Letters to the Editor should be typed double-spaced (including references) with conventional margins. The overall length is limited to five manuscript pages, including not more than one figure or one table.

More on Predictive Value of “AlbuScreen” and “AlbuSure”

Results

To the Editor:

Capps et al. (1) showed high specificity and sensitivity of the AlbuScreen latex-agglutination inhibition test for urinary albumin concentrations >50 mg/L, which confirms other studies (2, 3). A similar kit (AlbuSure) is available with a 20 mg/L cutoff. We have assessed the performance of both kits, and in particular we wish to comment on the "weak reactions" (partial agglutination in a milky background) that we observed with some samples.

The AlbuScreen kit was tested with a total of 169 urine samples, whose albumin concentrations were determined by radioimmunoassay (4) to be in the range 20–100 mg/L. Of these, 99 were in the range 26–45 mg/L. Thirty-seven samples gave the weak reaction, which could be classified ambiguously: 35 of these had albumin concentrations in the range 26–45 mg/L (35% of all samples in this range). If these weak reactions were counted as positive (greater than the nominal cutoff) then, overall, the AlbuScreen gave 4% false positives and 7% false negatives, i.e., 89% correct results (sensitivity 90%, specificity 87%). Nearly all the errors occurred for samples with values near the cutoff point. In samples with values away from the cutoff point, with albumin concentrations <25 mg/L or >45 mg/L, there were no false positives and one false negative, i.e., 99.4% correct. If the weak reactions were counted as negative, then the overall figures were 1% false positive and 27% false negative (72% correctly assigned).

We tested the AlbuSure kit with 135 urine samples with albumin concentrations of 1 to 60 mg/L (83 in the range 11–30 mg/L). Thirty-two of a total of 33 samples giving the weak reaction were in the range 16–35 mg/L. The overall results were (counting weak reactions as positive) 1.5% false positive, 4.4% false negative (94% correct; sensitivity 93%, specificity 96%). Again, the errors occurred around the cutoff point. In the 52 samples away from the cutoff point, with albumin concentrations <11 mg/L or >30 mg/L, allocation was 100% correct. Counting weak reactions as negative, overall there were no falsely positive and 27% falsely negative results (i.e., 73% correct). We conclude that the weak reactions observed in samples near the cutoff value with both these kits should be read as positive. With this proviso, both kits provide an accurate screening procedure for low albumin concentrations in urine.

References


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Performance of the SimuTRAC Free T4/TSH Assay during Pregnancy and Treatment with Amiodarone

To the Editor:

We read with interest the recent report of Desai et al. (1) on the evaluation of the SimuTRAC FT4/TSH assay (Becton Dickinson) and have two important remarks to add.

1. We tested serum samples from pregnant women at each trimester of gestation. With ongoing pregnancy, FT4 values gradually decreased; by the third trimester, 40% of the women showed FT4 values below the normal reference interval (10.6–17.5 mg/L), a mean decrease of 25% compared with the first-trimester values.

TSH values in serum showed no significant changes during pregnancy except in two patients in whom hyperthyroid values were detected in the first and early second trimester of gestation (TSH reference interval: 0.11–3.27 milli-int. units/L; classified hyperthyroid if TSH <0.06 milli-int. unit/L). In both patients all other thyroid variables were within normal limits and no thyroid disease was clinically apparent. Because serum gonadotropin (hCG) concentrations are maximal during this period of pregnancy, we suspected a cross reaction with hCG. To investigate this possibility we fortified a pooled specimen of human serum (endogenous TSH 18 milli-int. units/L) with amounts of hCG (Profasi-Serono, Switzerland) ranging from 400 int. units/L to 500 000 int. units/L and assayed. We detected negative interference with the TSH determination, increasing with increasing amounts of hCG (Figure 1).

During the first and early second trimester of pregnancy, a falsely low TSH concentration will be measured with this kit, but values for serum FT4 will remain within normal limits.

2. In five patients who were being treated with amiodarone, serum FT4 concentrations exceeded the reference interval, whereas values for TSH were within normal limits. Amiodarone inhibits the mono-deiodination of thyroxin (T4) to triiodothyronine (T3), resulting in increased concentrations of T4, FT4, and reverse triiodothyronine (rT3) and decreased concentrations of T3. The TSH response to thyrotropin remained within normal limits (3, 4). For the diagnosis of hyperthyroidism in patients on amiodarone therapy, FT4 measurement is of no diagnostic value;

Fig. 1. Results for TSH determination in serum fortified with increasing amounts of hCG.

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