LUMIPULSE® G1200, AN AUTOMATED CLEIA PLATFORM SHOWING GOOD PERFORMANCE FOR DIFFERENT TUMOUR MARKERS

Department of Molecular Medicine, Sapienza – University of Rome, ITALY

Aim of the Study

Aim of this study was to assess the concordance between an automated chemiluminescent enzyme immunoassay system (LUMIPULSE® G1200) and our reference methods using 6 tumor markers.

Materials and Methods

Serum samples from 821 subjects, representing a variety of diagnoses, were analyzed using LUMIPULSE® G1200 and our reference methods.

Serum values were measured for the following analytes: PSA, AFP, CEA, CA125, CA15-3, and CYFRA.

For the determination of CEA, AFP and PSA, an automatic analyzer based on chemiluminescence (Access2) was applied as reference method.

To assess CYFRA, CA125, and CA15-3, an immunoradiometric manual system was employed (CisBio).

Concordance

The concordance between LUMIPULSE® G1200 and both reference methods was as follows:

- PSA: 97%
- AFP: 96%
- CEA: 95%
- CA15-3: 91%
- CYFRA: 96%

CA125 showed a lower concordance: 82%.

A high disagreement between LUMIPULSE® G1200 (CLEIA) and the immunoradiometric manual system was found in 9 samples.

After diluting the samples and retesting with the reference method, a higher concordance (98%) with undiluted LUMIPULSE® G1200 values was obtained.

These data demonstrate the presence of the ‘hook effect’.

Precision

The precision of each assay was assessed by testing 6 serum samples. Each sample was analyzed for all tumour biomarkers in duplicate and in three different runs. The coefficients of variation (CVs) were less than 6.3% and 6.2% for within-run and between-run variation respectively.

Our data suggest an overall good agreement between all methods. However, some artifacts were obtained with immunoradiometric system and suggest the presence of ‘hook effect’.

CLEIA automated assay showed a good reliability in all samples.