AMP Rapid Test SARS-CoV-2 Ag

QUALITATIVE TEST

For professional *in vitro* diagnostic use only

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

CE

IVD

REF	CONT
RT2951	10 Cassettes
RT2952-S	25 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 naso- and oropharyngeal, as well as anterior nasal swab samples as an aid in rapid diagnosis of Coronavirus (Covid-19) infection.

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, extraction tube prefilled with buffer, tube holder

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- For external use only. Do not swallow.
- Wear protective clothing: laboratory coats, gloves, eye protection.
- 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.
- Discard test cassette and sampling accessories after use according to the local regulations or laboratory rules for disposal of potentially infectious waste.
- Extraction buffer contains 0.09% sodium azide as preservative. Flush with plenty of water in case of skin or eye contact. Sodium azide may react explosively, when in contact with lead or copper plumbing. Thus flush with plenty of water when disposing the solution through the sink.

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.

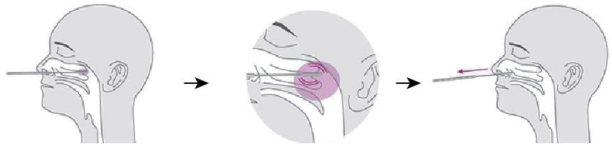
SAMPLE COLLECTION AND PREPARATION

Note: **Exclusively use swabs supplied in the kit.**

Nasopharyngeal swab:

1. Carefully insert the swab into the nostril of the patient until reaching the surface of the posterior nasopharynx, which presents the most secretion under visual inspection.
2. Swab the surface of the posterior nasopharynx and rotate the swab several times.
3. Withdraw the swab from the nasal cavity.

Note: **Do not use visually bloody or overly viscous samples.**



Oropharyngeal swab:

Carefully insert the swab into the rear area of the throat and tonsils and dab both tonsils and the back of the pharynx.

Note: **Avoid touching tongue, teeth or gums with the swab.**

Anterior nasal swab:

Carefully insert the swab about 2 cm into one nostril and rotate the swab 5 to 10 times against the nasal wall. Using the same swab repeat the procedure with the other nostril.

Sample transport:

Sample is to be tested immediately after collection. If immediate testing is not possible place the swab in a dry, clean and unused plastic tube labelled with the patient information and cap tightly. The sample is stable for up to 1 hour at room temperature (15° to 30°C) or up to 3 hours at +2° to +8°C. If the sample cannot be tested within this period of time a new sample has to be collected.

Note: **Do not return nasopharyngeal swab into the packaging.**

Sample preparation:

1. Remove the screw cap of the extraction tube resp. pull off the seal foil and insert the tube into the holder, making sure that it stands firmly.
2. Insert the sample swab into the extraction tube containing the extraction buffer.
3. Rotate the swab at least 6 times while pressing the head against the inside and the bottom of the tube to release the antigen collected with the swab.
4. Leave the swab in the extraction tube for **1 minute**.
5. Squeeze the tube with the fingertips to expel as much buffer solution from the swab as possible and withdraw the swab. Discard swab in accordance with biohazard waste disposal protocol.
6. Close the extraction tube with the screw cap and remove the screw cover of the dropper tip.

PROCEDURE

Test cassette 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 assay should be performed immediately.
2. Apply 4 drops of extracted solution (appr. 100 µL) to the sample well of the cassette.

REF RD2950-E V4.2.4.1-CE

AMEDA Labordiagnostik GmbH

Prepared by: I. Bajko
Approved by: G. Herfort, 2021-01-25

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

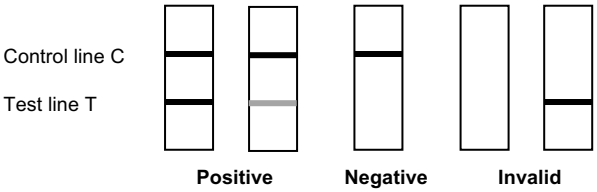
3. Wait for the colored lines to appear and read the test result after **15 minutes**.
   ***IMPORTANT:* Do not read the result after 20 minutes.**

INTERPRETATION OF RESULTS

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.

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

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.



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.
Nevertheless, use of external controls is recommended as part of Good Laboratory Practice to confirm and verify the test procedure and proper performance of the test. Positive and negative controls are available on request and are to be tested following the same procedure as applied for patient samples.

LIMITATIONS OF PROCEDURE

This test is for professional *in vitro* diagnostic use and is to be used for qualitative detection of nucleocapsid protein antigen to SARS-CoV-2 in human nasopharyngeal 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.
As for all diagnostic tests, results must be interpreted by a physician only after all clinical and laboratory findings have been evaluated.

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 +	AMP Rapid Test SARS-CoV-2 Ag -	Total
RT-PCR	+	216	6	222
	-	0	278	278
		216	284	500

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 oro-pharyngeal and 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 V4.2.4.1-CE
AMEDA Labordiagnostik GmbH
Prepared by: I. Bajko
Approved by: G. Herfort, 2021-01-25
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