AMP Rapid Test SARS-CoV-2 Ag

QUALITATIVE TEST

For home use and self testing acc. to temporary permission

Sample:	Anterior nasal swab
Reading:	Visual
Temperature:	Room temperature
Storage:	2°C - 30°C, well protected against moisture, light and heat

CE

IVD

REF	CONT
RT2950	1 Cassette
RT2955	5 Cassettes
RT2951	10 Cassettes

INTENDED USE

Rapid immunochromatographic test for the qualitative detection of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) nucleocapsid protein antigen in human anterior nasal swab samples as an aid in rapid diagnosis of Coronavirus (Covid-19) infection.
According to the usability study, this test is suitable for personal use by **adults and children aged 11 and over**. Supervised testing is recommended for children under the age of 11

PRINCIPLE

The test is performed by applying the extracted sample to the sample well (S) of the cassette and observing the formation of colored lines.
Nucleocapsid protein antigen to SARS-CoV-2 are detected by utilizing highly sensitive monoclonal antibodies.
The sample migrates by capillary effect along the membrane. If present in the sample, SARS-CoV-2 antigen react with monoclonal antibody conjugated colloid-gold particles and are captured by secondary monoclonal antibodies immobilized in the Test (T) region.
A colored line will form in the 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, sterile swab, tube prefilled with buffer, tube holder, disposal bag

ADDITIONAL MATERIAL NEEDED (not included in the kit)

Stop watch or timer

PRECAUTIONS

- For external use only. Do not swallow.
- Wash and dry hands thoroughly before performing the test.
- 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 and sampling accessories are intended for single use only.
- Do not use other swabs than the ones supplied in the kit.
- Do not use test cassette beyond expiry date.
- Do not use test cassette in case that the pouch is punctured or not sealed correctly.
- Keep out of the reach of children.
- Humidity and temperature can affect the results.
- Do not perform the test in a room with strong air flow, electric fan or strong air- conditioning.
- Extraction buffer contains 0.09% sodium azide as preservative. Flush with plenty of water in case of skin or eye contact. Do not discard solution through sink or toilette.

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.

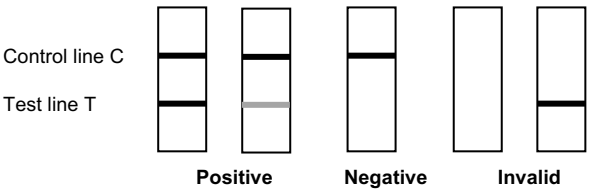
TESTPROCEDURE

1. Wash and dry hands thoroughly.
2. Unpack test accessories and place on a clean surface.
3. Place buffer tube in the tube holder and remove screw cap resp. pull off seal foil.
4. Unpack swab and carefully insert the swab about 2 cm into one nostril. Rotate swab 5 to 10 times against the nasal wall.

   Note: **Exclusively use swabs supplied in the kit.**
5. Carefully withdraw swab from the nostril and repeat procedure with the same swab in the other nostril.
6. Insert sample swab into the buffer tube and rotate the swab at least 6 times. Press head of the swab against the inside and the bottom of the tube.
7. Leave swab in the buffer tube for **1 minute**.
8. Squeeze the tube with the fingertips to expel as much buffer solution from the swab as possible. Withdraw swab and place in the disposal bag.
9. Close buffer tube with the screw cap and remove the screw cover of the dropper tip.
10. Remove test cassette from the foil pouch and place it on a flat and clean surface. Apply **4 drops** of sample solution to the sample well of the cassette.
11. Start stop watch or timer and read the test result after **15 minutes**.

    IMPORTANT: **Do not read the result after 20 minutes.**
12. Pack test cassette, closed buffer tube and swab in the disposal bag and dispose off in the household garbage.

INTERPRETATION OF RESULTS AND MEASURES



POSITIVE (+)

Two colored lines appear on the membrane. One line appears in the Control (C) and another line in the Test (T) region. The result is 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 antigen in the sample. Therefore, any shade of color in the Test (T) region is to be considered as a positive result.

Measures:

A COVID-19 infection is suspected. Contact your family doctor or the local health department immediately. Follow local guidelines for self-isolation and have a PCR test performed to confirm the test result.

REF RD2950-E V4.2.4-HU-CE

AMEDA Labordiagnostik GmbH

Prepared by: I. Bajko
Approved by: G. Herfort, 2021-02-02

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

NEGATIVE (-)

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

Measures:

A negative test result does not generally rule out the presence of SARS-CoV-2 viruses and, moreover, is always only a snapshot. Therefore, even in the case of a negative result, continue observing all the rules related to contacts and comply with protective measures. In case of suspect, repeat test after 1 – 2 days.

INVALID

If a colored line is visible only in the Test (T) region or no colored 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.

Measures:

Repeat test. If the result of the repeated test still remains invalid contact doctor or COVID-19 test center.

QUALITY CONTROL

A colored line appearing in the Control (C) region is the internal procedural control confirming sufficient sample volume and correct test procedure. External controls are not included in the kit.

DISPOSAL

Pack test cassette, closed buffer tube and swab in the disposal bag and dispose off in the household garbage.

LIMITATIONS OF PROCEDURE

This test is to be used for qualitative detection of nucleocapsid protein antigen to SARS-CoV-2 in human anterior nasal swab samples only.

No quantitative result or rate of increase in antigen concentration can be determined with this test.

The test is capable of detecting both viable and non-viable SARS-CoV-2. The performance depends on the antigen load and may not correlate with viral culture results performed on the same sample.

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

If the test result is negative, but clinical symptoms persist, additional testing using other clinical methods is advised. A negative test result does not rule out the presence of SARS-CoV-2 antigens in the sample, as the antigen concentration may be below the minimum detection limit or the sample may have been collected or transported improperly.

A positive test result does not rule out co-infections with other pathogens.

A positive test result does not differentiate between SARS-CoV and SARS-CoV-2.

PERFORMANCE

Detection limit (LOD):

The minimum detectable concentration of SARS-CoV-2 Ag is **1.15 x 10^2 $TCID_{50}$/mL**.

Sensitivity and specificity:

AMP Rapid Test SARS-CoV-2 Ag has been evaluated with clinical patient samples using a commercial molecular assay (RT PCR) as a reference method. Sensitivity, specificity and overall relative accuracy for nasopharyngeal swabs have been found to be as following:

		AMP Rapid Test SARS-CoV-2 Ag		
		+	-	Total
RT-PCR	+	108	3	111
	-	0	139	139
		108	142	250

Test sensitivity: 97.3% (95% CI: 90.0% - 99.8%)
Test specificity: 100.0% (95% CI: 96.6% - 100%)
Relative accuracy: 98.8% (95% CI: 91.8% - 99.9%)

Note: For physiological reasons, the test sensitivity for anterior nasal swabs can be lower (around 10%) depending on the viral load.

Interferences

The following substances did not show any interference:
Human blood (EDTA), anti-viral drugs, antibiotics/anti-bacterial drugs, nasal sprays or nose drops, nasal corticosteroids.

Precision:

Intra-assay:

Negative, low positive (LOD) and high positive (4 x LOD) samples have been tested in 10 replicates each. Results have been detected correctly for >99% of the samples.

Inter-assay:

Negative, low positive (LOD) and high positive (4 x LOD) samples have been tested in 10 replicates each with AMP Rapid Test SARS-CoV-2 Ag from 3 different lots. Results have been detected correctly for >99% of the samples.

Cross-reactivity

AMP Rapid Test SARS-CoV-2 Ag has been tested with samples containing the following pathogens at the indicated concentrations. Results did not show any cross-reactivity.

RSV – Type A	5.5 x 10^7PFU/mL	Human Coronavirus 229E	1 x 10^5PFU/mL
RSV – Type B	2.8 x $10^5$$TCID_{50}$/mL	Human Coronavirus OC43	1 x 10^5PFU/mL
Novel Influenza A H1N1	1 x 10^6PFU/mL	Human Coronavirus NL63	1 x 10^6PFU/mL
Seasonal Influenza A H1N1	1 x 10^5PFU/mL	Human Coronavirus HKU1	1 x 10^6PFU/mL
Influenza A H3N2	1 x 10^6PFU/mL	Parainfluenza virus 1	7.3 x 10^6PFU/mL
Influenza A H5N1	1 x 10^6PFU/mL	Parainfluenza virus 2	1 x 10^6PFU/mL
Influenza B Yamagata	1 x 10^5PFU/mL	Parainfluenza virus 3	5.8 x 10^6PFU/mL
Influenza B Victoria	1 x 10^5PFU/mL	Parainfluenza virus 4	2.6 x 10^6PFU/mL
Rhinovirus	1 x 10^6PFU/mL	Haemophilus influenza	5.2 x 10^6CFU/mL
Adenovirus 3	5 x $10^{7.5}$ $TCID_{50}$/mL	Streptococcus pyogenes	3.6 x 10^6CFU/mL
Adenovirus 7	2.8 x 10^6 $TCID_{50}$/mL	Streptococcus pneum.	4.2 x 10^6CFU/mL
EV-A71	1 x 10^5PFU/mL	Candida albicans	1 x 10^7CFU/mL
Mycobacterium tuberculosis	1 x 10^3bact/mL	Bordetella pertussis	1 x 10^4bact/mL
Mycoplasma pneumoniae	1.2 x 10^6CFU/mL	Chlamydia pneumoniae	2.3 x 10^6IFU/mL
Mumps	1 x 10^5PFU/mL	Legionella pneumophila	1 x 10^4bact/mL

BIBLIOGRAPHY

1. World Health Organization (WHO) - Coronavirus. https://www.who.int/health-topics/coronavirus
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

EXPLANATION OF SYMBOLS USED ON LABEL AND PACKAGING

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

REF RD2950-E V4.2.4-HU-CE

AMEDA Labordiagnostik GmbH

Prepared by: I. Bajko
Approved by: G. Herfort, 2021-02-02

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