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Diagnostic Systems Laboratories, Inc.
445 Medical Center Boulevard
Webster Texas 77598-4217 USA
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 10-3800 Androstenedione EIA Kit
Classification Name: Enzymeimmunoassay, Androstenedione
Analyte Code and Name: Androstenedione
Regulatory Class: I

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

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The DSL Androstenedione EIA kit was developed for the quantitative measurement of Androstenedione in human serum. The EIA format is a competitive binding protein assay. Enzyme-labeled androstenedione competes with un-labeled androstenedione in the serum sample for binding sites to the androstenedione antibody coated to the microtitration well provided with the kit. Separation of free from bound androstenedione is achieved by aspirating and washing the wells. The resultant is analyzed in a spectrophotometer for bound absorbance. The amount of enzyme-labeled androstenedione bound to the antibody is inversely proportional to the concentration of the androstenedione present in the sample.

The DSL Androstenedione EIA assay is intended for the quantitative determination of androstenedione in human serum. The measurement of androstenedione is used in the diagnosis and treatment of females with excessive levels of androgen production.

The DSL 10-3800 Androstenedione EIA is substantially equivalent to the DSL 3800 Androstenedione RIA. Both kits have the same intended use.

To demonstrate substantial equivalence between the two assays, patient samples (n=80) were collected and assayed using both methods. Samples were chosen based on expected Androstenedione 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 $Y=1.07(X) + 0.02$ with a correlation coefficient of $(r) = 0.85$.