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Analysis of Critical Alert Values in Clinical Microbiology Laboratory At A Tertiary Care Hospital

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ABSTRACT

Background: Critical alerts in microbiology laboratories represent life-threatening infectious conditions requiring immediate clinician notification and prompt clinical intervention. Effective identification and communication of these alerts are essential components of patient safety and laboratory quality management systems.
Objectives: To analyze the frequency, demographic distribution, departmental origin, disease pattern, and notification turnaround time of microbiology critical alerts in a tertiary care hospital.
Methods: A cross-sectional study was conducted at the Microbiology Laboratory of Apollo Institute of Medical Sciences and Research. Data were collected from the Critical Value Alert logbook over one year (November 2024 to October 2025). Age, sex, clinical department, type of infection, and notification turnaround time were analyzed using descriptive statistics. Notification timelines were evaluated in accordance with ISO 15189:2022.
Results: Of 40,037 tests performed, 138 (0.34%) met the threshold for a critical value alert. The highest number of alerts occurred in the 21–30 years age group (39.9%), followed by the 11–20 years age group (13%). Female patients accounted for 52.9% of alerts. General Medicine (52.9%) and Emergency Medicine (29%) contributed the most alerts. Dengue infection accounted for 70.3% of critical alerts. The majority of critical alert samples (76.1%) were received between 10 AM and 6 PM. All critical alerts were communicated within 10–30 minutes of validation, in compliance with ISO 15189:2022 guidelines.
Conclusion: Microbiology critical alerts in this study were predominantly associated with Dengue infection and were most frequent among young adults and females. General Medicine and Emergency Medicine departments contributed to the highest number of alerts. Adherence to standardized notification timelines ensured effective clinician communication and compliance with international quality standards. Continuous monitoring of critical alert trends and turnaround times is essential to enhance patient safety and optimize laboratory performance.

Keywords*: Critical alerts; Microbiology laboratory; Tertiary care hospital; Dengue.*

INTRODUCTION

The concept of critical values in laboratory medicine was introduced by George D. Lundberg in 1972, who defined them as laboratory results representing a pathophysiological state at such variance with normal as to be life-threatening unless something is done promptly, and for which some corrective action could be taken.[1] This led to widespread adoption of critical value reporting in clinical laboratories worldwide. Over time, the concept was incorporated into international laboratory quality standards and regulatory guidelines. Mireskandari subsequently extended the concept to surgical pathology, and Truijens et al. provided an updated framework emphasizing the distinction between critical results and significantly abnormal results, and the importance of differentiated thresholds and evidence-based notification policies.[2,3] Critical alerts in microbiology laboratories serve a uniquely vital role due to the life-threatening nature of the pathogens and conditions involved. The microbiology laboratory frequently detects organisms capable of causing rapidly

progressive, fatal infections including *Staphylococcus aureus* bacteremia, *Neisseria meningitidis* in cerebrospinal fluid, or multidrug-resistant Gram-negative bacilli in blood cultures.[4] Prompt communication of such results enables clinicians to initiate targeted antimicrobial therapy without delay, significantly reducing morbidity and mortality. Additionally, critical alerts are valuable for infection control enabling immediate containment of multidrug-resistant organisms (MDROs) such as MRSA, VRE, and carbapenem-resistant Enterobacteriaceae.[5]

Serological and biomarker tests play an important role in critical alert generation in microbiology. Elevated procalcitonin levels and positive serology for pathogens such as dengue NS1 antigen and IgM antibody may indicate severe infection, systemic sepsis, or conditions requiring urgent clinical escalation.[7] In tropical and endemic regions, dengue is a significant driver of microbiology critical alerts, particularly in young adults, where haemodynamic instability and plasma leakage may develop rapidly.[14]

The management of critical alerts is governed by internationally recognized standards. ISO 15189:2022 (Clauses 7.3.5 and 7.4.1.3) requires laboratories to establish written procedures for identifying critical results, ensuring rapid communication to authorized clinicians, and maintaining documentation of all notifications.[8] The National Accreditation Board for Testing and Calibration Laboratories (NABL), aligned with ISO 15189 requirements, mandates that accredited laboratories define a critical alert list, implement immediate reporting procedures, document notifications, and periodically review the system.[9] The Clinical and Laboratory Standards Institute (CLSI) guideline GP47 provides additional guidance on management of critical- and significant-risk results across all laboratory disciplines.[5]

Despite global standardization of reporting principles, the specific critical alert list remains institution-dependent, reflecting local patient demographics, test menu, and epidemiology.[8,9] While several studies have analyzed critical value reporting in clinical chemistry and haematology laboratories,[6,11,12,13] data specifically examining microbiology critical alerts in the South Asian context are limited. The present study was undertaken to systematically analyze microbiology critical alerts in a South Indian tertiary care hospital over a one-year period.

MATERIAL AND METHODS

Apollo Institute of Medical Sciences and Research is a tertiary care hospital offering comprehensive medical and surgical services, supported by a 24×7 functional Emergency and Trauma Centre. Laboratory services operate continuously to ensure timely diagnosis and critical support for patient care.

This cross-sectional descriptive study was conducted in the Microbiology and Serology Laboratory over one year, from November 2024 to October 2025, during which a total of 40,037 tests were performed. Data were collected prospectively from the Critical Value Alert logbook. For each alert, the following parameters were recorded: the generating analyte, patient age and sex, requesting clinical department, time of sample receipt, and time of critical alert notification to the clinician.

The microbiology critical alert list operative during the study period is shown in Table 1. This list was developed in accordance with ISO 15189:2022 and reviewed by the hospital's Laboratory Quality Committee, with analytes selected based on local disease burden, laboratory test menu, and infection control priorities.

Upon detection of a critical result, a senior laboratory technician verified the result and reviewed quality control records to exclude analytical errors. The result was then communicated to the responsible clinician by telephone, with acknowledgement obtained via a read-back protocol. All notifications were documented in the logbook, including the analyte, result, patient details, date and time of notification, acknowledgement details, and the identities of the reporting laboratory staff and receiving clinician.

Notification timeliness was defined as the interval from result validation to confirmed clinician communication. Compliance with ISO 15189:2022 requirements was assessed. The logbook was reviewed daily by the Laboratory In-Charge. Patient age was stratified into 10-year intervals, Qualitative variables (sex, clinical department, analyte type, age group, and time of sample receipt) were summarized as frequencies and percentages. The notification turnaround time, was analysed using descriptive statistics including mean, median, standard deviation (SD), and range. Statistical analysis was performed using Microsoft Office Excel and SYSTAT version 13.2. No inferential or comparative statistical testing was performed, as this was a descriptive study with the primary objective of characterizing the pattern and timeliness of critical alert notifications at a single institution over a defined study period.

Gap identification and quality improvement: A critical alert notification was classified as ‘timely’ if communicated within 30 minutes of result validation, in accordance with ISO 15189:2022 and institutional protocol. Any notification exceeding this threshold was classified as ‘delayed’ and documented with the reason for delay. The Laboratory In-Charge reviewed the logbook daily; delayed or missed notifications were escalated immediately for root cause analysis. Corrective actions including re-training of laboratory staff, review of escalation protocols, and audit of logbook entries

were implemented as required, and their effectiveness monitored in subsequent review cycles. During the study period, no missed notifications were recorded, and all 138 critical alerts were communicated within the 30-minute threshold.

Table 1: Microbiology and Serology Laboratory Critical Alert Analyte List

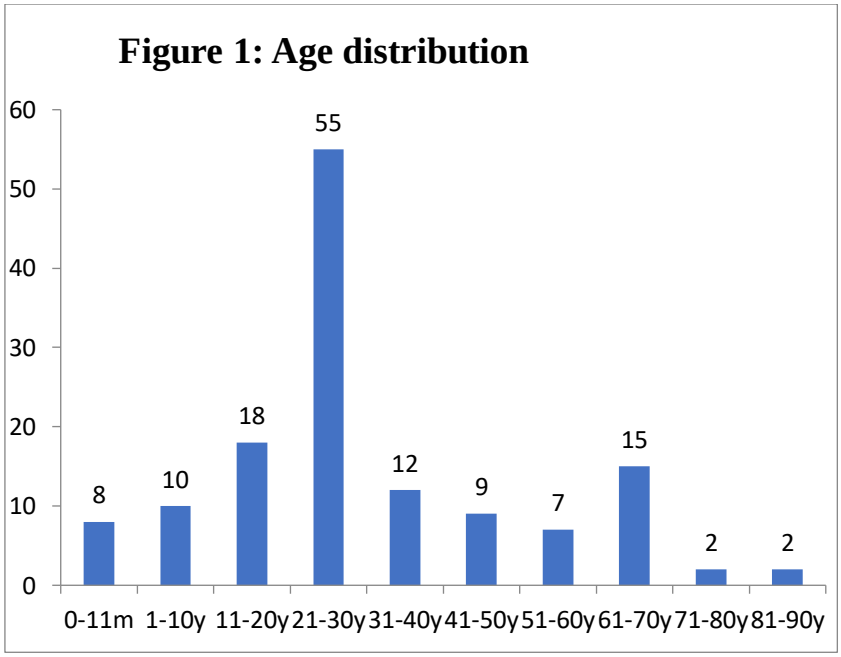
Analyte	Critical Result / Threshold	Acceptable Notification Time
CSF / Sterile Body Fluid Gram Stain*	Any organism detected (positive Gram stain only)	Within 30 minutes of result validation
CSF India Ink Preparation (for Cryptococcus)	Any yeast / encapsulated organism detected	Within 30 minutes of result validation
AFB Stain (Sputum / ET secretions / BAL)	Any AFB detected (positive only)	Within 30 minutes of result validation
Blood Culture Positive	Any organism isolated in blood culture	Within 30 minutes of result validation
Albert Stain (Corynebacterium diphtheriae)	Morphology suggestive of C. diphtheriae	Within 30 minutes of result validation
Dengue NS1 Antigen	Reactive / Positive	Within 30 minutes of result validation
Dengue IgM Antibody	Reactive / Positive	Within 30 minutes of result validation
Malaria Antigen Test	Any species detected (P. falciparum or P. vivax)	Within 30 minutes of result validation
Procalcitonin (PCT)	≥ 2.0 ng/mL (indicative of sepsis / severe bacterial infection)	Within 30 minutes of result validation

* Only positive CSF / sterile body fluid Gram stains trigger critical alert notification. Negative Gram stain results are reported through standard laboratory reporting channels.

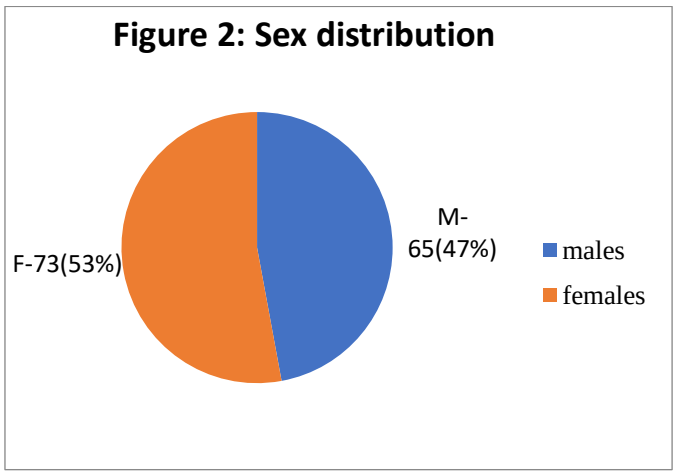
RESULTS

A total of 40,037 tests were analyzed in the clinical microbiology laboratory during the study period. Of these, 138 tests (0.34%) generated a critical alert, defined as results meeting or exceeding the laboratory's predefined critical threshold.

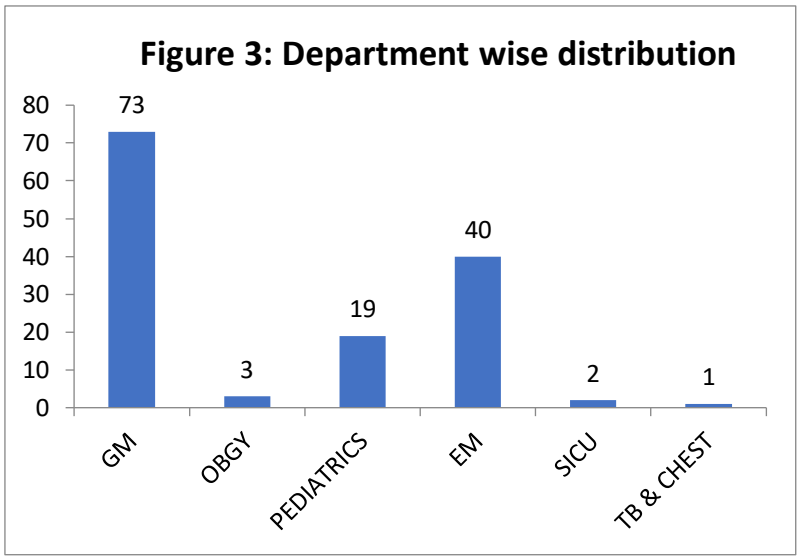
The highest frequency of critical alerts occurred in the 21–30 years age group (39.9%), followed by the 11–20 years age group (13%) (Figure 1).



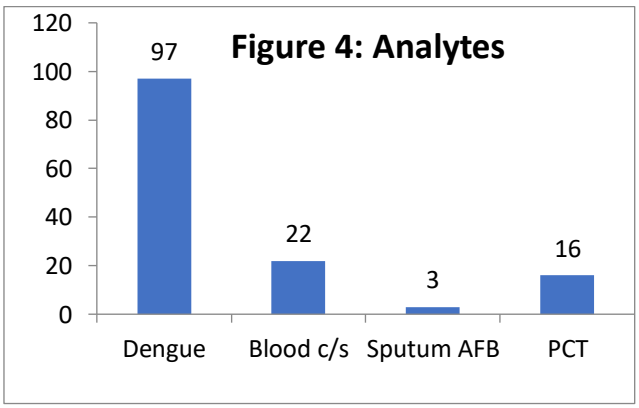
Female patients accounted for 52.9% of critical alerts, compared to 47.1% in males (Figure 2).



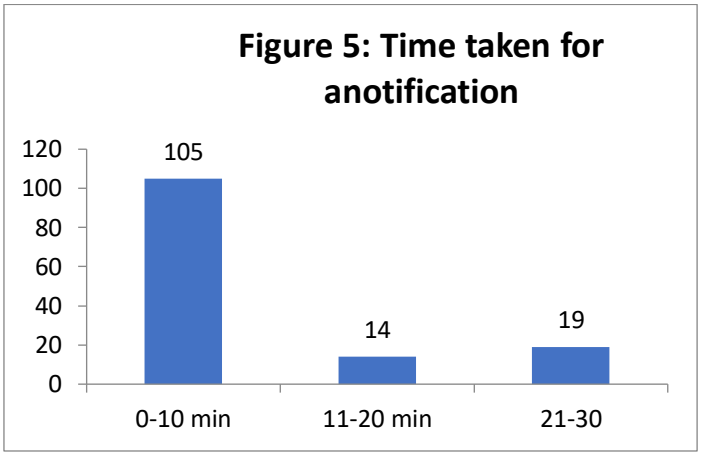
The majority of critical alerts originated from the General Medicine department (52.9%), followed by the Emergency Medicine department (29%) (Figure 3). Other departments including Obstetrics and Gynaecology, Paediatrics, and Surgery accounted for the remaining.



Dengue-related analytes (NS1 antigen and IgM antibody) together accounted for 70.3% of microbiology critical alerts (Figure 4). Procalcitonin contributed the second largest proportion. Blood culture positives, AFB stains, and other listed analytes accounted for the remainder.



The majority of critical alert samples were received between 10 AM and 6 PM (Figure 5).



All 138 critical alerts were communicated to the treating clinician within 30 minutes of result validation, demonstrating full compliance with ISO 15189:2022 requirements. Of these, 76.1% (n=105) were notified within 0–10 minutes, 10.1% (n=14) within 11–20 minutes, and 13.8% (n=19) within 21–30 minutes (Figure 6). The mean notification time was 8.8 minutes (median: 5 minutes; SD: 7.2 minutes; range: <10–30 minutes). No notifications exceeded the 30-minute threshold, and no missed notifications were recorded during the study period.

DISCUSSION

The critical alert rate in this study was 0.34% of all tests performed. This is consistent with other studies across tertiary settings. Dighe et al. reported a critical value rate of approximately 0.25% [6] while a five-year retrospective study from a 1000-bed tertiary hospital in China reported a rate of 0.49%.[10] A referral Spanish tertiary university hospital recorded 5,723 critical values over a six-month period.[11] Truijens et al. highlight that variations in reported frequencies across studies reflect differences in hospital size, patient demographics, laboratory workload, the specific analytes included in the critical alert list, and institutional threshold definitions.[3]

The predominance of critical alerts in the 21–30 years age group (39.9%) is consistent with the epidemiology of dengue infection in India, where young adults are more commonly affected due to greater outdoor exposure, occupational activity, and frequent travel..[14] In contrast, studies on biochemical critical alerts usually report higher frequencies among elderly patients or children because of conditions such as electrolyte imbalance, kidney injury, or metabolic disturbances.[12] The predominance of young adults in the present study reflects the disease-specific epidemiology of microbiology critical alerts, rather than a general pattern common to all laboratory disciplines.

The marginal female preponderance (52.9%) observed in this study is likely multifactorial. The sex distribution of dengue in India varies considerably across settings male predominance is often attributed to greater outdoor occupational exposure,[14] while in some hospital-based studies, females constitute a higher proportion of admissions due to healthcare-seeking patterns and the female majority in certain hospital catchment populations.[15] In the present study, the slight female predominance is best interpreted as a reflection of the composition of the hospital's inpatient and emergency population during the study period, rather than a biologically determined difference in dengue susceptibility or severity.

Dengue-related analytes (NS1 antigen and IgM antibody) accounted for 70.3% of all microbiology critical alerts, highlighting the high endemicity of dengue in Hyderabad, Telangana. Dengue can progress unpredictably from undifferentiated fever to haemorrhagic manifestations and dengue shock syndrome, and early laboratory identification of dengue infection followed by prompt clinical escalation is essential to prevent complications and mortality.[4,5] The inclusion of dengue NS1 antigen and IgM in the laboratory's critical alert list is clinically appropriate and consistent with the IDSA/ASM guidance on urgent communication of results indicating potentially life-threatening infections.[4]

The concentration of critical alerts in General Medicine (52.9%) and Emergency Medicine (29%) is consistent with findings from other tertiary-centre studies. Dighe et al. reported that the highest critical value originated from the emergency department and intensive care units,[6] and Aggarwal et al. similarly noted that critical value notification was highest in ICU and emergency areas.[12] These departments serve as primary receiving units for patients with undifferentiated acute illness and sepsis, generating proportionally high volumes of microbiological investigations, and consequently a higher frequency of critical alert-triggering results.

Critical alerts in this study were communicated to clinicians within 30 minutes of validation in all cases, with 76% notified within 10 minutes. ISO 15189:2022 (Clauses 7.3.5 and 7.4.1.3) requires laboratories to define and document a

critical result notification timeframe, and mandates that procedures ensure immediate communication.[8] A study by Wongkrajang P et al. demonstrated that timely critical value reporting led to initiation of treatment or close monitoring within 30 minutes in 80% of cases,[10] while the College of American Pathologists Q-Probes survey of 163 laboratories found variability in notification practices across institutions.[16] The rapid turnaround in the present study reflects the efficiency of a dedicated 24-hour laboratory supported by well-defined escalation protocols, read-back acknowledgement systems, and experienced laboratory personnel.

The clustering of sample receipt between 10 AM and 6 PM reflects the routine hospital workflow, as outpatient visits, ward rounds, and most investigations are commonly carried out during regular working hour.[6] After-hours critical alerts (outside 6 PM – 10 AM) accounted for a smaller proportion of the total, consistent with reduced clinical activity during these hours, though the laboratory maintained 24-hour readiness for prompt notification.

Several limitations of this study should be acknowledged. This is a single-centre study conducted over one year; multi-centre data across diverse geographic and institutional settings would strengthen the generalizability of the findings. The study was descriptive in design and did not evaluate clinical outcomes such as mortality, length of stay, or treatment response following critical alert notification. Additionally, the critical alert list is institutional, reflecting local disease burden and test menu; direct comparison with institutions using different analyte lists should be interpreted with caution.

CONCLUSION

Microbiology critical alerts in this study were most common among young adults, with slightly more alerts in female patients. Dengue infection accounted for 70.3% of all alerts, reflecting its high prevalence in the hospital's catchment area. Most alerts came from the General Medicine and Emergency Medicine departments. All critical alerts were communicated to clinicians within 30 minutes of result validation, and 76.1% were notified within 10 minutes, meeting ISO 15189:2022 standards. Regular monitoring of alert trends, seasonal preparedness for dengue, and strong communication between the laboratory and clinical departments are recommended to ensure continued patient safety.

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