AMP Rapid Test SARS-CoV-2 IgG/IgM

QUALITATIVE TEST

For professional *in vitro* diagnostic use only

Sample:	Whole blood, serum, plasma
Reading:	Visual
Temperature:	Room temperature
Storage:	2°C - 30°C, well protected against moisture, light and heat

CE

IVD

REF	CONT
RT2941	10 Cassettes
RT2942	25 Cassettes
RT2945	50 Cassettes

INTENDED USE

Rapid immunochromatographic test for the qualitative detection of IgG and IgM antibodies to Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) in human whole blood, serum and plasma samples as an aid in diagnosis of Coronavirus (Covid-19) infection.

PRINCIPLE

The test is performed by applying the whole blood, serum or plasma sample to the sample well (S) of the cassette and observing the formation of colored lines.

IgG/IgM antibodies to SARS-CoV-2 are detected by utilizing a combination of anti-human IgG, anti-human IgM, recombinant SARS-CoV-2 antigens conjugated with colloid gold, rabbit IgG gold conjugates, as well as a goat anti-rabbit IgG in the Control (C) region.

The sample migrates by capillary effect along the membrane.

IgG antibodies to SARS-CoV-2 bind to SARS-CoV-2 conjugate and are captured by anti-human IgG with the formation of a colored line in the IgG Test (T) region.

IgM antibodies to SARS-CoV-2 bind with SARS-CoV-2 conjugate and are captured by anti-human IgM with the formation of a colored line in the IgM Test (T) region.

The presence of this colored line indicates a positive result, while its absence indicates a negative result.

As a procedure control a coloured line has to appear in the Control (C) region confirming that sufficient sample has been absorbed.

COMPOSITION

Individually packed test cassette, desiccant, disposable pipette
Buffer

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- For external use only. Do not swallow.
- Samples are potentially infectious and therefore have to be treated cautiously.
- Avoid cross-contamination of samples by using a new sample collection container for each sample obtained.
- The test is designed for single use only. Discard after use according to the local regulations or laboratory rules for disposal of potentially infectious waste.
- Do not use test cassette beyond expiry date.
- Do not use test cassette in case that the pouch is punctured or not sealed correctly.
- Humidity and temperature can affect the results.
- Keep out of the reach of children.
- Wear protective clothing: laboratory coats, gloves, eye protection.
- Do not perform the test in a room with strong air flow, electric fan or strong air- conditioning.

STORAGE AND STABILITY

When stored in the sealed pouch at 2-30°C and protected from direct sunlight, moisture and heat the test cassette is stable until the indicated expiry date.

DO NOT FREEZE.

Care should be taken to protect components of the kit from contamination.

SAMPLE COLLECTION AND PREPARATION

Whole blood collected either from finger stick or by venipuncture, as well as serum and plasma can be used to perform the test.

Finger stick:

1. Clean puncture site with alcohol swab and allow to dry.
2. Massage hand without touching the puncture site to stimulate perfusion.
3. Puncture site with sterile lancet and wipe off first sign of blood.
4. Gently rub hand from wrist via palm to finger to form a round drop of blood over puncture site.

Whole blood sample collected by finger stick is to be tested immediately.

Venipuncture:

Collecting whole blood use EDTA, heparin or sodium citrate as anticoagulant.

Separate serum or plasma as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed sample.

Perform test as soon as possible. Do not leave sample at room temperature for a prolonged period of time.

Whole blood: may be stored at 2-8°C for up to 2 days
Do not freeze whole blood samples

Serum or plasma: may be stored at 2-8°C for up to 3 days
For long term storage keep sample below -20°C

Bring sample to room temperature prior to testing. Frozen samples must be completely thawed and mixed well prior to testing. Samples should not be frozen and thawed repeatedly.

PROCEDURE

Test cassette, buffer and sample must be at room temperature (15-30°C) prior to testing.

1. Remove test cassette from the foil pouch and place it on a flat and clean surface.
   For best results, the assay should be performed within one hour.
2. *Serum or plasma:*
   Hold disposable pipette vertically and draw sample up the sample line (5 µL), transfer to the sample well (S) of the cassette and **add 2 drops of buffer (appr. 80 µL**) to the buffer well (B) immediately. Avoid air bubbles.
   Note: For better precision use precision pipette to dispense 5 µL sample volume.
   Whole blood:
   Hold disposable pipette vertically and draw sample about 1 cm above the fill line (**appr. 10 µL**), transfer to the sample well (S) of the cassette and **add 2 drops of buffer (appr. 80 µL)** to the buffer well (B) immediately. Avoid air bubbles.
3. Wait for the colored lines to appear and read the test result after **10 minutes**.
   ***IMPORTANT:* Do not read the result after 15 minutes.**

REF RD2940-E V4.2-CE

AMEDA Labordiagnostik GmbH

Prepared by: I. Bajko
Approved by: G. Herfort, 2020-02-18

Krenngasse 12, 8010 Graz, Austria * Phone +43 316 69 80 69 * Fax +43 316 69 80 69 12 * e-mail: office.graz@amp-med.com

INTERPRETATION OF RESULTS

IgG Positive (+)

Two colored lines appear on the membrane. One line appears in the Control (C) and another line in the IgG Test (T) region. The result is IgG anti-SARS-CoV-2 positive.

IgM Positive (+)

Two colored lines appear on the membrane. One line appears in the Control (C) and another line in the IgM Test (T) region. The result is IgM anti-SARS-CoV-2 positive.

IgG and IgM Positive (+)

Three colored lines appear on the membrane. One line appears in the Control (C) and the other two lines appear in the IgG and IgM Test (T) region. The result is IgG and IgM anti- SARS-CoV-2 positive.

Note: Color intensity of the line appearing in the Test (T) region may vary depending on the concentration of SARS-CoV-2 antibodies in the sample. Therefore, any shade of color in the Test (T) region is to be considered as a positive result.

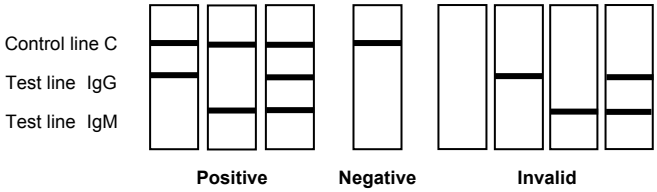
Negative (-)

Only one colored line appears in the Control (C) region. No colored line appears in the IgG/IgM Test (T) region.

Invalid

If a color line is visible only in the Test (T) region or no color line is visible at all the test is invalid and needs to be repeated with a new test cassette.

Note: Insufficient sample volume, incorrect procedure or expired test are most common reasons of invalid results.



QUALITY CONTROL

Although the test itself includes an internal procedural control, use of external controls is highly recommended as part of Good Laboratory Practice to confirm and verify the test procedure and proper performance of the test. Controls are to be tested following the same procedure as applied for patient samples. Positive and negative controls shall give the expected results.

LIMITATIONS OF PROCEDURE

This test is for professional *in vitro* diagnostic use and is to be used for qualitative detection of IgG/IgM antibodies to SARS-CoV-2 in human whole blood, serum or plasma samples only.

Fresh samples are to be used whenever possible. Frozen and thawed samples contain particles that can block the membrane. This slows the flow of reagents and can lead to high background color, making the interpretation of results difficult.

Optimal assay performance requires strict adherence to the assay procedure. Deviations may lead to aberrant results.

A negative result indicates absence of detectable anti- SARS-CoV-2 antibodies. However, a negative result does not preclude the possibility of exposure to or infection with SARS-CoV-2.

A negative result can occur if the quantity of anti- SARS-CoV-2 antibodies present in the sample is below the detection limits of the assay, or antibodies are not present during the stage of disease in which a sample is collected.

Some samples containing unusually high titer of heterophile antibodies or rheumatoid factor may affect the results.

As for all diagnostic tests, results must be interpreted by a physician only after all clinical and laboratory findings have been evaluated.

PERFORMANCE

Sensitivity and specificity:

AMP Rapid Test SARS-CoV-2 IgG/IgM has been tested versus RT PCR. Sensitivity, specificity and correlation among the two methods has been found to be as following:

IgM Test

Test sensitivity:	95.7 %
Test specificity:	97.3 %
Overall Agreement:	96.8 %

IgG Test

Test sensitivity:	91.8 %
Test specificity:	96.4 %
Overall Agreement:	95.0 %

BIBLIOGRAPHY

1. World Health Organization (WHO). WHO Statement Regarding Cluster of Pneumonia Cases in Wuhan, China. Beijing: WHO; 9 Jan 2020. [Accessed 26 Jan 2020]. https://www.who.int/china/news/detail/09-01-2020-who-statement-regarding- cluster-of-pneumonia-cases-in-wuhan-china
2. 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
3. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. Trends Microbiol 2016;24:490-502. PMID:27012512 DOI:10.1016/j.tim.2016.03.003
4. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019;17:181-192.PMID:30531947 DOI:10.1038/s41579-018-0118-9
5. World Health Organization (WHO) - Coronovirus. https://www.who.int/health-topics/coronavirus

EXPLANATION OF SYMBOLS USED ON LABEL AND PACKAGING

	Temperature limitation / Store at
REF	Code
IVD	For in vitro diagnostic use
CONT	Contents of kit
LOT	Lot number
	Use by (last day of the month)
	Manufacturer
	Consult instructions for use
	Do not reuse

REF RD2940-E V4.2-CE

AMEDA Labordiagnostik GmbH

Prepared by: I. Bajko
Approved by: G. Herfort, 2020-02-18

Krenngasse 12, 8010 Graz, Austria * Phone +43 316 69 80 69 * Fax +43 316 69 80 69 12 * e-mail: office.graz@amp-med.com