SARS-CoV-2 IgM/IgG antibody test kit (Colloidal Gold Method)

Retrospective Study on Recipients of Pfizer Vaccine and Sero-Conversion Study on Recipients of Pfizer Vaccine

Biohit Healthcare (Hefei) Co., Ltd.

1. Research Purpose

The objective of this retrospective study was to evaluate the efficacy of the SARS-CoV-2 IgM/IgG antibody test kit (Colloidal Gold Method) produced by Biohit Healthcare (Hefei) Co., Ltd. to detect antibodies in the elderly population following vaccination with Pfizer vaccine.

The Biohit IgM/IgG antibody test contains both immunogold labelled recombinant S and N antigen and the purpose was to prove that the assay can be used to determine the immune-status of patients following vaccination. Previous independent publications (1) have already shown that this serological test is highly sensitive and specific to determine the immune-status following wild-type virus infections

The study also includes 2 sero-conversion panels of young adult vaccine recipients (both ER physicians) from whom samples were taken at day 0, 7, 14 and 21 post vaccination of the first dose. Such seroconversion panels are useful to determine the clinical sensitivity of test systems and show that the lateral flow rapid tests must contain S protein to detect a vaccine response.

2. Research Methods

Serum samples were collected from 20 patients who had tested COVID-19 negative by PCR and received two doses of vaccine. These patients had no previous clinical history of COVID-19. These patients were tested on different days after receiving the second vaccination to detect the presence of antibodies. The test were performed under the supervision of Prof.Y.Adler, Carmel Medical Center, Haifa, Israel during the second week of January 2021.

For the sero-conversion panels volunteers were identified who were vaccinated on15.01.21 and 300 ul of capillary blood was taken on day 0, 7, 14 and 21 post vaccine. Samples were collected and processed at the laboratory of Dialane AG, Felsberg, Switzerland under the supervision of Dr.C.Mauracher and frozen at -20 °C until use.

2.1. Reagents and samples

Retrospective study with vaccine recipients following second dose of vaccine

The SARS-CoV-2 IgM/IgG antibody test kit (Colloidal Gold Method) produced by Biohit Healthcare (Hefei) Co., Ltd., batch number: SA201106 was used. Tests were performed following the manufacturer's instructions. Patients were tested using 10 ul serum obtained from venipuncture

Sero-conversion study following first dose of vaccine

The SARS-CoV-2 IgM/IgG antibody test kit (Colloidal Gold Method) produced by Biohit Healthcare (Hefei) Co., Ltd., batch number SA201105 was used. Tests were performed following manufacturers instructions.

Sero-conversion panels used 10 ul serum obtained from capillary blood collection.

2.2. Vaccine

All individuals received the Pfizer vaccine and were vaccinated according to the manufacturer's instructions.

3. Research Results

(1) Sensitivity of IgG

Days after 2nd vaccination	Positive (case)	Negative (case)	Total (case)
0-7	7	2	9
7-14	10	0	10
>14	1	0	1
Total (case)	18	2	20

Sensitivity 0 – 7 days: 7/9 = 77 %

Sensitivity > 7 days: 11/11 = 100%

(2) Sensitivity of IgM

Days after 2nd vaccination	Positive (case)	Negative (case)	Total (case)
0-7	1	8	9
7-14	0	10	10
>14	0	1	1
Total (case)	1	19	20

Sensitivity 0 – 7 days: 1/9 = 11%

Sensitivity > 7 days: 0/11 = 0 %

(2) Sensitivity of Total Antibody

Days after 2nd vaccination	Positive (case)	Negative (case)	Total (case)
0-7	7	2	9
7-14	10	0	10
>14	1	0	1
Total (case)	18	2	20

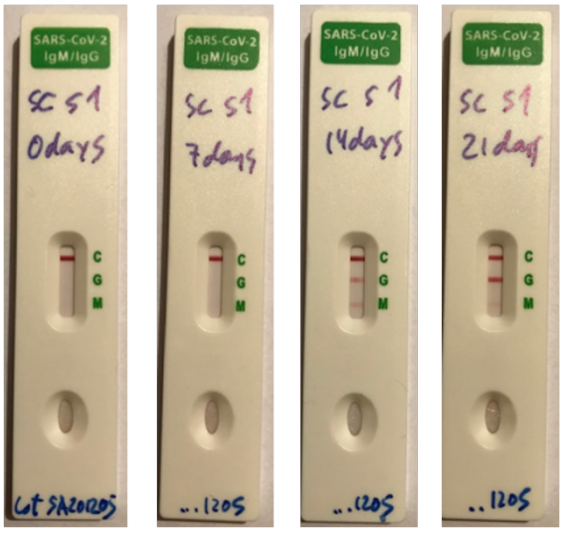
Sensitivity 0 – 7 days: 7/9 = 77 %

Sensitivity > 7 days: 11/11 = 100%

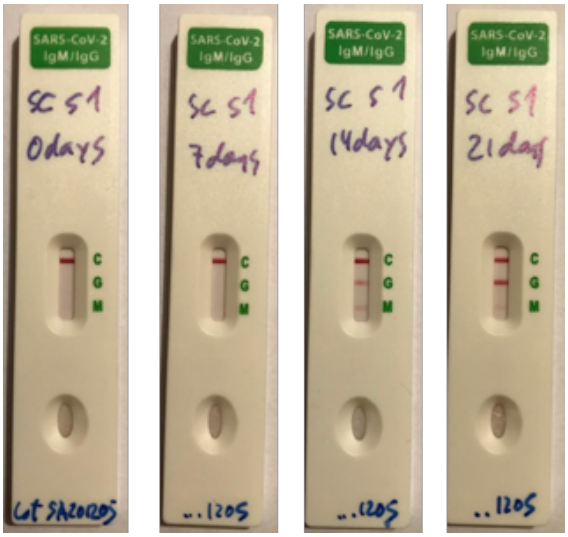
(4) Sero-Conversion Panels Using Biohit SARS-CoV-2 IgM/IgG Kit Test Kit

	Day 0		Day 7		Day 14		Day 21	
	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG
Sample 1	neg	neg	neg	neg	pos	pos	pos	pos
Sample 2	neg	neg	neg	neg	pos	pos	pos	pos

Sero-conversion panel: Sample 1

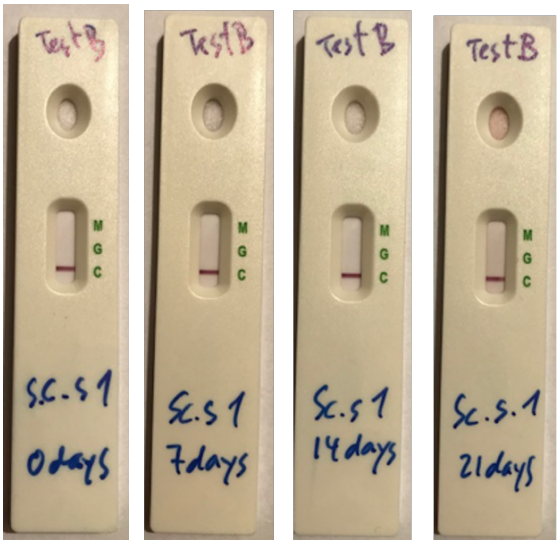


Sero-conversion panel: Sample 2

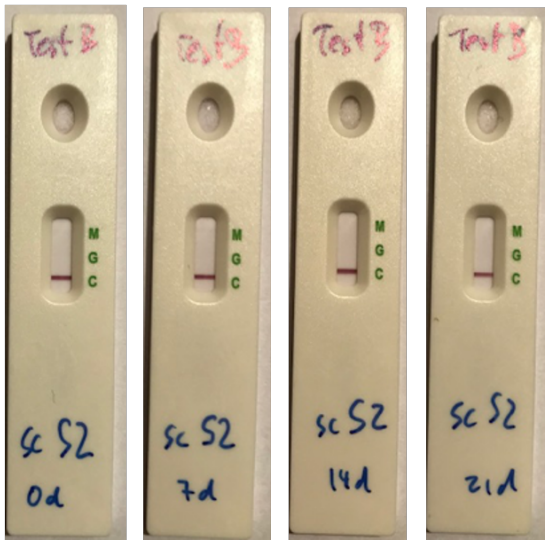


(5) Sero-Conversion panels Using a SARS-CoV-2 IgM/Rapid Test Which Is Based on the SARS-CoV-2 N-Antigen Only

Sero-conversion panel: Sample 1



Sero-conversion panel: Sample 2



4. Conclusion

(1) Retrospective study of vaccine recipients

The test system used in this study was capable of showing a positive immune status to COVID-19 vaccine in the patient population. After testing antibodies from serum samples of patients who had tested SARS-CoV-2 negative by PCR and had no clinical history of COVID-19, the sensitivity of SARS-CoV-2 IgM/IgG antibody test kit (Colloidal Gold Method) was found to be 100%, 7 days after receiving the second dose of vaccine. As this was a retrospective study we did not have the opportunity to collect samples at day 0 of the first vaccine, however all patients had a complete medical history and had not presented with COVID-19 symptoms.

(2) Sero-Conversion Study

When using sero-conversion panels on the Biohit test system, both patients show a positive antibody response of both IgM and IgG by day 14 after receiving the first vaccine dose. The intensity of the IgG response increases over time. IgM responses were weaker in both samples and only detected border line in Sample 2. When using the sero-conversion panels on an old-generation test, which contains only N-protein as the labelling antigen, no positive signals are detected. Tests which contain the N-protein detection system will fail in determine the immune status of COVID-19 vaccine recipients.

It is concluded that the Biohit IgM/IgG test can be used for the determination of immune-status after SARS-CoV-2 vaccination with the Pfizer vaccine as it includes both recombinant S- and N-proteins as detection antigens.
Biohit will continue further research in order to investigate its assays with recipients of other vaccine brands. These studies are ongoing.

5. References

Minteer et al., Multi-site Validation of a SARS-CoV-2 IgG/IgM Rapid Antibody Detection Kit. https://doi.org/10.1101/2020.05.25.20112227.