Multicenter evaluation of the analytical and clinical performance of the Elecsys S100 immunoassay in patients with malignant melanoma.

The aim of this multicenter study was to evaluate the technical and clinical performance of the Elecsys S100 electrochemiluminescence immunoassay and to assess its utility as a tumor marker in patients with malignant melanoma. Imprecision studies yielded within-run coefficients of variation (CVs) of 0.7-2.0% and between-day CVs of 1.0-6.4%. Serum samples that were distributed to 11 participating laboratories for a comparability analysis resulted in excellent recoveries of 93-105% related to the median for all laboratories. The functional sensitivity of the assay was determined to be below 0.02 microg/L. The lot-to-lot reproducibility of Elecsys S100 was tested by analyzing 110 sera with three different reagent lots on an E2010 analyzer. This lot-to-lot comparison showed excellent correlation, with a coefficient of 0.99. A 95th percentile cut-off value of 0.10 microg/L was calculated from values measured in 206 healthy individuals. Using this cut-off value, sensitivity of 41% was found, with positive and negative predictive values of 0.50 and 0.91, respectively. Method comparison with the Sangtec 100 luminescence immunoassay, run on two different analyzers, showed correlation with coefficients ranging from 0.76 to 0.95. A comparison of S100 values obtained with both tests showed identical patterns in 68 serial samples from 15 patients with malignant melanoma during follow-up. These findings
indicate that serial measurements with the Elecsys S100 assay are useful for the follow-up and monitoring of therapy in patients with malignant melanoma.