AMP Rapid Test SARS-CoV-2 Ag Sputum

QUALITATIVE TEST

For professional *in vitro* diagnostic use only

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
RT3952	20 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 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, tube holder, bio-safety bag

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 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.
- 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: **Sputum sample has to be collected exclusively with the sampling devices supplied in the kit.**

1. ***Important:*** Instruct the patient 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.
2. Mount a new sample collection funnel on a new extraction tube.
3. Instruct the patient to deeply cough 3 to 5 times to release sputum from the deep throat to the mouth.
4. Slightly squeeze the extraction tube and present sample collection funnel and extraction tube to the patient.
5. Ask the patient to spit into the funnel and release the pressure from the extraction tube.
6. Check the volume of the sputum sample collected. The sputum volume has to be appr. **0.5 mL** (lower mark on the extraction tube).
   If the collected volume is less than 0.5 mL ask the patient to repeat the procedure.
   If the collected volume is more than 0.5 mL use a single use pipette to remove the excessive volume from the extraction tube.

Note: **The appropriate volume of sputum sample is essential for the accuracy of the test result.**

Sample storage:

Sample is to be tested as soon as possible after collection. If immediate testing is not possible, the sample is stable for up to 8 hours at room temperature (15° to 30°C) or up to 24 hours at +2° to +8°C.

Sample preparation:

1. Take one portion of extraction buffer and dispense the whole volume into the extraction tube.
2. Gently shake the extraction tube and mix the content by repeatedly squeezing the lower end of the tube for **10 seconds**.
3. Fit a new dropper dip on the extraction tube.

Note: The extracted sample is stable for 2 hours at room temperature (15° to 30°C) or 24 hours at +2° to +8°C.

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 2 drops of extracted solution to the sample well of the cassette.
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.**

REF RD3950-E V4.1-CE

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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.

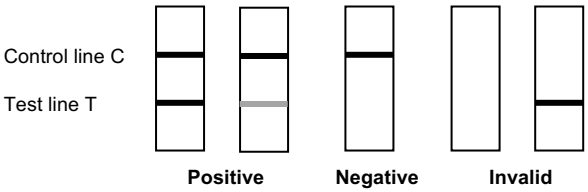
Negative (-)

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 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.

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 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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