Clin Lab. 2013;59(1-2):185-92.
doi: 10.7754/clin.lab.2012.111112.

European proficiency study with control serum for the tumor marker CA 19-9 measured on different test systems

T Bertsch [1], C Aschenneller, N Bewarder, R Beyrau, B L Herrmann, E Jansen, R Klapdor, M Klemm, J Meissner, S Pfeiffer, I Schauer, M M Stratmann, C Theimer, H M van de Loo, D A Wildbredt, C Wolff, P Wollenberg
Affiliations expand

- PMID: 23505925 DOI: 10.7754/clin.lab.2012.111112

Abstract

Background: Reliable and precise CA 19-9 testing is required for the long-term follow-up of patients with pancreatic carcinoma during therapy. The aim of this longitudinal proficiency study was to evaluate the comparability, linearity, and precision of CA 19-9 determinations performed in different laboratories using currently available test systems under routine conditions.

Methods: During the one year study period, 15 laboratories applied 7 different tests and included a liquid BIOREF control serum with pancreatic carcinoma derived CA 19-9 in their routine testing and quality control procedures. The results were collected centrally and evaluated statistically.

Results: The comparability of CA 19-9 results is limited especially when different tests are used, albeit, some tests show a good correlation: The CA 19-9 values obtained by different laboratories using different test systems vary up to a factor of 2. The precision of CA 19-9 determinations was acceptable in most laboratories with coefficients of variation ranging between very low 3.2% and high 17.8%. The imprecision was slightly increased when automatic dilution procedures of the analysers were used.

Conclusions: The comparability of CA 19-9 test results must be improved. The precision is acceptable in most cases. In order to monitor key performance parameters, every laboratory should participate in external quality assessment schemes and should perform a routine internal quality control with a control serum independent from the test kit manufacturer.