Verification of the analytical performance of the serum gamma-glutamyl transferase assay on the Abbott Alinity ci®: Experience of the biochemistry laboratory of the Mohammed VI university hospital of Oujda

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Abstract

Introduction: As part of our study, we set out to evaluate the analytical performance of the gamma-glutamyl transferase (GGT) assay using an Abbott kit on the Alinity ci® automated system in the biochemistry laboratory of the CHU Mohammed VI in Oujda.

Materials and methods: This study assessed the repeatability and reproducibility of Alinity ci® and compared the results obtained by the Alinity ci® and Architect ci-8200® automated systems.

Results: The results obtained met the acceptability criteria recommended by the supplier and the Valtec protocol of the Société Française de Biologie Clinique (SFBC), demonstrating overall satisfaction with the study. The Alinity ci® automated system demonstrated the analytical performance required for accurate and reliable determination of GGT levels.

Discussion: Validation of an analytical method is an essential step in guaranteeing that the result obtained is as close as possible to the reference value of a sample. Several standards and technical guides set out requirements for the performance criteria of an analytical method, notably NF EN ISO 15 189.

Conclusion: the verification study of the GGT assay method produced satisfactory results, providing a high level of reliability for analysis results from the central laboratory of the CHU Mohammed VI d'Oujla. This work forms an essential basis for developing an accreditation procedure, which is part of the quality approach to which our laboratory is committed.

Keywords: Gamma-glutamyl transferase; Verification; Repeatability; Reproducibility; Alinity ci®

1. Introduction

Gamma-glutamyl-transferase (GGT) is a glycosylated protein located on the outer surface of the plasma membrane of many tissues, principally the kidneys in the proximal tubules and the loop of Henle. It is also found in the pancreas, liver, bile ducts, spleen, brain, heart, intestine and seminal vesicles. GGT is a microsomal enzyme responsible for transferring the glutamyl groups of gamma glutamyl peptides to a variety of acceptor molecules, such as water, certain L amino acids and peptides. This process leads to the production of cysteine, helping to maintain intracellular homeostasis and mitigate oxidative stress[1].

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GGT has been considered a marker for various types of liver disease, such as cholestatic syndromes, drug-induced liver damage, alcohol-related liver disease and non-alcoholic steatohepatitis [2].

In addition, GGT has been frequently used to monitor the progression of alcohol-related liver disease, as well as to assess alcohol abstinence in individuals with alcohol-related liver disease [2].

GGT has recently been shown to be associated with a number of other organs and their pathologies, and there is considerable evidence to suggest that elevated GGT activity is associated with an increased risk of cardiovascular disease such as coronary heart disease, hypertension, stroke and heart failure [3],[4].

Similarly, elevated plasma GGT is an early biomarker of type II diabetes and gestational diabetes mellitus [5],[6].

GGT has also been identified as a factor in bone reabsorption and implicated in the progression of various cancers [7],[8].

Accurate measurement of GGT by the medical biology laboratory is essential for the diagnosis and monitoring of these pathologies. Hence the importance of method verification, a requirement of NF EN ISO 15189.

Abbott’s Alinity ci® and Architect ci8200® are two well-established platforms in our laboratory for the assay of biochemical markers.

The Abbott Alinity ci® is a clinical chemistry system incorporating advanced features for automated analysis of biochemical markers.

Before introducing a new GGT assay on this instrument, it is important to check analytical performance to ensure reliable and accurate results.

In our work, we wanted to evaluate the analytical performance of the serum GGT assay method using an Abbott kit on the Alinity ci® automated system in the biochemistry laboratory of the CHU Mohammed VI d’Oujda.

2. Material and methods

2.1. Principle of method

GGT catalyzes the transfer of the gamma-glutamyl group from the donor substrate (L-gamma-glutamyl-3-carboxy4-nitroaniline) to the acceptor glycylglycine to form 3-carboxy-4-nitroaniline. The increase in absorbance at 416 nm is directly proportional to the concentration of GGT in the sample.

2.2. Verification processes

This is a comparative descriptive study conducted at the biochemistry laboratory of the CHU Mohammed VI d’Oujda over a period from June 06, 2023 to July 06, 2023.

The biochemistry laboratory at CHU Mohammed VI d’Oujda is carrying out a rigorous verification of the analytical performance of GGT assay kits using the Abbott Alinity ci® automated system.

We adopted a working methodology based on the recommendations of the COFRAC GTA 04 accreditation technical guide protocol.

The objective was to evaluate the analytical performance of the Abbott Alinity ci® automated system in terms of repeatability and reproducibility, using both samples from

The results were then compared with those obtained with an Abbott Architect ci8200 analyzer to ensure consistency and reliability.

We also used the Bland-Altman diagram, where the difference between the two measurement methods is always expressed as a function of the mean obtained with each.

Statistical processing of the data was carried out using the EVM intermediate module from BYG Informatics.
During the performance evaluation process, standard deviations (SD) and coefficients of variation (CV) were carefully evaluated and analyzed.

To guarantee the reliability of the results obtained, we compared these measurements with the standards set by the Société Française de Biologie Clinique (SFBC)[9]. These standards represent important references in the field of clinical biology, and serve as guidelines to ensure the validity of the analyses performed.

Subjects were selected randomly in the usual workflow, without applying exclusion criteria related to gender, age, clinical information...

Serum or plasma is generally used as the biological sample for the GGT assay. It is prepared from a venous blood sample and separated by centrifugation at 4000 rpm for 10 minutes at room temperature.

The total number of samples was 90. Analyses were carried out on the same day as the request.

The sample was first measured on Architect ci8200® and then repeated by the same operator the same day on Alinity ci®.

Method calibrations were carried out on each PLC, and corrective measures were taken in the event of quality control outliers,

Internal quality controls were carried out daily on both analyzers. Three levels of control were performed on each analyzer (Alinity ci : Level 1 target value = 21-23 IU/L, Level 2 target value = 69-77 IU/L, Level 3 target value = IU/L) Westgard standard rejection rules were applied. All GGT results are expressed in IU/L.

3. Results

The results obtained for the different GGT assay verification criteria show satisfactory repeatability for all three levels (1:low / 2:medium /3:high) with respectively CV1 = 1.47%, CV2 = 1.08%, CV3: 0.52 on 30 samples, as shown in Table 1.

Table 1 Repeatability results for GGT on the Alinity ci® automated system

<table>
<thead>
<tr>
<th>Sample</th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
<th>CV%</th>
<th>CV SFBC</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>30</td>
<td>25.83 U/L</td>
<td>0.379 U/L</td>
<td>1.47 %</td>
<td>4.50 %</td>
<td>Validated</td>
</tr>
<tr>
<td>Level 2</td>
<td>30</td>
<td>78.97 U/L</td>
<td>0.850 U/L</td>
<td>1.08 %</td>
<td>4.50 %</td>
<td>Validated</td>
</tr>
<tr>
<td>Level 3</td>
<td>30</td>
<td>146.10 U/L</td>
<td>0.759 U/L</td>
<td>0.52 %</td>
<td>3.75 %</td>
<td>Validated</td>
</tr>
</tbody>
</table>

Intra-laboratory reproducibility was satisfactory for all three levels, with CV1= 4.553%, CV2=5.9% and CV3= 3.326% respectively on 30 samples (Table 2).

Table 2 Reproducibility results for GGT on Alinity ci® automated system

<table>
<thead>
<tr>
<th>Sample</th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
<th>CV%</th>
<th>CV% SFBC</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>30</td>
<td>21.38</td>
<td>0.973</td>
<td>4.553%</td>
<td>6%</td>
<td>Validated</td>
</tr>
<tr>
<td>Level 2</td>
<td>30</td>
<td>72.38</td>
<td>4.27</td>
<td>5.9%</td>
<td>6%</td>
<td>Validated</td>
</tr>
<tr>
<td>Level 3</td>
<td>30</td>
<td>127.61</td>
<td>4.245</td>
<td>3.326%</td>
<td>5%</td>
<td>Validated</td>
</tr>
</tbody>
</table>

Comparing these results with the CVs adopted by the SFBC, we note that the results are in line with and below the tolerated limits.
The methods were compared on 30 samples. The Bland-Altman diagram shows that the mean bias between the two automata is approximately 11.61% (Figure 1) with a linear regression equation $Y = 0.90X - 1.14$. The correlation coefficient ($r$) was 1 (Figure 2), with a mean difference of 10.8 U/L and a standard deviation of 9.179 U/L.

**Figure 1** The Bland-Altman diagram for GGT

**Figure 2** Correlation study for GGT

### 4. Discussion

The assessment of serum GGT is crucial in medical practice, so an accurate result from the medical biology laboratory is essential, helping to preserve the laboratory’s reputation and credibility. Hence the importance of method verification, which is a requirement of NF EN ISO 15189[10].
It consists of evaluating the performance of an analytical method according to a precise protocol, then comparing it with pre-established analytical objectives. Every biologist must master this process [10].

Verification of an analytical method is an essential step in guaranteeing the quality and safety of results delivered to patients [11].

Incorrect results can lead to incorrect diagnoses and inappropriate therapeutic management. In order to minimize the risk of error and improve the quality of patient service, accreditation to ISO 15189 is now compulsory [12].

It is important to note that method verification is specific to the laboratory and must be carried out in accordance with current guidelines and standards [12].

Compliance with these standards is essential to maintain the integrity of laboratory tests and guarantee the validity and reliability of results obtained by patients [13].

The verification process consists of a comprehensive assessment of the test's performance characteristics, such as repeatability, reproducibility, specificity, sensitivity, linearity and measurement uncertainty [13].

Repeatability assessment determines the consistency and accuracy of a measurement under identical conditions, and verifies the correct operation of the system, including reagents and instruments for the parameter being assessed. Reproducibility assesses the reliability of results by varying factors such as operators, reagent batches, time and calibration [12], [13]. The results of the repeatability and reproducibility study for GGT show satisfactory performance in relation to the supplier's data and the CFB's criteria. Thus, the study reveals that the two automated systems give similar results for GGT when using the same samples for comparison.

The Laboratory of the CHU Mohammed VI d'Oujda is committed to a quality approach in order to satisfy the needs of its customers: patients, prescribers, sample takers, whether inside or outside the establishment.

As part of its commitment to quality, the central laboratory has set up a method verification procedure and an accreditation process.

The importance of these studies lies in their contribution to the establishment of a robust accreditation process for the laboratory's analyses, thus ensuring the reliability and accuracy of the results obtained.

5. Conclusion

At the end of this work, we can conclude that the Abbott Alinity ci® meets the requirements laid down by learned societies for the determination of GGT using the gamma glytamyl transferase reagent.

Reliable results from GGT analyses are essential for accurate patient care. ISO 15189 compliance enables medical laboratories to demonstrate their technical competence, reliability and commitment to continuous improvement. This reinforces the confidence of patients, healthcare professionals and regulatory bodies in the services provided by these laboratories.

Compliance with ethical standards

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The authors declare no conflict of interest in preparing this article.

Statement of ethical approval

The ethical committee approval was not required give the article type.
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