Analytical Validation of the Maglumi for Gastrin measurement: Performance and Comparison with radioimmunoassay method.

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Objectives:

Gastrin (GST), a peptide hormone responsible for stimulating gastric acid secretion, plays a crucial role in diagnosing gastrointestinal diseases. Elevated or suppressed GST levels are associated with conditions such as Zollinger-Ellison syndrome, characterized by gastrin-secreting tumors, and chronic atrophic gastritis, linked to pernicious anemia or Helicobacter pylori infections. Accurate GST measurement is critical for clinical diagnoses and treatment. This study validates the Maglumi X3 (Snibe) chemiluminescent immunoassay (CLIA) analyzer for GST quantification in human serum and compares its results with established laboratory methods (Figure 1).

Figure 1: MagLumi device (Snibe ®)

Materials and Methods:

The Maglumi X3 analyzer quantified GST in human serum samples. Performance was evaluated at five concentration levels (2.2 – 321 pmol/L) for intra-assay and inter-assay precision, trueness, and measurement uncertainty, following European Medicines Agency (EMA) guidelines. The validation standards were analyzed in triplicate over three days. Method comparison used 80 residual patient samples to assess Maglumi's performance against DiaSource radioimmunoassay (RIA). Statistical analyses included Passing-Bablok regression and Bland-Altman plots via MedCalc software, with analytical validations supported by Enoval software (Arlenda).

Results:

The Maglumi X3 analyzer showed intra-assay and inter-assay coefficient of variations (CVs) at 3.26% and 5.30% for GST. Trueness evaluation revealed a maximum relative bias of 6.00%. Measurement uncertainty analysis showed a maximum relative expanded uncertainty of 11.3% (Table 1). The Passing-Bablok regression equation was: GSTMaglumi = -2.017 + 0.2233 GSTRIA (95% CI for intercept: -3.465 to -0.8477, 95% CI for slope: 0.1902 to 0.2572). Systematic and proportional differences were observed. Bland-Altman plots confirmed agreement, there was no impact on the clinical diagnostic (Figure 2 and 3). The method is considered as valid within the range for which the accuracy profile is within the acceptance limits of 15%. This approach gives the guarantee that each further measurement of unknown samples is included within the tolerance limits at the 5.0 % level (Figure 4).

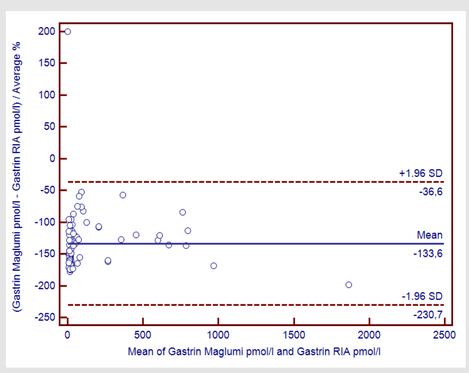

Figure 2: GST Bland-Altman

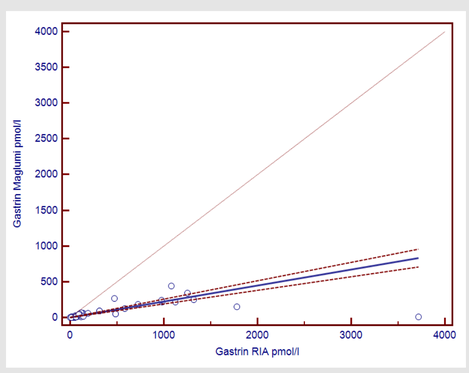

Figure 3: GST Passing-Bablok

Comparison between RIA and MagLumi methods

Table 1: GST Enoval results

Mean introduced concentration (pmol/L)	Repeatability (RSD%)	Intermediate precision (RSD%)	Relative expanded uncertainty (%)
2,175	3,26	5,30	11,3
10,15	1,14	1,53	3,22
49,89	1,86	2,54	5,38
106,0	1,61	1,88	3,91
321,1	1,48	2,06	4,37

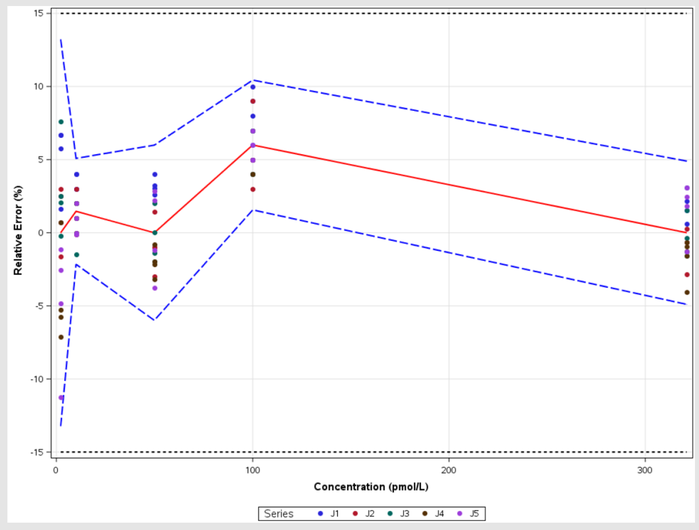

Figure 4: Accuracy profiles for GST

Conclusion:

The Maglumi X3 analyzer provides accurate GST measurements with acceptable precision and uncertainty. Despite systematic and proportional differences compared to RIA, clinical diagnostic outcomes remain unaffected. New reference intervals for Maglumi X3 are recommended to enhance diagnostic accuracy. The device is a valuable tool for assessing GST-related disorders and has replaced our RIA assay.