EVALUATION OF AN ELISA FOR QUANTIFYING CYFRA 21-1 PROTEIN IN SERUM AND CORRELATION WITH AN AUTOMATED CHEMILUMINESCENCE ENZYME IMMUNOASSAY

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ABSTRACT

Introduction. CYFRA 21-1 is a 18-kDa oncofetal intermediate filament protein found to be expressed in epithelial cells. A multi-antibody cocktail of CYFRA 21-1, CEA, and TPS (EA-1) utilized by our ELISA is highly specific, and has clinical utility in the prognostic monitoring and staging of patients with non-small cell lung carcinoma. Its primary use is for monitoring tumor response to therapy.

Materials and Methods. CYFRA 21-1 ELISA was monitored according to the kit manufacturer’s testing protocol. CYFRA 21-1 sera were measured in the manufacturer’s specified range of 0.5-11.0 ng/mL. The assay’s imprecision was acceptable with CVs of 6.9% or less inter-assay and 12.8% or less intra-assay.

RESULTS

The y-axis is expressed on a normal scale with a lower limit of 0.4 ng/mL and upper limit at 2.3 ng/mL CYFRA 21-1 at the 97.5th percentile. There are no significant differences for intra-assay (n=6). The slope is 1.781 (95% CI = 1.597 to 1.965), a y-intercept of -0.54 (95% CI = -0.97 to -0.10) with an \( r^2 \) value of 0.999 (n = 6).

CONCLUSIONS

Both the manual CanAg ELISA and automated Lumipulse CLEIA have acceptable performance characteristics for measuring CYFRA 21-1 protein in serum.

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REFERENCES


