

# Performance of Commercially Available Rapid Serological Assays for The Detection of SARS-CoV-2 Antibodies

Anwar M Hashem (✉ [amhashem@kau.edu.sa](mailto:amhashem@kau.edu.sa))

<https://orcid.org/0000-0002-8471-7011>

**Rowa Y Y Rowa Y Alhabbab**

King Abdulaziz University

**Abdullah Algaissi**

Jazan University

**Mohamed A Alfaleh**

King Abdulaziz University

**Sharif Hala**

King Abdullah University of Science and Technology

**Turki S Abujamel**

King Abdulaziz University

**M-Zaki ElAssouli**

King Abdulaziz University

**Afrah A AL-Somali**

Ministry of Health Saudi Arabia

**Fadwa S Alofi**

Ministry of Health Saudi Arabia

**Asim A Khogeerk**

Ministry of Health Saudi Arabia

**Almohanad A Alkayyall**

University of Tabouk

**Ahmad B Mahmoud**

Taibah University

**Naif AM Almontashiri**

Taibah University

**Amab Pain**

King Abdullah University of Science and Technology

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# Abstract

**Background:** The Coronavirus Disease 2019 (COVID-19) pandemic, caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), continues to spread globally. Although several commercial SARS-CoV-2 rapid serological assays have been developed, little is known about their performance and accuracy in detecting SARS-CoV-2 specific antibodies in COVID-19 patient samples.

**Method:** We have evaluated the performance of seven commercially available rapid lateral flow immunoassay (LFIA) serological assays obtained from different manufacturers, and compared them to in-house developed and validated ELISA assays for the detection of SARS-CoV-2 specific IgG and IgM antibodies in COVID-19 patients.

**Results:** While all evaluated LFIA assays showed high specificity, our data showed a significant variation in sensitivity of these assays in which it ranged from 0 to 54% for samples collected early during infection (3-7 days post symptoms onset) and from 54 to 88% for samples collected at later time points during infection (8-27 days post symptoms onset).

**Conclusion:** Commercially available LFIA assays for detection of SARS-CoV-2 specific antibodies may be specific and show high degree of variation in their sensitivity. Further evaluations and validation of rapid serological assays is needed before being routinely used in detecting IgM and IgG in COVID-19 patients.

## Background

In late December 2019, a cluster of atypical pneumonia was reported in people from Wuhan city in China. The etiological agent was later identified as a novel coronavirus (CoV) and subsequently named as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Today, the virus has spread almost to all corners of the globe causing devastating impacts on the global public health and economy. SARS-CoV-2 belongs to the betaCoV genus of the CoVs family which also includes the two others highly pathogenic CoVs; the severe acute respiratory syndrome coronavirus (SARS-CoV) and the Middle East respiratory syndrome coronavirus (MERS-CoV) (Cui et al., 2019). These three viruses can cause respiratory illnesses ranging from mild to severe infections which might be associated with fatal outcomes (Gao et al., 2020). CoVs are large family of viruses that can infect a wide range of hosts including humans. CoVs are enveloped viruses that contain a positive-sense, single-stranded RNA genome. In humans, CoVs were not recognized as highly pathogenic until SARS-CoV outbreak occurred in 2002, China (Cui et al., 2019; Drosten et al., 2003; Zhong et al., 2003). Subsequently, MERS-CoV appeared in 2012 as another life-threatening pathogen in the Middle East (Degnah et al., 2020; Zaki et al., 2012), and today the entire globe is suffering from the Coronavirus Disease 2019 (COVID-19) pandemic caused by SARS-CoV-2 (WHO, 2020). The rapid and continuous spread of SARS-CoV-2 globally, has led to its declaration as global pandemic on March 11, 2020 by the World Health organization (WHO). It is suggested that one reason behind the explosive spread of SARS-CoV-2 is the high rate of undocumented and asymptomatic cases which are

able to spread the infection silently in the community (Niu and Xu, 2020). Thus, a quick and effective detection of cases and their contacts is critical in controlling the spread of the virus (Konrad et al., 2020).

Currently, real-time reverse transcriptase polymerase chain reaction (RT-PCR) is used as a standard method for SARS-CoV-2 diagnosis (Li et al., 2020). However, RT-PCR tests have many limitations including long turnaround time (~ 8–10 hrs), high cost, and the need for specified machines and highly skilled personnel. Furthermore, there has been a growing concern recently because of a global shortage in the supply of RNA extraction kits which are required for the RT-PCR assays. Moreover, RT-PCR can provide false negative results due to several reasons such as the timing as well as the quality of the collected swab samples, especially that the viral load declines in the upper respiratory tract with time (Jacofsky et al., 2020; Wolfel et al., 2020). Additionally, RT-PCR is only valid for patients with active infections and do not provide any data on the patients' immune status. Therefore, there is an urgent need to complement such assays with a rapid test to quickly identify new, asymptomatic and recovered COVID-19 cases to aid in limiting SARS-CoV-2 spread.

Several companies have developed and produced rapid and specific immunoassays such as enzyme-linked immunosorbent assay (ELISA) and lateral flow immunoassays (LFIAs) to detect both IgM and IgG antibodies. Unlike ELISA, which is usually performed by well-trained personal in clinical laboratory settings, LFIAs overcome these challenges and provide a rapid, qualitative and simple point-of-care test (POCT) to detect the presences of both IgM and IgG antibodies. Prior to their use to screen and identify infected or immune individuals including asymptomatic as well as recovered patients, the performance of these assays must be evaluated and validated. Thus, in this study, we aimed to evaluate the performance of several commercially available immunoassays and compare them to our in-house developed and validated ELISA using samples derived from RT-PCR confirmed COVID-19 patients and healthy controls.

## Methods

### Samples and testing protocols

A total of 46 human serum samples from acute RT-PCR confirmed COVID-19 patients collected at various time points ranging from day 3 to 27 from symptoms onset, and 15 serum samples from healthy subjects collected prior the COVID-19 pandemic were included in this study. All samples were examined for IgM and IgG responses by in-house ELISA and seven commercially available LFIAs. However, the total number of samples used to test the strips varied between commercial manufacturers due to the number of supplied devices. All samples were anonymized and used based on ethical approvals obtained from the Unit of Biomedical Ethics in King Abdulaziz University Hospital (Reference No 245-20), the Institutional Review Board at the Ministry of Health, Saudi Arabia (IRB Numbers: H-02-K-076-0320-279 and H-02-K-076-0420-285), and the Global Center for Mass Gatherings Medicine (GCMGM) (No. 20/03A).

### ELISA for detection of SARS-CoV-2 specific IgM and IgG antibodies.

In-house indirect ELISA based on the nucleocapsid (N) protein was performed as previously describe (Algaissi et al., 2020). Briefly, 96-well ELISA microplates were coated with in-house produced recombinant SARS-CoV-2 N protein at a concentration of 4 µg/ml in phosphate-buffered saline (PBS). After overnight incubation at 4°C, the plates were washed three times with PBS containing 0.05% tween-20 (PBS-T), and blocked with 5% skim milk in PBS-T buffer at room temperature for 1 hr. After blocking, plates were washed three times and serum samples at a dilution of 1:100 in PBS-T with 5% milk were added and kept for 1 hr at 37°C. Next, plates were washed three times again with PBS-T and incubated with HRP-conjugated goat anti-human IgM or IgG antibodies (Jackson ImmunoResearch, West Grove, PA) for 1 hr. The plates were washed again, and incubated with TMB substrate (KPL, Gaithersburg, MD) at room temperature for 30 min before terminating the reaction by adding 100 µl per well of stop solution (0.16 M sulfuric acid). The absorbance was measured at 450 nm using the ELx808™ Absorbance Microplate Reader (BioTek, Winooski, VT). Positive samples were identified based on pre-determined cut-off values (0.55 for IgM and 0.4 for IgG) as previously described (Algaissi et al., 2020).

### **SARS-CoV-2 IgM and IgG antibodies by LFIA.**

Seven available LFIA devices developed to detect SARS-CoV-2 IgM and IgG antibodies were tested in this study. The manufacturers were anonymized and have been given numbers from 1 to 7. The kits were tested according to the manufacturer instructions by generally adding 10-20µl from the test serum samples into the sample well plus several drops from the associated buffer. After 10-15 minutes incubation at room temperature, the results were recorded as positive, negative or invalid. Positive results showed colored bands at both the control and the test lines, whereas negative results have only provided colored band at the control line. The invalid results showed no colored band at the control line.

### **Statistical analysis.**

Comparisons between groups were performed using one-way ANOVA and a Fisher's LSD or Kruskal-Wallis test, and for all the proportions binomial 95% confidence intervals (CI) were calculated. Analyses were performed using GraphPad Prism software, version 8.

## **Results**

### **SARS-coV-2 IgM and IgG antibodies detection by ELISA.**

Here, we analyzed the relationship between the levels of serum antibodies and time since symptoms onset. A total of 46 samples were collected from RT-PCR confirmed COVID-19 patients at several time points ranging from 3 to 27 days post symptoms onset, and the levels of SARS-CoV-2 specific IgM and IgG antibody responses were determined using in-house ELISA that we recently developed and validated. As shown in Figure 1A, the level of IgM antibodies started to increase by the end of the first week and reached their highest levels at day 11 before dropping down to lower levels which were maintained above the initial levels until day 27. Similarly, IgG levels started to elevate by day 7 and peaked by day 10 to levels that were remained high until day 27 post symptoms onset.

The ELISA median optical density (OD) of the negative samples was 0.4 (ranging from 0.03 to 0.53) for IgM and 0.14 (ranging from 0.1 to 0.2) for IgG. On the other hand, the median OD values of the 46 RT-PCR confirmed positive cases were significantly higher for both IgM (0.82; ranging from 0.08 to 4.86) and IgG (2.75; ranging from 0.07 to 4.16). Based on the predetermined cut-off values (Algaissi et al., 2020), and the samples used in this study, the overall sensitivity of IgG ELISA vs RT-PCR was 83% (95% CI: 63-91%; 38/46). All the 8 false negative samples were from samples collected at early time points post symptoms onset (6 samples during the first week and 2 samples on day 8). Thus, the IgG positivity in samples collected at late time points post symptoms onset was detected in 33/35 of the RT-PCR confirmed cases resulting in 94% sensitivity (95% CI: 81-99%). Importantly, all samples collected post day 8 were IgG positive, confirming our previous high sensitivity of IgG ELISA based on N protein (Algaissi et al., 2020). As expected, lower overall sensitivity of 75% was observed for the IgM ELISA (95% CI 83-63%; 30/46) compared to IgG ELISA, with 16 false negative samples divided between early (9 samples during the first week) and late time points (7 samples between days 8 and 11) post symptoms (Figure 1B). Nevertheless, all samples that were negative for IgG antibodies were IgM negative as well.

### **Detection of SARS-CoV-2 specific antibodies by ELISA and LFIA vs RT-PCR.**

Next, we compared the performance of seven LFIA devices as well as our in-house ELISA with RT-PCR results, considering the levels of serum antibodies at early and late time-points post symptom onset (Figure 1), and the difference in measured targets by serological assays and RT-PCR. Therefore, any LFIA and ELISA positive results (IgG, IgM or both) were considered positive, and results were divided into two sets based on the peaking time points post symptoms onset (set1: one week and set2: after one week). To this end, the sensitivity of the seven tested LFIA devices and the ELISA compared to RT-PCR positive cases for set1 was very low ranging from 0% (95% CI 0-49%) to 54% (95% CI 28-79%) (Figure 2A). However, the sensitivity of the seven LFIA devices was increased to range from 54% (95%CI 38-69%) to 88% (95% CI 73-95%) for set2 (Figure 2B). This increase was also observed with the ELISA achieving 94% (95% CI 81-99%) sensitivity (Figure 2B). Moreover, the overall specificity of the seven LFIA devices and the ELISA was 100% (95% CI 80-100%) (Figure 2C).

### **Detection of SARS-coV-2 antibodies by ELISA vs LFIA**

Having demonstrated differences in the sensitivity between early and late time points post symptoms onset compared to RT-PCR, ELISA was used as an alternative standard assay to evaluate LFIA performance. However, since LFIA is qualitative and ELISA results are quantitative, any IgM or IgG OD reading that exceeded the ELISA cut-off value was considered positive as a qualitative measure of antibodies. Figure 3 summarizes the IgM and IgG antibodies results detected by the seven LFIA assays included in our study compared to the in-house ELISA. While no false positive results were observed out of the 15 healthy subjects consistent with the ELISA, several of the RT-PCR confirmed cases that showed no antibody response by the in-house ELISA were found seropositive by many of the LFIA devices (Figure 3). As shown in Figure 4A, IgM antibodies sensitivity ranged from 0% to 100% at early points and from 32% to 91% at late time points after symptoms onset. IgG sensitivity of the seven LFIA during the first

week post symptoms onset ranged from 0% (95% CI 0-82%) to 66% (95% CI 30-94) and from 58% (95% CI 41-73%) to 93% (95% CI 68-99%) at late time points post symptoms onset (Figure 4B). The overall specificity for IgM and IgG detection by the seven LFIA ranged from 70% (95% CI 52-83%) to 100% (95% CI 85-100%) as shown in Figure 4C.

## Discussion

LFIA is a rapid serological assay that provides cheap, easy and Point-of-care testing (POCT) to test and evaluate the level of exposure to SARS-CoV-2 in a given population. Although ELISA is cheap as well compared to RT-PCR, it cannot be used as POCT and requires well-trained clinical laboratory staff and special tools and equipment to be performed. The determination of antibody responses to SARS-CoV-2 is crucial to identify immune individuals and therefore reducing anxiety and can serve as a tool to release individuals from isolation or lock-down. Moreover, the fact that sampling time, particularly as infection progresses, could result in false negative results by RT-PCR, highlighting the need to include serological testing in the testing protocol to improve the detection sensitivity. Furthermore, serological assays can also serve in quantifying and evaluating the immunogenicity of vaccines entering clinical trials. However, determining the sensitivity and specificity of such assays is important before releasing them for use in clinical setting as high sensitivity and specificity are generally required in clinical diagnostics.

By utilizing a cohort serum samples from RT-PCR confirmed COVID-19 patients, we characterized the performance of commercially available LFIA assays obtained from seven different commercial manufacturers for the detection of SARS-CoV-2 specific IgM and IgG antibodies. While only 45% of the 11 RT-PCR confirmed cases were detected by ELISA during the first week post symptoms onset, 94% of the 35 RT-PCR positive serum samples collected after one-week from symptoms onset were ELISA seropositive. On the other hand, the sensitivity of the tested LFIA showed high variability between manufacturers compared to either RT-PCR or ELISA, although their specificity seems to be high upon testing serum obtained from healthy subjects. Importantly, very low sensitivity and higher variability were seen during early time points post symptoms onset as expected, consistent with the often delayed seroconversion in COVID-19 patients which could be delayed to day 11 to day 19 post symptoms onset (Hoffman et al., 2020). Similarly, we observed that antibody responses could peak around this time range, in which our ELISA results detected the initial increase of antibodies post day 7 of symptoms onset and peaking at day 11. Therefore, improving the sensitivity of these assays is crucial for early detection of antibodies post symptoms onset.

The assessment in this study was based on small number of LFIA assays, limiting the estimate of performance and providing wide confidence intervals. Therefore, increasing the numbers and brands of the tested LFIA rapid assays would provide more assurance, however, the associated high cost might be considered as unjustified expense. Moreover, full assessment should also include different populations such as patients with immunological diseases, children, and populations from different ethnicities and locations.

Collectively, rapid serological assays for SARS-CoV-2 specific antibody testing are important for diagnosis, contact tracing, and epidemiological studies. Furthermore, such serological assays would be important to make informed decisions as some countries are considering relaxing some of their control measures such as lockdowns and travel restrictions. It also important to make sure these assays are accurate and have been appropriately validated. Although some of the tested LFIA assays in this study provide low sensitivity compared to ELISA and RT-PCR particularly at early time points after symptom onset, some of the devices were of high sensitivity. Importantly, our data demonstrated a high degree of variation in their sensitivity in detecting SARS-CoV-2 specific IgM and IgG antibodies and the need for proper validation of such assays before their deployments.

## **Abbreviations**

COVID-19: Coronavirus Disease 2019

CoV: Coronavirus

SARS-CoV-2: severe acute respiratory syndrome coronavirus 2

MERS-CoV: Middle East Respiratory Syndrome

LFIA: Lateral Flow Immunoassay

WHO: World Health Organization

ELISA: Enzyme Immunosorbent Assay

RT-PCR: Real Time-Polymerase Chain Reaction

IgG: Immunoglobulin G

IgM: Immunoglobulin M

POCT: Point-of-care testing

OD: Optical density

CI: Confidence interval

## **Declarations**

### **Ethics approval and consent to participate**

Ethical approvals were obtained from the Unit of Biomedical Ethics in King Abdulaziz University Hospital (Reference No 245-20), the Institutional Review Board at the Ministry of Health, Saudi Arabia (IRB

Numbers: H-02-K-076-0320-279 and H-02-K-076-0420-285), and the Global Center for Mass Gatherings Medicine (GCMGM) (No. 20/03A), with informed consent obtained from all participants.

### **Consent for publication**

Not applicable

### **Availability of data and materials**

All data generated or analyzed during this study are included in this published article

### **Competing interests**

The authors declare that they have no competing interests

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### **Authors' contributions**

AMH, RYA, TSA and AA conceptualized and designed the study. AMH, RYA, AA, MAA and MZE performed experiments and analyzed the data. MAA, SH, TSA, AAA, FSA, AAK, AAAlk, ABM, NAMA, AP collected and processed samples. AMH and RYA wrote the first draft of the manuscript. All authors commented on, read and approved the final manuscript.

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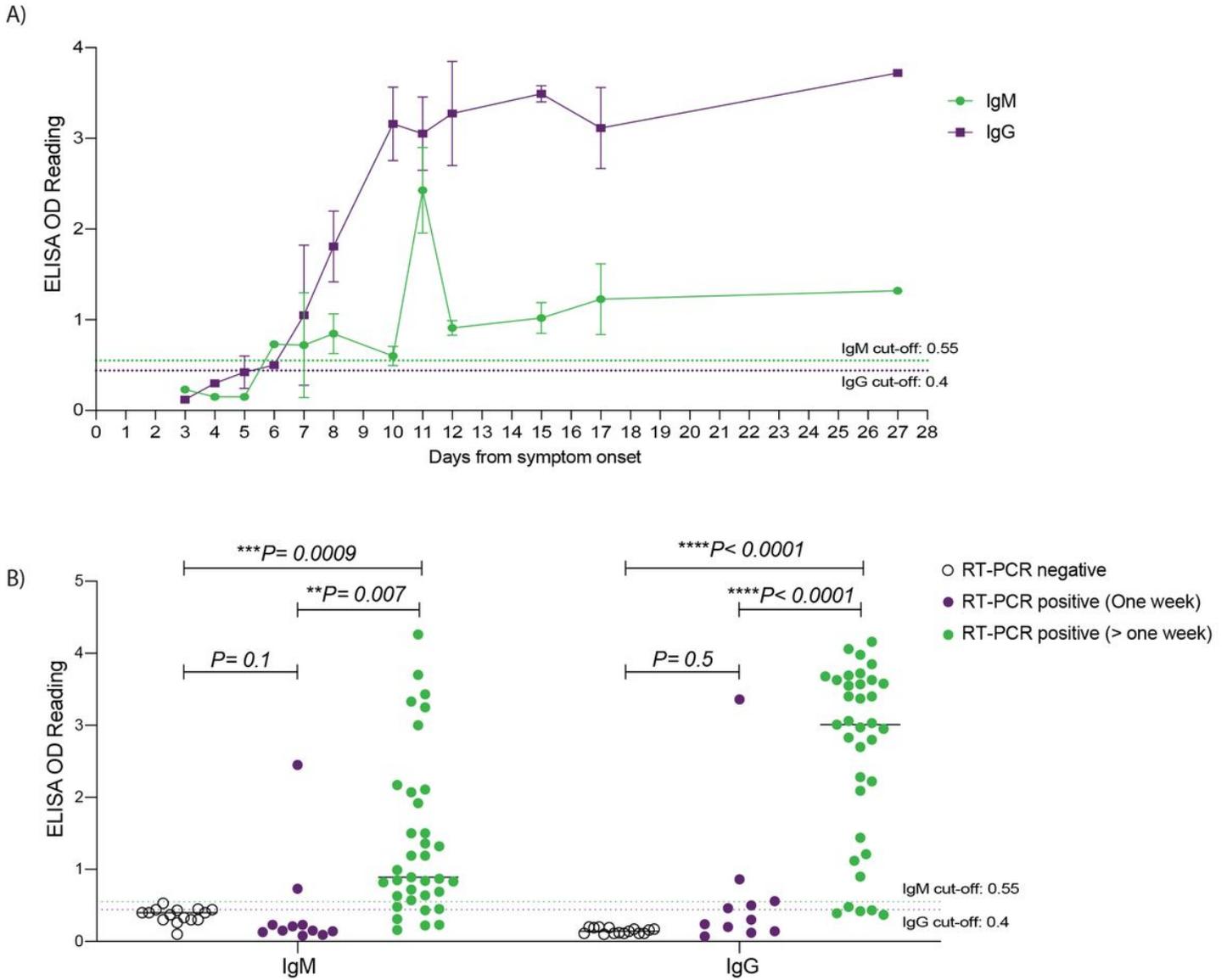
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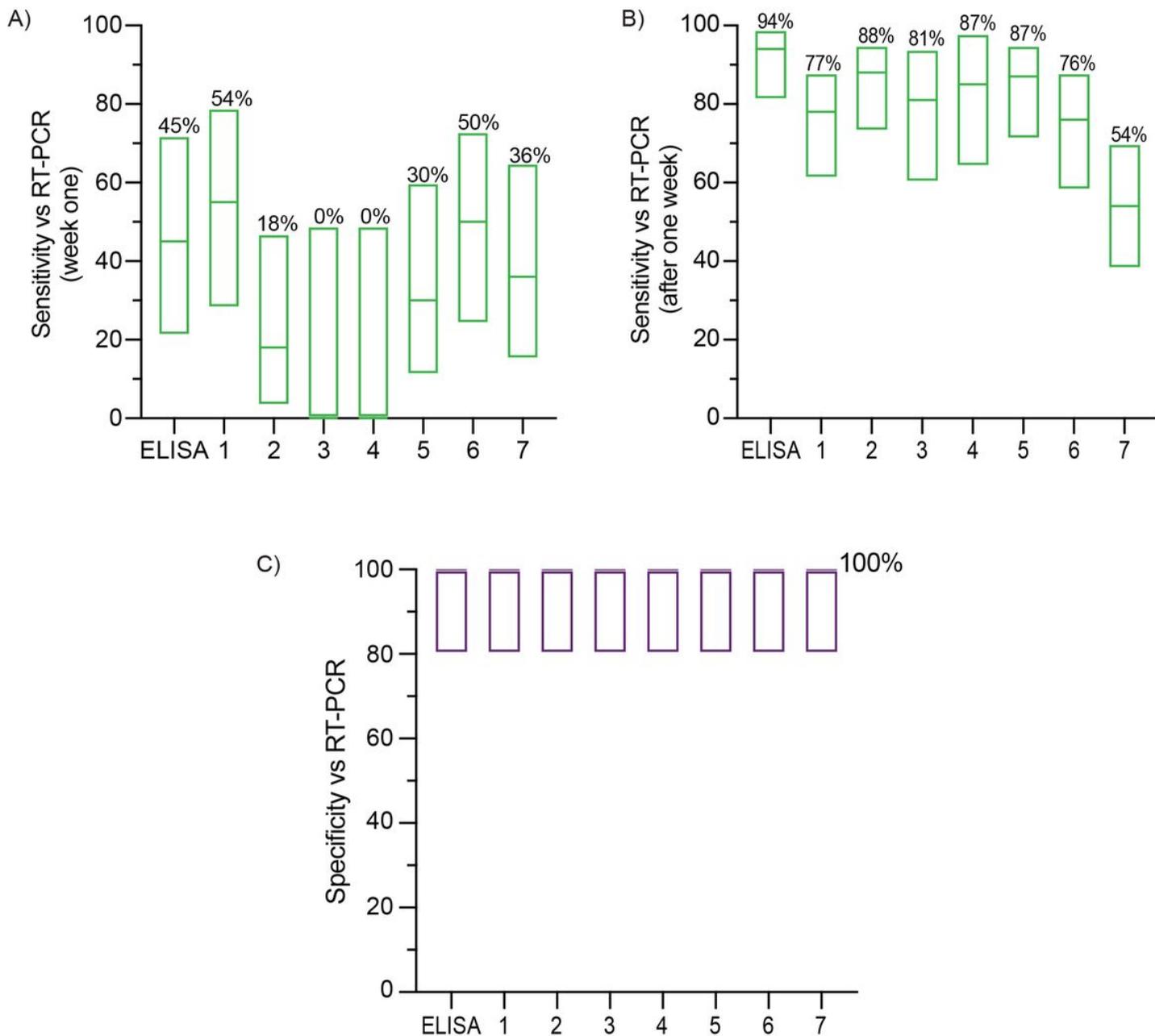
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## Figures



**Figure 1**

SARS-CoV-2 IgM and IgG antibodies detection by ELISA. A total of 46 serum samples collected from RT-PCR confirmed COVID-19 patients were tested by ELISA to detect the levels of serum IgM and IgG antibodies specific for SARS-CoV-2 at several time points post symptom onset. Plots show ELISA OD reading for IgM and IgG antibodies (A) over time after symptoms onset (n=46) and (B) for negative subjects (n=15) as well as RT-PCR positive cases before (n=11) and after (n=35) one-week post symptom onset. The cut-off threshold values of for IgM and IgG antibodies were 0.55 and 0.4, respectively. Statistics were calculated by one-way ANOVA and Fishers LSD test and p value <0.05 were considered significant.



**Figure 2**

Detection of SARS-CoV-2 antibodies by ELISA and LFIA vs RT-PCR. The results obtained from serum samples collected from a total of 46 RT-PCR confirmed SARS-CoV-2 patients were divided into two groups based on the collection time points (one-week and after one-week post symptom onset), and negative samples were collected from healthy individuals. All groups including the negative control were tested for SARS-CoV-2 IgM and IgG antibodies by ELISA and seven LFIA devices. Floating plots show the overall sensitivity (A and B) and specificity (C) with 95% confidence intervals of the ELISA and the seven LFIA devices against RT-PCR. Means are shown as percentages on the top of each plot from samples collected (A) during the first week and (B) after one-week post symptom onset. Statistics were calculated by Wilsom/Brown methods.

Figure 3

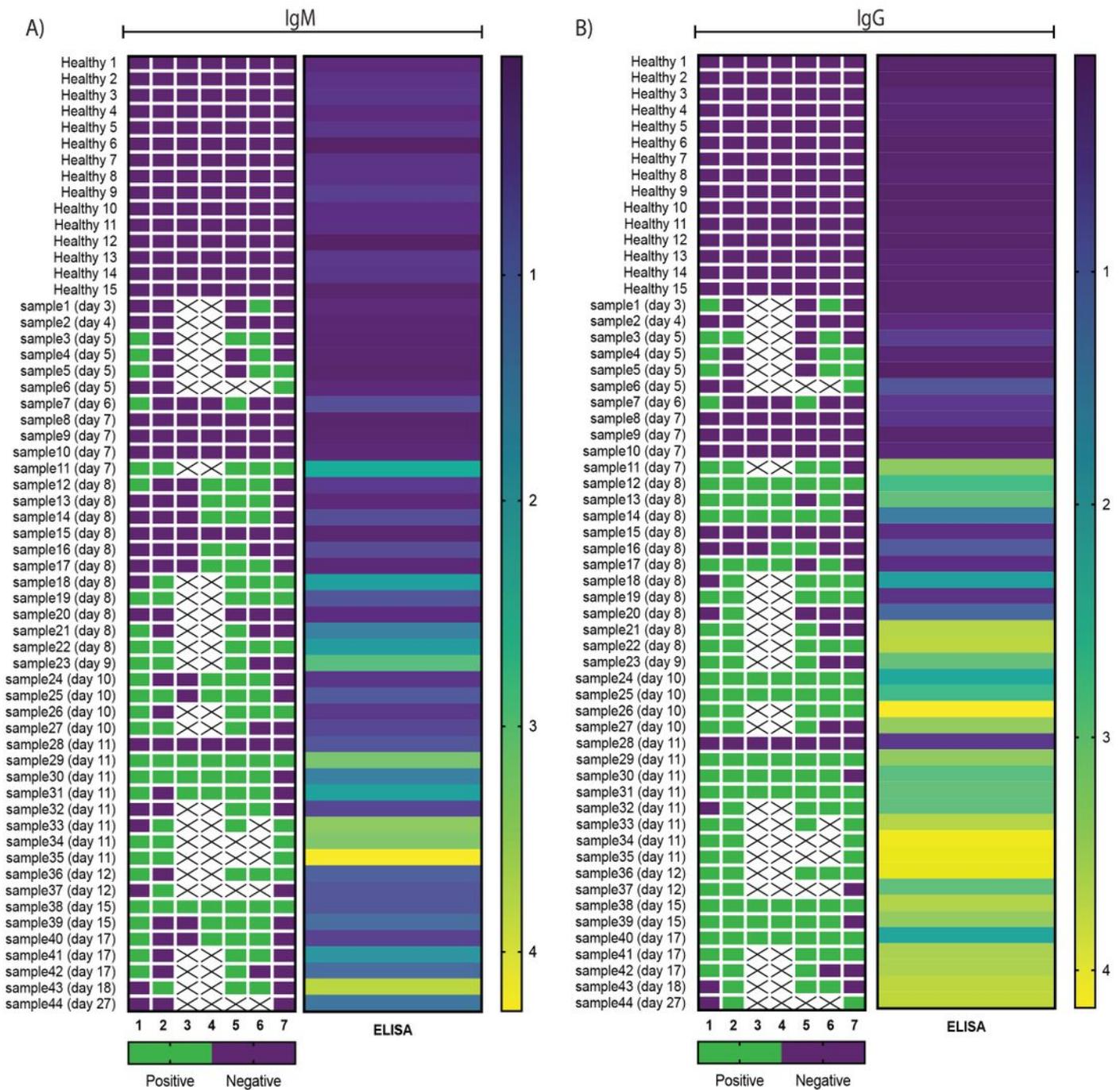
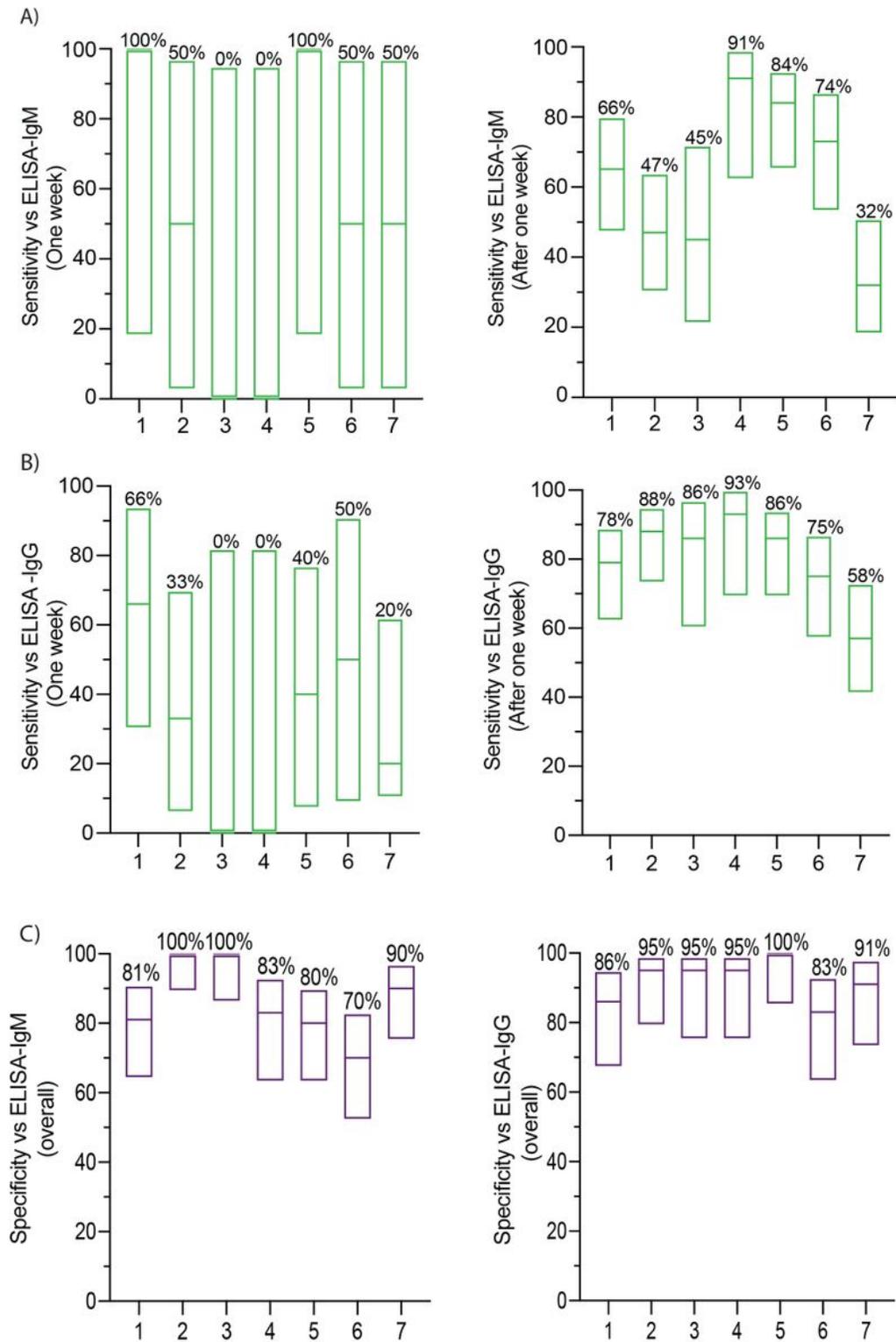


Figure 3

Detection of SARS-CoV-2 antibodies by ELISA vs LFIA. Heat map of 46 serum samples of SARS-CoV-2 positive by RT-PCR and 15 plasma samples collected from healthy individual were tested by ELISA and seven LFIA devices for SARS-CoV-2 (A) IgM and (B) IgG antibodies.



**Figure 4**

The sensitivity and specificity of the five LFIA devices vs ELISA. Positive and negative samples for SARS-CoV-2 antibodies by ELISA were used as an alternative reference method to show the sensitivity and specificity of the seven LFIA devices vs ELISA. Floating plots show the sensitivity of (A) IgM and (B) IgG, and the overall specificity (C) with 95% confidence intervals for each LFIA device against ELISA during the

first week and after one-week post symptom onset. Means are shown as percentages on the top of each plot. Statistics were calculated by Wilsom/Brown methods.