CA19.9 assays provide clinically different results for the patients

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Introduction:

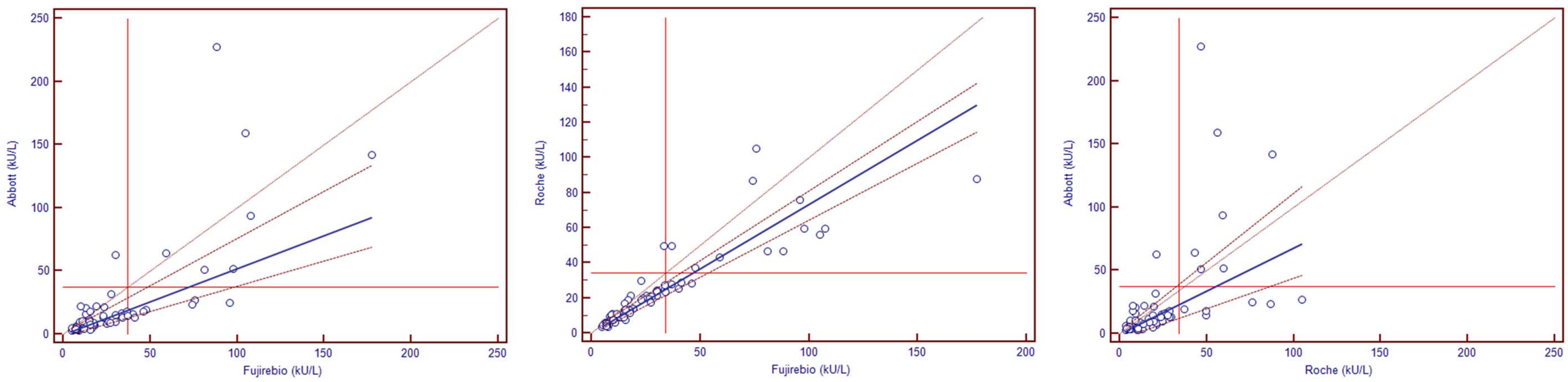
CA19.9 is a carbohydrate antigen secreted by pancreatic, biliary, gastric, colic, endometrial and salivary cells (1). Its lack of specificity does not make it a good screening marker for pancreatic cancer, but it remains precious for its diagnosis, treatment, prognosis and follow-up. The CA19.9 can also be increased in various benign digestive pathologies (pancreatitis, gallstones, hepatitis, etc.) pulmonary (mucovisidosis, severe bronchopathies), in unbalanced diabetes or in other malignancies (digestive, bronchial, gynecological cancers) (1,2). The aim of this study was to assess the concordance of CA19.9 results between Alinity i ® (Abbott), Lumipulse G ® (Fujirebio) and Cobas e411 ® (Roche) for patient follow-up and to compare the 3 methods.

Material and Methods:

We selected randomly 65 sera for which a CA19.9 assay had been requested in the routine of the CHU of Liège. These samples were frozen at -80°C after the Alinity measurement then tested in a single batch on the Lumipulse and the Cobas. All these assays use the same 1116-NS-19-9 monoclonal antibody. Abbott states that the CA19.9 assay on Alinity is standardized against a reference standard prepared by Fujirebio. Thus the reference value of CA19.9 Lumipulse and Alinity are identical <37 kU/L while the Cobas is <34 kU/L. We realized Passing-Bablok regressions and Chi-squared tests with the Medcalc Software.

Results:

The Passing-Bablok regression equations give Abbott = -0.90 + 0.62 Fujirebio. The 95% confidence interval (95% CI) of the intercept is -4.05 to 0.92 and that of the slope 0.46 to 0.90. Cobas = 0.45 + 0.72 Fujirebio. The 95% CI of the intercept is -0.46 to 2.10 and that of the slope 0.62 to 0.79. Abbott = -1.63 + 0.88 Cobas. The 95% CI of the intercept is -7.21 to 1.23 and that of the slope 0.57 to 1.26. The Chi-squared test contingency coefficients are 0.604 when compared Cobas/Lumipulse, 0.543 for Cobas/Alinity and 0.527 Lumipulse/Alinity.



(1) (2) (3)

Graphics (1) (2) (3) : Passing-Bablok regressions for (1) Abbott/Fujirebio, (2) Roche/Fujirebio, (3) Abbott/Roche. The red lines correspond to the cut-offs.

Conclusions:

Our results show a significant bias between Alinity/Lumipulse and Cobas/Lumipulse assays. There is variability between the kits from different industries. The worst contingency coefficient was obtained between Alinity and Lumipulse. Abbott appears to have lost alignment with the reference method; Abbott has to review its standardization and its cut-off as the clinical implications may be important. This highlights the importance of following patients in the same laboratory to avoid analytical discrepancy in CA19.9 results.

1. Scatena R. Advances in Cancer Biomarkers - From biochemestry to clinic for a critical revision. Adv Exp Med. 2015;867:361
2. Luo G, Fan Z, Cheng H, Jin K, Guo M, Lu Y, et al. New observations on the utility of CA19-9 as a biomarker in Lewis negative patients with pancreatic cancer. Pancreatology. 2018;18(8):971–6