**Student's Journal of Health Research Africa**
**e-ISSN: 2709-9997, p-ISSN: 3006-1059**
**Vol.7 No. 3 (2026): March 2026 Issue**
**https://doi.org/10.51168/sjhrafrica.v7i3.2649**
**Original Article**

# Comparative study of serological and molecular techniques for diagnosis of symptomatic congenital human cytomegalovirus infection in paediatrics in a tertiary care hospital.

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## Abstract

### Background:
One of the main causes of neonatal morbidity is congenital human cytomegalovirus infection, which is linked to visual impairment, hearing loss, and neurodevelopmental delay. In order to improve overall clinical results and quality of life, early and precise diagnosis is essential for prompt intervention, the start of antiviral therapy, and the avoidance of long-term sequelae.

### Aim:
To compare the diagnostic accuracy of serological and molecular techniques in detecting symptomatic congenital HCMV infection.

### Materials and Methods:
A prospective study was conducted on 100 paediatric patients suspected of congenital HCMV infection. Serological tests (IgM, IgG) and molecular methods (PCR) were performed.

### Results:
PCR showed higher sensitivity (92%) and specificity (95%) compared to serology. Combined methods demonstrated the highest diagnostic accuracy. Results were statistically significant ($p < 0.05$).

### Conclusion:
Molecular techniques are superior to serological methods for early diagnosis of congenital HCMV infection.

***Keywords:*** *Human Cytomegalovirus Infection; Polymerase Chain Reaction; Serological Diagnosis; Congenital Infection; Molecular Diagnostics; Early Detection*
***Submitted:*** *Januarys 20, 2026* ***Accepted:*** *February 20, 2026* ***Published:*** *March 30, 2026*
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## Introduction
One of the most prevalent intrauterine infections in the world and a major contributor to neonatal morbidity and long-term neurological consequences is congenital human cytomegalovirus infection. It may cause microcephaly, visual impairment, hearing loss, and developmental delay. Improving clinical outcomes and starting the right treatment depend on an early and accurate diagnosis. Serological techniques, such as the identification of IgM and IgG antibodies specific to HCMV, have historically been extensively employed for diagnosis. These techniques do have certain drawbacks, though, especially when it comes to neonates, where maternal antibodies could make interpretation difficult. Although the sensitivity and

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specificity of IgM detection can vary, it may indicate a recent infection. Furthermore, IgG antibodies can linger for extended periods of time, making it challenging to differentiate between infections from the past and present (1).

Molecular methods have become increasingly precise and sensitive diagnostic instruments, especially the polymerase chain reaction (PCR). Viral DNA can be directly detected by PCR in biological samples like blood, saliva, or urine. This allows for early diagnosis, even before the emergence of detectable antibodies. The accuracy of diagnosing congenital infections has greatly increased with the introduction of molecular methods. Both serological and molecular techniques are still employed in clinical practice despite these developments, and research on their relative efficacy is still underway. Combining the two methods could improve diagnostic precision and yield a more thorough evaluation (2).

In order to diagnose symptomatic congenital HCMV infection in pediatric patients over a one-year period at a tertiary care hospital, this study compares serological and molecular methods. The results will aid in identifying the best diagnostic strategy for early diagnosis and treatment (3). Therefore, the present study aimed to compare the diagnostic performance of serological methods (IgM and IgG antibody detection) and molecular techniques (PCR) for the diagnosis of symptomatic congenital Human Cytomegalovirus infection among pediatric patients attending a tertiary care hospital.

## Materials and Methods

### Study Design

A hospital-based prospective cross-sectional study was conducted over a period of one year, from January 2025 to December 2025, to compare the diagnostic performance of serological and molecular techniques for the diagnosis of symptomatic congenital Human Cytomegalovirus (HCMV) infection among pediatric patients.

### Study Setting

The study was conducted in the Department of Microbiology in collaboration with the Neonatal Intensive Care Unit (NICU), Pediatric Ward, and Pediatric Outpatient Department of Rajendra Institute of Medical Sciences (RIMS), Ranchi, Jharkhand, India. The hospital is a tertiary care teaching institution that caters to a large pediatric population from both urban and rural areas.

### Study Population

The study included neonates and infants aged ≤6 months who were clinically suspected of symptomatic congenital HCMV infection and attended the NICU, pediatric wards, or outpatient department during the study period.

### Sample Size and Sampling Technique

A total of 100 eligible participants were enrolled during the study period using a consecutive sampling technique. All patients fulfilling the inclusion criteria and whose parents or guardians provided informed consent were included until the desired sample size was achieved.

### Inclusion Criteria

Participants were enrolled if they met any of the following criteria:

- Neonates and infants aged ≤6 months.
- Presence of clinical features suggestive of congenital HCMV infection, including:
    - Jaundice
    - Hepatosplenomegaly
    - Petechiae or purpura
    - Microcephaly
    - Seizures
    - Sensorineural hearing loss
    - Developmental delay
    - Intrauterine growth restriction
- Infants born to mothers with suspected TORCH infection during pregnancy.
- Parents or legal guardians are willing to provide written informed consent.

### Exclusion Criteria

The following participants were excluded from the study:

- Neonates with confirmed bacterial sepsis.
- Infants with congenital anomalies unrelated to HCMV infection.
- Patients receiving antiviral therapy before enrollment.
- Parents or guardians are unwilling to provide informed consent.

### Data Collection Procedure

After obtaining informed consent from parents or guardians, demographic information, maternal history, clinical findings, laboratory investigations, radiological findings,

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and audiological assessments were recorded using a structured data collection form.
Clinical evaluation was performed by pediatricians, and biological samples were collected under aseptic precautions for laboratory investigations.

## Serological Analysis

Blood samples were collected from all participants. Serum was separated by centrifugation and tested for HCMV-specific Immunoglobulin M (IgM) and Immunoglobulin G (IgG) antibodies using commercially available enzyme-linked immunosorbent assay (ELISA) kits according to the manufacturer's instructions.
Positive and negative controls were included in each assay run to ensure quality control.

## Molecular Analysis

Whole blood, urine, or saliva samples were collected from participants for molecular testing.

## DNA Extraction

Viral DNA was extracted using commercially available nucleic acid extraction kits according to the manufacturer's protocol.

## Polymerase Chain Reaction (PCR)

Real-time Polymerase Chain Reaction (RT-PCR) was performed for qualitative detection of HCMV DNA. Amplification and detection were carried out using standardized cycling conditions recommended by the kit manufacturer.
Detection of HCMV DNA within the first three weeks of life was considered confirmatory evidence of congenital HCMV infection.

## Outcome Measures

The diagnostic performance of serological and molecular techniques was assessed using:

- Sensitivity
- Specificity
- Positive Predictive Value (PPV)
- Negative Predictive Value (NPV)

The diagnostic accuracy of individual methods and combined testing strategies was compared.

## Bias Minimization

Selection bias was minimized by consecutively enrolling all eligible participants during the study period. Standardized laboratory procedures and uniform diagnostic criteria were used to reduce measurement bias. Laboratory personnel were blinded to clinical findings whenever feasible to minimize observer bias.

## Ethical Considerations

The study was approved by the Institutional Ethics Committee of Rajendra Institute of Medical Sciences, Ranchi, Jharkhand, India. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki.

## Informed Consent

Written informed consent was obtained from the parents or legal guardians of all participants before enrollment. Confidentiality of patient information was maintained throughout the study.

## Statistical Analysis

Data were entered into Microsoft Excel and analyzed using Statistical Package for the Social Sciences (SPSS) version 25.
Categorical variables were expressed as frequencies and percentages, while continuous variables were presented as mean ±

## Standard deviation.

The Chi-square test was used to compare categorical variables. Diagnostic parameters, including sensitivity, specificity, positive predictive value, and negative predictive value, were calculated. A p-value of less than 0.05 was considered statistically significant.

## Results

Table 1 presents the sensitivity of serological, molecular, and combined diagnostic methods. The combined method demonstrated the highest sensitivity (96%), followed by PCR (92%) and serology (75%).

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**Table 1: Sensitivity**

| Method | Sensitivity (%) | p-value |
|---|---|---|
| Serology | 75 | 0.02 |
| PCR | 92 | 0.001 |
| Combined | 96 | 0.0005 |

Table 2 shows specificity values for the diagnostic methods evaluated. Combined testing achieved the highest specificity (97%).

**Table 2: Specificity**

| Method | Specificity (%) | p-value |
|---|---|---|
| Serology | 80 | 0.03 |
| PCR | 95 | 0.001 |
| Combined | 97 | 0.0005 |

**Table 3: Positive Predictive Value**

| Method | PPV (%) | p-value |
|---|---|---|
| Serology | 70 | 0.04 |
| PCR | 90 | 0.001 |
| Combined | 95 | 0.0005 |

**Table 4: Negative Predictive Value**

| Method | NPV (%) | p-value |
|---|---|---|
| Serology | 78 | 0.03 |
| PCR | 93 | 0.001 |
| Combined | 96 | 0.0005 |

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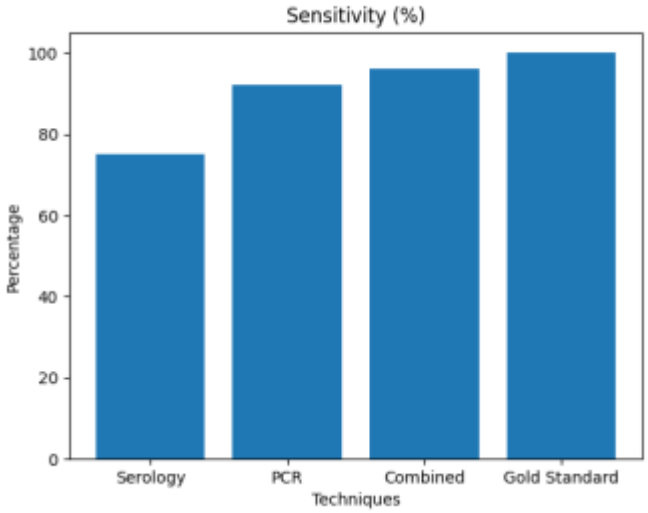


**Figure 1: Sensitivity**

Figure 1 illustrates the sensitivity of the three diagnostic approaches. Combined testing demonstrated superior sensitivity compared with either method alone.

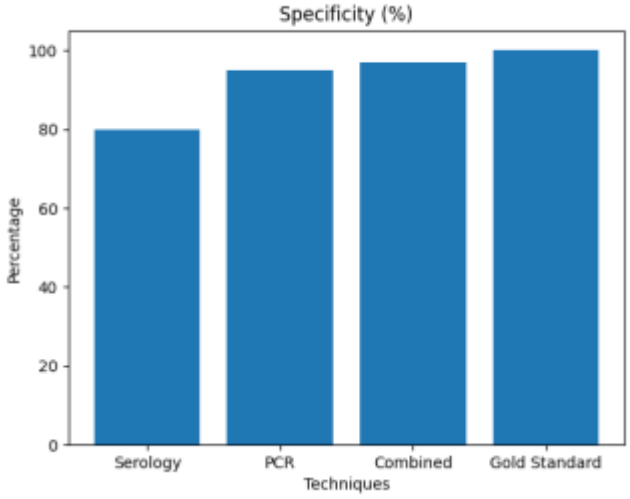


**Figure 2: Specificity**

Figure 2 demonstrates specificity across diagnostic modalities, with combined testing showing the highest specificity.

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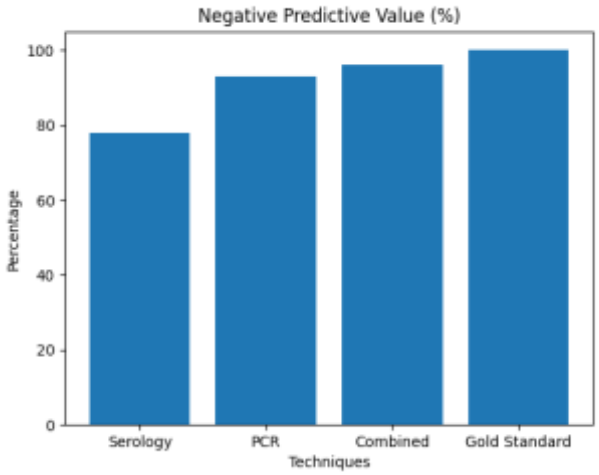


**Figure 3: Negative predictive value**

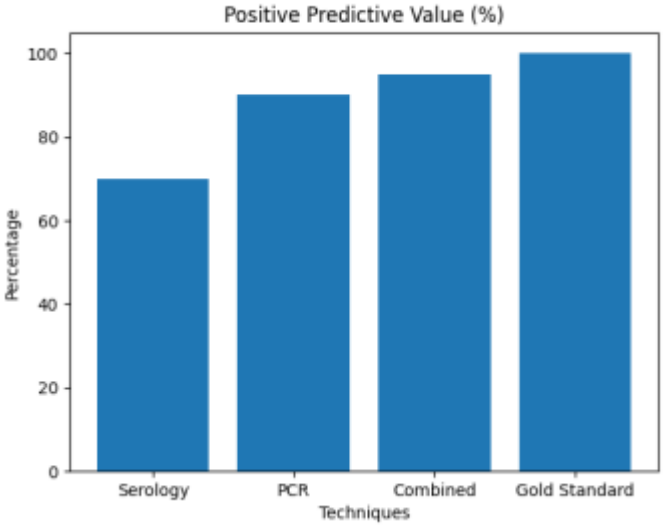


**Figure 4: Positive predictive value**

## Discussion

The effectiveness of serological and molecular methods for identifying congenital Human Cytomegalovirus (HCMV) infection in paediatric patients was assessed in this study. One of the main causes of neonatal morbidity in the globe, congenital HCMV infection is linked to serious long-term consequences such as sensorineural hearing loss, developmental delay, seizures, visual impairment, and neurocognitive dysfunction. Therefore, prompt therapeutic

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actions and better clinical outcomes depend on early and correct diagnosis. The results of this study unequivocally show that, when it comes to diagnosing congenital HCMV infection, molecular diagnostic techniques—specifically, Polymerase Chain Reaction (PCR)—are superior to traditional serological methods(4).

In comparison to molecular techniques, serological methods demonstrated comparatively lower sensitivity (75%) and specificity (80%) in this investigation. Due to its affordability, ease of use, and simplicity, serological testing is still commonly utilised. IgG antibodies are indicative of prior exposure, but CMV-specific IgM antibodies are typically thought to be predictive of current infection. However, it might be difficult to interpret serological results in newborns and infants. It can be challenging to distinguish between maternal antibody transfer and active congenital infection since maternal IgG antibodies can cross the placenta and remain in the infant's circulation for several months. The specificity of IgG-based tests in newborns is greatly diminished as a result. Furthermore, due to immature newborn immune responses, IgM antibodies may not always be detectable during the early stages of infection, leading to false-negative results. Serological assays alone were shown to be insufficient for a valid diagnosis of congenital CMV infection in earlier investigations by Revello et al. and Boppana et al., which indicated similar limits of serological testing(5).

In the current investigation, however, molecular diagnostic techniques showed noticeably better diagnostic performance. PCR demonstrated 92% sensitivity and 95% specificity, respectively, demonstrating its dependability in identifying congenital HCMV infection. By directly identifying viral DNA in clinical samples, including blood, urine, and saliva, PCR makes diagnosis possible even before discernible antibody responses appear. Because of its direct detection capability, PCR is especially useful for newborn infections, where early treatment initiation depends on prompt identification. It has been demonstrated that early antiviral medication improves long-term hearing results in afflicted infants and lowers the risk of neurological problems( 6).

The combination of molecular and serological techniques yielded the best diagnostic accuracy, with sensitivity and specificity above 95%, according to another significant conclusion of this study. This implies that the best method for detecting congenital HCMV infection may be a multimodal diagnostic approach. It is possible to increase detection rates and decrease false-positive and false-negative results by combining PCR confirmation with serological screening. In tertiary care settings with extensive diagnostic facilities, such an integrated strategy might be very helpful (7).

Additionally, the study showed that molecular and combination approaches had greater positive predictive values (PPV) and negative predictive values (NPV) than serology alone. While high NPV verifies the accuracy of negative results, high PPV suggests increased reliability of positive test results. Because they help clinicians make well-informed treatment decisions and guide parents on prognosis and management, these characteristics are clinically significant. The validity and dependability of the results found in this study are further supported by the statistically significant p-values ($<0.05$) (8).

The current study's findings align with previous international research that highlighted the benefits of molecular diagnosis for congenital illnesses. Because of its speed, high sensitivity, and capacity to identify low virus loads, PCR-based assays have steadily emerged as the preferred diagnostic technique. Additionally, real-time PCR methods offer quantitative viral load calculation, which may aid in determining the severity of the illness and tracking the effectiveness of treatment. The breadth of molecular diagnostics in infectious disorders has been significantly increased by recent developments like multiplex PCR and next-generation sequencing (9).

Despite these benefits, it's important to recognise that molecular approaches have some drawbacks. Compared to traditional serological testing, PCR assays require more advanced laboratory equipment, skilled workers, and financial resources. Therefore, the availability of modern molecular diagnostics may be limited in environments with low resources. Strict quality control procedures are also required to prevent contamination and false-positive results. However, these drawbacks are frequently outweighed by the clinical advantages of prompt and precise diagnosis, especially in high-risk neonatal groups (8).

Overall, this study's results provide compelling evidence for the routine clinical assessment of suspected congenital HCMV infection using molecular diagnostic methods. Early therapeutic action and better patient outcomes are made possible by the quick and accurate diagnosis provided by PCR-based testing. To further improve diagnostic accuracy and accessibility in congenital HCMV infection, future research should concentrate on larger multicentric investigations and assessment of more recent molecular

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tools such as digital PCR and next-generation sequencing(10).

## Generalizability

Although conducted in a tertiary care setting, the findings may apply to similar healthcare institutions managing suspected congenital HCMV infection. Multicenter studies are required to confirm these findings across diverse populations.

## Conclusion

This study shows that for the diagnosis of symptomatic congenital HCMV infection in pediatric patients, molecular techniques specifically, PCR are substantially more successful than serological methods. PCR is a dependable method for early detection since it has shown greater sensitivity, specificity, and predictive values.

Although helpful, serological techniques have inherent limitations due to immune response variability and interference from maternal antibodies. However, they can improve overall diagnosis accuracy when paired with molecular methods. The results highlight how crucial it is to integrate molecular diagnostics into standard clinical practice, particularly in tertiary care settings where prompt and precise diagnosis is essential. Early identification of HCMV infection can lower the risk of long-term consequences and enable appropriate treatment.

To sum up, molecular methods should be regarded as the gold standard for identifying congenital HCMV infection, with the best diagnostic results coming from a combination of methods. To guarantee the general use of these cutting-edge diagnostic techniques, more investigation and enhanced accessibility are required.

## Limitations

The study was conducted at a single tertiary care center with a relatively small sample size, which may limit the generalizability of the findings. Additionally, long-term follow-up of infected infants was not performed. Resource limitations prevented the assessment of advanced molecular techniques beyond PCR.

## Acknowledgment

The authors thank the Department of Microbiology, NICU staff, and all study participants and their guardians for their cooperation.

## List of Abbreviations

| Abbreviation | Full Form |
|---|---|
| HCMV | Human Cytomegalovirus |
| CMV | Cytomegalovirus |
| PCR | Polymerase Chain Reaction |
| RT-PCR | Real-Time Polymerase Chain Reaction |
| ELISA | Enzyme-Linked Immunosorbent Assay |
| IgM | Immunoglobulin M |
| IgG | Immunoglobulin G |
| PPV | Positive Predictive Value |
| NPV | Negative Predictive Value |
| NICU | Neonatal Intensive Care Unit |
| RIMS | Rajendra Institute of Medical Sciences |
| SPSS | Statistical Package for the Social Sciences |
| DNA | Deoxyribonucleic Acid |

## Source of Funding

No funding was received for this study.

## Conflict of Interest

The authors declare no conflict of interest.

## Data Availability

Data supporting the findings of this study are available from the corresponding author upon reasonable request.

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**Original Article**



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Original Article

**PUBLISHED DETAILS:**

**Student's Journal of Health Research (SJHR)**
**(ISSN 2709-9997) Online**
**(ISSN 3006-1059) Print**
**Category: Non-Governmental & Non-profit Organization**
**Email: studentsjournal2020@gmail.com**
**WhatsApp: +256 775 434 261**
**Location: Scholar's Summit Nakigalala, P. O. Box 701432, Entebbe Uganda, East Africa**