AMP Rapid Test SARS-CoV-2 Ag Cassette

Technical Documentation

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1. Product Description

1.1 Order Information

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

Part No.	Product Denomination	Sample Type	Contents
RT2951	AMP Rapid Test SARS-CoV-2 Ag	NP, OP or AN swab	10 Tests
RT2952	AMP Rapid Test SARS-CoV-2 Ag	NP, OP or AN swab	25 Tests
RT2952-C	AMP Rapid Test SARS-CoV-2 Ag w. controls	NP, OP or AN swab	25 Tests plus control swabs
RT2952-S	AMP Rapid Test SARS-CoV-2 Ag	NP, OP or AN swab	25 Tests

NP = nasopharyneal OP = oropharyngeal AN = anterior nasal

1.2 Kit Composition

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

	RT2951	RT2952	RT2952-C	RT2952-S
➢ 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, which also contains dessicant to ensure dry storage of the test cassette	10	25	25	25
➢ Respective number of sterile swabs, each separately packed	10	25	25	25
➢ Respective number of extraction tubes packed in a plastic zip-lock bag together with respective number of dropper tips	---	25	25	---
➢ Respective number of pre-filled buffer tubes	10	---	---	25

➢ Control swabs (1 positive, 1 negative)	---	---	1 / 1	---
➢ Respective number of pre-filled buffer tubes	---	2	2	---
➢ Tube holder	1	1	1	1
➢ Instructions for Use	1	1	1	1
➢ Kit seal	1	1	1	1

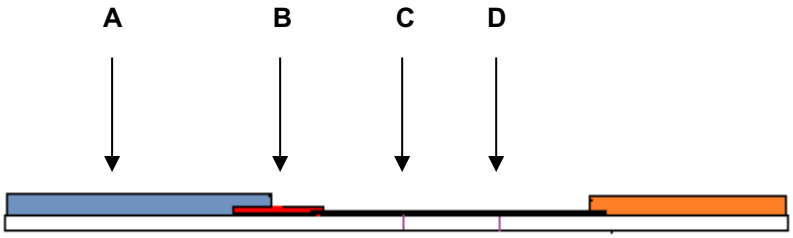
2. Test Description

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 pharyngeal or nasal 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-mouse IgG to detect nucleocapsid protein antigen extracted from pharyngeal or nasal 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 in 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

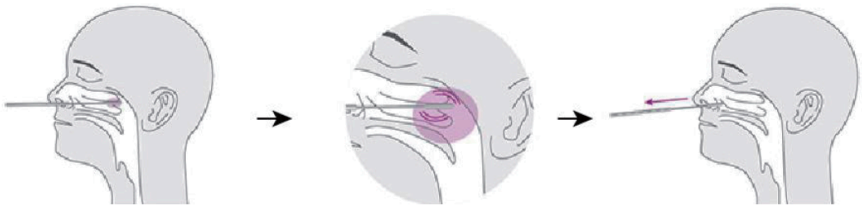
2.3 Test Procedure

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:

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.



Oropharyngeal swab:

1. Carefully insert the swab into the rear area of the throat.
2. Dab both tonsils and the back of the pharynx.
3. Withdraw the swab carefully and avoid touching tongue, teeth or guims with the swab.

Anterior nasal swab:

1. Carefully insert the swab about 2 cm into one nostril.
2. Rotate the swab 5 to 10 times against the nasal wall.
3. 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 tempoerarure (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.

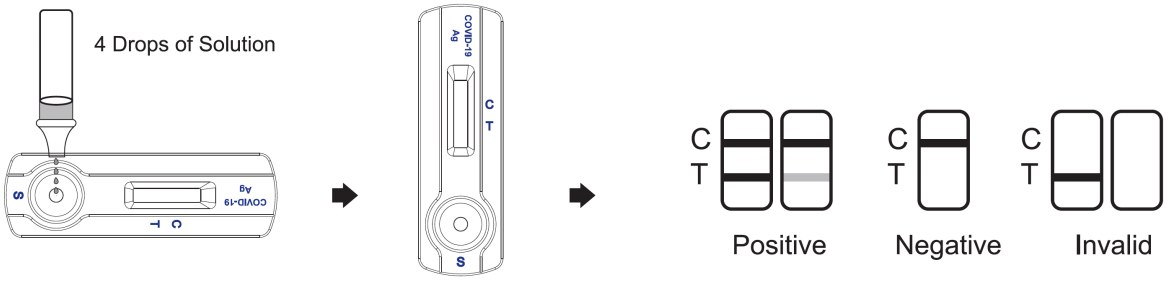
2.3.2 Sample Preparation

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 naso-, oropharyngeal or 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.

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 Detection Limit (LOD - Analytical Sensitivity)

To determine the limit of detection (LOD) sample material with a confirmed concentration of 4.6 x 10^5 $TCID_{50}$/mL was used as the stock solution. The viral sample was inactivated by heating at 65°C for 30 minutes.

The material was spiked into a volume of pooled human nasal matrix obtained from healthy donors confirmed to be SARS-CoV-2 negative.

As an initial range finding study a series of 10-fold dilutions was performed and tested in triplicate with tests from three different lots. For each dilution step 50 µL of sample was added to a swab and then tested following the standard test procedure.

Dilution step	Concentration	Lot No. 20060001			Lot No. 20060002			Lot No. 20060003		
1	4.6 x 10^5 $TCID_{50}$/mL	+	+	+	+	+	+	+	+	+
1/10	4.6 x 10^4 $TCID_{50}$/mL	+	+	+	+	+	+	+	+	+
1/100	4.6 x 10^3 $TCID_{50}$/mL	+	+	+	+	+	+	+	+	+
1/1000	4.6 x 10^2 TCID50/mL	+	+	+	+	+	+	+	+	+
1/10000	4.6 x 10 TCID50/mL	-	-	-	-	-	-	-	-	-

The last dilution giving positive results for all tests was used for further investigation of the detection limit.

Starting with this concentration further dilutions in 2-fold steps were prepared. Each dilution was tested in 20 replicates with tests from three different lots. The limit of detection is defined as the concentration at which a positive agreement is achieved for ≥ 90 %.

Dilution step	Concentration	Lot No. 20060001	Lot No. 20060002	Lot No. 20060003	Positive Results	Positive Agreement
1	4.6 x 10^2 $TCID_{50}$/mL	20/20	20/20	20/20	60/60	100%
1/2	2.3 x 10^2 $TCID_{50}$/mL	20/20	20/20	20/20	60/60	100%
1/4	1.15 x 10^2 $TCID_{50}$/mL	20/20	20/20	20/20	60/60	100%
1/8	5.75 x 10 TCID50/mL	6/20	3/20	5/20	14/60	23.3%
1/16	2.88 x 10 TCID50/mL	0/20	0/20	0/20	0/60	0.0%

Conclusion: The Limit of Detection (LOD) has been determined to be **1.15 x 10^2 $TCID_{50}$/mL**.

4.2 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	-	-	-	-	-	-	-	-	-

Pathogen	Concentration	Lot No. 20060001			Lot No. 20060002			Lot No. 20060003		
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: There is no cross-reaction with the pathogens at the concentrations tested.

4.3 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	-	-	-	+	+	+	+	+	+

Test	Negative			Low Positive			High Positive		
	L1	L2	L3	L1	L2	L3	L1	L2	L3
7	-	-	-	+	+	+	+	+	+
8	-	-	-	+	+	+	+	+	+
9	-	-	-	+	+	+	+	+	+
10	-	-	-	+	+	+	+	+	+

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

4.4 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	+	+	+	+	+	+	+	+	+

Low Positive Sample		Concentration	Lot 20060001			Lot 20060002			Lot 20060003		
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)	+	+	+	+	+	+	+	+	+

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%)
Overall accuracy:	98.8%	(95% CI: 91.8% - 99.9%)
Positive Predictive Value:	100.0%	(95% CI: 96.8% - 100%)
Negative Predictive Value:	97.9%	(95% CI: 91.7% - 99.9%)

Line data:

Days	days from symptom onset
AG	test result of AMP Rapid Test SARS-CoV-2 Ag
ORF	PCR result (ct - open reading frame)
N	PCR result (ct - n gene reading)

No	Age	Sex	Days	AG	PCR	ORF	N
1	46	F	2	-	-	n.a.	n.a.
2	49	M	1	+	+	24.45	21.91
3	33	M	3	+	+	29.40	27.01
4	39	M	4	+	+	29.77	27.57
5	61	F	1	+	+	26.45	24.13
6	34	M	2	+	+	27.75	26.00
7	74	F	2	+	+	29.34	27.16
8	65	F	4	-	-	n.a.	n.a.
9	28	M	5	-	-	n.a.	n.a.
10	52	M	6	-	-	n.a.	n.a.
11	35	F	1	+	+	24.36	21.76
12	51	M	7	-	-	n.a.	n.a.
13	77	M	7	+	+	27.88	25.72
14	49	F	3	+	+	26.98	24.79
15	40	F	2	+	+	29.02	25.56
16	45	F	1	+	+	23.27	20.81
17	74	F	5	+	+	26.64	23.38
18	46	M	2	+	+	29.64	27.73
19	51	F	4	+	+	25.81	23.16
20	72	F	4	-	-	n.a.	n.a.
21	72	F	3	+	+	29.88	26.58
22	63	F	2	+	+	27.88	24.54
23	55	F	3	-	-	n.a.	n.a.
24	45	F	3	+	+	29.84	29.82
25	47	F	3	+	+	28.03	25.54
26	15	F	5	+	+	29.77	26.92
27	55	F	3	+	+	29.84	28.20
28	57	F	2	+	+	23.56	21.93
29	71	M	3	-	-	n.a.	n.a.
30	49	M	1	+	+	26.17	24.35
31	41	F	2	-	-	n.a.	n.a.
32	63	M	2	-	-	n.a.	n.a.
33	51	M	3	+	+	29.93	27.60
34	57	M	5	-	-	n.a.	n.a.
35	78	M	4	+	+	29.92	30.33
36	63	F	2	+	+	28.34	26.21
37	25	M	2	-	-	n.a.	n.a.
38	34	M	1	+	+	26.48	24.59
39	58	M	4	-	-	n.a.	n.a.
40	60	M	2	+	+	22.58	20.90
41	2	F	2	-	-	n.a.	n.a.
42	33	F	4	-	-	n.a.	n.a.
43	63	M	3	-	-	n.a.	n.a.
44	32	F	1	+	+	25.75	23.77
45	35	M	3	-	-	n.a.	n.a.

No	Age	Sex	Days	AG	PCR	ORF	N
126	55	M	5	+	+	31.35	28.53
127	29	F	4	-	-	n.a.	n.a.
128	54	F	7	+	+	32.37	30.19
129	29	F	4	-	-	n.a.	n.a.
130	55	M	5	-	+	32.11	32.05
131	45	M	4	+	+	30.60	27.93
132	52	F	5	+	+	29.60	26.87
133	52	F	4	+	+	29.79	27.64
134	41	M	4	-	-	n.a.	n.a.
135	35	M	5	+	+	31.68	28.55
136	44	F	5	-	-	n.a.	n.a.
137	27	M	3	+	+	29.19	27.77
138	28	F	5	+	+	31.59	29.48
139	22	F	4	-	-	n.a.	n.a.
140	48	F	5	+	+	31.31	28.85
141	36	F	4	-	-	n.a.	n.a.
142	26	F	4	+	+	30.85	28.94
143	33	M	5	-	-	n.a.	n.a.
144	48	F	4	-	-	n.a.	n.a.
145	69	M	5	-	-	n.a.	n.a.
146	45	M	4	-	-	n.a.	n.a.
147	54	F	5	-	-	n.a.	n.a.
148	23	M	4	-	-	n.a.	n.a.
149	45	F	5	-	-	n.a.	n.a.
150	27	M	5	-	-	n.a.	n.a.
151	40	F	5	-	-	n.a.	n.a.
152	21	M	3	-	-	n.a.	n.a.
153	56	M	4	+	+	27.73	26.89
154	40	F	3	-	-	n.a.	n.a.
155	41	M	5	-	-	n.a.	n.a.
156	44	F	4	+	+	31.35	30.68
157	46	F	3	+	+	29.42	29.12
158	24	F	4	-	-	n.a.	n.a.
159	38	F	3	-	-	n.a.	n.a.
160	19	M	3	-	-	n.a.	n.a.
161	50	F	4	+	+	31.98	30.28
162	51	M	4	-	-	n.a.	n.a.
163	53	M	3	-	-	n.a.	n.a.
164	20	F	4	-	-	n.a.	n.a.
165	46	M	7	+	+	32.25	31.19
166	56	F	5	-	-	n.a.	n.a.
167	27	F	4	-	-	n.a.	n.a.
168	43	F	5	+	+	28.16	26.94
169	38	F	5	+	+	29.64	28.75
170	3	M	4	-	-	n.a.	n.a.

No	Age	Sex	Days	AG	PCR	ORF	N
46	44	F	2	-	-	n.a.	n.a.
47	27	M	2	+	+	28.53	26.10
48	61	M	4	-	-	n.a.	n.a.
49	42	F	3	-	-	n.a.	n.a.
50	61	F	5	+	+	27.89	24.63
51	54	F	3	-	+	34.75	33.03
52	39	M	6	+	+	29.92	28.23
53	48	M	2	+	+	28.79	27.09
54	51	F	5	+	+	26.72	24.97
55	67	M	3	-	-	n.a.	n.a.
56	48	M	5	-	-	n.a.	n.a.
57	51	M	3	+	+	28.97	26.57
58	28	F	4	+	+	27.35	26.12
59	73	F	3	-	-	n.a.	n.a.
60	42	M	4	-	-	n.a.	n.a.
61	53	F	3	-	-	n.a.	n.a.
62	61	M	2	+	+	26.34	23.52
63	64	M	5	+	+	28.64	27.96
64	19	M	7	-	-	n.a.	n.a.
65	55	F	4	+	+	27.36	26.85
66	43	M	3	+	+	30.29	28.91
67	39	F	5	-	-	n.a.	n.a.
68	67	F	4	+	+	28.48	26.93
69	48	M	3	-	-	n.a.	n.a.
70	25	M	4	-	-	n.a.	n.a.
71	51	M	10	+	+	31.79	30.54
72	46	F	7	+	+	31.72	29.69
73	53	F	2	+	+	27.87	25.76
74	47	F	2	+	+	28.31	26.48
75	48	M	4	+	+	31.51	29.48
76	29	F	3	+	+	30.79	28.42
77	57	M	5	+	+	30.19	27.90
78	56	M	4	+	+	30.96	28.17
79	66	M	6	-	+	32.45	32.83
80	47	F	7	+	+	31.55	29.15
81	57	F	9	+	+	31.33	30.44
82	62	M	7	-	-	n.a.	n.a.
83	31	F	5	-	-	n.a.	n.a.
84	40	M	5	-	-	n.a.	n.a.
85	28	F	8	+	+	31.98	30.87
86	63	F	7	-	-	n.a.	n.a.
87	81	F	3	+	+	30.52	27.77
88	45	F	4	-	-	n.a.	n.a.
89	71	M	7	+	+	31.02	30.84
90	19	F	5	-	-	n.a.	n.a.
91	18	F	8	-	-	n.a.	n.a.
92	42	F	5	+	+	28.87	27.42.
93	15	M	6	-	-	n.a.	n.a.
94	25	M	4	-	-	n.a.	n.a.
95	52	M	7	+	+	29.24	27.58.
96	39	F	7	-	-	n.a.	n.a.

No	Age	Sex	Days	AG	PCR	ORF	N
171	55	M	5	-	-	n.a.	n.a.
172	26	M	6	-	-	n.a.	n.a.
173	59	M	6	-	-	n.a.	n.a.
174	43	F	5	-	-	n.a.	n.a.
175	35	F	3	-	-	n.a.	n.a.
176	44	F	4	-	-	n.a.	n.a.
177	48	M	7	+	+	31.41	28.66
178	42	M	5	-	-	n.a.	n.a.
179	27	M	4	-	-	n.a.	n.a.
180	39	M	7	-	-	n.a.	n.a.
181	47	F	5	-	-	n.a.	n.a.
182	57	M	4	+	+	29.36	26.20
183	42	M	4	-	-	n.a.	n.a.
184	57	M	5	-	-	n.a.	n.a.
185	43	M	5	+	+	31.74	29.33
186	41	F	6	-	-	n.a.	n.a.
187	35	M	4	-	-	n.a.	n.a.
188	42	F	5	-	-	n.a.	n.a.
189	62	F	4	+	+	29.76	28.34
190	32	F	4	-	-	n.a.	n.a.
191	49	F	4	-	-	n.a.	n.a.
192	35	F	5	+	+	31.15	30.09
193	42	F	4	-	-	n.a.	n.a.
194	36	M	6	-	-	n.a.	n.a.
195	37	F	3	-	-	n.a.	n.a.
196	64	M	5	+	+	30.49	29.34
197	31	F	4	-	-	n.a.	n.a.
198	61	F	5	-	-	n.a.	n.a.
199	16	M	4	-	-	n.a.	n.a.
200	28	F	3	-	-	n.a.	n.a.
201	32	M	5	-	-	n.a.	n.a.
202	61	M	7	-	-	n.a.	n.a.
203	27	M	4	-	-	n.a.	n.a.
204	52	M	3	-	-	n.a.	n.a.
205	48	F	7	-	-	n.a.	n.a.
206	21	M	4	-	-	n.a.	n.a.
207	43	F	4	-	-	n.a.	n.a.
208	26	F	3	-	-	n.a.	n.a.
209	58	M	4	-	-	n.a.	n.a.
210	42	M	5	+	+	30.80	33.26
211	62	M	5	-	-	n.a.	n.a.
212	23	M	3	-	-	n.a.	n.a.
213	61	M	5	-	-	n.a.	n.a.
214	27	F	4	-	-	n.a.	n.a.
215	29	M	3	-	-	n.a.	n.a.
216	35	F	4	-	-	n.a.	n.a.
217	85	M	3	-	-	n.a.	n.a.
218	19	M	5	-	-	n.a.	n.a.
219	61	M	3	+	+	29.74	32.03
220	32	M	3	-	-	n.a.	n.a.
221	36	M	4	-	-	n.a.	n.a.

No	Age	Sex	Days	AG	PCR	ORF	N
97	76	M	7	+	+	30.98	29.71
98	29	F	6	-	-	n.a.	n.a.
99	43	F	5	-	-	n.a.	n.a.
100	81	F	4	+	+	31.75	27.01
101	48	F	6	+	+	31.00	28.49
102	48	M	6	-	-	n.a.	n.a.
103	80	M	5	+	+	28.43	26.82
104	46	M	7	+	+	31.13	29.96
105	26	M	5	-	-	n.a.	n.a.
106	34	M	4	-	-	n.a.	n.a.
107	16	M	6	-	-	n.a.	n.a.
108	34	F	5	-	-	n.a.	n.a.
109	38	F	4	+	+	30.52	29.43
110	22	M	6	-	-	n.a.	n.a.
111	27	F	5	-	-	n.a.	n.a.
112	33	F	5	-	-	n.a.	n.a.
113	2	M	5	+	+	31.11	30.64
114	41	F	6	-	-	n.a.	n.a.
115	50	F	4	+	+	29.79	27.64
116	66	M	3	+	+	28.13	25.29
117	43	M	5	+	+	30.58	28.56
118	42	M	3	-	-	n.a.	n.a.
119	41	M	5	+	+	31.54	29.27
120	57	M	4	+	+	29.45	27.42
121	53	F	6	+	+	30.66	28.14
122	57	M	4	+	+	30.19	27.65
123	50	F	7	+	+	31.06	29.14
124	56	F	5	+	+	29.13	29.18
125	31	F	4	-	-	n.a.	n.a.

No	Age	Sex	Days	AG	PCR	ORF	N
222	64	M	4	-	-	n.a.	n.a.
223	28	M	3	-	-	n.a.	n.a.
224	70	M	3	-	-	n.a.	n.a.
225	43	M	6	-	-	n.a.	n.a.
226	34	F	4	-	-	n.a.	n.a.
227	45	F	6	-	-	n.a.	n.a.
228	62	M	5	+	+	25.49	24.32
229	29	F	5	+	+	27.89	26.46
230	37	F	4	-	-	n.a.	n.a.
231	42	F	7	-	-	n.a.	n.a.
232	48	M	5	+	+	26.37	26.03
233	57	M	5	+	+	27.86	26.51
234	36	F	3	+	+	31.50	30.85
235	42	M	4	-	-	n.a.	n.a.
236	62	M	6	+	+	28.19	27.73
237	78	F	5	-	-	n.a.	n.a.
238	68	F	5	+	+	30.48	29.42
239	51	M	6	+	+	32.68	3129
240	43	M	4	-	-	n.a.	n.a.
241	49	M	7	-	-	n.a.	n.a.
242	57	F	4	+	+	29.47	28.08
243	51	M	5	-	-	n.a.	n.a.
244	36	F	5	+	+	27.28	26.14
245	47	F	6	-	-	n.a.	n.a.
246	55	F	5	+	+	29.38	27.96
247	63	M	7	+	+	28.56	27.94
248	41	M	6	-	-	n.a.	n.a.
249	35	F	4	-	-	n.a.	n.a.
250	58	F	3	-	-	n.a.	n.a.

5.2 Correlation Study

A study was conducted with 45 samples from patients confirmed SARS-CoV-2 positive by RT-PCR to evaluate the correlation of test results for nasopharyngel, oropharyngeal and anterior nasal swab samples. All three types of samples have been collected from the patients and were compared with the results of RT-PCR.

No	PCR	ct	NP	OP	AN
1	+	22.5	+	+	+
2	+	27.4	+	+	+
3	+	26.7	+	+	+
4	+	25.5	+	+	+
5	+	26.8	+	+	+
6	+	27.3	+	+	+
7	+	24.4	+	+	+
8	+	26.3	+	+	+
9	+	23.3	+	+	+
10	+	26.6	+	+	+
11	+	25.8	+	+	+
12	+	27.9	+	+	+

No	PCR	ct	NP	OP	AN
24	+	30.6	+	-	-
25	+	27.2	+	+	+
26	+	28.3	+	+	+
27	+	32.4	-	-	-
28	+	27.2	+	+	+
29	+	25.3	+	+	+
30	+	24.9	+	+	+
31	+	26.6	+	+	+
32	+	27.3	+	+	+
33	+	24.9	+	+	+
34	+	25.6	+	+	+
35	+	23.9	+	+	+

No	PCR	ct	NP	OP	AN
13	+	26.8	+	+	+
14	+	26.2	+	+	+
15	+	25.4	+	+	+
16	+	29.5	+	+	-
17	+	27.7	+	+	+
18	+	23.2	+	+	+
19	+	25.6	+	+	+
20	+	26.3	+	+	+
21	+	25.6	+	+	+
22	+	27.6	+	+	+
23	+	25.3	+	+	+

No	PCR	ct	NP	OP	AN
36	+	26.2	+	+	+
37	+	27.6	+	+	+
38	+	24.4	+	+	+
39	+	26.8	+	+	+
40	+	27.5	+	+	+
41	+	25.6	+	+	+
42	+	26.6	+	+	+
43	+	24.6	+	+	+
44	+	26.8	+	+	+
45	+	25.9	+	+	+

Conclusion: The study confirmed that for samples with a ct of up to 28 the test results of samples collected with nasopharyngeal, oropharyngel and anterior nasal swabs are perfectly correlating. For physiological reasons the sensitivity of the test is decreasing for samples with a lower viral load, if collected with oropharyngeal or anterior nasal swab.

5.3 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	+	+	+	+	+	+	+	+	+
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	+	+	+	+	+	+	+	+	+

55°C Day	Sample	Lot no. 20060001			Lot no. 20060002			Lot no. 20060003		
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	+	+	+	+	+	+	+	+	+

2 - 8°C Month	Sample	Lot no. 20060001			Lot no. 20060002			Lot no. 20060003		
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	+	+	+	+	+	+	+	+	+

30 ± 3°C Month	Sample	Lot no. 20060001			Lot no. 20060002			Lot no. 20060003		
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: The Real Time stability test is ongoing. Data available after 6 months confirm the stability of the test.

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 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									
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									

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									
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									

Conclusion: The Transport Stability test is ongoing. Data available after 6 months confirm the stability of the test.