TechNote TN-07

March 2021

Verification of immune response after SARS-CoV-2 vaccination using TAmiRNA SARS-CoV-2 IgM/IgG Antibody Rapid Test

Summary

The rapid increase in prophylactic vaccinations against the SARS-CoV-2 virus requires simple, scalable and cheap methods for detecting immune status in the population. So-called antibody rapid tests allow for rapid detection, but are generally less sensitive than laboratory-based methods. The aim of this study was to test the sensitivity of the TAmiRNA SARS-CoV-2 IgM/IgG Antibody Rapid Test, which targets the RBD domain of the S1 protein to detect an immune response in vaccinated individuals.

The results show that the test was able to detect both IgM and IgG antibodies in the capillary blood in 14 days after the first partial vaccination with an mRNA vaccine in 100% of the participants, and is therefore suitable for a rapid and simple assessment of the immune status.

Introduction

Coronavirus disease 2019 (Covid-19) has affected more than 100 million people (https://coronavirus.jhu.edu/map.html) worldwide since it was declared a pandemic by the World Health Organization (WHO) on March 11, 2020. Effective prophylactic vaccines are urgently needed to contain this pandemic and to curb potentially devastating medical, economic and social consequences. Many vaccine candidates are in clinical development and by March 2021, three vaccines have been approved in the European Union for use in patients.

Prophylactic vaccinations are vector or mRNA-based and aim to form neutralizing antibodies against the receptor-binding domain of the SARS-CoV-2 virus. This is to block the absorption of the virus into the target cells via the ACE-2 receptor and thus to suppress the reproduction of the virus in the host organism.

The effectiveness of these vaccines can therefore be demonstrated by the specific detection of antibodies against the RBD domain of the spike protein.

The TAmiRNA SARS-CoV-2 IgM/IgG Antibody Rapid Test is an immunochromatographic test for fast (<15 min), qualitative detection of the IgM and IgG antibody against SARS coronavirus 2 (SARS-CoV-2) in human whole blood, serum or plasma. In an independent validation study of the Medical University of Innsbruck with 350 samples, a sensitivity of 98.25% and a specificity of 100% was demonstrated. Thus, the test is comparable to the quality of ELISA tests, with the advantage that the TAmiRNA SARS-CoV-2 IgM/IgG Antibody Rapid Test can be performed on site without laboratory infrastructure.

Aim

The aim of the study was to measure the immune response after vaccination with the Pfizer/Biontech Comirnaty vaccine in adult healthy volunteers using the antibody rapid test system produced by TAmiRNA.

- The main objective of this study was to determine whether the TAmiRNA SARS-CoV-2 IgM/IgG Antibody Rapid Test is sufficiently sensitive to detect the IgM and IgG mediated immune response to the Pfizer/Biontech vaccine with the RBD domain of the S1 protein in capillary blood samples.
- The secondary objective of this study was to determine the time of the first/second vaccination from which IgM and/or IgG antibody levels are detectable using the rapid antibody test directed against the S1 protein.

Study protocol

All participants were voluntarily, older than 18 years, and had been tested exclusively negatively for SARS-CoV-2 since the start of the pandemic, and thus seronegative with respect to SARS-CoV-2 S1 IgG and IgM antibodies at the beginning of the study. All participants were trained at the beginning of the study in the safe and correct application of the antibody rapid test. After the training, all participants received five antibody tests and the necessary accessories for self-use, as well as a template for documenting the test results.

Antibodytests were carried out weekly from day 7 after the first partial vaccination up to 14 days after the second partial vaccination (see Figure 1). All participants were tested weekly for SARS-CoV-2 infections using PCR during the study.

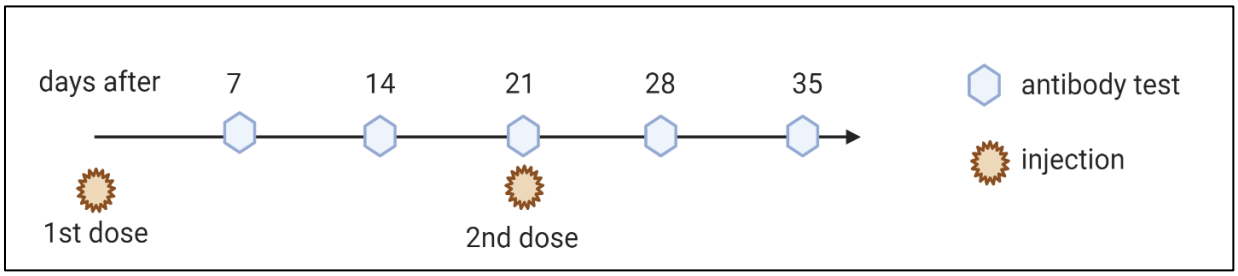

Figure 1: Timeline of the study

After a total of 35 days (14 days after the 2nd partial vaccination), eine optional laboratory-based evaluation of antibody titers was performed at the end of the study.

Material and methods

TAmiRNA SARS-CoV-2 IgM/IgG Antibody Rapid Test

This test is based on the principle of immunochromatographic detection of SARS-CoV-2-IgG/IgM antibodies with specificity against the S1 protein in human whole blood, serum and plasma.
The sample is absorbed into the cassette by capillary action after dropping into the sample window, mixes with the SARS-CoV-2 antigen dye conjugate and flows through the pre-coated membrane (see Figure 2).

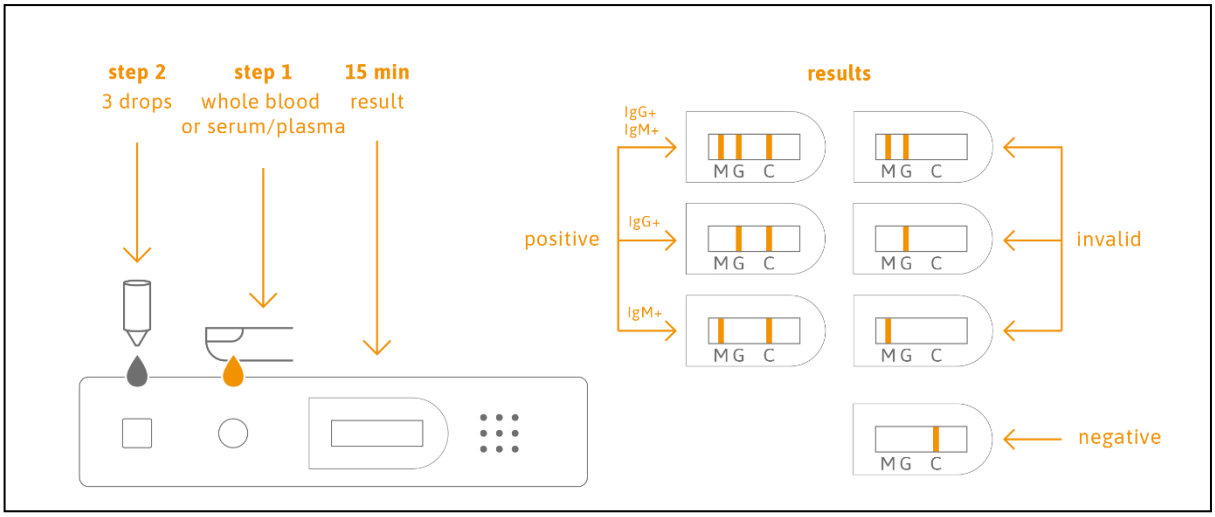

Figure 2: Test method and evaluation of test results

The antibodies of class IgM/IgG formed by the immune system of the infected against the SARS-CoV-2 in the sample react with the recombinant SARS-CoV-2 antigen bound to gold particles. This complex travels along the membrane and reaches the test lines to which a monoclonal anti-human IgM/IgG antibody directed against the SARS-CoV-2-IgM/IgG complex is bound. If the SARS-CoV-2 antibody level in the sample is zero or below the target limit, there is no visible colored band. This indicates a negative result.

Collection of capillary blood with a lancet

A safety lancet was used to make a finger prick. 20µL (one drop) whole blood was collected and with the help of the pipette included in the test and dropped into the sample window of the test cassette. Afterwards, 120µL (3 drops) sample buffer was applied in the buffer window. The results were read after 15minutes.

Evaluation

The results of the antibody tests were independently read, photographed and documented by all test subjects.

Only valid test results (with visible C-band) were considered for the evaluation. IgM and IgG bands were interpreted as negative, weak-positive, or positive.

Results

In total, 12 of the 12 participants successfully completed the evaluation. They had not been infected with SARS-CoV-2 or Covid-19 since the onset of the pandemic and until the first partial vaccination. Thus, all participants were seronegative for S1 protein specific IgM and IgG antibodies. During the 35-day evaluation, infections with the SARS-CoV-2 virus were detected by PCR or antigen rapid tests.

On day 7 after the first partial vaccination, all 12 subjects IgG negative, while one subject measurable IgM titer (see Figure 3A).

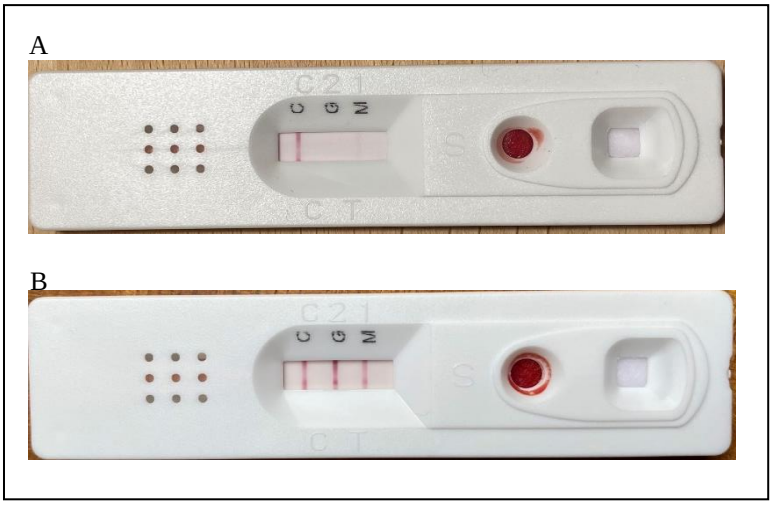

Figure 3: Representative TAmiRNA SARS-CoV-2 IgM/IgG Antibody Rapid Test Results.

3A: slightly IgM positive test on day 7 after the 1st partial vaccination;

3B: IgM/IgG positive test on day 14 after the first partial vaccination.

Within 14 days after the first partial vaccination, both IgG and IgM antibodies were detected by TAmiRNA SARS-CoV-2 IgM/IgG antibodies in 75%/83,3% of the participants. Even 14 days after the 2nd partial vaccination, IgM antibodies were detectable in 10 out of 12 participants, as well as IgG antibodies in 100%of the participants (Figure 3B and 4, respectively).

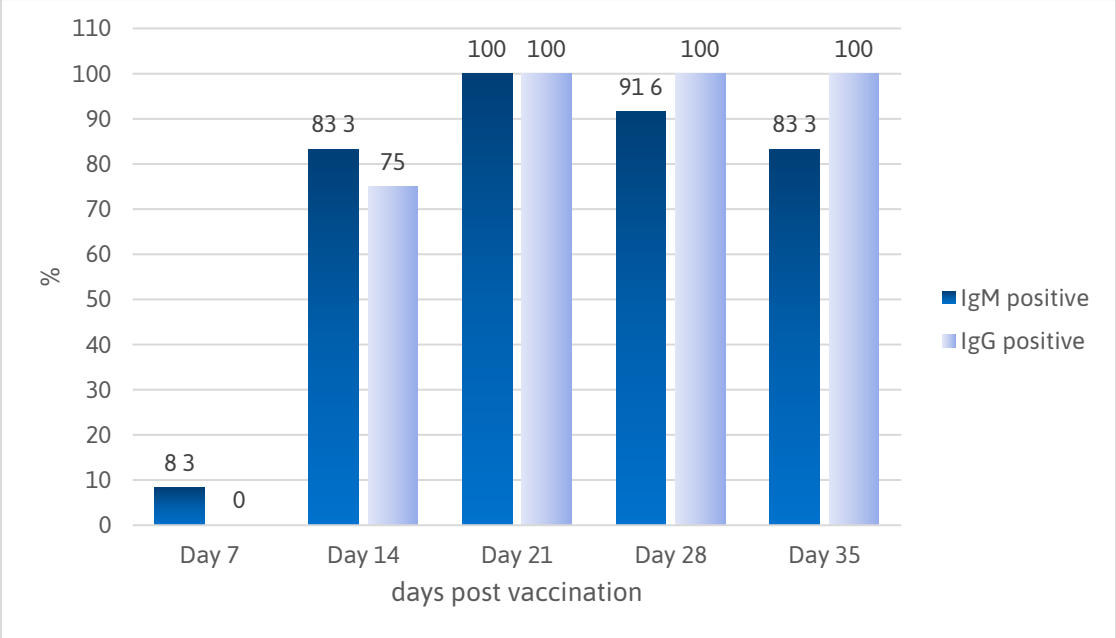

Figure4: Overview of the time-dependent detectability of IgM and IgG antibodies over the entire duration of the study. The frequency of positive results for IgM (dark blue) and IgG antibodies (light blue) is given in percent.

Discussion

The aim of this study was to investigate whether SARS-CoV-2 antibody rapid tests using S1 protein are sufficiently sensitive to detect the immune responses of subjects after immunization with the Pfizer/Biontech mRNA vaccine. **It has been clearly demonstrated that the TAmiRNA SARS-CoV-2 IgM/IgG Antibody Rapid Test can detect both IgM and IgG antibodies against S1-RBD in capillary whole blood.** Both IgM and IgG antibodies were detected in 100% of participants.

Furthermore, it could be shown that in all subjects, IgG as well as IgM antibodies can be detected by rapid test within 14 days after the first partial vaccination. IgM antibodies were also detectable in 83.3%at the last time of measurement after 35 days, while IgG antibodies were detectable in 100% of the subjects.