

## Validation of the MagLumi for Gastrin (GST) and Reverse T3 (RT3) determination

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### Objectives:

Gastrin is a hormone that stimulates gastric acid secretion, and its measurement is crucial for diagnosing conditions like Zollinger-Ellison syndrome and chronic atrophic gastritis. Reverse T3 is an inactive form of triiodothyronine, and its levels are useful in evaluating thyroid function in conditions such as non-thyroidal illness syndrome and distinguishing types of hypothyroidism. The study aims to validate the analytical performance of the Maglumi (Snibe) for determining gastrin (GST) and reverse T3 (RT3) levels, and to compare these results with those obtained using standard laboratory methods.



Figure 1: MagLumi device ( Snibe ®)

### Methods:

The Maglumi, a chemiluminescent immunoassay analyzer, was evaluated for quantifying GST and RT3 in human whole blood/serum/plasma. An analytical evaluation was conducted at five concentration levels to validate intra- and inter-assay variation, trueness, and measurement uncertainty. The comparison was performed using 80 residual samples for GST and RT3. The laboratory methods for GST and RT3 were a radioimmunoassay (RIA) from DiaSource. Passing-Bablok regression and Bland-Altman tests were used for comparisons (MedCalc), and analytical validation was performed using Enoval (Arlenda).

### Results:

On the Maglumi, the maximum intra- and inter-assay CVs were 3.26% and 5.30% for GST, 1.87% and 2.53% for RT3, respectively. The maximum relative bias was 6.00% for GST and 4.20% for RT3. The maximum relative expanded uncertainty was 11.3 % for GST and 5.41% for RT3. The regression equation for GST was:  $\text{GST Maglumi} = -2.017 + 0.2233 \text{ GST RIA}$  (95% CI of the intercept: -3.465 to -0.8477, 95% CI of the slope: 0.1902 to 0.2572). For RT3, the regression equation was:  $\text{RT3 Maglumi} = 0.02124 + 0.5187 \text{ RT3 RIA}$  (95% CI of the intercept: 0.008949 to 0.03136, 95% CI of the slope: 0.4773 to 0.5630). A systematic and proportional difference was found between the two methods for both compounds, likely due to different antibodies used in the kits.

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                              |

Table 2: RT3 Enoval results

| Mean introduced concentration (ng/mL) | Repeatability (RSD%) | Intermediate precision (RSD%) | Relative expanded uncertainty (%) |
|---------------------------------------|----------------------|-------------------------------|-----------------------------------|
| 0,08100                               | 1,40                 | 1,77                          | 3,71                              |
| 0,1340                                | 1,54                 | 2,53                          | 5,41                              |
| 0,2000                                | 1,69                 | 1,69                          | 3,46                              |
| 0,4780                                | 1,87                 | 1,87                          | 3,83                              |
| 1,000                                 | 0,948                | 1,59                          | 3,40                              |

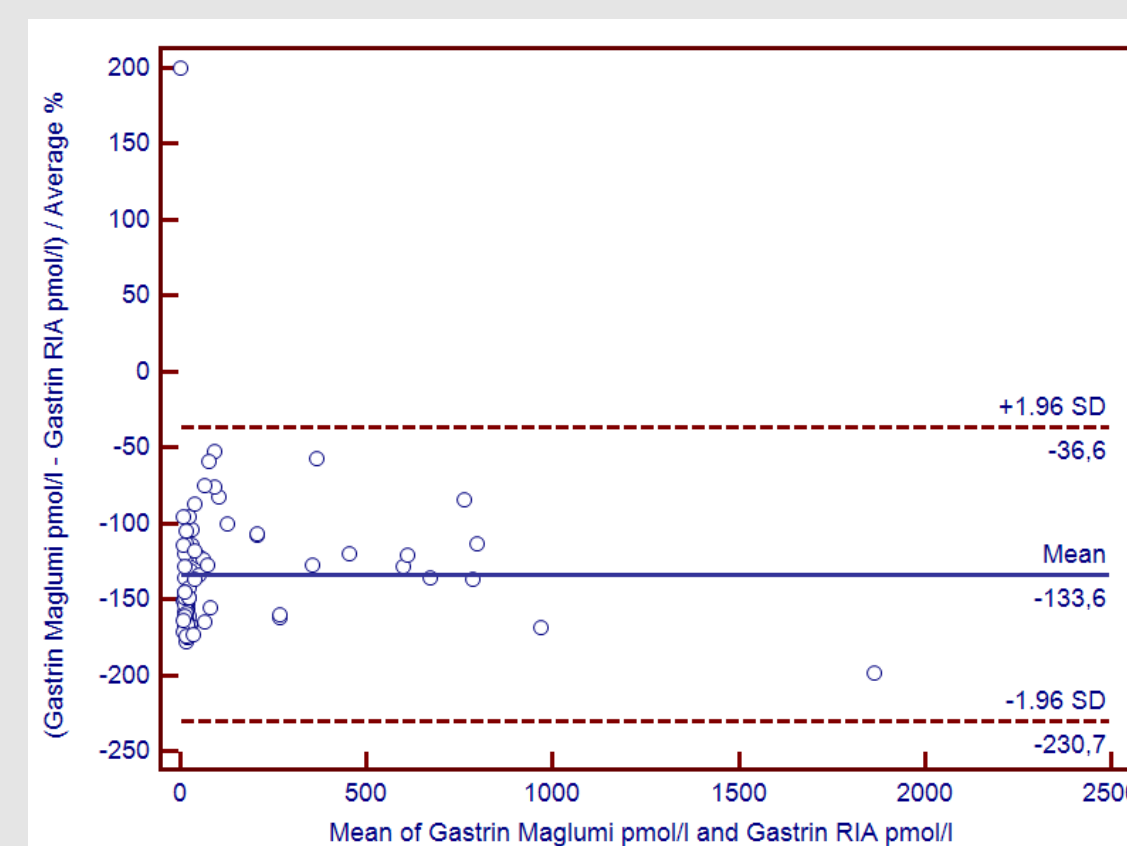


Figure 2: GST Bland-Altman

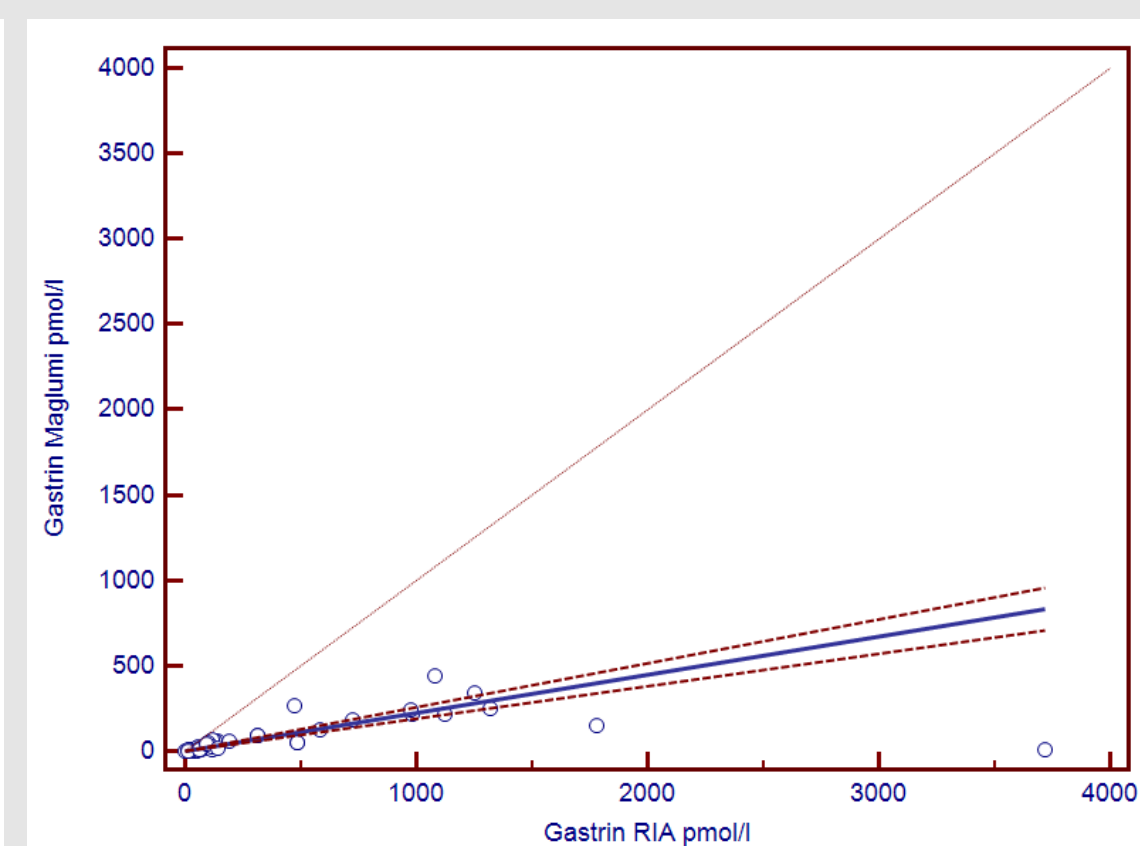


Figure 3: GST Passing-Bablok

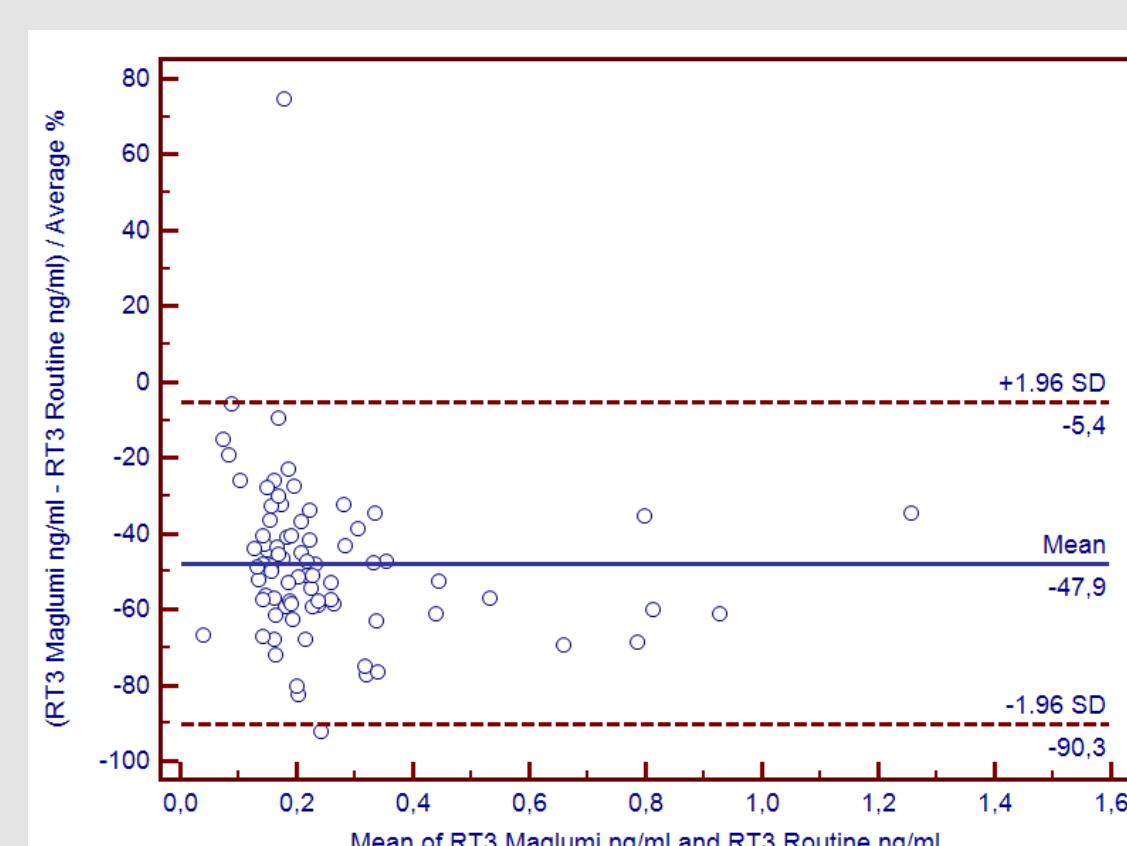


Figure 4: RT3 Bland-Altman

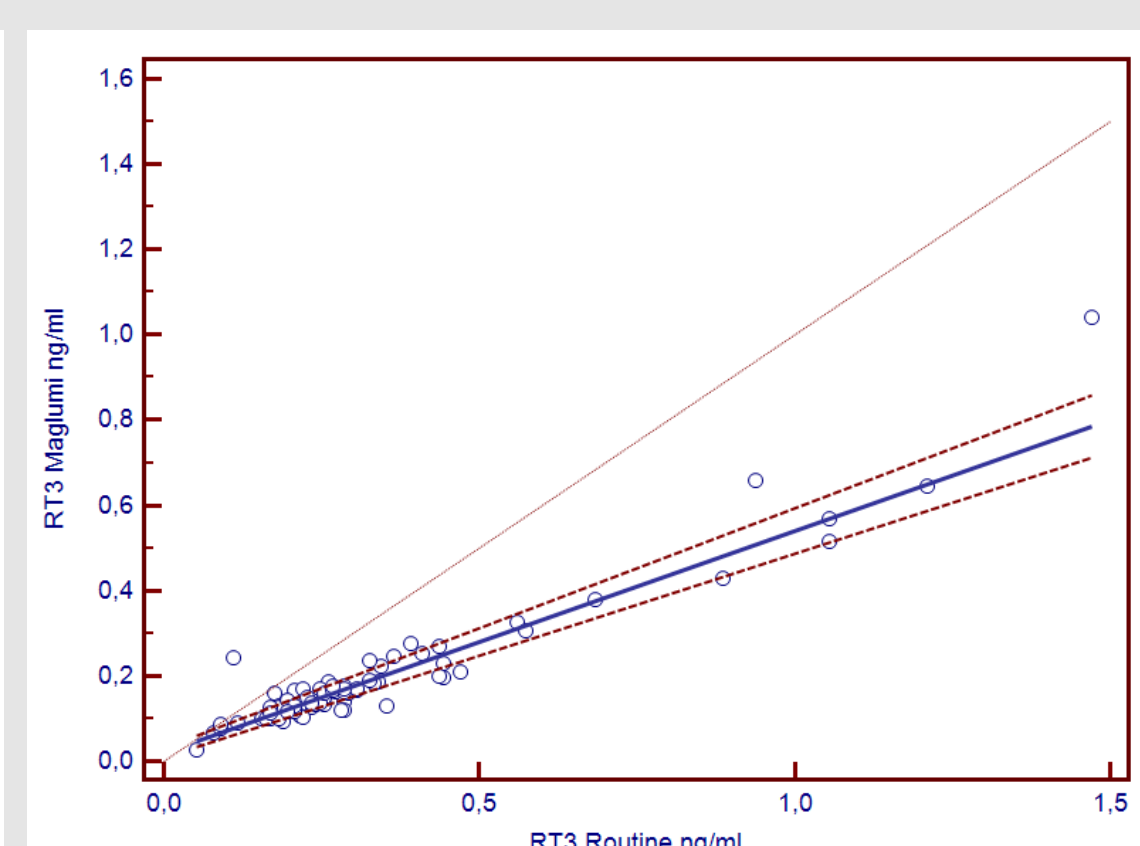


Figure 5: RT3 Passing-Bablok

Comparison between RIA and MagLumi methods

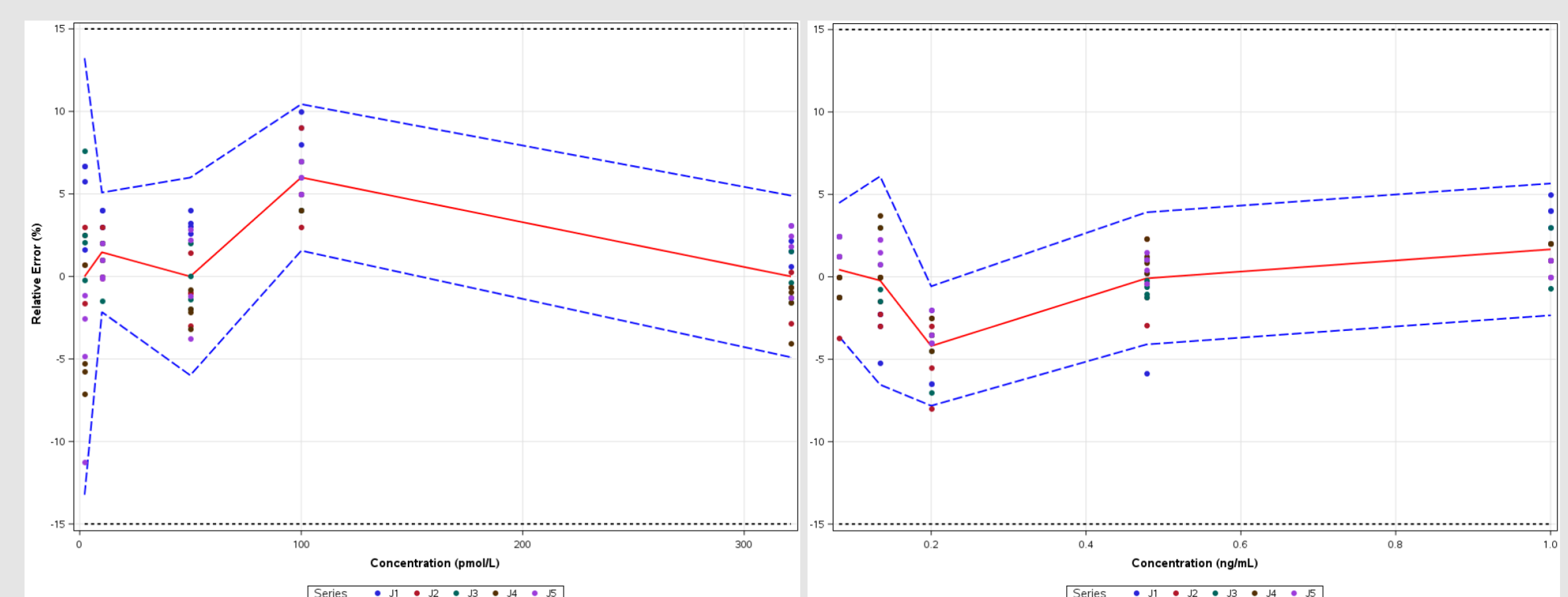


Figure 6: Accuracy profiles for GST (left) and RT3 (right)

### Conclusion:

MagLumi device is accurate and correlates well with RIA lab method used before. Despite some variation in results, the diagnostic outcome remains consistent for both compounds. This device can aid emergency physicians in quickly identifying conditions related to abnormal gastrin and reverse T3 levels with confidence in the accuracy of the results.