

# Sensitivity and Specificity of a COVID-19 Lateral Flow Immunoassay Compared to RT-PCR in Pregnant Women at Arifin Achmad General Hospital Pekanbaru, Indonesia

Imelda EB Hutagaol<sup>1,2</sup>, Muhamad Yusuf<sup>1,2</sup>, NickoPisceski Kusika<sup>3,4</sup>, Suyanto<sup>5</sup>, Shinta Puja Tilusari<sup>6,7</sup>

<sup>1</sup>Consultant, Department of Obstetrics and Gynecology, Faculty of Medicine, University of Riau, Pekanbaru, Riau, Indonesia, <sup>2</sup>Consultant, Department of Obstetrics and Gynecology, Arifin Achmad Hospital, Pekanbaru, Riau, Indonesia, <sup>3</sup>Assistant Professor, Department of Obstetrics and Gynecology, Faculty of Medicine, University of Riau, Pekanbaru, Riau, Indonesia, <sup>4</sup>Assistant Professor, Department of Obstetrics and Gynecology, Arifin Achmad Hospital, Pekanbaru, Riau, Indonesia, <sup>5</sup>Assistant Professor, Department of Public Health, Faculty of Medicine, University of Riau, Pekanbaru, Riau, Indonesia, <sup>6</sup>Resident, Department of Obstetrics and Gynecology, Faculty of Medicine, University of Riau, Pekanbaru, Riau, Indonesia, <sup>7</sup>Resident, Department of Obstetrics and Gynecology, Arifin Achmad Hospital, Pekanbaru, Riau, Indonesia

## Abstract

Coronavirus disease 2019 (COVID-19) is significant global treat including to pregnant woman in Indonesia. A point-of-care diagnostic tool that is able to early diagnose and has a good sensitivity and specificity is critical during the pandemic. The aim of this study was to describe the clinical, laboratory and outcomes of pregnant women with presumptive COVID-19 and to compare the sensitivity and specificity between COVID-19 rapid test (lateral flow immunoassay) and real-time reverse transcription polymerase chain reaction (RT-PCR). Pregnant women with presumptive COVID-19 symptoms were recruited at Arifin Achmad General Hospital between April 2020 and December 2020. Demographic and clinical data were collected and patients were tested with COVID-19 rapid test as well as RT-PCR. Analyze was conducted to determine the sensitivity and specificity. We included 120 patients with presumptive COVID-19 of which 48 (40%) and 72 (60%) of patients were reactive for IgM and IgG antibody anti severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), respectively and 51 (42.5%) were reactive for both IgM and IgG. The sensitivity and the specificity of rapid test was 64.0% and 33.3%, respectively. The positive and negative predictive value was 61.5% and 35.7%, respectively. In conclusion, lateral flow immunoassay-based rapid test has relatively low sensitivity and specificity in diagnosing COVID-19 in pregnant women.

**Keywords:** Sensitivity, specificity, rapid test, RT-PCR, COVID-19

## Introduction

On December 2019, coronavirus disease 2019 (COVID-19) cases, cause by a new coronavirus, severe

acute respiratory syndrome coronavirus 2 (SARS-CoV-2), were firstly reported in Wuhan, China. World Health Organization (WHO) then declared COVID-19 as pandemic on March 11 2020.<sup>1</sup>SARS-CoV-2 is a single-stranded ribonucleic acid (RNA) virus. The virus is able to survive at least for 12 hours on plastic surface, sensitive to sunlight and heat, easy to be inactivated with lipophilic substance such as ethanol and disinfectant contained chlorine, peroxyacetic acid and chloroform. The incubation of SARS-CoV-2 is about 5 to 7 days and is transmitted through droplet from symptomatic

---

### Corresponding author:

**Dr. NickoPisceski Kusika**

Department of Obstetrics and Gynecology, Faculty of Medicine, University of Riau

Jl. Diponegoro No.1, SukaMulia, Kec. Sail, Kota

Pekanbaru, Riau 28133, Indonesia

Email: pisceski@lecturer.unri.ac.id

nicko.pisceski@lecturer.unri.ac.id

persons.<sup>2,3,4</sup>The natural reservoir of SARS-CoV-2 is bats; however, some evidence suggested that weasel or racoon are also potential natural hosts.<sup>5</sup>

COVID-19 causes an acute respiratory syndrome result in death which clinical and laboratory findings are similar between pregnant and non-pregnant woman. Pneumonia is the main finding in thorax CT-scan in patients with COVID-19 and some of frequent complications are acute respiratory distress syndrome (ARDS) and disseminated intravascular coagulopathy.<sup>2,5</sup>A study in New York found that pregnant woman with COVID-19 were more likely to be hospitalized, required intubation, mechanical ventilation, and admitted to the intensive care unit (ICU) than non-pregnant woman.<sup>2</sup>This is mainly because of the physiologic changes during pregnancy, such as decrease functional residual capacity, increased diaphragm, edema of respiratory mucosa, and change of immune system lead to increased susceptibility to virus infection.

In Indonesia, the first COVID-19 cases were identified in the capital Jakarta in March 2, 2020. As of March 26, 2021 more than 1.4 million cases and more than 40,000 deaths have been reported.<sup>6</sup>COVID-19 has caused multisectoral disruptions including economics, healthcare system including children vaccination.<sup>7,8</sup>Riau is one of the provinces in Indonesia with the highest COVID-19 cases.<sup>9</sup>In Indonesia, COVID-19 rapid test is a screening tool that mainly to early detect COVID-19 and the result of rapid test will be confirmed with real-time reverse transcription polymerase chain reaction (RT-PCR). In the early of the COVID-19 pandemic, multiple brands of rapid test are available in the country with relatively limited in sensitivity and specificity assessments in the population. The aim of this study was to determine the sensitivity and specificity level of COVID-19 rapid test in comparison to gold standard RT-PCR in pregnant women.

## Methods

A cross-sectional study was conducted from April 2020 to December 2020 at Arifin Achmad Hospital, Pekanbaru, Riau, Indonesia. Pregnant women with

presumptive COVID-19 were tested with COVID-19 rapid test. In the first visit, data of demographic, exposure to COVID-19 cases and clinical data were collected. The COVID-19 rapid test was Healgen COVID-19 IgG/IgM Rapid Test Cassette (Healgen Scientific LLC, Houston, TX, USA). This kit detects both IgM and IgG antibodies to SARS-CoV-2 from whole blood serum or plasma and the test was conducted per manufacture protocol.

The patients with reactive for IgG/IgM rapid test then were re-tested with RT-PCR targeting at least two gene of SARS-CoV-2 using available kits at Arifin Achmad General Hospital Riau Indonesia (mainly using LiliF COVID-19 Real-time RT-PCR (iNtRON Biotechnology, Gyeonggi-do, Korea) or Live Rifer Novel Coronavirus COVID-19 (2019-nCoV) Real-Time Multiplex RT-PCR Kit (Shanghai ZJ Bio-Tech, Shanghai, China)). The samples for RT-PCR were nasal and oropharynx swabs. All run of RT-PCR were conducted per manufacture protocol.

The patients were also followed and data of outcome, time of stay in the hospital, intrapartum treatments or procedures were collected. The RT-PCR results of the new born baby was also collected. The sensitivity, specificity, positive prediction value (PPV) and negative prediction value (NPV) of rapid test were calculated.

## Results

We included 120 patients with presumptive COVID-19. Characteristics of demographic, clinical, laboratory and outcomes of the patients are presented in **Table 1**. Almost 45% of the patients aged between 26–30-year-old (**Table 1**). There were 48.3% patients who were housewife, 28.3% general employees and 23.3% civil servants. More than two-third of the patients (76.6%) had caesarean section and only 13 (10.8%) had normal vaginal delivery. Our data suggested that less than 10% of the total patients had at least one of COVID-19 comorbidity.

Based on IgM and IgG antibody rapid test, 48 (40%) and 72 (60%) of patients were reactive for IgM and IgG anti-SARS-CoV-2, respectively (**Table 1**). Out of total

patients, 51 (42.5%) patients were reactive for both IgM and IgG anti-SARS-CoV-2.

**Table 1. Characteristics of demographic, clinical, laboratory and outcomes of pregnant women with COVID-19 (n=120)**

Characteristic	Details	Number	%
Demographics	Level of education		
	Bachelor	24	20.0
	Senior high school	52	43.0
	Junior high school	32	32.0
	Elementary school	12	10.0
	Age (year)		
	18-25	17	14.1
	26-30	52	43.3
	31-35	29	24.1
	36-40	1	15.8
	41-45	3	2.5
	Occupation		
	Housewife	58	48.3
	Civil servant	28	23.3
General employee	34	28.3	
Clinical	COVID-19 screening score		
	Less than 6	54	45.0
	6-10	66	55.0
	Had fever (38oC) or had fever in 2 last weeks	12	10.0
	Intrapartum management		
	Conservative	8	6.6
	Vaginal delivery	13	10.8
	Caesarean section	92	76.6
	Vacuum extraction	5	4.1
	Un-hospitalized on own request	2	1.6
	Obstetric care's length		
	1 day	10	8.3
	2 days	13	10.8
3 days	97	80.8	
Exposure	Direct contact with COVID-19 case in last 2 weeks	16	13.3
	In the same room with a COVID-19 case within 1-2 meterfor more than 15 minutes	20	16.6
Comorbidity	Had at least one comorbidity (diabetes, hypertension, heart disease, stroke, TBC, or cancer)	10	8.3

**Cont... Table 1. Characteristics of demographic, clinical, laboratory and outcomes of pregnant women with COVID-19 (n=120)**

<b>Laboratory test</b>	Immunology test		
	IgM reactive	48	40.0
	IgG reactive	72	60.0
	IgG and IgM reactive	51	42.5
	Swab RT-PCR		
	RT-PCR positive	52	43.4
	RT-PCR negative	68	56.6
	Total baby with positive swab test	4	3.3
<b>Outcome</b>	Death	1	0.8

**Table 2. Sensitivity, specificity, positive prediction value (PPV) and negative prediction value (NPV) of rapid test compared to RT-PCR in pregnant women (n=120)**

<b>Rapid test</b>	<b>RT-PCR</b>			<b>PPV / NPV</b>
	<b>COVID-19 (+)</b>	<b>COVID-19 (-)</b>	<b>Total</b>	
Reactive	48	30	78	61.5% (PPV)
Non-reactive	27	15	42	35.7% (NPV)
Total	75	45	120	
Sensitivity / Specificity	64.0% (Sensitivity)	33.3% (Specificity)		

We compared the sensitivity and specificity of rapid test with RT-PCR. Our data suggested that the sensitivity and specificity of COVID-19 rapid test was 64.0% and 33.3%, respectively (**Table 2**). The positive prediction value (PPV) and negative prediction value (NPV) of rapid test compared to RT-PCR was 61.5% and 35.7%, respectively.

### Discussion

RT-PCR as a gold standard has a high sensitivity and specificity in detecting the presence of SARS-CoV-2 in specimens although in very small quantities. However, it requires high-skilled staff as well as high standard laboratory. Therefore, easy to use and cheap point-of-care diagnostic modality is critical during the COVID-19 pandemic particular in low- and middle-income

countries. One of the rapid tests developed during the pandemic was lateral flow immunoassay that detects and differentiate IgM and IgG antibodies anti-SARS-CoV-2. We tested one of the lateral flow immunoassay rapid tests developed by Healgen Scientific LLC, Houston, TX, USA in pregnant women. Our data indicated that the sensitivity and specificity of COVID-19 rapid test was 64% and 33.3% with 61.5% and 35.7% PPV and NPV, respectively. The data suggest that the COVID-19 rapid test has relatively low power in diagnosing COVID-19 in pregnant women.

There are some possible reasons of low sensitivity and specificity of lateral flow immunoassay found in this study. Some of the patients in this study probably in the early phase of infection since the sensitivity of this kit for those in their early infection is unknown and negative

results do not preclude acute SARS-CoV-2 infection. In addition, faults during nasal and oropharyngeal swab procedure could also be reasons since inadequate amount of virus could cause negative results during the rapid test. Some of the samples in this study were processed in virus inactivated viral transfer media and inactivation of the virus might affect the test results of rapid test.<sup>10,11</sup> In addition, false positive results may occur due to cross-reactivity from pre-existing antibodies against other viruses.

### Conclusion

The sensitivity and specificity of IgG and IgM lateral flow immunoassay in diagnosing COVID-19 of pregnant women at Arifin Achmad Hospital was 64% and 33.3%, respectively with PPV and NPV was 61.5% and 35.7%, respectively. Apart from sampling time and cross-reactivity, some other factors related to personnel and instrumental issues might associate with the results.

**Acknowledgement:** We would like to thank to all patients and to the management of Arifin Achmad Hospital, Indonesia.

**Ethical Clearance:** The study protocol was approved by Arifin Achmad Hospital, Indonesia.

**Source of Funding:** Self

**Conflict of Interest:** Nil

### References

1. Akhtar H, Patel C, Abuelgasim E, Harky A. COVID-19 (SARS-CoV-2) Infection in Pregnancy: A Systematic Review. *Gynecol Obstet Invest.* 2020;85(4):295-306.
2. Brandt JS, Hill J, Reddy A, et al. Epidemiology of coronavirus disease 2019 in pregnancy: risk factors and associations with adverse maternal and neonatal outcomes. *Am J Obstet Gynecol.* Published online 2020:1-9.
3. Susilo A, Rumende CM, Pitoyo CW, et al. Coronavirus disease 2019: Tinjauan literatur Terkini. *J Penyakit Dalam Indones.* 2020;7(1):45.
4. Christyani F, Padang AF. Transmisi Vertikal COVID 19 selama Kehamilan. 2020;47(9):663-667.
5. Rasmussen SA, Smulian JC, Lednicky JA, Wen TS, Jamieson DJ. Coronavirus Disease 2019 (COVID-19) and pregnancy: what obstetricians need to know. *Am J Obstet Gynecol.* 2020;222(5):415-426.
6. Kementrian Kesehatan RI. DATA COVID-19 2020. Data covid Update 2020. Published online 2020. [www.kemkes.go.id](http://www.kemkes.go.id)
7. Fahriani M, Anwar S, Yufika A, Bakhtiar B, et al. Disruption of childhood vaccination during the COVID-19 pandemic in Indonesia. *Narra J* 2021;1(1): e7. Doi: 10.52225/narraj.v1i1.7.
8. Harapan H, Itoh N, Yufika A et al. Coronavirus disease 2019 (COVID-19): A literature review. *J Infect Public Health* 2020;13(5):667-673
9. Dinas Kesehatan Provinsi Riau. Situasi Covid-19 Provinsi Riau update COVID-19 RIAU. Updat Data Covid RIAU. Published online 2020:1-23. <http://dinkes.riau.go.id>
10. Asadi L, Tabatabaei RS, Safinejad H, Mohammadi M. New corona virus (COVID-19) management in pregnancy and childbirth. *Arch Clin Infect Dis.* 2020;15
11. Mei Y, Luo D, Wei S, et al. Obstetric management of COVID-19 in pregnant women. *Front Microbiol.* 2020;11:1-9.