



K960357

MAY - 7 1996

Diagnostic Systems Laboratories, Inc.
445 Medical Center Boulevard
Webster Texas 77598-4217
Tel 713.332.9678
Fax 713.554.4220

Customer Assistance Center
Tel 800.231.7970
Fax 713.338.1895

SUMMARY OF SAFETY AND EFFECTIVENESS

Name of Device: DSL 8300 I-hCG IRMA Kit
Classification Name: Radioimmunoassay, Human Chorionic Gonadotropin
Analyte Code and Name: Human Chorionic Gonadotropin
Regulatory Class: II

Submitter: John Willis
Diagnostic Systems Laboratories, Inc.
445 Medical Center Boulevard
Webster, Texas 77598
Phone:713-332-9678

Date: January 24, 1996

The DSL I-hCG IRMA kit was developed for the quantitative measurement of I-hCG in human serum. The IRMA format is a non-competitive assay in which the analyte to be measured is "sandwiched" between two antibodies. The first antibody is immobilized to the inside wall of the test tube, the other antibody is radiolabelled for detection. The analyte present is bound by both the antibodies to form a "sandwiched" complex. Unbound materials are removed by decanting and washing the tubes. The resultant is analyzed in a gamma counter for bound counts per minute. The amount of bound hCG is directly proportional to the concentration of the hCG present in the sample.

The DSL I-hCG IRMA assay is intended for the quantitative determination of I-hCG in human serum. It is intended for in vitro diagnostic use by professional laboratory personnel as an aid in the detection of pregnancy.

The DSL I-hCG IRMA is substantially equivalent to the DPC hCG IRMA.

To demonstrate substantial equivalence between the two assays, patient samples (n=53) were collected and assayed using both methods. Samples were chosen based on expected hCG 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 $Y=0.86(X) + 9.5$ with a correlation coefficient of $(r) = 0.96$.