510 (k) Summary
Safety and Effectiveness Information for VIDAS Progesterone (PRG) Assay

K965084

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JAN - 9 1997

Summary preparation date - 1/6/97

The VIDAS Progesterone (PRG) assay is intended for use with a Vitek ImmunoDiagnostic Assay Systems (VIDAS) as an automated enzyme-linked fluorescent immunoassay (ELFA) for the quantitative determination of progesterone in serum or plasma. The VIDAS Progesterone assay is intended for use as an aid in the diagnosis and treatment of disorders of the ovaries and placenta.

The Product Classification for the VIDAS Progesterone (PRG) assay is under 21CFR 862.1620 Progesterone test system and is a Class I, Triage Tier II test system. The product classification number for the VIDAS Progesterone (PRG) is 75 JLS. The common or usual name is Enzyme-linked Fluorescent Immunoassay (ELFA) for the quantitative detection of progesterone.

The DPC Coat-A-Count Progesterone assay was used as the predicate device for the determination of substantial equivalence.

The VIDAS Progesterone (PRG) assay is an enzyme-linked fluorescent immunoassay (ELFA) that is performed in an automated VIDAS instrument. All assay steps and assay temperature are controlled by the instrument. A pipette tip-like disposable device, the Solid Phase Receptacle (SPR), serves as a solid phase for the assay as well as a pipetting device. At the time of manufacture, the SPR is coated with mouse anti-progesterone antibodies. Reagents for the assay are located in the sealed Reagent Strips. The sample is transferred into the well containing a progesterone derivative conjugated with alkaline phosphatase. Wash steps remove unbound conjugate. A fluorescent substrate, 4-methylumbelliferyl phosphate, is cycled through the SPR and flouresences. The intensity of fluorescence is measured by the optical scanner in the instrument; it is inversely proportional to the progesterone concentration present in the sample.

The technological characteristics of the bioMerieux Progesterone enzyme-linked fluorescent immunoassay (ELFA) are different from the radiological method (RIA) of DPC Progesterone Coat-A-Count in that ELFA uses enzymes as labels instead of radioisotopes. Therefore enzyme activity not radioactivity is measured. Enzyme-linked fluorescent immunoassay is a well established method for assaying analytes present in human serum or plasma.

Non-clinical (analytical) study summary

1. **Crossreactivity** - Specificity studies demonstrate that the monoclonal antibody used in the VIDAS PRG assay is specific for progesterone. No cross-reactivity is seen with testosterone, corticosterone, 20α hydroxy-progesterone, 6β hydroxyprogesterone, 16α hydroxyprogesterone, Corticosterone, Estrone, Estriol and Estradiol. Cross-reactivity does exist with two metabolites of progesterone, specifically 5α and 5β dihydroxyprogesterone. The package insert cautions customers that individuals undergoing micronized progesterone therapy may exhibit elevated results when using the VIDAS PRG assay. 17α hydroxyprogesterone and deoxycorticosterone demonstrated minimal crossreactivity. However, the normal concentrations found in a patient sera is far below that of

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progesterone. For example, in women, 17 α hydroxyprogesterone is 0.4ng/ml during the follicular phase and 1.8ng/ml in the luteal phase. In men the normal concentration is 1ng/ml. For deoxycorticosterone the normal range is 40 - 160pg/ml. It is not likely that the VIDAS PRG assay will cause a falsely elevated progesterone result, due to the relative weak sera concentrations of 17α hydroxyprogesterone and deoxycorticosterone.

2. **Interfering Substances** - No interference in VIDAS PRG assay performance was seen with serum collected in dry glass tubes, tubes containing a separating gel, and tubes containing lithium heparin and EDTA. No interference in the VIDAS PRG assay performance was seen with a range of concentrations of hemoglobin, lipids, or bilirubin.

3. **Precision/Reproducibility** - **Intra-assay precision** studies showed coefficients of variation ranging from 14.3% for 0.46 ng/ml to 3.8% for 45.1 ng/ml. **Inter-assay** reproducibility over a eight-week time period showed coefficients of variation ranging from 24.3% for 0.4 ng/ml to 3.1% for 45 ng/ml. **Inter-assay, inter-instrument** reproducibility for five different serum samples in eight assays on different instruments yields coefficients of variation that do not exceed 5.4%.

Clinical study summary

1. **Correlation**
   a. Comparison of the VIDAS PRG assay with the DPC Coat-A-Count Progesterone assay yields a line with the equation y = 1.0193x + -0.453 and a correlation coefficient of 0.985.

   b. The calibrator in the kit ensures that the master curve stored by the VIDAS instrument is valid for the shelf life of that kit. The body of data supports the use of a single calibrator for this purpose.

2. **Sensitivity** - The limit of detection is determined to be 0.1 ng/ml of progesterone with a 95 % confidence interval.

✳ The conclusions drawn from the non-clinical and clinical tests demonstrate that the VIDAS PRG assay, if used as instructed in the package insert, is safe, effective and performs as well as or better than the legally marketed device identified in this submittal. The package insert should always be consulted along with the Operator's Manual to ensure that the assay is being performed properly. For additional information, references are listed in the package insert.

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