

K960412

510 (K) Summary ~~Statement~~

To The Reviewer:

Biomerica's T3 microwell EIA is Enzyme Immuno-assay test for the quantitative determination of Triiodothyronine (T3) in human serum. This test is substantially equivalent to T3 Coat-a- Count RIA test (DPC kit) for the quantitative determination of T3 in human serum.

This device is an in vitro diagnostic test kit.

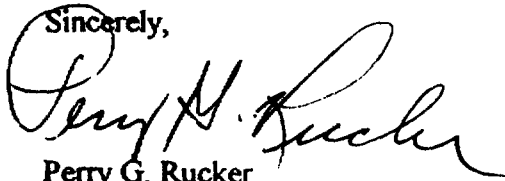
Biomerica's T3 EIA is a sensitive solid phase enzyme immunoassay system for the quantitative determination of T3 in patient serum or plasma. Specific antibodies to T3 are immobilized on the inside surface of microwells of microtiter plate (96). A known volume of serum or plasma containing T3 and an enzyme labeled T3 conjugate are added to the antibody coated microwells. Both the T3 in the sample and the enzyme conjugated T3 compete for a limited number of binding sites available on the antibody. The unbound T3-enzyme conjugate is washed off from the microwells. A chromogen substrate mixture is added to the bound T3 enzyme conjugate to develop color. The intensity of the color developed is measure by the microtiter reader and is inversely proportional to the amount of T3 present in the patient's sample. The quantity of T3 present in the patient's sample (serum or plasma) is measured by extrapolating from the dose response curve (DRC) .

DRC is prepared by plotting known concentrations of T3 on X-axis and the corresponding color absorbance on Y-axis, using a semi-log graph sheet or a Software program for microtiter plate reader.

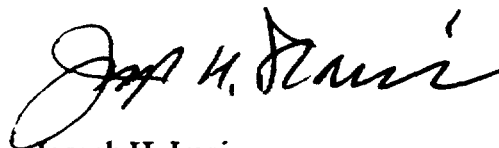
Data submitted in this 510 (K) premarket notification is correct and has been compared to be substantially equivalent to a 510 (K) cleared commercially available predicate device (DPC RIA kit) in the market.

The performance data and clinical data is on file and is available to any qualified individual upon request. Biomerica is responsible for all of the information submitted which is true and authentic to the best of our knowledge.

Sincerely,



Perry G. Rucker
Manager, Regulatory Affairs



Joseph H. Irani
President

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