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Diagnostic test of Rapid antigen SARS Cov-2 against RT-PCR on suspected symptomatic COVID-19 patients at Rato Ebu Hospital Bangkalan

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ABSTRACT COVID-19 is caused by the SARS-CoV-2 virus. Two tests to detect the SARS-CoV-2 virus are the rapid antigen test and RT-PCR. The gold standard for testing for COVID-19 is RT-PCR. The high number of Covid-19 sufferers in Madura plus the RT-PCR examination takes a long time. Rapid antigen examination is one of the Covid-19 screening solutions that should be tested because it offers fast examination times. This study aims to determine the sensitivity and specificity of the SARS COV-2 rapid antigen test to RT PCR for the diagnosis of COVID 19. This type of research is an analytical study with a cross-sectional design. The study was conducted at Rato Ebu Hospital Bangkalan from July-September 2021. The sample of this study was suspected symptomatic COVID-19 patients who were examined using the SARS-CoV-2 rapid antigen and RT-PCR using purposive sampling of as many as 60 people. Diagnostic test method by measuring the sensitivity and specificity of rapid antigen to RT-PCR. Based on the results of the study, it can be concluded that the sensitivity of the SARS Cov-2 Rapid Antigen to RT-PCR is 82.97% and the specificity of the SARS Cov-2 Rapid Antigen to RT-PCR is 100%.

INDEX TERMS: Sensitivity and specificity, Rapid Antigen, RT-PCR\

I. INTRODUCTION

Coronavirus disease 2019 (COVID-19), an infectious disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has developed into a global pandemic and is still a major health problem worldwide. The initial outbreak of SARS-CoV-2 began in Wuhan, China, in December 2019 [1,2]. SARS-CoV-2 severely affected the global economy and mental health due to restrictions to prevent and control disease transmission [3,4].

Highly effective, rapid, and inexpensive diagnostic screening in susceptible populations is urgently needed to control the source of viral infection. Laboratory tests to detect SARS-CoV-2 fall into two categories. The first tests to detect the virus itself are rapid antigen tests and RT-PCR. The second to detect the response of the host is the Rapid antibody. Each test has advantages and disadvantages [5].

The gold standard for COVID-19 examination is Real-Time Reverse Transcription Polymerase Chain Reaction (RT-PCR) using samples of nasopharyngeal or oropharyngeal swab material, sputum, or bronchial lavage (bronchial lavage) by detecting the E gene (Envelope), gene N (nucleocapsid), gene S (Spike) and RdRp gene. A patient is confirmed positive for COVID-19 if detection by RT-PCR finds a unique sequence of viral RNA [6,7,8]. Other COVID-19 tests based on host response (antibody) use serological tests to detect IgM-IgG or total antibodies. A rapid antigen test in principle is an immunoassay test that detects the presence of SARS-CoV-2 virus antigens. The sample used for the rapid antigen test is a nasopharyngeal swab which is then placed in the assay extraction buffer. Rapid antigen test results come out in 15-20 minutes. The rapid antigen test has been approved by the CDC as a screening method. If the results of the rapid antigen test are positive, a confirmation test must still be carried out using the RT-PCR method [9,10].

The antigen sensitivity of rapid tests according to FDA EUAs ranges from 84%-97.6% when compared to RT-PCR. The specificity of the fast antigen is quite high, almost equal to that of RT-PCR. However, the drawback of this rapid antigen test is that if the patient's viral load is low (high CT values above 30), the probability of antigen being detected is also low. Therefore, the CDC recommends that rapid antigen testing be performed during the early stages of infection when there is a high viral load. In a study conducted by Berger et. Al. CT values ranging from 14.2-25.1 can produce a sensitivity of 93.9% (95% CI 86.5-97.4%) and a specificity of 100% (95% CI 92.1%-100%) [11,12]. The study of suspected Covid-19 patients at Siriraj

Hospital, Bangkok, Thailand from March–May 2020 found that the sensitivity and specificity of Rapid antigen to RT-PCR were 98.33% and 98.73% [9].

SARS-CoV-2 infected more than 211 million people and killed more than 4.4 million people worldwide. People infected with SARS-CoV-2 experience a variety of symptoms, including fever, cough, fatigue, shortness of breath, headache, sore throat, and loss of smell and taste [13,14]. The high number of Covid-19 sufferers in Madura plus the RT-PCR examination takes a long time. Rapid antigen examination is one of the Covid-19 screening solutions that should be tested because it offers fast examination times. Compared to previous studies, this study focused on carrying out diagnostic tests by measuring the sensitivity and specificity of the SARS-CoV-2 rapid diagnostic test against RT-PCR on suspected symptomatic COVID-19 patients at Rato Ebu Hospital Bangkalan in a cross-sectional.

This study aims to measure the sensitivity and specificity of the SARS-CoV-2 rapid diagnostic test against RT-PCR at Rato Ebu Hospital Bangkalan.

II. METHOD

This type of research is analytic with a cross-sectional design. This study aims to determine the sensitivity and specificity of the rapid SARS Cov-2 antigen as a diagnosis of COVID-19 with RT-PCR as the gold standard. The study was carried out at Rato Ebu Bangkalan Hospital from July to September 2021. The population was suspected COVID-19 patients who were examined for infection with the SARS cov-2 virus at Rato Ebu Bangkalan Hospital using SARS Cov-2 rapid antigen and RT-PCR. The sample is a suspected COVID-19 patient at Rato Ebu Hospital Bangkalan who was examined using the SARS-CoV-2 rapid antigen and RT-PCR selected by purposive sampling. Samples were taken based on the following criteria: Experiencing symptoms of respiratory tract infection (ARI) such as fever or a history of fever with a temperature > 38ºC, having symptoms of respiratory disease, such as cough, shortness of breath, sore throat, and runny nose, anosmia and dysgeusia. Samples were taken from as many as 60 people suspected of Covid-19. The independent variable in this study was the result of the SARS Cov-2 rapid antigen test. The dependent variable in this study was the result of the RT-PCR test. Data retrieval using primary data through rapid antigen examination of SARS-CoV-2. Diagnostic test sensitivity and reliability are measured by the formula:

$$\text{Sensitivity} = \frac{T\ p}{T\ p + F\ n}$$

$$\text{Sensitivity} = \frac{T\ n\ ati}{T\ n\ e + F\ p}$$

III. RESULTS

The results of the examination of suspected symptomatic COVID-19 patients at Rato Ebu Hospital Bangkalan using the SARS Cov-2 rapid antigen and RT-PCR obtained the following data:

1. *Gender*

Based on TABLE 4.1, it is known that the most suspected Covid-19 patients are 39 women (65%), and 21 men (35%).

TABLE 1
Characteristics Of Suspected Symptomatic Covid-19 Patients At Rato Ebu Hospital Bangkalan By GENDER

Gender	Total	%
Man	21	35
Woman	39	65
Total	60	100

2. *Age*

Based on TABLE 4.2, it is known that the majority of suspected symptomatic COVID-19 patients aged 26-45 years are 22 people (36.67%), 10-25 years are 19 people (31.67%), 46-60 years are 12 people (20%) , < 10 years are 4 people (6.67%) and > 60 years are 3 people (5%).

TABLE 2
Characteristics Of Suspected Symptomatic Covid-19 Patients At Rato Ebu Hospital Bangkalan By Age

Age	Total	%
< 10	4	6.67
10-25	19	31.67
26-45	22	36.67
46-60	12	20.00
> 60	3	5.00
Total	60	100

3. *The Results of The Rapid Antigen Test For Sars Cov-2*

After obtaining the results of the SARS Cov-2 Rapid Antigen test in patients with suspected symptomatic COVID-19 patients. The listed results are as follows (TABLE 3).

TABLE 3.
The Results of The Rapid Antigen Sars Cov-2 Examination On Suspected Symptomatic Covid-19 Patients At Rato Ebu Hospital Bangkalan

Test Results	Total	%
Positive	39	65
Negative	21	35
Total	60	100

Based on FIGURE 1 shows the results of the Rapid Antigen SARS Cov-2 examination in suspected symptomatic COVID-19 patients, 39 people (65%) had positive results, and 21 (35%) had negative results.

4. *RT-PCR Test Results*

After obtaining the data from the RT-PCR test results in patients with suspected symptomatic COVID-19 patients. The listed results are as follows (TABLE 4)

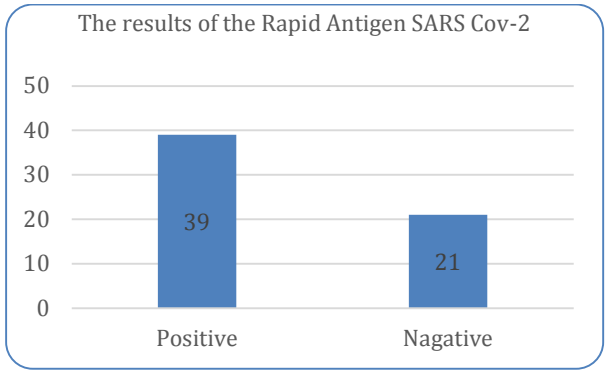

FIGURE 1. The results of the Rapid Antigen SARS Cov-2 examination on suspected symptomatic Covid-19 patients at Rato Ebu Hospital Bangkalan

TABLE 4
The Results Of The Rt- Pcr Examination On Suspected Symptomatic Covid-19 Patients At Rato Ebu Hospital Bangkalan

test results	Total	%
Positive	47	78.33
Negative	13	21.67
Total	60	100

Based on FIGURE 2 shows the results of the RT-PCR examination on suspected symptomatic COVID-19 patients, 47 people (78.33%) were positive and 13 people (21.67%) were negative.

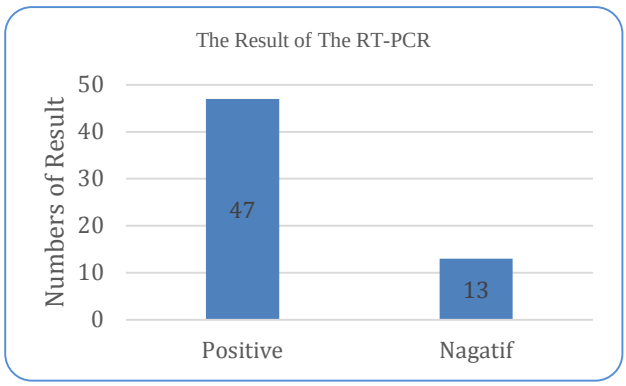

FIGURE 2. The results of the RT- PCR examination on suspected symptomatic Covid-19 patients at Rato Ebu Hospital Bangkalan

5. Data analysis

The inspection data obtained are then tabulated in a 2 x 2 table as follows:

TABLE 5.
Cross-Tabulation Of The Results Of Rapid Antibody And Rt-Pcr Examinations

fast antigen SARS-CoV-2	PCR		Total
	Positive	Negative	
Positive	39 (a)	0 (b)	39
Negative	8 (c)	13 (d)	21
Total	47 (a+c)	13 (b+d)	60

Then calculated by the formula:

$$\text{Sensitivity} : \frac{a}{(a+c)} x100\%$$

$$: \frac{39}{(39+8)} x100\%$$

$$: 82{,}97\%$$

The results of the rapid antigen SARS Cov-2 against PCR (Gold standard) have a sensitivity of 82.97% (high).

$$\text{Specificity} : \frac{d}{(b+d)} x100\%$$

$$: \frac{13}{(13+0)} x100\%$$

$$: 100\%$$

The results of the rapid antigen SARS Cov-2 against PCR (Gold standard) have a specificity of 100% (high).

IV. DISCUSSION

The results of the examination of 60 suspected symptomatic COVID-19 patients at Rato Ebu Bangkalan Hospital using the SARS Cov-2 rapid antigen, found that 39 people (65%) were positive and 21 people were negative (35%). The results of RT-PCR on suspected symptomatic COVID-19 patients showed positive results for as many as 47 people (78.33%) and negative as many as 13 people (21.67%). The results of the rapid SARS Cov-2 antigen diagnostic test against RT-PCR showed a sensitivity of 82.97% and specificity of 100%. These results indicate that the sensitivity and specificity of the SARS Cov-2 rapid antigen are high enough that it can be used as a reliable COVID-19 screening tool.

The results of this study are in line with WHO (2020) which states that the Rapid Antigen SARS Cov-2 has a sensitivity of 80% and a specificity of 97% [10]. Other studies stated that the sensitivity and specificity of rapid antigen were 80.3% and 100% [15] and 82.35% and 100% [16].

In symptomatic patients, the results of this study showed a higher sensitivity of RAT when used for symptomatic patients [17,18]. The lower the CT value, the greater the sensitivity and specificity of RAT, while the higher the CT value, the lower the sensitivity and specificity of RAT. Ct values, on the other hand, cannot be directly compared between tests and should be interpreted with caution as they are influenced by sample type, sample collection time, and test design [19].

A rapid antigen test in principle is an immunoassay test that detects the presence of SARS-CoV-2 virus antigens. The sample used for the rapid antigen test is a nasopharyngeal swab which is then placed in the assay extraction buffer. Rapid antigen test results come out in 15-20 minutes. Currently, the rapid antigen test has been approved by the CDC as a screening method. If the results

of the rapid antigen test are positive, a confirmatory test using the RT-PCR method must still be carried out [20,21]. The way fast antigens work is that antigens are molecules that can stimulate an immune response. These molecules can be proteins, polysaccharides, lipids, or nucleic acids. Each antigen has different surface features that are recognized by the immune system. SARS-CoV-2, the virus that causes COVID-19, has several known antigens, including nucleocapsid phosphoproteins and spike glycoproteins. Rapid antigen tests can reveal whether a person is currently infected with a pathogen such as the SARS-CoV-2 virus. Unlike the PCR test which detects the presence of genetic material, the rapid antigen test detects proteins or glycans, such as the spike protein found on the surface of SARS-CoV-2. Rapid antigen testing works best when the person is tested in the early stages of SARS-CoV-2 infection, where viral loads are generally highest [22,23,24].

Rapid antigen SARS-CoV-2 has high sensitivity and specificity but has a disadvantage, namely if the patient's viral load is low (high CT value > 30), the probability of detecting antigen is also low. This creates a false negative result. The CDC recommends that rapid antigen testing be performed during the early phase of infection when there is a high viral load [22].

In the future, the use of rapid antigens must be increased in Covid-19 screening activities because of their high sensitivity and specificity

V. CONCLUSION

Based on the results of the study, it can be concluded: The results of the Rapid Antigen SARS Cov-2 examination in suspected symptomatic COVID-19 patients were 39 people (65%) positive and 21 people (35%). The results of the RT-PCR examination on suspected symptomatic COVID-19 patients showed positive results for as many as 47 people (78.33%) and negative as many as 13 people (21.67%). The sensitivity of the SARS Cov-2 Rapid Antigen to RT-PCR was 82.97% and the specificity of the SARS Cov-2 Rapid Antigen to RT-PCR was 100%.

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