoV-2 virus antibodies in the specimen.

KIT COMPONENTS

1. *StrongStep*® SARS-CoV-2 IgM/IgG Test Card in foil pouch
2. Sample Buffer
3. Instructions for Use

MATERIALS REQUIRED BUT NOT PROVIDED

1.Sepcimen collection container
2.1-20 µL Pipetter
3.Timer

PRECAUTIONS

1. This kit is for ***IN VITRO*** diagnostic use only.
2. This kit is for ***PROFESSIONAL*** use only.
3. Read the instructions carefully before performing the test.
4. This product does not contain any human source materials.
5. Do not use kit contents after the expiration date.
6. Handle all specimens as potentially infectious.
7. Follow standard Lab procedure and biosafety guidelines for handling and disposal of potentially infective material. When the assay procedure is completed, dispose specimens after autoclaving them at 121° C for at least 20 minutes. Alternatively, they can be treated with 0.5% Sodium Hypochlorite for 1-2 hours before disposal.
8. Do not pipette reagent by mouth and no smoking or eating while performing assays.
9. Wear gloves during the whole procedure.

STORAGE AND STABILITY

The sealed pouches in the test kit may be stored between 2-30°C for the duration of the shelf life as indicated on the pouch.

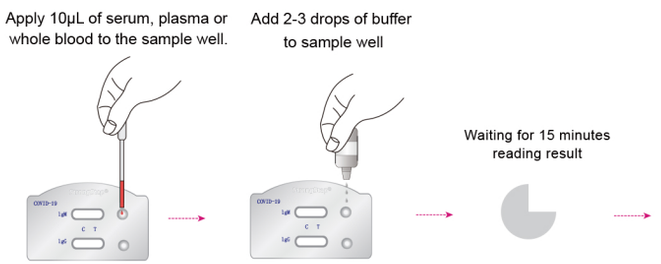
SPECIMEN COLLECTION AND STORAGE

1. No prior special preparation of the patient is required before sample collection by approved techniques.
2. The test works best on fresh whole blood / serum / plasma samples. If testing cannot be performed immediately,serum / plasma may be stored at 2-8°C up to 3 days in case of delay in testing. For long-term storage, serum /plasma specimens can be frozen at -20°C for 3 months or -70°C for longer period. Blood samples collected with a suitable anticoagulant such as EDTA or Heparin or Oxalate may be stored at 2-8°C up to 3 days. Blood samples should not be frozen.
3. Repeated freezing and thawing of the specimen should be avoided.
4. Do not use haemolysed, clotted, contaminated, lipamic and viscous/ turbid specimen.
5. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only used for testing.
6. Do not inactivate the sample by heating.
7. Shipment of specimens should comply with local regulations for transportation of etiologic agents.

PROCEDURE

1. Bring the kit components to room temperature before testing. Open the pouch and remove the Card .
2. Once opened, the test card must be used immediately .
3. Label the test card with patients identity.
4. Apply 10µL of serum, plasma or whole blood to the sample well.
5. Add 2-3 drops of sample buffer to the sample well.
6. At the end of 15 minutes read the results. A strong positive sample may show result earlier.

Note: Result after 15 minutes may not be accurate.



Result

Note:Control band fails to appear should be regarded as invalid results.

INTERPRETATION OF RESULTS

POSITIVE RESULT: C T	Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).
NEGATIVE RESULT: C T	Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).
INVALID RESULT: C T C T	Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

QUALITY CONTROL

The control band is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.

1. Good Laboratory Practice recommends the daily use of control materials to validate the reliability of the device.

LIMITATIONS OF THE TEST

1.The test is for qualitative detection of anti- SARS-CoV-2 antibody in human serum, plasma or blood sample and does not indicate the quantity of the antibodies.

2. The test is for *in vitro* diagnostic use only.

3. As in case of all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test but should rather be made after all the clinical findings have been evaluated, especially conjunct with SARS-CoV-2 PCR test.

PERFORMANCE CHARACTERISTICS

•Accuracy

IgM

	PCR Test		
StrongStep® SARS-CoV-2 IgM Test		Positive	Negative
	Positive	112	0
	Negative	61	33
	Agreement	64.7%	100%

IgG

	PCR Test		
StrongStep® SARS-CoV-2 IgG Test		Positive	Negative
	Positive	143	0
	Negative	30	33
	Agreement	82.7%	100%

No cross reactivity was observed with specimens from patients infected with HAV, HIV, HCV, HBV, HTLV, and CMV.

•Interference

No interference was found with bilirubin (10 mg/dL), hemoglobin (20 mg/dL) or triglycerides (600 mg/dL) on the sensitivity and specificity of the test.

GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use by
	Manufacturer	Σ	Contains sufficient for <n> tests
	Do not reuse	EC REP	Authorized representative in the European Community

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