AMP Rapid Test SARS-CoV-2 Ag Cassette

Technical Documentation

Status : 01.10.2020

Contents: **Page**

AMEDA Labordiagnostik GmbH Krenngasse 12, 8010 Graz, Austria * Phone +43 316 69 80 69 * Fax ext. -12

1. Product Description

1.1 Order Information

AMP Rapid Test SARS-CoV-2 Ag Cassette is available in the following commercial units:

Part Number	Product Denomination	Sample Type	Contents
RT2951	AMP Rapid Test SARS-CoV-2 Ag	Nasopharyngeal swab	10 Tests
RT2952	AMP Rapid Test SARS-CoV-2 Ag	Nasopharyngeal swab	25 Tests

1.2 Kit Composition

Each of the aforementioned commercial kits of AMP Rapid Test SARS-CoV-2 Ag Cassette consists of:

- Kit box (made of cardboard)
- Kit label

  Label contents:

  - Part number
  - Product Denomination
  - Kit contents
  - Storage conditions
  - Lot number
  - Expiry date
  - CE mark
  - IVD symbol
  - Reference to Instructions for Use
- Respective number of test cassettes, each separately packed in sealed foil pouch

  The foil pouch also contains dessicant to ensure dry storage of the test cassette
- Respective number of sterile swabs, each separately packed
- Respective number of extraction tubes packed in a plastic zip-lock bag together with respective number of dropper tips
- Foldable cardboard tube holder
- Extraction buffer
- Instructions for use
- Kit seal

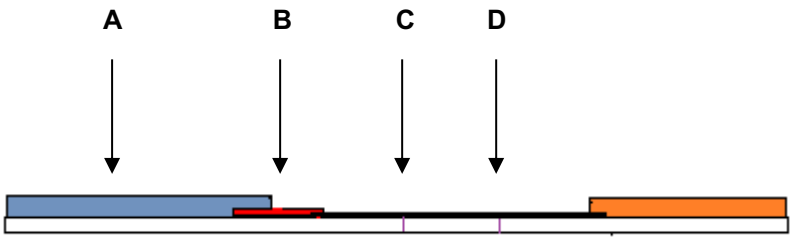
2. Test Description

2.1 Test Principle

AMP Rapid Test SARS-CoV-2 Ag is a rapid chromatographic immunoassay for qualitative detection of nucleocpsid protein antigen to Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) in human nasopharyngeal swab samples as an aid in diagnosis of Coronavirus (COVID-19) infection. It utilizes a combination of monoclonal SARS-CoV-2 antibody conjugated with colloid gold, heterophilic antibody and goat anti-mopuse IgG to detect nucleocapsid protein antigen extracted from nasopharyngeal swab sample.

The test is performed by applying the extracted sample to the sample well of the cassette and observing the formation of colored lines.

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 inj the Test (T) region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of sample has been added and membrane wicking has occurred.



The sample (A) migrates via capillary action along the membrane to react with the gold conjugate (B). Nucleocapsid protein antigen present in the sample bind with SARS-CoV-2 antibody conjugate, forming a colored antibody-antigen complex, which is captured by secondary antibody immobilized in the test region. The formation of a visible colored line in the test region (C) indicates a positive result. The absence of a colored line in the test region indicates a negative result. In the control region of the membrane, immobilized goat anti-mouse IgG captures colored conjugate regardless of the sample composition. The visible colored line (D) developed in the control region confirms correct performance of the test.

For convenient, reliable and safe performance of the test the test strip is mounted inside the cassette housing. This enables convenient application of the correct sample volume to the sample well. Test and Control line will appear in the results window of the cassette and are marked accordingly on the cassette for easy identification.

2.2 Test Composition

The test strip contains:

- Monoclonal SARS-CoV-2 antibody
- Goat anti-mouse IgG
- Blocker
- Sample pad
- Label pad
- Colloid gold
- Heterophilic antibody
- NC membrane
- Absorbant pad
- Plastic card

The test strip is mounted inside the plastic cassette and the cassette is packed together with desiccant in a tamper-proof foil pouch.

The extraction buffer contains:

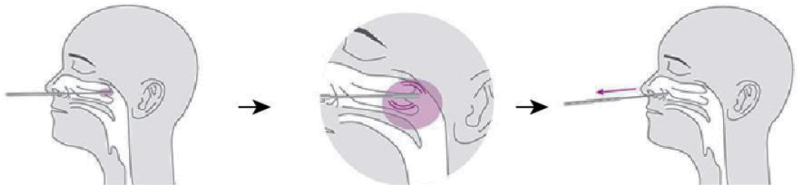
- Distilled Water
- NaCl
- Sodium Azide (0.09%)
- Proclin 300
- Tris buffer
- Tween 20

2.3 Test Procedure

2.3.1 Sample Collection and Storage

It is important to exclusively use the swab supplied as part of the test kit for collection of the nasopharyngeal sample. Proceed as following:

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.



Sample transport:

Sample should be tested as soon as possible after collection. If transport with viral transport medium (VMT) is required, a maximum volume of 1 mL or less is to be used to avoid reduced test sensitivity due to dilution.

Sample transport:

Based on experience with Influenza virus nasopharyngeal swab samples are anticipated to be stable for up to 72 hours at 2° to 8°C.

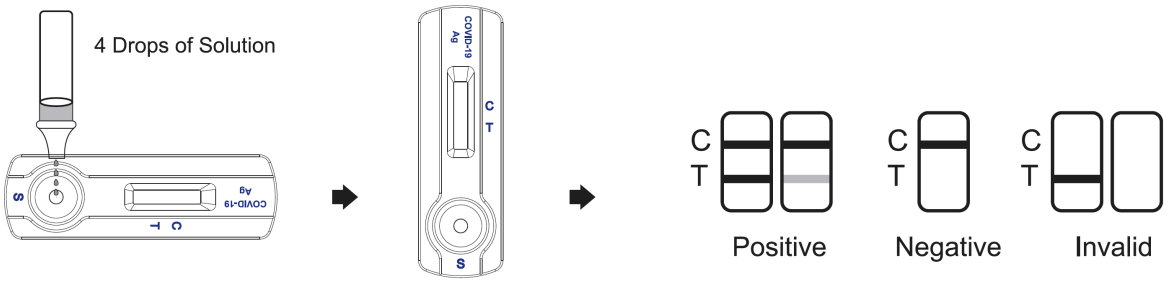
2.3.2 Sample Preparation

1. Insert extraction tube into the tube holder and make sure that the tube is standing firmly.
2. Hold **Buffer** bottle vertically and add 0.3 mL (appr. 10 drops) into the extraction tube.
3. Insert the sample swab into the extraction tube containing the extraction buffer.
4. 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.
5. Leave the swab in the extraction tube for **1 minute**.
6. Squeeze the tube with the finger tips to expel as much buffer solution from the swab as possible and withdraw the swab. Discard swab in accordance with biohazard waste disposal protocol.
7. Fit a new dropper dip on the extraction tube.

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



2.3.4 Interpretation of Test Results

Positive (+)

Two colored lines appear on the membrane. One line appears in the Control (C) and another 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 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.

2.3.4 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.

2.3.5 Limitations

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.

3. Manufacturing Procedure

1) Coat label pad with colloidal gold conjugated monoclonal SARS-CoV-2 antibody.
2) Use spayer to dispense monoclonal SARS-CoV-2 antibody and goat anti-mouse IgG onto the membrane.
3) Assemble test by applying membrane, label pad, absorbent pad, sample pad and antigen pad for test identification to the plastic card in the correct position.
4) Use cutter to cut the plastic card into strips.
5) Place the strip in the foreseen position in the lower part of the test cassette and mount the upper part of the test cassette.
6) Pack cassette, single use pipette and desiccant into the foil pouch and seal the pouch.
7) Test the adequate number of cassettes as defined in the QC protocol for release of the production batch.

4. Performance Data

4.1 Cross Reactivity

Cross reactivity has been tested with a variety of pathogens eventually present in clinical samples. Samples were tested in three replicates using tests from three different lots and reading results after 15 minutes.

Pathogen	Concentration	Lot No. 20060001			Lot No. 20060002			Lot No. 20060003		
RSV – type A	5.5 x 10^7PFU/mL	-	-	-	-	-	-	-	-	-
RSV – type B	2.8 x $10^5$$TCID_{50}$/mL	-	-	-	-	-	-	-	-	-
Novel Influenza A H1N1	1 x 10^6PFU/mL	-	-	-	-	-	-	-	-	-
Seasonal Influenza A H1N1	1 x 10^5PFU/mL	-	-	-	-	-	-	-	-	-
Influenza A H3N2	1 x 10^6PFU/mL	-	-	-	-	-	-	-	-	-
Influenza A H5N1	1 x 10^6PFU/mL	-	-	-	-	-	-	-	-	-
Influenza B Yamagata	1 x 10^5PFU/mL	-	-	-	-	-	-	-	-	-
Influenza B Victoria	1 x 10^5PFU/mL	-	-	-	-	-	-	-	-	-
Rhinovirus	1 x 10^6PFU/mL	-	-	-	-	-	-	-	-	-
Adenovirus 3	5 x $10^{7.5}$$TCID_{50}$/mL	-	-	-	-	-	-	-	-	-
Adenovirus 7	2.8 x $10^6$$TCID_{50}$/mL	-	-	-	-	-	-	-	-	-
EV-A71	1 x 10^5PFU/mL	-	-	-	-	-	-	-	-	-
Mycobacterium tuberculosis	1 x 10^3bact/mL	-	-	-	-	-	-	-	-	-
Mycoplasma pneumoniae	1.2 x 10^6CFU/mL	-	-	-	-	-	-	-	-	-
Mumps	1 x 10^5PFU/mL	-	-	-	-	-	-	-	-	-
Human Coronavirus 229E	1 x 10^5PFU/mL	-	-	-	-	-	-	-	-	-
Human Coronavirus OC43	1 x 10^5PFU/mL	-	-	-	-	-	-	-	-	-
Human Coronavirus NL63	1 x 10^6PFU/mL	-	-	-	-	-	-	-	-	-
Human Coronavirus HKU1	1 x 10^6PFU/mL	-	-	-	-	-	-	-	-	-
Paravirus virus 1	7.3 x 10^6PFU/mL	-	-	-	-	-	-	-	-	-
Paravirus virus 2	1 x 10^6PFU/mL	-	-	-	-	-	-	-	-	-
Paravirus virus 3	5.8 x 10^6PFU/mL	-	-	-	-	-	-	-	-	-
Paravirus virus 4	2.6 x 10^6PFU/mL	-	-	-	-	-	-	-	-	-
Haemophilus influenza	5.2 x 10^6CFU/mL	-	-	-	-	-	-	-	-	-
Streptococcus pyogenes	3.6 x 10^6CFU/mL	-	-	-	-	-	-	-	-	-
Streptococcus pneumon.	4.2 x 10^6CFU/mL	-	-	-	-	-	-	-	-	-
Candida albicans	1 x 10^7CFU/mL	-	-	-	-	-	-	-	-	-
Bordetella pertussis	1 x 10^4bact/mL	-	-	-	-	-	-	-	-	-
Chlamydia pneumoniae	2.3 x 10^6IFU/mL	-	-	-	-	-	-	-	-	-
Legionella pneumphila	1 x 10^4bact/mL	-	-	-	-	-	-	-	-	-

Conclusion: The re is no cross-reaction with the pathogens at the concentrations tested.

4.2 Reproducibility

Intra-assay:

Negative, low positive (LOD) and high positive (4 x LOD) samples were tested in 10 replicates using the same lot of test cassettes (lot no. 20060001). Results were read after 15 min.

Test	Negative	Low Positive	High Positive
1	-	+	+
2	-	+	+
3	-	+	+
4	-	+	+
5	-	+	+
6	-	+	+
7	-	+	+
8	-	+	+
9	-	+	+
10	-	+	+

Conclusion: Test results confirm consistent and reproducible performance.

Inter-assay:

Negative, low positive (LOD) and high positive (4 x LOD) samples were tested in 10 replicates each using three different lots of test cassettes. Results were read after 15 min.

Lot No. 1 (L1): 20060001 Lot No. 2 (L2): 20060002 Lot No. 3 (L3): 20060003

Test	Negative			Low Positive			High Positive		
	L1	L2	L3	L1	L2	L3	L1	L2	L3
1	-	-	-	+	+	+	+	+	+
2	-	-	-	+	+	+	+	+	+
3	-	-	-	+	+	+	+	+	+
4	-	-	-	+	+	+	+	+	+
5	-	-	-	+	+	+	+	+	+
6	-	-	-	+	+	+	+	+	+
7	-	-	-	+	+	+	+	+	+
8	-	-	-	+	+	+	+	+	+
9	-	-	-	+	+	+	+	+	+
10	-	-	-	+	+	+	+	+	+

Conclusion: Test results confirm satisfactory lot-to-lot stability

4.3 Interference Study

Various substances commonly found in the nasopharyngeal cavity were spiked individually, at the concentrations indicated, into negative and low positive samples. The samples were tested in triplicate with tests from 3 different lots. Test results were read after 15 minutes.

Negative Sample		**Concentration**	**Lot 20060001**			**Lot 20060002**			**Lot 20060003**		
	Human Blood	20% (v/v)	-	-	-	-	-	-	-	-	-
	Mucin	5 mg/mL	-	-	-	-	-	-	-	-	-
Antiviral drugs	Oseltamivir phosphate	5 mg/mL	-	-	-	-	-	-	-	-	-
	Ribavirin	5 mg/mL	-	-	-	-	-	-	-	-	-
Antibiotics / antibacterial drugs	Levofloxacin	5 mg/mL	-	-	-	-	-	-	-	-	-
	Azithromycin	5 mg/mL	-	-	-	-	-	-	-	-	-
	Meropenem	5 mg/mL	-	-	-	-	-	-	-	-	-
	Tobramycin	2 mg/mL	-	-	-	-	-	-	-	-	-
Nasal spray Nose drops	Phenylephrine	20% (v/v)	-	-	-	-	-	-	-	-	-
	Oxymetazoline	20% (v/v)	-	-	-	-	-	-	-	-	-
	0.9% sodium chloride	20% (v/v)	-	-	-	-	-	-	-	-	-
	Alkalol	20% (v/v)	-	-	-	-	-	-	-	-	-
Nasal corti-costeroids	Beclomethasone	20% (v/v)	-	-	-	-	-	-	-	-	-
	Hexadecadrol	20% (v/v)	-	-	-	-	-	-	-	-	-
	Flunisolide	20% (v/v)	-	-	-	-	-	-	-	-	-
	Triamcinolone	20% (v/v)	-	-	-	-	-	-	-	-	-
	Budesonide	20% (v/v)	-	-	-	-	-	-	-	-	-
	Mometasone	20% (v/v)	-	-	-	-	-	-	-	-	-
	Fluticasone	20% (v/v)	-	-	-	-	-	-	-	-	-
	Fluticasone propionate	20% (v/v)	-	-	-	-	-	-	-	-	-

Low Positive Sample		**Concentration**	**Lot 20060001**			**Lot 20060002**			**Lot 20060003**		
	Human Blood	20% (v/v)	+	+	+	+	+	+	+	+	+
	Mucin	5 mg/mL	+	+	+	+	+	+	+	+	+
Antiviral drugs	Oseltamivir phosphate	5 mg/mL	+	+	+	+	+	+	+	+	+
	Ribavirin	5 mg/mL	+	+	+	+	+	+	+	+	+
Antibiotics / antibacterial drugs	Levofloxacin	5 mg/mL	+	+	+	+	+	+	+	+	+
	Azithromycin	5 mg/mL	+	+	+	+	+	+	+	+	+
	Meropenem	5 mg/mL	+	+	+	+	+	+	+	+	+
	Tobramycin	2 mg/mL	+	+	+	+	+	+	+	+	+
Nasal spray Nose drops	Phenylephrine	20% (v/v)	+	+	+	+	+	+	+	+	+
	Oxymetazoline	20% (v/v)	+	+	+	+	+	+	+	+	+
	0.9% sodium chloride	20% (v/v)	+	+	+	+	+	+	+	+	+
	Alkalol	20% (v/v)	+	+	+	+	+	+	+	+	+

Low Positive Sample		Concentration	Lot 20060001			Lot 20060002			Lot 20060003		
Nasal corti-costeroids	Beclomethasone	20% (v/v)	+	+	+	+	+	+	+	+	+
	Hexadecadrol	20% (v/v)	+	+	+	+	+	+	+	+	+
	Flunisolide	20% (v/v)	+	+	+	+	+	+	+	+	+
	Triamcinolone	20% (v/v)	+	+	+	+	+	+	+	+	+
	Budesonide	20% (v/v)	+	+	+	+	+	+	+	+	+
	Mometasone	20% (v/v)	+	+	+	+	+	+	+	+	+
	Fluticasone	20% (v/v)	+	+	+	+	+	+	+	+	+
	Fluticasone propionate	20% (v/v)	+	+	+	+	+	+	+	+	+

Conclusion: None of the tested substances interfered with the test results.

5. Clinical Studies

5.1 Sensitivity and Specificity

Nasopharyngeal samples of 250 patients were collected in clinical environment and tested with AMP Rapid Test SARS-CoV-2 Ag. Results were read after 15 minutes and compared with RT-PCR as the reference method. Sensitivity, specificity and relative accuracy have been found to be as following:

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

Sensitivity: 97.3% (95% CI: 90.0% - 99.8%)
Specificity: 100.0% (95% CI: 96.6% - 100%)
Relative accuracy: 98.8% (95% CI: 91.8% - 99.9%)

5.2 Precision

A study was conducted at three different hospitals by untrained operators using three different lots of AMP Rapid Test SARS-CoV-2 Ag to demonstrate the within run, between run and between operator precision. Identical sets of samples, containing negative and positive samples were provided to each site.

Lot 20060002	Samples	Site A		Site B		Site C	
		-	+	-	+	-	+
Negative	20	20	0	20	0	20	0
Positive	20	0	20	0	20	0	20

Conclusion: The study confirmed a high precision of AMP Rapid Test SARS-CoV-2 Ag.

6. Stability Studies

6.1 Accelerated Stability

To evaluate the product shelf life of AMP Rapid Test SARS-CoV-2 Ag an accelerated stability test was performed. Tests from three different lots have been placed in incubators with a calibrated temperature of 55°C. Relative humidity (RH) inside the incubators was controlled to be 60%.

Tests in 3 replicates have been performed for each lot using negative, low positive and high positive samples after 0, 7, 14, 21, 28, 35, 42, 56, 77 and 84 days for the tests kept at 45°C and after 0, 7, 14, 21, 28, 35 and 42 days for the tests kept at 55°C.

Results were as following:

45°C Day	Sample	Lot no. 20060001			Lot no. 20060002			Lot no. 20060003		
0	Negative	-	-	-	-	-	-	-	-	-
	Low Positive	+	+	+	+	+	+	+	+	+
	High Positive	+	+	+	+	+	+	+	+	+
7	Negative	-	-	-	-	-	-	-	-	-
	Low Positive	+	+	+	+	+	+	+	+	+
	High Positive	+	+	+	+	+	+	+	+	+
14	Negative	-	-	-	-	-	-	-	-	-
	Low Positive	+	+	+	+	+	+	+	+	+
	High Positive	+	+	+	+	+	+	+	+	+
21	Negative	-	-	-	-	-	-	-	-	-
	Low Positive	+	+	+	+	+	+	+	+	+
	High Positive	+	+	+	+	+	+	+	+	+
28	Negative	-	-	-	-	-	-	-	-	-
	Low Positive	+	+	+	+	+	+	+	+	+
	High Positive	+	+	+	+	+	+	+	+	+
35	Negative	-	-	-	-	-	-	-	-	-
	Low Positive	+	+	+	+	+	+	+	+	+
	High Positive	+	+	+	+	+	+	+	+	+
42	Negative	-	-	-	-	-	-	-	-	-
	Low Positive	+	+	+	+	+	+	+	+	+
	High Positive	+	+	+	+	+	+	+	+	+
56	Negative	-	-	-	-	-	-	-	-	-
	Low Positive	+	+	+	+	+	+	+	+	+
	High Positive	+	+	+	+	+	+	+	+	+
77	Negative	-	-	-	-	-	-	-	-	-
	Low Positive	+	+	+	+	+	+	+	+	+
	High Positive	+	+	+	+	+	+	+	+	+

45°C Day	Sample	Lot no. 20060001			Lot no. 20060002			Lot no. 20060003		
84	Negative	-	-	-	-	-	-	-	-	-
	Low Positive	+	+	+	+	+	+	+	+	+
	High Positive	+	+	+	+	+	+	+	+	+

55°C Day	Sample	Lot no. 20060001			Lot no. 20060002			Lot no. 20060003		
0	Negative	-	-	-	-	-	-	-	-	-
	Low Positive	+	+	+	+	+	+	+	+	+
	High Positive	+	+	+	+	+	+	+	+	+
7	Negative	-	-	-	-	-	-	-	-	-
	Low Positive	+	+	+	+	+	+	+	+	+
	High Positive	+	+	+	+	+	+	+	+	+
14	Negative	-	-	-	-	-	-	-	-	-
	Low Positive	+	+	+	+	+	+	+	+	+
	High Positive	+	+	+	+	+	+	+	+	+
21	Negative	-	-	-	-	-	-	-	-	-
	Low Positive	+	+	+	+	+	+	+	+	+
	High Positive	+	+	+	+	+	+	+	+	+
28	Negative	-	-	-	-	-	-	-	-	-
	Low Positive	+	+	+	+	+	+	+	+	+
	High Positive	+	+	+	+	+	+	+	+	+
35	Negative	-	-	-	-	-	-	-	-	-
	Low Positive	+	+	+	+	+	+	+	+	+
	High Positive	+	+	+	+	+	+	+	+	+
42	Negative	-	-	-	-	-	-	-	-	-
	Low Positive	+	+	+	+	+	+	+	+	+
	High Positive	+	+	+	+	+	+	+	+	+

Conclusion: AMP Rapid Test SARS-CoV-2 Ag is stable for 84 days at 45°C and 42 days at 55°C. Plotting these stability data on an Arrhenius Plot confirms that the shelf life of AMP Rapid Test is at least 24 months from the date of production.

6.2 Real Time Stability

Real Time Stability studies are ongoing with 2 batches of 3 different lots. One batch is stored at a temperature between 2 - 8°C and the other one at 30 ± 3°C.

Tests in 3 replicates are performed for each lot negative and SARS-CoV-2 positive samples after 0, 3, 6, 9, 12, 15, 18, 21, 24 and 27 months for the tests kept at 2 - 8°C and after 0, 3, 6, 9, 12, 15, 18, 21, 24 and 27 months for the tests kept at 30 ± 3°C as well.

Results were as following:

2 - 8°C Month	Sample	Lot no. 20060001			Lot no. 20060002			Lot no. 20060003		
0	Negative	-	-	-	-	-	-	-	-	-
	Low Positive	+	+	+	+	+	+	+	+	+
	High Positive	+	+	+	+	+	+	+	+	+
3	Negative	-	-	-	-	-	-	-	-	-
	Low Positive	+	+	+	+	+	+	+	+	+
	High Positive	+	+	+	+	+	+	+	+	+
6	Negative									
	Low Positive									
	High Positive									
9	Negative									
	Low Positive									
	High Positive									
12	Negative									
	Low Positive									
	High Positive									
15	Negative									
	Low Positive									
	High Positive									
18	Negative									
	Low Positive									
	High Positive									
21	Negative									
	Low Positive									
	High Positive									
24	Negative									
	Low Positive									
	High Positive									
27	Negative									
	Low Positive									
	High Positive									

30 ± 3°C Month	Sample	Lot no. 20060001			Lot no. 20060002			Lot no. 20060003		
0	Negative	-	-	-	-	-	-	-	-	-
	Low Positive	+	+	+	+	+	+	+	+	+
	High Positive	+	+	+	+	+	+	+	+	+
3	Negative	-	-	-	-	-	-	-	-	-
	Low Positive	+	+	+	+	+	+	+	+	+
	High Positive	+	+	+	+	+	+	+	+	+
6	Negative									
	Low Positive									
	High Positive									
9	Negative									
	Low Positive									
	High Positive									
12	Negative									
	Low Positive									
	High Positive									
15	Negative									
	Low Positive									
	High Positive									
18	Negative									
	Low Positive									
	High Positive									
21	Negative									
	Low Positive									
	High Positive									
24	Negative									
	Low Positive									
	High Positive									
27	Negative									
	Low Positive									
	High Positive									

Conclusion: AMP Rapid Test SARS-CoV-2 IgG/IAg is stable for XX months at 2 - 30°C.

6.3 Transport Stability

Transport stability studies have been started and are actually ongoing.

6.3.1 Transport stability – Temperature study

Temperature conditions during transport have been simulated by treating tests from 3 different lots according to the following two different protocols:

1) three consecutive cycles of freezing at -20°C ± 10°C and thawing at 15°C to 30°C
2) storage in an oven at 55°C for 2 days

After this treatment the tests are kept at 25°C for the remaining period of the study.

3 x FT / 25°C	Sample	Lot no. 20060001			Lot no. 20060002			Lot no. 20060003		
Day/Month										
0 days	Negative	-	-	-	-	-	-	-	-	-
	Low Positive	+	+	+	+	+	+	+	+	+
	High Positive	+	+	+	+	+	+	+	+	+
7 days	Negative	-	-	-	-	-	-	-	-	-
	Low Positive	+	+	+	+	+	+	+	+	+
	High Positive	+	+	+	+	+	+	+	+	+
28 days	Negative	-	-	-	-	-	-	-	-	-
	Low Positive	+	+	+	+	+	+	+	+	+
	High Positive	+	+	+	+	+	+	+	+	+
56 days	Negative	-	-	-	-	-	-	-	-	-
	Low Positive	+	+	+	+	+	+	+	+	+
	High Positive	+	+	+	+	+	+	+	+	+
6 months	Negative									
	Low Positive									
	High Positive									
9 months	Negative									
	Low Positive									
	High Positive									
12 months	Negative									
	Low Positive									
	High Positive									
15 months	Negative									
	Low Positive									
	High Positive									
18 months	Negative									
	Low Positive									
	High Positive									

3 x FT / 25°C Day/Month	Sample	Lot no. 20060001			Lot no. 20060002			Lot no. 20060003		
21 months	Negative									
	Low Positive									
	High Positive									
24 months	Negative									
	Low Positive									
	High Positive									
27 months	Negative									
	Low Positive									
	High Positive									

2 d. 55°C / 25°C Day/Month	Sample	Lot no. 20060001			Lot no. 20060002			Lot no. 20060003		
0 days	Negative	-	-	-	-	-	-	-	-	-
	Low Positive	+	+	+	+	+	+	+	+	+
	High Positive	+	+	+	+	+	+	+	+	+
7 days	Negative	-	-	-	-	-	-	-	-	-
	Low Positive	+	+	+	+	+	+	+	+	+
	High Positive	+	+	+	+	+	+	+	+	+
28 days	Negative	-	-	-	-	-	-	-	-	-
	Low Positive	+	+	+	+	+	+	+	+	+
	High Positive	+	+	+	+	+	+	+	+	+
56 days	Negative	-	-	-	-	-	-	-	-	-
	Low Positive	+	+	+	+	+	+	+	+	+
	High Positive	+	+	+	+	+	+	+	+	+
6 months	Negative									
	Low Positive									
	High Positive									
9 months	Negative									
	Low Positive									
	High Positive									
12 months	Negative									
	Low Positive									
	High Positive									
15 months	Negative									
	Low Positive									
	High Positive									

2 d. 55°C / 25°C Day/Month	Sample	Lot no. 20060001			Lot no. 20060002			Lot no. 20060003		
18 months	Negative									
	Low Positive									
	High Positive									
21 months	Negative									
	Low Positive									
	High Positive									
24 months	Negative									
	Low Positive									
	High Positive									
27 months	Negative									
	Low Positive									
	High Positive									