

# “A Comparative Study of Qualitative Latex Agglutination Test and Quantitative Turbido Metric Immunoassay Method for the Detection of C-Reactive Protein from Human Sera” In the Early Stages of Covid Patients at A Tertiary Care Centre, Kanpur”

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## Abstract

**Introduction:** COVID-19 is a new infectious disease, for which there is currently no treatment. It is therefore necessary to explore biomarkers to determine the extent of lung lesions and disease severity, CRP detection is the preferred test in evaluation of inflammatory conditions.

**Aim of the Study:** The aim of this study was to compare qualitative slide Latex Agglutination test (LAT) with quantitative Turbidimetric Immunoassay (TIA) method for the detection of CRP, in the early stages of Covid patients at a tertiary care centre, Kanpur.

**Material and Methods:** Total 50 serum samples were collected from the patients, clinically suspected to have systemic inflammation. The study was carried out from June 2020 to Dec 2020. CRP concentrations were determined in serum samples using commercial qualitative slide LAT (RHELAX-CRP, Tulip) and TIA (SD Bio Sensor, Tulip). Testing was done according to the manufacturer's guidelines for both the tests. All the statistical data (sensitivity, specificity, were calculated by using the SPSS 15.0

**Results:** In this study, from a total of 50 patients, 31 were males & 19 were females. Majority of the patients were between the age group of 50-60 years. About 30(70%) patients were from the ward, 15 (30%) from the ICU. Out of 50 sera, 33 (66%) were positive & 17 (34%) were negative by TIA while 28 (56%) were positive & (44%) were negative by slide LAT Slide LAT gave false negative results for 5 patients. The sensitivity of the slide LAT was only 54% in comparison to the TIA (100%). Both the tests were equally specific (100%).

**Conclusion:** The study revealed a significant difference between two methods. It seems that in the early stages of inflammatory disease, quantitative methods are preferred to qualitative methods. Also, in cases that the CRP test results are weakly positive by qualitative methods, they should be controlled by quantitative methods too.

**Key Words:** CRP Test Quantitative; Qualitative.

## Introduction

CRP is an acute phase reactant, a protein made by the liver and released into the blood within a few hours after tissue injury, the start of an infection, or other cause of inflammation. Its short half-life makes it a particularly good marker to detect and follow any disease activity. The C - reactive protein test is based on the principle of the latex agglutination. When latex particles complexes human anti-CRP are mixed with a patient's serum containing C reactive proteins, an visible agglutination reaction will take place within 2 minutes. New corona virus pneumonia (COVID-19) is a health emergency due to its high infectiousness [1] and high case fatality in critically ill patients. Clinical monitoring and appropriate treatment strategies were

Essential to improve case fatality. CT scan played an important role in assessing the disease [2]. Other sensitive indicators able to reflect lung lesion changes and disease severity had to be explored. C-reactive protein (CRP) levels can be used in the early diagnosis of pneumonia [3], and patients presenting with severe pneumonia had high CRP levels. Until the late 1970s, CRP was measured using qualitative or semi-quantitative laboratory technique, most commonly latex agglutination, which precluded its use as differential diagnostic test because any degree of inflammation produced positive results [4]. Presently, accurate and rapid quantitative measures of CRP are obtained using laser nephelometry, turbid metric immunoassay, and enzyme immunoassay. The quantitative method is widely used in developed countries because it provides rapid, highly sensitive and specific results [5, 6]. We have therefore investigated the use of a quantitative turbid metric Immunoassay (TIA) & compared it with slide Latex Agglutination test (LAT).

## Material and Methods

Total 50 serum samples were collected from the patients, at RMCH &RC, Mandhana, and Kanpur.

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Clinically suspected to have systemic inflammation the study was carried out from June 2020 to Dec 2020. CRP concentrations were determined in serum samples using commercial qualitative slide LAT (RHELAX-CRP, Tulip) and TIA (SD Biosensor, Tulip). Testing was done according to the manufacturer's guidelines for both the tests. All the statistical data (sensitivity, specificity, were calculated by using the SPSS 15.0

## Results

In our study we found out that, from a total of 50 patients, 31 were males & 19 were females. Majority of the patients were between the age group of 50-60 years. About 30(70%) patients were from the ward, 15 (30%) from the ICU. Out of 50 sera, 33 (66%) were positive & 17 (34%) were negative by TIA while 28 (56%) were positive & (44%) were negative by slide LAT Slide LAT gave false negative results for 5 patients. The sensitivity of the slide LAT was only 54% in comparison to the TIA (100%). Both the tests were equally specific (100%).

## Discussion

In our study we found that the Turbid metric immunoassay method is more powerful than the semi-quantitative methods and is used in human medicine to share their many qualities such as the precision, the speed, the quantification and the possibility of being automated [7,8]. The excellent reproducibility of results read by an instrument and the expression of the results in quantitative international units are an advantage over traditional agglutination techniques, where the subjective interpretation of slide LAT causes problems with accuracy and precision [9]. In our study, from a total of 50 patients, 31 were males & 19 were females which was similar to the study conducted by Miao Yang in 2020 [10]. Majority of the patients were between the age group of 50-60 years [10]. About 30(70%) patients were from the ward, 15 (30%) from the ICU. Out of 50 sera, 33 (66%) were positive & 17 (34%) were negative by TIA while 28 (56%) were positive & (44%) were negative by slide LAT Slide LAT gave false negative results for 5 patients. The sensitivity of the slide LAT was only 54% in comparison to the TIA (100%). Both the tests were equally specific (100%) which were in accordance with studies [10, 11].

## Conclusion

From our study we conclude that slide Latex agglutination test & turbid metric immunoassay method are both equally specific but Turbid metric immunoassay is more sensitive. Turbid metric immunoassay is also easier to perform & allows processing of hundreds of samples in a short time, making it suitable for laboratories with large diagnostic workloads especially for the detection of CRP protein in human sera in early stage of Covid 19.

## References

1. Chen N, Zhou M, Dong X, Qu J, Gong F, Han Y. Epidemiological and clinical characteristics of 99 cases of 2019 novel corona virus pneumonia in Wuhan. China: a descriptive study. *Lancet*. 2020; 395(10223):507–513.
2. Lin C., Ding Y., Xie B., Sun Z., Li X., Chen Z. Asymptomatic novel corona virus pneumonia patient outside Wuhan: the value of CT images in the course of the disease. *Clin Imaging*. 2020; 63(3):7–9.
3. Warusevitane A., Karunatilake D., Sim J., Smith C., Roffe C. Early diagnosis of pneumonia in severe stroke: clinical features and the diagnostic role of C-reactive protein. 2016; 11(3):e0150269.
4. Powell LJ. C-reactive protein-a review. *Is J Med Tech*. 1979; 45:138–48.
5. Clyne B, Olshaker JS. The C-reactive protein. *J Emerg Med*. 1999; 17:1019–25.
6. Deodhare SG. C-Reactive Protein: Clinical Applications, Pathology. Update: Microbiology and Clinical Pathology Series, 2001.
7. Yamashita K., Fujinaga T., Miyamoto T., Hagio Mr., Izumisawa Y., Kotani T., Relationship between serum cytokine activity and acute phase protein in human. *The Medical newspaper off human Science*, 2006; 56(3):487-492.
8. Collet B. Proteins of L-ignition, Thesis of Doctorate University, Claude Bernard, Lyon, 1995; 39-60.
9. Lisa M. Melamies, Helka M. Ruutsalo, Evaluation of a quantitative immunoturbidimetric assay for Rheumatoid factors. *Clin. Chem*, 1986; 32(10) : 1890-1894.
10. Miao Yang, Xiaoping Chen, Yancheng XA. Retrospective Study of the C - reactive protein to Lymphocyte Ratio and Disease Severity in 108 Patients with Early COVID-19 Pneumonia in Wuhan. *Med Sci Monit* . 2020; 11; 26.
11. Manisha N. Dhamecha, Mayurika K. Patel, Urvesh V. Shah. A Comparative Study of Semi Quantitative Latex Agglutination Test and Quantitative Turbidimetric Immunoassay Method for the Detection of C - reactive protein from Human Sera. *GCSCMC J Med Sci Vol (II) No (II) July-December 2013..*