B-Human Chorionic Gonadotropin, Follicle Stimulating Hormone, Prolactin, Human Mononuclear Cells (HC/GF/SH/LH/PRLs VAST-10)

Fertility Panel Test System

Product Code: 8320-200

1.0 INTRODUCTION

Intended Use: The Quantitative Determination of HCG, LH, FSH and LH & FSH in Human Serum by a Microtiter Enzyme Immunoassay, Colorimetric

2.0 SUMMARY AND EXPLANATION OF THE TEST

Human chorionic gonadotropin (HCG) is a glycoprotein hormone that dynamically in blood and urine during normal pregnancy. HCG is secreted by placental tissue, beginning with the pregnancy implantation and continuing throughout the gestation period. The measurement of HCG by assay systems with suitable sensitivity and specificity allows accurate pregnancy diagnosis and the diagnosis and monitoring of preimplantation developmental progression. Follicle stimulating hormone (FSH) and luteinizing hormone (LH) are hormones involved in ovulation. FSH and LH are involved in ovulation and are transported by the blood to the ovaries, where they initiate the development of the follicle and the corpus luteum.

The employment of several serum references of known hormone levels permits the specific hormone concentration. The measurement of HCG, LH, and FSH by immunometric assay permits the specific hormone concentration. The measurement of HCG, LH, and FSH by immunometric assay permits to ascertain the concentration of each corresponding hormone in unknown specimens.

One (1) vial containing enzyme labeled antibody and biotinylated monoclonal mouse IgG specific for HCG/FSH. Each vial contains one (1) vial containing control antigen labeled antibody specific for PRL in buffer, green dye, and preservative. Store at 2-8°C.

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10. All applicable national standards, regulations and laws, including, but not limited to, LH /FSH is suppressed by estrogen but in woman taking oral contraceptives the level

In order for the assay results to be considered valid the following criteria should be

Expected levels for hCG during normal pregnancy3 are listed in Table 2.

If computer controlled data reduction is used to interpret the results of the test, it is

The absorbance (OD) of the highest calibrator of any antigen should be > 1.3

False positive results may occur in the presence of a wide variety of trophoblastic and

If test kits are altered, such as by mixing parts of different kits, which could produce

The reagents for the test system have been formulated to eliminate maximal

The cross-reactivity of the PRL method to selected substances was evaluated by subtracting the interfering substance to a serum matrix at various concentrations. The cross-reactivity was calculated by deriving a ratio between the interfering substance to dose of 

The few cross reactivities of the antibodies employed in this system permits the use of calibrators due to essentially zero cross reaction (ZCR).


Substance

1000ng/ml

Concentration

% Cross-reactivity

Significance of Symbols

The cross-reactivity of the LH method to selected substances was evaluated by adding the interfering substance to a serum matrix at various concentrations. The cross-reactivity was calculated by deriving a ratio between dose of interfering substance to dose of Follitropin required to produce the same absorbance.

The cross-reactivity of the FSH method to selected substances was evaluated by adding the interfering substance to a serum matrix at various concentrations. The cross-reactivity was calculated by deriving a ratio between dose of interfering substance to dose of Follitropin (FSH) required to produce the same absorbance.