10. Performance characteristics

10.1. Sensitivity

The performance of the SARS-CoV-2 Antibody Test was examined using the results of other serological procedures. Samples were evaluated as positive if they were tested positive in addition to an already existing positive PCR result in at least one serological procedure.

Two serological test kits were used as a reference:

1. Euroimmun, anti-SARS-CoV-2 -IgG ELISA (anti-S1 proof, Euroimmun, Lübeck, Germany)
2. Abbott, SARS-CoV-2 IgG immunoassay (anti-N proof, Abbott, Illinois, USA)

The TAmiRNA Antibody Test identified 56 of 57 samples that were positive in one of the two serological methods (Abbott, Euroimmun) (Table 1). Using this procedure, the test shows a **sensitivity of 98.25%** for the detection of antibodies against SARS-CoV-2 and a congruence of 98.25%.

Table 1: Comparison of TAmiRNA SARS-CoV-2 Antibody Test and ELISA in PCR positive samples.

		Standard	
		Positiv	Negativ
TAmiRNA	Positiv	56	0
	Negativ	1	0

When testing with dilution series, the SARS-CoV-2 Antibody Test showed a detection limit of 1:100. The limit of the Euroimmun ELISA is 1:1000 (Figure 2)

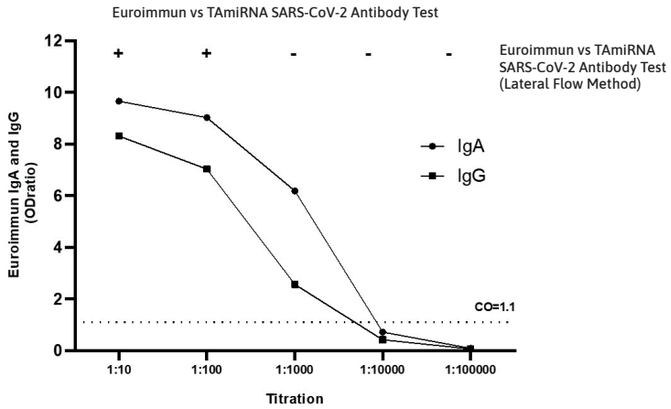


Figure 2: Sensitivity analysis using dilution series

10.2. Specificity

To determine the specificity, 312 blood samples from blood donors from the previous year, which usually should be negative, were tested. All 312 blood donors were recognized negative with the SARS-CoV-2 Antibody Test, resulting in a specificity of 100%.

11. Time-dependent test sensitivity

141 samples from persons with PCR confirmed SARS-CoV-2 infections were used to determine the diagnostic sensitivity. The period between PCR testing and blood sampling was also considered.

Of the 141 PCR confirmed blood samples, 132 were recognized as positive with the TAmiRNA Antibody Test. The sensitivity for the detection of an existing or previous SARS-CoV-2 infection is therefore 93,6%. After the exclusion of 19 blood samples in which the blood sample were taken 7 days or less after positive PCR, the sensitivity increases to 95%. The sensitivity is highest from the 22nd day after the diagnostic PCR (Table 2)

Table 2: Sensitivity of TAmiRNA SARS-CoV-2 Antibody Tests (n=141)

Tage post-PCR (n)	positiv	negativ	total	Sensitivität
0-7	15	4	19	78.9%
8-14	22	3	25	88%
15-21	43	2	45	95.6%
22-28	10	0	10	100%
>28	42	0	42	100%
	132	9	141	93.6%

12. Cross reactivity

No cross reaction with the following targets: Parainfluenza virus antibody, Influenza A antibody, Influenza B antibody, Chlamydia pneumonia antibody, Mycoplasma pneumoniae antibody, Adenovirus antibody, Respiratory syncytial virus antibody, Hepatitis B surface antibody, Hepatitis C virus antibody, Treponema pallidum antibody, HIV antibody, EB virus antibody, Measles virus antibody, Cytomegalovirus antibody, Enterovirus type 71 antibody, Mumps antibody, Varicella-zoster virus positive sample.

13. Procedural notes

- Read this manual carefully before using this test.
- The interpretation of the test results must be carried out in strict accordance with this manual.
- Testing has to be done in a laboratory with proper testing conditions. All samples and materials in the testing process shall be handled according to the operation specifications of infectious diseases laboratories.
- Protect the product from moisture.
- All reagents and samples should reach room temperature (15-30 °C) before use.
- Do not use lipid samples.
- Do not use hemolytic samples.
- Do not use turbid contaminated samples.
- Do not dilute the sample for testing.
- Do not store this kit in frozen condition

14. Explanation of the symbols used

IVD	*In-vitro*-diagnostic		Manufacturer		Do not use if package is damaged
REF	Catalogue number		Do not re-use		Consult instruction for use
LOT	Batch code		Use by	2°C 30°C	Store at 2°C-30°C

TAmiRNA GmbH, Leberstrasse 20, 1110 Vienna, Austria

15. References

1. World Health Organization (WHO). WHO Statement Regarding Cluster of Pneumonia Cases in Wuhan, China. Beijing: WHO; 9 Jan 2020.
2. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011;81:85-164.
3. Cui J, Li F, Shi ZL. Origin and evolution of pathogeniccoronaviruses. Nat Rev Microbiol 2019; 17:181-192.
4. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. TrendsMicrobiol 2016;24:490- 502

TAmiRNA
SARS-CoV-2 Antibody Test
(Lateral Flow Method)

Instructions For Use

V 1.0 06/2020

TAMIRNA
stability for life.

CE	
IVD	*In-vitro*-diagnostic
2°C 30°C	Store at 2°C–30°C
REF	TAMAK-10 10
REF	TAMAK-50 50
	TAmiRNA GmbH Leberstrasse 20 1110 Vienna, Austria T +43 1 391 33 22 office@tamirna.com www.tamirna.com

1. Intended use

The TAmiRNA SARS-CoV-2 Antibody Test (Lateral Flow Method) is an immunochromatographic assay for rapid, qualitative detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) IgM & IgG antibody in human whole blood, serum or plasma sample. The test is to be used as an aid in the diagnosis of coronavirus infection disease (COVID-19), which is caused by SARS-CoV-2.

The test provides preliminary test results. Negative results do not preclude SARS-CoV-2 infection. Test results cannot be used as the sole basis for treatment or other management decision.

For *in-vitro*-diagnostic use only. For professional use only.

2. Test Principle

This kit is based on the principle of capture immunoassay for determination of SARS-CoV-2 IgG/IgM antibodies in human whole blood, serum and plasma. When the specimen is added into the test device, the specimen is absorbed into the device by capillary action, mixes with the SARS-CoV-2 antigen-dye conjugate and flows across the pre-coated membrane.
When the SARS-CoV-2 antibody level in the specimen is at or above the target cutoff (the detection limit of the test), the antibodies bound to the antigen-dye conjugate are captured by anti-human IgG antibody and anti-human μ chain antibody immobilized in the Test Region (T) of the device, and this produces a colored test band that indicates a positive result. When the SARS-CoV-2 antibody level in the specimen is zero or below the target cutoff, there is no visible colored band in the Test Region (T) of the device. This indicates a negative result.
To serve as a procedure control, a colored line will appear at the Control Region (C), if the test has been performed properly.

3. Reagents and Materials Provided

Reagents and materials provided

TAMAK-10: 10 tests/kit SARS-CoV-2-Antibody Lateral Flow Test
- 10x Sars-CoV-2-Antibody Lateral Flow Test cassettes with disposable pipet (packaged together in an aluminum foil bag)
- 1x Sample Buffer 4mL
- 1x Instruction for use

TAMAK-50: 50 tests/kit SARS-CoV-2-Antibody Lateral Flow Test
- 50x Sars-CoV-2-Antibody Lateral Flow Test cassettes test with disposable pipet (packaged together in an aluminum foil bag)
- 2x Sample Buffer 4mL
- 1x Instruction for use

Material required but not provided
- Specimen collection container
- Centrifuge (for plasma only)
- Timer
- Sterile Lancets (for whole blood only)
- Micropipettes
- Disinfectant for skin disinfection before specimen collection
- Personal protective equipment

4. Warnings and precautions

1. This kit is for *in-vitro*-diagnostic use only. Do not use after expiration date.
2. The test should be carried out only by appropriately trained health care personnel.
3. All blood specimens should be treated as potentially infectious. Take appropriate precautions in the collection, handling, storage and disposal of patient samples and used kit contents, and follow biosafety level 2 or higher guidelines.
4. Do not use test if the aluminum foil bag is damaged.
5. If collecting plasma use a blood collection tube containing suitable anticoagulant (containing EDTA, Heparin or Citrated sodium). **Other anticoagulants have not been validated and may give incorrect result.**
6. Centrifuge whole blood and separate the plasma from red blood cell immediately after collection to avoid hemolysis.
7. Test should be performed within 8 hours after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum or plasma specimens may be stored at 2°C–8°C for up to 3 days prior to testing. Serum or plasma specimens may be stored at -20°C for up to 9 days. **Note: Bring specimens to room temperature before testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly. Severe hemolytic or heat-inactivated specimens are not recommended.**
8. Please ensure that appropriate sample volumes are used for testing. Insufficient or excess sample volume may lead to incorrect results.
9. The used test should be discarded as biohazard waste according to local regulations.

5. Storage conditions and shelf life

Store at 2°C–30°C. Under correct storage and intact packaging, the shelf life is 12 months from manufacturing date.
After opening the aluminum foil bag, the test cassette should be used as soon as possible within 8 hours. The sample buffer should be capped immediately after opening and placed in a cool place.

Please use before expiration date.
Production date: See product label.
Expiration date: See product label.

6. Sample requirements

The test is compatible with human serum, plasma, and venous whole blood samples.

Serum / plasma sample collection: Serum and plasma should be separated immediately after blood collection to avoid hemolysis. The separated serum and plasma should be tested as soon as possible within 8 hours. If serum/plasma samples cannot be used within 8 hours they can be stored at 2°C to 8°C for up to 3 days, or at -20°C for up to 9 days. Make sure to bring reagents and materials to room temperature before use. Avoid multiple freeze-thaw cycles. Hemolytic and heat-inactivated samples are not recommended.

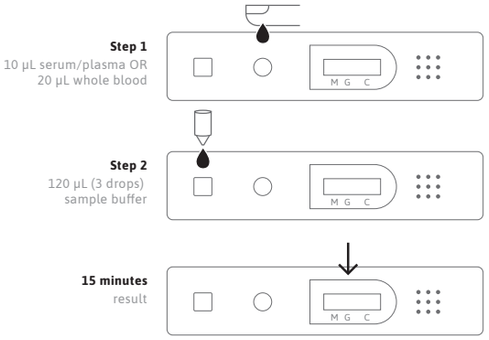
Collection of capillary blood using a lancet: It is recommended to use a safety lancet to make a finger prick. After puncturing the skin, use clean gauze to wipe away the first drop of blood to avoid specimen dilution with interstitial fluid. With the patient's hand pointing downward, firmly grasp the finger towards the base with your thumb placed along the length of the patient's finger. Gently massage along the length of the finger towards the tip, using a light squeeze-and-release motion to allow large droplets of blood to form and encourage continuous blood flow. If using a capillary tube or pipette, allow a large drop of blood to form, position the device horizontally, and lightly touch the drop of blood (avoid touching the skin); allow the blood drop to be drawn into the collection vessel by capillary action, avoiding air bubbles.

7. Test procedures

Please read the instruction manual carefully before testing. The samples to be tested, detection reagents and other materials used for testing need to be equilibrated to room temperature. The test should be performed at room temperature.

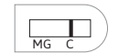
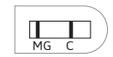
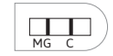
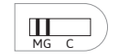
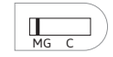
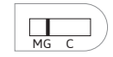
1. Bring the test cassette, sample and sample buffer to room temperature before performing the test. Mix the sample well before testing.
2. Remove the test cassette by opening it along the tear of the aluminum foil bag and lay it flat.
3. Add **10 μL** of serum / plasma OR **20 μL** of whole blood sample to the round sample well (near the membrane) of the test cassette, and then add 120 μL (3 drops) dilution buffer to the square buffer well (far away from the membrane).
4. Results can be read after 15 minutes. Results visible only after 20 minutes or more have no clinical significance.

Figure 1: Testing method



8. Interpretation of the results

Quality Control: The test contains a built-in control. When a line forms in the control region (C), the test has been performed correctly.

Negative: A line appears in the control region (C). No line appears in the test region (G) and (M).	
IgM Positive: Two lines develop, one in the control region (C) and one in the test region (M). Indication of an acute SARS-CoV-2 infection.	
IgM and IgG Positive: Three lines develop, one in the control region (C), one in the test region (G) and one in the test region (M). Indication of an ongoing SARS-CoV-2 infection.	
IgG Positive: Two lines develop, one in the control region (C) and one in the test region (G). Indication of a past SARS-CoV-2 infection.	
Invalid Result: If no line appears in the control region (C), the test result is invalid.	  

9. Limitation of the procedures

- The results of this test are only intended to assist the clinical diagnosis.
- Negative results do not rule out a SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic method (PCR) should be considered to rule out an infection in these individuals.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection.
- The test is only intended for in vitro diagnostic purposes. The test can only be used for the detection of SARS-CoV-2 antibodies in human whole blood, serum or plasma samples. Neither the quantitative value nor the rate of increase of the SARS-CoV-2 antibody concentration can be determined with this qualitative test.
- A negative result can occur if the antibody concentration of the tested sample is below the lower detection limit of the test. Negative results do not rule out a SARS-CoV-2 infection.
- As with all diagnostic tests, all results must be interpreted together with other clinical information and other test methods that are available to the physician.