



4970915 MAY 16 1997

Diagnostic Systems Laboratories, Inc.
445 Medical Center Boulevard
Webster Texas 77598-4217 USA
Tel 281.332.9678
Fax 281.554.4220

Customer Assistance Center
Tel 800.231.7970
Fax 281.338.1895
Email mktg@dslabs.com

SUMMARY OF SAFETY AND EFFECTIVENESS

Name of Device: DSL 5400 Estrone-Sulfate RIA Kit
Classification Name: Radioimmunoassay, Estrone-Sulfate
Analyte Code and Name: Estrone-Sulfate
Regulatory Class: I

Submitter: John Willis
Diagnostic Systems Laboratories, Inc.
445 Medical Center Boulevard
Webster, Texas 77598
Phone:281-332-9678

Date: March 11, 1997

The DSL 5400 Estrone-Sulfate RIA kit was developed for the quantitative measurement of Estrone-Sulfate in human serum or EDTA plasma. The RIA format is a competitive binding protein assay. Radio-labeled Estrone-Sulfate competes with un-labeled Estrone-Sulfate in the serum or plasma sample for binding sites to the Estrone-Sulfate antiserum provided with the kit. Separation of free from bound Estrone-Sulfate is achieved by the addition of a second antibody containing goat anti-rabbit gamma globulin serum with polyethylene glycol as a precipitating aid, centrifugation and decantation of the tubes. The resultant is analyzed in a gamma counter for bound counts per minute. The amount of radio-labeled Estrone-Sulfate bound to the antibody is inversely proportional to the concentration of the Estrone-Sulfate present in the sample.

The DSL 5400 Estrone-Sulfate RIA assay is intended for the quantitative determination of Estrone-Sulfate in human serum or EDTA plasma. The measurement of Estrone-Sulfate is used for *in vitro* diagnostic use in the diagnosis and treatment of numerous disorders, including infertility, amenorrhea, differentiation of primary and secondary ovarian malfunction, especially estrogen secreting testicular and ovarian tumors and precocious puberty in females.

The DSL 5400 Estrone-Sulfate RIA is substantially equivalent to the DSL 8700 Estrone RIA. Both kits have the same intended use.

To demonstrate substantial equivalence between the two assays, patient samples (n=43) were collected and assayed using both methods. Samples were chosen based on expected Estrone-Sulfate levels so that samples with low, intermediate and high levels would be evaluated. Linear regression analysis of the results obtained for the comparison gave the equation $Y=0.04(X) + 2.89$ with a correlation coefficient of $(r) = 0.82$.