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VALIDATION OF A NEW IMMUNOENZYMATIC METHOD FOR THE DETERMINATION OF THYROGLOBULIN IN SERUM

VALIDAZIONE DI UN NUOVO METODO IMMUNOENZIMATICO PER LA DETERMINAZIONE DELLA TIREOGLOBULINA NEL SIERO

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Introduction: human thyroglobulin (TG) is a glyco-protein produced only by thyroid tissue. This feature ensures that it can be used as a sensitive and specific marker in the follow-up of differentiated thyroid carcinoma (DTC).

Aim of this study was to validate the new Chorus TG kit (Diesse Diagnostica Senese SpA, Siena-Italy) by comparing the results with those of a commercial test (Immulite 2000 TG-Siemens).

Materials and methods. The study was performed on a total of 217 sera. The Chorus TG kit was validated by determining the analytical and functional sensitivity of the method. For the standard curve, double dilutions (in TG-free serum) of the reference standard European (CRM-457) have been used, starting from a concentration of 100 ng / ml. The intra-and inter-assay and inter-Chorus reproducibility of the Chorus TG test has been evaluated using three samples at high, medium and low level of TG. The correlation between the results obtained with the two methods has been calculated and the results were also evaluated in terms of diagnostic sensitivity and specificity both on the total of the sera that in a subset of sera obtained from patients (n = 88) with CDT. 179/217 (82.5%) sera were also assayed for anti-thyroglobulin antibody (aTG).

Results. The functional sensitivity of the kit resulted equal to 0.8 ng/ml and the analytical sensitivity to 0.2 ng/ml. The reproducibility, expressed as CV% (average of data obtained with the three samples) gave the following results: intra-assay 3.5%, inter-assay 5.8%, inter-Chorus 8.0%. A good correlation was found between the two methods for serum TG (R^2 0.98, P value <0.0001). The Chorus TG was detectable in 166/167 (sensitivity: 99.4%) of sera with detectable Immulite TG and undetectable in 47/50 (specificity: 94.0%) of sera with undetectable Immulite TG. In the subgroup of patients with CDT sensitivity was 98% and specificity 94.7% and a good correlation was observed between the two methods of determination (R^2 0.98, P value <0.0001). In 21/179 (11.7%) sera aTG autoantibody was detected and TG was undetectable in 17/21 and undetectable in 4/21 sera with both methods.

Conclusions. The two methods show a good correlation and concordance with no differences with regard to possible interference with antibodies. The good functional sensitivity allows its use in the follow-up of patients with CDT.