

Research Article

Can the *Wondfo*[®] SARS-CoV-2 IgM/IgG antibodies be used as a rapid diagnostic test?

Lysandro Pinto Borges¹, Makson Gleydson Brito De Oliveira^{2*}, Daniela Raguer Valadão de Souza³, Kezia Alves Dos Santos¹ and Luana Heimfarth⁴

¹Department of Pharmacy, Federal University of Sergipe, Marechal Rondon Avenue, S/N, Rosa Elza, CEP: 49.000-100, São Cristóvão, SE, Brazil

²Department of Medicine, Federal University of Sergipe, Lagarto, SE, Brazil

³Department of Education and Health, Federal University of Sergipe, Lagarto, SE, Brazil

⁴Department of Physiology, Federal University of Sergipe, Marechal Rondon Avenue, S/N, Rosa Elza, CEP: 49.000-100, São Cristóvão, SE, Brazil

More Information

*Address for Correspondence:

Makson Gleydson Brito de Oliveira, PhD, Professor, Medicine Department, Federal University of Sergipe, Av. Governador Marcelo Déda, 13, CEP 49400-000 Lagarto, Sergipe, Brazil, Tel: 55 (79) 36322080. Email: makson_gbo@hotmail.com

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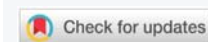
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Keywords: COVID-19; New coronavirus; Immunochromatographic assay; Validation; Fluorescence immunoassay test



Abstract

Background: An outbreak of novel coronavirus (SARS-CoV-2) disease (COVID-19) has rapidly spread worldwide. The aim of this study was to evaluate and validate the performance of the *Wondfo*[®] lateral-flow immunochromatographic assay that detect SARS-CoV-2- IgG, IgM antibodies (*Wondfo*[®] IC), using the results obtained by the fluorescence immunoassay test as reference diagnostic.

Material and methods: 97 serum specimens collected and analyzed by four independent laboratories of Sergipe/Brazil was used for validated the *Wondfo*[®] SARS-CoV-2 IgM/IgG antibodies test. The COVID-19 positive serum specimens were determined by fluorescence immunoassay technique, used as reference standard.

Results: An overall of 97 serum specimens show 39 (39/97) SARS-CoV-2 IgG positive specimens, 33 (33/97) SARS-CoV-2 IgM positive specimen and 25 non-reagent specimens (25/97). However, the *Wondfo*[®] IC assay detected only 9 (9/97) IgM/IgG positive specimen and 25 (25/97) no-reagent specimen. A weak correlation was found between the outcomes of the *Wondfo*[®] IC assay and fluorescence test. The accuracy between the two tests was 32.08%. The sensitivity, specificity, positive predictive value, and negative predictive value of *Wondfo*[®] IC assay were of 11.12%, 100%, 100% and 25.27%, respectively. Moreover, no false positive sample was determinate, whereas 88.89% of false negative results were found.

Conclusion: The *Wondfo*[®] IC test failed in providing a quick, valid, and reliable results and appears not to be a good alternative for clinical use in detecting pandemic coronavirus. However, if the limitations of the rapid test are known, some correction factors can be used in order to adjust the epidemiological data.

Introduction

An outbreak of novel coronavirus (SARS-CoV-2) disease (COVID-19) was first identified in Wuhan City, Hubei Province, China in December 2019 and has rapidly spread worldwide, since been declared a pandemic by the World Health Organization (WHO) [1]. In the May 2020, COVID-19 has inflicted more than 4 million people globally with about 307.537 death [2]. Most people that are infected by SARS-

CoV-2 present mild or no symptoms, but some COVID-19 patients develop severe pneumonia, acute respiratory distress syndrome (ARDS), multiorgan failure that could evolve to death [3].

Adequate diagnosis of SARS-CoV-2 infection is crucial for define the therapeutic management of patients, the establishment of infection control protocols and prevent the dissemination of the virus to new communities. Quantitative

reverse-transcription polymerase chain reaction (RT-PCR) analysis for SARS-CoV-2 RNA is considered the gold standard for detecting COVID-19 disease, however the sensitivity of this method may vary by the time of infection and the viral load [4,5], as well as the RT-PCR is an expensive assay because require special equipment and reagents. Therefore, an alternative laboratorial test was necessary. In this context, the detection of IgG, IgM and IgA antibodies against the SARS-CoV-2 have been gain importance in the diagnosis of COVID-19 due to its rapid and reliable diagnostic test. The serological test become essential for epidemiological information and contribute to adequate lockdown exit strategies and vaccine development [6,7].

One serological test that have been obtained notoriety in the diagnostic of COVID-19 is the immunochromatographic (IC) assay for IgM and IgG antibodies against the virus. The IC assay is a rapid and high-throughput method for diagnosing viral infections and it is accepted as a point-of-care test [8]. Recently, various commercial IC assays were developed for COVID-19 diagnostic, and these tests have been used in clinical setting. However, their efficacy and clinical usefulness need to be evaluated and validate. An appropriate diagnostic method for a disease must have a high sensibility and specificity, as well as a good performance under various conditions [9].

Therefore, the aim of this study was to evaluate and validate the performance of the *Wondfo*[®] lateral-flow immunochromatographic assay that detect SARS-CoV-2 IgG, IgM antibodies, comparing with the results obtained by the fluorescence immunoassay test (FIA). The clinical detection sensitivity and specificity of *Wondfo*[®] IC test were measured using blood samples collected from 72 FIA confirmed COVID-19 patients and 25 negative patients at 4 different laboratories.

Material and methods

Study design

This study included 97 residual human sera obtained by venous blood from patients and healthy people of four laboratories of Sergipe/Brazil, Lab1(UFS): 31 samples; Lab2 (CIRURGIA Laboratory): 25 samples; Lab3 (CLIMED Laboratory): 21 samples; Lab4 (SOLIM Laboratory): 20 samples. The SARS-CoV-2 IgM or IgG specimen were diagnosed positive using a fluorescence immunoassay technique (FIA). We use a FIA with a semi-quantitative detection of IgG and IgM antibodies for SARS-COV-2 in the semi-automatic device iChroma2 by Bodytech (south korea) Samples were divided in COVID-19 reagent and non-COVID-19 reagent based in FIA COI value, COI<0.9 is detected as non-reagent and COI >1.1 is detected as reagent.

The sample was collected in April 2020 by blood puncture in tubes with separating gel, centrifuged at 3000 RPM for 10 min and the serum was separated to SARS-

CoV-2 IgM or IgG antibody analysis. The FIA assay and the immunochromatographic test were performed on the same day of collection following the manufacturing protocol. All *Wondfo*[®] SARS-CoV-2 IgM/IgG antibody test was performed and analyzed by a blinded operator. For kit precision/reproducibility study, 30 specimens were blinded and randomized chosen, and the *Wondfo*[®] IC assay was performed in triplicate.

The inclusion criterium require non reagent diagnostic for influenza virus, Influenza A, Influenza B, HIV, Epstein-bar virus, hepatitis B and hepatitis C antibody.

Wondfo[®] Lateral-flow immunochromatographic assay that detect SARS-CoV-2 IgM/IgG antibodies (*Wondfo*[®] IC test)

Wondfo[®] SARS-CoV-2 IgM/IgG antibody test is an immunochromatographic assay for rapid and quantitative detection of SARS-CoV-2 IgM/IgG antibody in human biological samples. Venous blood serum was subjected to the SARS-CoV-2 IgM/IgG antibody test, using lateral flow method assay in accordant with the manufacturer's protocol (Guangzhou Wondfo Biotech). In brief, 10 µL of serum specimen were added onto the sample loading area followed by 80 µL (2 drops) of buffer. After 15 min of incubation, viral IgM- or IgG-containing positive samples could show up both the T line (test) and C line (control); the samples with only C line were regarded as negative.

Statistical analysis

The numbers of IgM positive, IgG positive and either IgM/IgG positive specimens were counted, and the total absolute number and the percentages were calculated. The accuracy, sensitivity, specificity, positive predictive value, negative predictive value, false-positive and false-negative were calculated. The FIA results were used as reference standard.

The following formula was used to calculate accuracy, sensitivity, specificity, positive predictive value, negative predictive value.

$$\text{Accuracy} = \frac{NTP + NTN}{(NTP + FN + FP + NTP)}$$

$$\text{Sensibility} = \frac{NTP}{(NTP + FN)}$$

$$\text{Specificity} = \frac{NTN}{(FP + NTN)}$$

$$\text{Positive predictive value} = \frac{NTP}{(NTP + FP)}$$

$$\text{Negative predictive value} = \frac{NTN}{(NTN + FN)}$$



Where, NTP, number of true positive; NTN, number of true negative; FP, number of false positive; FN, number of false negative

Ethical statement

The study was approved by the Research Ethics Committee of the Federal University of Sergipe, nº CAAE 31018520.0.0000.5546, April 24, 2020.

Results

IgM and IgG antibodies for SARS-CoV-2 could be detected by lateral-flow immunochromatographic assay (IC) and this rapid test have been currently used for the diagnostic of COVID-19 patients. In this study we compare the result obtain by *Wondfo*® IC assay (*Wondfo*® SARS-CoV-2 antibody test) and results obtain from fluorescence immunoassay (FIA), taken as reference standard.

An overall of 97 serum samples were collected and analyzed by four different and independent laboratories (Lab1: n=31; Lab2: n=25; Lab3: n=21; Lab4: n=20) through fluorescence immunoassay technique (FIA) and the results show 39 (39/97) SARS-CoV-2 IgG positive specimen (COI 2.2-53.2), 33 (33/97) SARS-CoV-2 IgM positive specimen (COI 1.3-5.0) and 25 non-reagent specimen (COI <0.9) (25/97) (Table A), accounting an 74.22% (72/97) SARS-CoV-2 IgG/IgM positive specimens detected by the reference standard technique. The FIA findings were used by define SARS-CoV-2 IgG or IgM positive or negative specimen.

Afterward, the same 97 samples were analyzed by *Wondfo*® COVID-19 IgM/IgG rapid immunochromatographic test (*Wondfo*® IC) and the results were summarized in table A. *Wondfo*® IC assay captures total SARS-CoV-2 immunoglobulin (IgG and IgM). All total sample size analyzed at *Wondfo*® IC assay was successfully performed, because the line in the control zone was clearly visible after 15 min of migration after the specimen was inserted in the cassette.

The *Wondfo*® IC results show that SARS-CoV-2 IgG/IgM antibody was detected in 9 (9.3%) of the 97 serum specimens collected. As expected, all 25 non-COVID-19 people were negative in *Wondfo*® IC test. A weak correlation was found between the outcomes of the *Wondfo*® IC assay (9.3% of SARS-CoV-2 IgM/IgG positive samples) and fluorescence test (74.22% of SARS-CoV-2 IgM/IgG positive samples) (Table A). Table B and C represent a descriptive result of each specimen with the individual data of *Wondfo*® IC test result, comparing COI number obtained in FIA.

Table A: IC assay and FIA assay findings for patients with COVID-19.

	FIA (n = 97)		<i>Wondfo</i> ® SARS-CoV-2 antibody test (n = 97)	
	Number Positive /Total	%	Number Positive /Total	%
IgM	33 / 97	34.0		
IgG	39 / 97	41.2		
Total IgG/IgM	72 / 97	74.2	9 / 97	9.3
Non-reagent	25 / 97	27.8	25/97	25.8

FIA: fluorescence immunoassay

Table B: IC assay findings for patients with COVID-19 determined by FIA assay with SARS-CoV-2 IgG positive diagnostic (n = 39).

	Lab1		Lab2		Lab3		Lab4	
	FIA (COI)	<i>Wondfo</i> ® IC test	FIA (COI)	<i>Wondfo</i> ® IC test	FIA (COI)	<i>Wondfo</i> ® IC test	FIA (COI)	<i>Wondfo</i> ® IC test
29.5	NR	37.3	NR	9.4	NR	26.3	R	
29.6	NR	6.2	NR	12.3	NR	10.5	NR	
32.0	R	2.2	NR	2.7	NR	8.1	NR	
34.0	NR	14.6	NR	11.2	NR	36.8	R	
36.0	NR	13.4	NR	21.1	NR	26.7	R	
36.4	NR	24.5	NR	5.1	NR	27.8	R	
36.9	NR	46.9	NR	36.6	NR	12.2	R	
37.2	NR	37.7	NR	9.0	NR	7.7	NR	
47.0	NR	50.3	NR	3.4	NR	6.8	R	
49.0	NR	53.2	NR			5.4	NR	

FIA: Fluorescence Immunoassay; R: IgG Reagent; NR: Non-Reagent; COI: Cut off Index. FIA cut off index: COI<0,9 non-reagent, COI >1.1 reagent.

Table C: IC assay findings for patients with COVID-19 determined by FIA assay with SARS-CoV-2 IgM positive diagnostic (n=33).

	Lab1		Lab2		Lab3		Lab4	
	FIA (COI)	<i>Wondfo</i> ® IC test	FIA (COI)	<i>Wondfo</i> ® IC test	FIA (COI)	<i>Wondfo</i> ® IC test	FIA (COI)	<i>Wondfo</i> ® IC test
2.0	R (+)	1.8	NR	1.6	NR	2.4	NR	
2.4	NR	1.6	NR	2.4	NR	2.1	NR	
2.6	NR	5.0	NR	4.1	NR	2.9	NR	
2.8	NR	2.8	NR	2.9	NR	2.9	NR	
3.1	NR	2.2	NR	1.9	NR	2.7	NR	
3.2	NR	2.2	NR	1.3	NR			
3.4	R(+++)	2.6	NR	1.8	NR			
4.0	NR	1.3	NR	1.6	NR			
4.0	NR	2.0	NR					
4.3	NR	2.8	NR					

FIA: Fluorescence Immunoassay; R: IgM Reagent; NR: Non-Reagent; COI: Cut off Index. + represent a weak reaction; +++ represent a strong reaction. FIA cut off index: COI<0,9 non-reagent, COI >1.1 reagent

Table D represent the performance characteristic of the *Wondfo*® IC assay compared to the fluorescence assay, taken as reference standard, on the 97 serum specimens. The accuracy between the two tests was 32.08 %. The sensitivity, specificity, positive predictive value and negative predictive value of *Wondfo*® IC assay was of 11.12%, 100%, 100% and 25.27%, respectively. Moreover, no false positive sample was determinate, whereas 88.89% of false negative results were found (Table D). The analysis shows that *Wondfo*® IC assay is reproductively (data not shown).

In order to confirm the previous findings, an additional test was performed using specimen that have the rRT-PCR for RNA viral positive. The RT-PCR is considered the gold

Table D: Accuracy of rapid immunochromatographic tests in 97 specimens of SARS-CoV-2 IgG/IgM reagent and non-reagent cases classified according to the reference test.

	<i>Wondfo</i> ® SARS-CoV-2 antibody test
Sensibility	11.12%
Specificity	100%
Positive predictive value	100%
Negative predictive value	25.27%
False-positive	0.0%
False-negative	88.89%
Accuracy	32.08%



standard assay for COVID-19 diagnostic. The fluorescence assay results show that the specimen was IgM reagent (SARS-CoV-2 IgM positive) (COI 1.4), whereas in *Wondfo*[®] IC test, the same sample was detected as non-reagent.

Discussion

The tracking of SARS-CoV-2 virus in the population help the control of the epidemic situation and facilitate the diagnostic of new cases, becoming an important tool for public health [4]. The adequate diagnosis test is essential for obtain effective and reliable results. This ensures laboratory findings can be traced and patients identified for orientation, isolation, and treatment. Currently recommendation of the WHO for COVID-19 diagnosis indicate the use of molecular tests targeting SARS-CoV-2 virus RNA. However, due to RT-PCR infrastructure limitations and lack of supplies, which limit the number of people with access of a diagnostic tests, a rapid serologic assay was develop to expand laboratories testing capacity and reach all the population [10]. In this line, several rapid tests based on immunochromatographic method for SARS-CoV-2 IgM/IgG antibody have been developed [8,11]. Nevertheless, to achieve the goal of help in public health, this test needs to be a well-validated diagnostic tool that are sensitive, rapid and specific for the detection of SARS-CoV-2.

Demey, et al. [11] using 4 different immunochromatographic rapid tests describe that this kind of diagnostic tool have good performance for the detection of antibodies after SARS-CoV-2 infection. However, Vásárhelyi, et al. [12] found low efficacy in a rapid immunochromatographic tests detecting IgM and IgG antibodies against SARS-CoV-2 virus, suggesting that this test should not be used in the differential diagnosis of coronavirus infection. So, the controversial literature about immunological rapid test lead to the necessity of validation of the SARS-CoV-2 IgM/IgG diagnostic kits in the target population for the purpose of improve the quality of the analysis.

In the present study we evaluated the *Wondfo*[®] IC test (*Wondfo*[®] SARS-CoV-2 antibody test), trying to validate this immunochromatographic assay. The results obtained by fluorescence immunoassay test (FIA), performed by 4 independents laboratory, was used as reference standard. The analytical results of a commercial *Wondfo*[®] IC test kit and the findings obtained by fluorescence test for patients with COVID-19 was compared. The *Wondfo*[®] IC assay showed low sensitivity (11.12%) and high specificity (100%) for COVID-19, with a huge number of false-negatives results. The fluorescence assay detected 72 IgG/IgM antibodies specimens, whereas the *Wondfo*[®] IC assay just reproduce the same result in 9 of this samples, obtaining a low accuracy. Moreover, the *Wondfo*[®] IC assay also failed in detected the SARS-CoV-2 IgM protein in additional specimen confirmed positive for SARS-CoV-2 virus with real-time RT-PCR, set as the gold standard. All this results together, suggest that the *Wondfo*[®] IC test did not present a good agreement with the reference standard test or with the RT-PCR assay.

Furthermore, the low negative predictive values indicate that *Wondfo*[®] IC kit stumble in detecting the presence of SARS-CoV-2 IgM and IgG against virus infection in several specimen, becoming not suitable for screening COVID-19 infection in the general population. So, based in low sensitivity and elevated negative predictive values, we could propose that the *Wondfo*[®] IC test showed low "validity".

It is important to note that in this study we used specimen collected by blood puncture in tubes with separating gel, centrifuged quickly and SARS-CoV-2 IgM or IgG serological tests were done on the same day. It is worth remembering that samples cooled and kept for several days can impair the detection of antibodies. Therefore, the prolonged time to perform the analysis after the collection of the specimen could affect the result of the immunological test, due to the degradation of the reagent protein. For better results, it is recommended that immunological assays be performed as soon as possible.

In addition, the inefficacy of *Wondfo*[®] IC test in detected SARS-CoV-2 IgG or IgM could be associated to the timing of sampling. The COVID-19 disease has different infections stages, which the immunological response vary with the disease pathology [13,14]. Studies have been demonstrated that the timing of sampling reflects in the sensitivity and specificity of serological tests. Imai, et al. [15] show that the sensitivity of IC assay was low during the early phase in symptomatic and asymptomatic patients. Cassaniti, et al. [16] reported that the VivaDiag[®] COVID-19 IgM/IgG Rapid Test present a weak positive serology in acute patients. In this study the rapid test detected just 18.4% of positive samples of patients confirmed to be positive for COVID-19 by real time RT-PCR. This contradiction could be related to the timing of sampling because it reflects the develop of the disease. In this context, Pan, et al. [8] suggest that that the sensitivity of IC assay fluctuate with the disease progression, the authors shows that the positive rates of SARS-CoV-2 IgM or IgG in the early stage are relatively low, and gradually increase during the disease evolution. So, the stage of the infection, which was reflected in the timing of sampling, could infer in the results of an immunochromatographic assay.

This study has some limitations. The number of serological samples and the rapid tests performed. The use of only one serological methodology as a reference for the presence of antibodies. In addition, the positive and negative samples distribution could be a limitation of the study.

Conclusion

Thus, the *Wondfo*[®] IC test failed in providing a quick, valid and reliable results and appears not to be a good alternative for clinical use in detecting pandemic coronavirus. However, if the limitations of the rapid test are known, some correction factors can be used in order to adjust the epidemiological data. Further studies may be necessary to determine the



usefulness of this kit in different settings and communities. To further understand the reasons behind the lower sensitivity of the immunochromatographic assay, future research should be designed to investigate the possibility of interferences of sample timing and collection in the kit result.

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Contribution

LPB, LQJ and AASA contributed to conception and design of the study. LPB, MGB, DR and KAS contributed to the acquisition of data and analysis of data. LPB, LQJ and AASA contributed to analysis and interpretation of the data. LH, LPB and LQJ drafting the article or revising it critically for important intellectual content. LPB, MGB, DR, LH, LQJ and AASA approved the version to be submitted.

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