

Quality Assurance and Control in SGOT and SGPT Testing: A Study case in Type C Hospitals in Sidoarjo

Devani Aprilia Duwi Purwanti¹, Miftahul Mushlih^{1*}, Nurul Yulida Rahmatika², Nesha Femia Fattach¹, Ersah Rahmaneng Azizah¹, Yuniar Azzahroh¹, Aulia Azzahra¹, Fenola Suci Rahmawarni¹, Rizka Putri Anggraeni¹, Natasya Eka Saputri¹, Balgis Dewi Ruhillah¹, Aisyah Nur Maulida¹, & Yoga Abimanyu¹

¹D4 Medical Laboratory Technology Study Program, Muhammadiyah University of Sidoarjo, Indonesia

²Bhayangkara Hospital, Sabhara Education Center, Sidoarjo, East Java

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*Corresponding author:

mif.mushlih@umsida.ac.id

Abstract

Quality management in SGOT and SGPT examinations is vital to ensure accurate and precise laboratory results, which are essential for diagnosing and monitoring liver function. Internal quality assurance is performed daily to assess results, detect deviations, and implement corrective actions. This study uses a descriptive explorative approach based on field observations to analyze quality assurance practices for SGOT and SGPT tests at a type C hospital in Sidoarjo. Data were collected through direct observation, review of quality control documentation, and interviews with laboratory staff over a one-month period in August 2025. Inclusion criteria included laboratories implementing both internal and external quality assurance systems, while those focusing solely on instrument test outputs were excluded. Observations revealed that quality assurance practices consisted of daily internal QC, monthly external QC participation, and periodic instrument calibration. These practices were found to significantly enhance test reliability and reduce error rates. The findings highlight that consistent monitoring, timely corrective actions, and adherence to standard protocols are essential for ensuring valid and accountable results in liver function testing. This study provides an overview of the implementation, benefits, and challenges of quality assurance in clinical laboratories, emphasizing its critical role in improving the accuracy and reliability of SGOT and SGPT examinations.

INTRODUCTION

Clinical laboratories play a critical role in healthcare systems by providing essential data that support diagnosis, disease monitoring, and prevention. As diagnostic services become increasingly central to patient care, the demand for reliable and high-quality laboratory testing has risen significantly (Gunawan, 2019). This importance is reinforced by national regulations, including Law No. 44/2009 on Hospitals and Ministry of Health Regulation No. 43/2013, which emphasize the laboratory's responsibility for ensuring patient safety and effective medical interventions (Anggraini, 2022; Rachmawati, 2018; Republic of Indonesia, 2013).

To meet clinical expectations, laboratories must implement comprehensive Quality Management Systems (QMS) covering pre-analytical, analytical, and post-analytical phases. Optimal performance in each phase is essential to minimize errors that compromise test validity. Studies indicate that most laboratory errors occur during the pre- and post-analytical stages, highlighting the need for standardized procedures and continuous quality control (Riyono, 2007).

Among routine biochemical assays, liver function tests measuring Serum Glutamic Oxaloacetic Transaminase (SGOT/AST) and Serum Glutamic Pyruvic Transaminase (SGPT/ALT) are widely used as sensitive markers of hepatocellular injury. Elevated levels of these enzymes are crucial for detecting liver dysfunction, monitoring disease progression, and evaluating therapeutic response (Reza, 2017).

Modern laboratories use automated analyzers (autolyzers) based on IFCC methods to perform SGOT and SGPT tests, ensuring better standardization and efficiency. However, accuracy and reliability remain highly dependent on strict adherence to standard operating procedures and robust internal and external quality assurance systems (Widarti, 2019; Widyastuti, 2020). Recent evaluations

have revealed inconsistencies in test performance due to poor instrument calibration, reagent instability, and inadequate staff training (Widyastuti, 2020). These challenges underscore the urgent need to strengthen quality assurance, particularly for commonly performed tests like SGOT and SGPT (Rinovanchapo, 2025).

Given the clinical significance of liver enzyme testing, this study aims to evaluate the implementation of quality management standards in SGOT-SGPT examinations using autolyzers. The objective is to assess laboratory compliance with national and international quality guidelines and to identify areas for improvement to ensure accurate and reliable diagnostic outcomes.

METHODS

This study employs a descriptive qualitative approach using a literature review (library research) as a supporting method. The primary objective is to explore and describe the implementation of quality management standards in liver function testing (SGOT-SGPT) using autolyzers within clinical laboratory settings. Relevant literature was obtained from PubMed and Google Scholar (2007–2025) to provide theoretical context.

To enhance the validity of the findings, the study incorporated a non-interventional field observation conducted over one month in a Type C hospital laboratory in Sidoarjo, East Java, Indonesia. The observation focused on routine SGOT-SGPT testing procedures using autolyzers, the application of internal and external quality control systems, and compliance with Standard Operating Procedures (SOPs) as mandated by the Indonesian Ministry of Health. By combining literature review and direct field observation, this study provides a practical overview of quality management practices in SGOT-SGPT testing and highlights existing gaps and challenges in the implementation of standards in real-world laboratory conditions.

RESULTS AND DISCUSSION

Application of the Dialab Autolyser in Liver Function Testing at Hospitals

This study includes observations conducted at a Type C hospital in the Sidoarjo region, East Java, focusing on the implementation of quality management systems in liver function testing. The hospital was selected because it represents a typical medium-level healthcare facility in Indonesia, playing a crucial role in providing primary referral services and routine laboratory diagnostics, including SGOT and SGPT testing. Moreover, its laboratory actively utilizes an autolyzer for liver function analysis, making it directly relevant to the research objectives. The site was chosen based on its technical readiness, data accessibility, and willingness to support non-interventional observation, thereby making it sufficiently representative of similar urban healthcare settings with limited but functional resources.

Routine SGOT (AST) and SGPT (ALT) testing in the observed hospital laboratory is performed using the Dialab Autolyser, an automated chemistry analyzer capable of processing up to 250 tests per hour within a wavelength range of 300–800 nm. This instrument supports rapid and consistent detection of liver enzyme activity, aligning with the hospital's commitment to delivering high-quality, technology-driven laboratory services.

The implementation of the Dialab Autolyser in hospital laboratories has significantly enhanced the quality of liver function testing. Its automation system reduces the risk of human error, accelerates workflow, and generates stable, reproducible results that meet clinical laboratory quality standards and accreditation requirements.

The Dialab Autolyser operates based on UV-enzymatic photometry, the gold-standard method for measuring enzyme activity. It detects changes in absorbance—particularly at 340 nm—as light passes through reagent-sample mixtures, with results displayed in real time on a digital system. Reusable plastic cuvettes are employed following proper disinfection and drying procedures, promoting both operational efficiency and environmental sustainability (Lippi, 2013).

Since its introduction by Han in 1959, the automated chemistry analyzer has become an essential tool for evaluating biochemical parameters such as glucose, electrolytes, creatinine, enzymes, and lipids. Its application in SGOT and SGPT testing strengthens liver disease diagnosis and underscores the reliability of modern clinical laboratories (Armbruster, 2014).



Figure 1. Dialab autolyser

Quality Control in SGOT and SGPT Testing: The Importance of Quality Evaluation

The accuracy and reliability of SGOT/SGPT testing depend heavily on rigorous Quality Control (QC) procedures. Pre-analytical errors—like sample contamination or improper cuvette handling—can compromise the process (Lippi, 2013). Cuvettes, as integral components of the photometric system in chemistry analyzers, must be optically clean, free from residual specimen or detergent stains, and adequately dried prior to reuse. Any residual contaminants can interfere with light transmission and adversely affect absorbance measurements, thereby distorting analytical outcomes. As part of internal quality assurance, cuvette maintenance involves immersion in disinfectant (e.g., sodium hypochlorite), thorough rinsing with laboratory-grade detergent, and air drying, ensuring they remain within acceptable optical parameters.

Analytical QC is reinforced through regular instrument calibration and reagent evaluation. Control samples with known concentrations are analyzed daily, monthly, and annually to detect drift or degradation. If results fall outside acceptable ranges, retesting is done using fresh controls and recalibration steps are followed to confirm instrument readiness (Ambruster, 2014)

In resource-limited healthcare environments, such as Class C hospitals, the implementation of comprehensive Internal Quality Assurance (IQA) and External Quality Assurance (EQA) systems presents notable challenges. These challenges often stem from limited financial resources, inadequate infrastructure, and a shortage of trained personnel. Despite these constraints, strict adherence to Standard Operating Procedures (SOPs) and the continuous technical training of laboratory staff remain essential to maintaining the consistency and reliability of analytical results (Albetkova, 2011).

Within the IQA framework, particular emphasis is placed on pre-analytical controls, including patient preparation, sample collection, labeling, and specimen verification. These steps are crucial for minimizing pre-analytical errors, which are known to account for a significant portion of laboratory inaccuracies. All procedures are thoroughly documented and become part of routine audits during EQA inspections. These audits typically involve reviewing sample logbooks, specimen collection checklists, and other quality-related documentation to ensure compliance with established standards (Albetkova, 2011).

By integrating well-documented pre-analytical verification procedures and structured analytical QC processes, clinical laboratories can effectively reduce result variability and ensure that diagnostic data accurately reflect the patient's true clinical condition. This approach not only minimizes the risk of error but also enhances the overall reliability of laboratory testing. Furthermore, fostering a strong quality-oriented culture within the laboratory—characterized by consistent documentation, adherence to protocols, and continuous evaluation—builds clinical confidence in the results produced. This trust is essential in supporting evidence-based medical decision-making, ultimately contributing to improved patient safety and healthcare outcomes (Rachmawati, 2018).

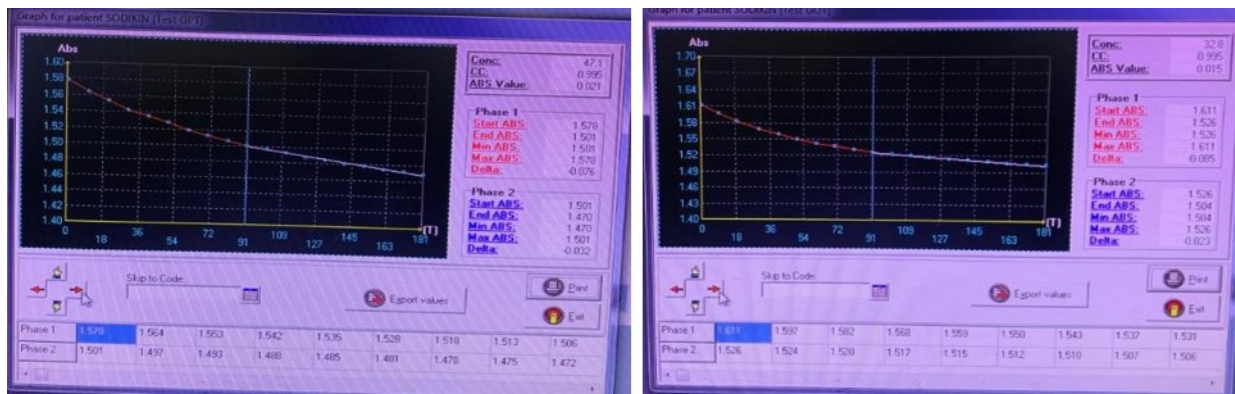


Figure 2. Internal Quality Control (QC) Testing for SGOT: Diagram Showing Normal Results

The IQA laboratory begins each morning with a comprehensive inspection to ensure all components are functioning optimally. This includes routine instrument calibration, equipment cleanliness checks, and verification of reagent availability and expiration dates. This initial assessment is documented in a daily analytical logbook, which is an integral part of the IQAS to maintain test result accuracy and minimize errors. Calibration procedures are typically performed using control samples with predetermined target values to validate instrument performance. If the calibration falls outside acceptable limits, a repeat measurement is performed using the same control sample to ensure consistency. If the results remain unsatisfactory, a new control sample is used to verify the issue. If discrepancies persist, a third retest using the original control sample is performed to assess the resolution of the results before further corrective action is taken. Routine maintenance and recalibration are performed in coordination with a certified calibration service provider. After service, instrument performance is revalidated using a new control sample. Only if the calibration results fall within acceptable tolerances is the instrument approved for operational use.

The EQA is implemented through monthly and annual assessments involving collaboration with external institutions or other reference laboratories. These evaluations include instrument calibration, reagent suitability verification, and inter-laboratory sample comparisons to ensure consistency and accuracy of test results. The results of these inspections are compiled into monthly and annual reports, which provide detailed documentation of quality assurance activities and performance trends over time.

The post-analytical phase, though often overlooked, is just as important as the pre-analytical and analytical phases. This phase focuses on the accurate, clear, and timely communication of laboratory results to healthcare providers and patients. The speed and accuracy of result reporting are considered important indicators of overall laboratory performance and service quality (Siregar, 2018). To support accuracy in the post-analytical process, many laboratories have integrated a Laboratory Information System (LIS) as part of their IQAS strategy. This system automates key functions such as data entry, validation, and report generation, significantly reducing the risk of human error associated with manual handling (Albetkova, 2011).

Furthermore, within the EQA framework, the use of information technology reflects the laboratory's adaptation to evolving standards and best practices, reinforcing its commitment to continuous quality improvement and regulatory compliance in healthcare delivery.

The study has observed that in Type C Hospitals located in the Sidoarjo area, daily control testing has been effectively carried out using the Dialab Autoanalyzer. This allows technicians to detect any deviations in the test results. If any results do not meet the quality control standards, corrective actions can be taken immediately without having to wait for the annual calibration. This quality control testing helps ensure that test results remain accurate during the period between calibrations.

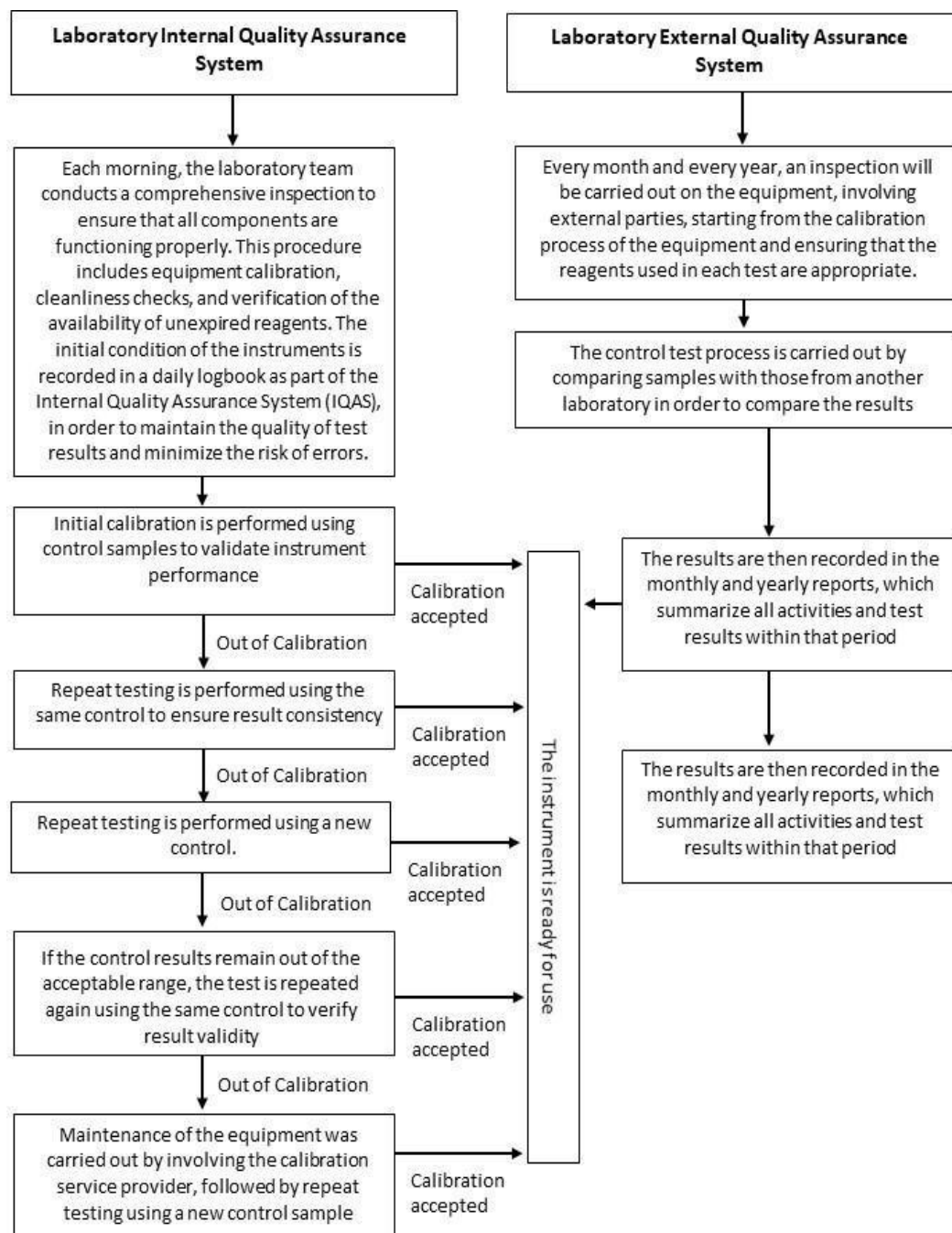


Figure 3. Internal and External Quality Assurance Systems in Laboratory

CONCLUSION

The implementation of the Dialab Autolyser combined with rigorous Internal Quality Assurance (IQA) and External Quality Assurance (EQA) significantly enhances the accuracy, reliability, and efficiency of SGOT and SGPT testing in Type C hospitals. Daily internal QC, proper instrument calibration, and adherence to SOPs effectively reduce errors and ensure consistent results. Despite resource limitations, structured QC practices and staff training strengthen diagnostic reliability, support evidence-based decision-making, and improve patient safety in clinical settings.

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