# *Polymerase Chain Reaction (PCR) and IgG/IgM Antibodies Rapid Test as Tools in COVID-19 Diagnosis: A Comparative Study.

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**A B S T R A C T**

The study aimed to determine the effectiveness of the Polymerase Chain Reaction (PCR) and IgG/IgM Antibodies Rapid Test as Tools in COVID -19 Diagnosis. Specifically, this study aimed to answer the following questions: 1.) What is the incidence of COVID-19 among the clients of Selected Clinic at Tripoli, Libya utilizing Polymerase Chain Reaction (PCR) tests? 2.) What is the incidence of COVID-19 among the clients of Selected Clinic at Tripoli, Libya utilizing IgG/IgM Antibodies Rapid Test? 3.) Is there a significant difference between the utilization of Polymerase Chain Reaction (PCR) tests and IgG/IgM Antibodies Rapid Test as tool in the diagnosis of COVID-19? The findings that the researcher was able to extract from the study were: 1.)that among the 19 patients, 7 or 37% yielded a Negative result and 12 or 63% yielded a positive result on the PCR test. 2.) that out of the 19 patients, 26.32% yielded a positive result, 52.63% Negative and 21.05% have recovered and is not infectious. 3.) there is a difference between the two variables. After the statistical analysis, the computed value is higher than the table value which pave the inference of rejecting the null hypothesis. Based on the findings, the following conclusions were drawn; 1.It can be said that the incidence of COVID-19 utilizing the PCR test are high among the samples taken at the patients of Selected Clinic at Tripoli, Libya. 2. Based on the results of the study, it can be said that the incidence of COVID-19 utilizing the IgG/IgM Antibody Rapid Test is lower on the samples taken at the patients of Selected Clinic at Tripoli, Libya. 3. It can be drawn that the variables of the study has significant difference and that indeed PCR test still proves it accuracy as to the diagnosis of COVID-19.

**Keywords:** COVID-19, Diagnostic Tool, PCR Test

**Introduction**

Coronavirus disease (COVID-19) is an infectious disease caused by a newly discovered coronavirus. Most people infected with the COVID-19 virus will experience mild to moderate respiratory illness and recover without requiring special treatment. Older people, and those with underlying medical problems like cardiovascular disease, diabetes, chronic respiratory disease, and cancer are more likely to develop serious illness.

Over the course of the Covid-19 crisis, the importance of reliable, accessible testing to screen for the disease has become increasingly apparent. Tests for Covid-19 can be divided into antigen or antibody tests, both of which use different kinds of samples to search for different hallmarks of the SARS-CoV-2 virus.

The COVID-19 outbreak has had a major impact on clinical microbiology laboratories in the past several months. The ongoing, unprecedented outbreak of COVID-19 globally has emphasized the importance of the laboratory diagnosis of human coronavirus infections in order to limit the spread as well as to appropriately treat those patients who have a serious infection. [1]

It is essential to distinguish between asymptotic, suspected, or confirmed cases of COVID-19 before quarantine. One who has been exposed to SARS-CoV-2 and has developed symptoms of COVID-19, such as cough, fever, fatigue, etc., is considered as a suspected case and is therefore in need of further identification. So far, hundreds of testing kits have been available in the market to meet the exponential demand in testing, targeting antigens, antibodies [immunoglobulin G (IgG) and immunoglobulin M (IgM)], and the viral RNA of SARS-CoV-2 to confirm infection. [2]

Twenty-nine (29) COVID-19 labs (out of 34) reported 57,109 new lab tests done in Epi-week 31 of August 2-8, 2021. Thus, out of the total 1,391,098 tests in Libya since the beginning of the response, 269847 (19.4%) were confirmed positive for SARS-Cov-2 (COVID-19). [3]

Nowadays, many countries produce a large number of COVID-19 test kits; a large proportion of the population, in fact, have been tested. The number of test kits should soon meet the demand. However, that alone will not solve the enormous coronavirus testing backlog. Having test kits will not complete the whole process of SARS-CoV-2 detection because a test is not a single device. COVID-19 testing involves several steps, each one requiring different supplies, and there are shortages at various phases of the process at different times and in different places. The healthcare labor force in some countries is not enough to meet the demand for COVID-19 virus detection, so even if these countries have enough test kits, it cannot solve the problem.

Since the COVID-19 pandemic is ongoing, there is still a continuing demand for test kits. The robust spread of the disease across the world has alarmed healthcare workers. Medical device manufacturers have increased the development and production of COVID-19 detection kits. Therefore, medical device manufacturers can earn a large amount of profit. The market size for COVID-19 detection kits was valued at USD 3.3 billion till now in 2020 and is expected to witness 17.3% compound annual growth rate (CAGR) from 2020 to 2026. Studies showed that the oropharyngeal swab is expected to account for around USD 920 million in market value in 2020. The immunoassay test strips/cassettes segment is anticipated to account for nearly USD 141 million market value in 2020, owing to the growing demand for rapid test avenues. Besides, studies showed that the diagnostic centers segment accounted for around 32% market share in 2020. These phenomena may produce problems, such as poor qualities of COVID-19 test kits and long wait times for results, and the detection process may not be vigorously

pursued since manufacturers and diagnostic centers may want to earn more profit from it. [4]

We, at the University of Tripoli, Faculty of Nursing believes for the need for continued access to research and learning. It has never been far more important. At this juncture, we, in the academe recognize our role in this, thus we bent on the study entitled "Polymerase Chain Reaction (PCR) and IgG/IgM Antibodies Rapid Test as Tools in COVID-19 Diagnosis: A Comparative Study."

## METHODS

This study employed the Comparative method of research. These are studies that examine several intact groups to find out the difference between and among them in certain dependent variables on interest. The respondents of this study were the patients from a selected Clinic at Tripoli, Libya who had their PCR test on the period of study of August to September 2021. There were 21 Rapid Test kits provided by the researchers, however the 2 kits had a malfunction, so a total of nineteen (19) patients formed the sample of the study. Convenience type of sampling technique was utilized. Those patients who are available during the data collection date formed the sample of the study. Instruments are specially prepared tools or devices used to collect needed data or information and facilitate observation and measurement of research variables, consistent with the purpose of the study. Research instruments must be valid and reliable to avoid inaccurate data and consequent spurious results. The researcher made use of 2 devices as mechanical instruments as a tool for data collection. For the PCR test, it was the instrument used in the Selected Clinic at Tripoli, Libya and for the Rapid IgG/IgM test, the researchers provided the kit and was sent to the selected Clinic for the data collection. The researcher coordinated with the Medical Technologist at the selected Clinic at Tripoli, Libya to be the venue for the data collection. After permission had been sought, the researchers handed over the Rapid Test Kits to the Medical Technologist who would perform the PCR swab test as well as the Rapid Test. Both test will be administered to the same client on the same time and day so as to ensure internal validity of data and avoid other extraneous variables in the data collection process. After the result had been out, the Rapid test kit was placed adjacent to the PCR test result and a photo of both was taken and was sent to the researchers for data analysis. The researchers also omitted the patients name to ensure confidentiality. The data gathered were treated statistically utilizing Frequency & Percentage and T-Test.

## RESULTS

Detailed scrutiny of Figure 1 reveals that among the 19 patients, 7 or 37% yielded a Negative result and 12 or 63% yielded a positive result on the PCR test.
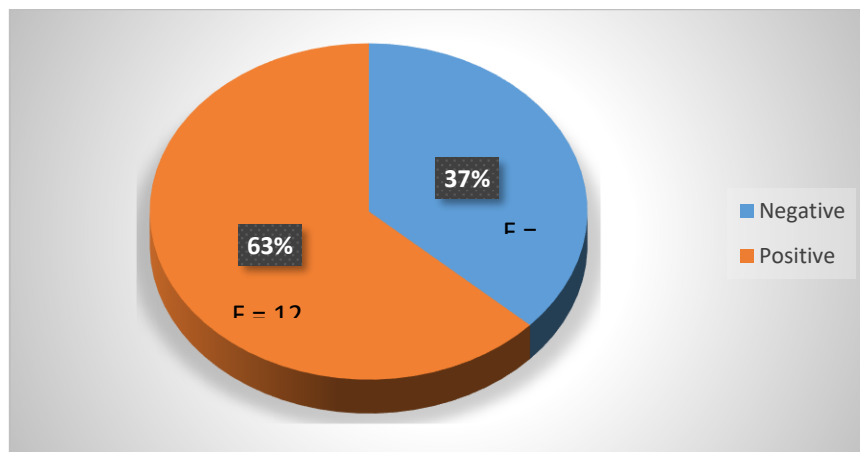
Figure 1. Covid-19 Test Utilizing Polymerase Chain Reaction (PCR)

Cursory inspection of Table 1 reflecting the results that out of the 19 patients, 26.32% yielded a positive result, 52.63% Negative and 21.05% have recovered and is not infectious

Table 1

Frequency & Percentage and Verbal Interpretation of the incidence of COVID-19 among the clients of Selected Clinic at Tripoli Libya utilizing **IgG/IgM Antibodies Rapid Test**

| Indicator | F&P | Verbal Interpretation |
|---|---|---|
| IgM (+) & IgG (+) | (5) 26.32% | Infection at intermediate stage of the disease |
| IgM (-) & IgG (-) | (10) 52.63% | Antibody test cannot detect an infection in the initial stage |
| IgM (+) & IgG (-) | 0% | Infection in the early stage of the disease. The patient is Infectious. |
| IgM (-) & IgG (+) | (4) 21.05% | There is recovery from the disease and the patient is not infectious. |
| **Overall** | **100%** | |

Detailed analysis of table 2 reflecting the difference between the two variables. After the statistical analysis, the computed value is higher than the table value which pave the inference of rejecting the null hypothesis.

Table 2
T Test between the Polymerase Chain Reaction (PCR) test and IgG/IgM Antibodies Rapid Test as a Tool in Diagnosis of COVID – 19.

| Variables | | |
|---|---|---|
| Polymerase Chain Reaction (PCR) Test (X) | T test value | 1.45 |
| | Level of Sig | .10 |
| | N | 19 |
| | X | 31.68 |
| IgG/IgM Antibodies Rapid Test (Y) | T Test value | 1.45 |
| | Level of Sig | .10 |
| | N | 19 |
| | X | 31.68 |

With a t=1.45> 1.330 @ df =18, REJECT the Null Hypothesis. There is therefore a difference between the 2 variables.

## DISCUSSION

"PCR gives us a good indication of who is infected," says University of Sussex senior lecturer in microbiology Dr Edward Wright. "They can be isolated and get in contact with people they've been in touch with so they can be quarantined too, just in case. That's the true advantage of the current major diagnostic tests; you can break that transmission chain and get a clearer picture of what's happening." [5]

Unlike PCR tests, which commonly use swabs to detect Covid-19, blood samples are usually used for antibody tests. This is because there will be a very small amount of Covid-19 circulating in the blood compared to the respiratory tract, but a significant and measurable antibody presence in the blood following infection.

Only a few people have knowledge about antibody tests. Testing of specific antibodies of SARS-CoV-2 in patient blood is suitable for rapid, simple, highly sensitive diagnosis of COVID-19. Compared with RT-PCR, it saves time, and it does not require equipment; it is simple to perform and only requires minimal training. It will be more convenient to use finger stick blood or heel blood instead of vein blood for out of clinic screening. However, this test only provides evidence of recent infection; it also has the risk of false-positive and false-negative results. Therefore, the combination of nucleic acid RT-PCR and the IgM–IgG antibody test can provide more accurate results. [6]

## CONCLUSION

It can be said that the incidence of COVID-19 utilizing the PCR test are high among the samples taken at the patients

of Selected Clinic at Tripoli, Libya. It can also be said that the incidence of COVID-19 utilizing the IgG/IgM

Antibody Rapid Test is lower on the samples taken at the patients of Selected Clinic at Tripoli, Libya. It can be

drawn that the variables of the study has significant difference and that indeed PCR test still proves it accuracy as to

the diagnosis of COVID-19. Based on the outcome of the study and conclusions derived from it, the researchers

were able to formulate the following recommendations: A more in depth study could be done considering more

samples and to include other recent diagnostic modalities such as the Rapid Antigen. Information Dissemination to

Libyan populace that although we have the different means provided for us to choose which diagnostic tool we

would want to choose, it is still but important to do the PCR Test for accuracy of testing. Trainings, Symposiums

and workshops could also be provided to the students of University of Tripoli spearheaded by the Faculty of Nursing

on the results of the study, as early screening or detection is as one of the thrust of
        Primary Health Care. This can be
embedded on the activities under community service of the Faculty of Nursing.

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