AMP Rapid Test SARS-CoV-2 Ag Sputum

QUALITATIVE TEST

For home use and self testing acc. to temporary permission

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

CE

IVD

REF	CONT
RT3950	1 Cassette
RT3951	10 x 1 Cassette

INTENDED USE

Rapid immunochromatographic test for the qualitative detection of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) nucleocapsid protein antigen in human sputum 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, sample collection funnel, extraction tube, dropper tip, single use pipette, pre-portioned buffer, bio-safety bag

ADDITIIONALLY REQUIRED MATERIAL (not included in the test kit)

Stopwatch or timer

PRECAUTIONS

- For external use only. Do not swallow.
- Before performing the test wash and dry hands thoroughly.
- Samples are potentially infectious and therefore have to be treated cautiously.
- Avoid cross-contamination of samples by using a new set of sample collection devices for each sample obtained.
- The test and sampling accessories are intended for single use only.
- 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

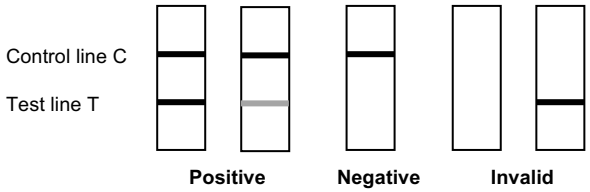
When stored in the sealed pouch at 2-30°C and protected from direct sunlight, moisture and heat the test cassette is stable until the indicated expiry date.
DO NOT FREEZE.
Care should be taken to protect components of the kit from contamination.

TEST PROCEDURE

Important: Do not to place anything in the mouth for at least 10 minutes prior to sample collection – no food, no drink, no sweets, no chewing gum, no medicine, no tobacco.

1. Wash and dry hands thoroughly.
2. Unpack test accessories and place on a clean surface. Open buffer solution and keep it ready
   ATTENTION: Hold buffer container away from the body and carefully break off the tip.
3. Place the funnel on the sample tube.
4. Cough vigorously up to 5 times to release secretions from the throat.
5. Gently squeeze the sample tube and spit into the funnel.
6. Release pressure from the sample tube – secretion is sucked into the tube.
7. The collected sputum volume has to be appr. **0.5 mL**. This is the case when the liquid volume reaches the lower mark on the tube. Disregard existing foam.
   If the collected volume is too small repeat steps 4 to 6. If the collected volume is too large, please aspirate the excess volume with the pipette.
   Note: **The appropriate volume of sputum sample is essential for the accuracy of the test result.**
8. Completely empty the buffer solution into the tube and attach the dropper tip.
9. Gently shake the sample tube and mix the contents by pulsing the lower end of the tube for 10 seconds.
10. Remove the test cassette from the foil pouch and place it on a flat surface. Apply 2 drops of sample solution to the sample well (S) of the cassette.
11. Start stop watch or timer and read test result after **15 minutes**.
    IMPORTANT: **Do not read the result after 20 minutes.**
12. Pack test cassette and test accessories in the disposal bag and dispose off in the household garbage.

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

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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.

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 and test accessories 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 sputum 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 Sputum has been evaluated with clinical patient samples using a commercial molecular assay (RT PCR) as a reference method. Sensitivity, specificity and overall relative accuracy have been found to be as following:

AMP Rapid Test SARS-CoV-2 Ag Sputum

		+	-	Total
RT-PCR	+	130	11	141
	-	0	189	189
		130	200	330

Test sensitivity:	92.2%	(95% CI: 86.1% - 96.6%)
Test specificity:	100.0%	(95% CI: 98.5% - 100%)
Relative accuracy:	96.7%	(95% CI: 94.7% - 98.2%)

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	5 x 10^5PFU/mL
RSV – Type B	2.8 x $10^5$$TCID_{50}$/mL	Human Coronavirus OC43	1 x 10^6PFU/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 H1N1	3.16 x 10^5PFU/mL	Parainfluenza virus 1	1.58 x 10^7PFU/mL
Influenza A H3N2	1 x 10^5PFU/mL	Parainfluenza virus 2	1.58 x 10^7PFU/mL
Influenza B Yamagata	3.16 x 10^6PFU/mL	Parainfluenza virus 3	1.58 x 10^8PFU/mL
Influenza B Victoria	3.16 x 10^6PFU/mL	Parainfluenza virus 4	1.58 x 10^8PFU/mL
Rhinovirus	1 x 10^6PFU/mL	Haemophilus influenza	5.2 x 10^6CFU/mL
Adenovirus 3	3.16 x 10^4 $TCID_{50}$/mL	Streptococcus pyogenes	3.6 x 10^6CFU/mL
Adenovirus 7	1.58 x 10^5 $TCID_{50}$/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

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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		

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