1.0 INTRODUCTION

Intended Use: The Quantitative Determination of Progesterone Concentration in Human Serum or Plasma by a Microplate Enzyme Immunoassay, Chemiluminescence

2.0 SUMMARY AND EXPLANATION OF THE TEST

Measurement of progesterone in serum or plasma is considered to be the most reliable way to assess its rate of production. Progesterone is a steroid hormone, which plays an important role in the preparation for and maintenance of pregnancy. It is synthesized from cholesterol as pregnenolone which is then rapidly metabolized to progesterone in the ovary. The employment of several serum references of known progesterone concentration permits construction of a graph of the ovulatory phase of menstrual cycles, reaching a maximum approximately 5 days after the midcycle LH peak. Unless pregnancy occurs, a steep decline to follicular levels sets in about 4 days after the last biotin administration, preferably overnight to ensure fasting sample. Samples may be refrigerated at 2-8°C for a maximum period of five (5) days. If the specimen(s) cannot be assayed within this time, the sample(s) may be stored at temperatures of -20°C for up to 30 days. Avoid use of contaminated devices. Avoid repetitive freezing and thawing assayed in duplicate, 0.050ml (50µl) of the specimen is required.

7.0 QUALITY CONTROL

Each laboratory should assure controls at levels in the low, normal and high reference ranges to monitor assay performance. These controls should be treated as unknowns and values determined in every test procedure performed. Quality control charts should be maintained to follow the performance of the supplied reagents. Pertinent statistical methods should be employed to ascertain trends. The individual laboratory should set acceptance limits for assay performance limits. In addition, maximum absorbance should be consistent with past experience. Significant deviation from established performance may indicate uncontrolled change in experimental conditions or degradation of kit reagents. Fresh reagents should be used to determine the reason for the variance.

8.0 REAGENT PREPARATION

Dilute the samples suspected of concentrations higher than 60ng/ml 1:10 with progesterone 0’ ng/ml calibrator or male patient serum pools with a known low value for progesterone.

5.0 PRECAUTIONS

For In Vitro Diagnostic Use

Not for Internal or External Use in Humans or Animals

All products that contain human serum have been found to be non-reactive for antibodies to hepatitis A, B, C, and HIV. Antibodies by FDA required tests. Since no known test can offer complete assurance that infectious agents are absent, all human serum products should be handled as potentially hazardous and capable of transmitting disease. Good laboratory procedures for handling blood products can be found in the Center for Disease Control and Prevention's "Guidelines for the Hospital and Biomedical Laboratories," 2nd Edition, 1988, HHS Publication No. (CDC) 88-935.

Safe Disposal of kit components must be according to local laboratory procedures where the kit is used. This kit has been shown to be non-reactive for Hepatitis B Surface Antigen, HIV 1&2 and HCV antibodies by FDA required tests. Since no known test can offer complete assurance that infectious agents are absent, all human serum products should be handled as potentially hazardous and capable of transmitting disease. Good laboratory procedures for handling blood products can be found in the Center for Disease Control and Prevention's "Guidelines for the Hospital and Biomedical Laboratories," 2nd Edition, 1988, HHS Publication No. (CDC) 88-935.

9.0 TEST PROCEDURE

Before proceeding with the assay, bring all reagents, serum reference calibrators and controls to room temperature (20-27°C).
11.0 Q.C. PARAMETERS

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

1. The Dose Response Curve should be within established parameters.
2. Four out of six quality control pools should be within the established ranges.

12.0 RISK ANALYSIS

The MSDS and Risk Analysis Form for this product are available upon request from Monobind Inc.

12.2 Interpretation

1. Measurements and interpretation of results must be performed by a trained professional.
2. Laboratory results alone are only one aspect for determining patient care and should not be the sole basis for therapy, particularly if used in conflict with other determinants.
3. The reagents for the test system have been formulated to eliminate minimal interference; however, potential interaction between serum specimens and test reagents can cause erroneous results. Heterophilic antibodies often cause these interactions and have been known to be problems for all kinds of immunoassays (Boscato LM, Stuart MC. Heterophilic antibodies; a problem for all immunoassays. Clin. Chem. 1983;31:3427-33). For diagnostic purposes, the results from this assay should be in combination with clinical examination, patient history and all other clinical findings.
4. If a valid test result is obtained and other parameters must be within the listed ranges and assay requirements.
5. If test kits are altered, such as by mixing parts of different kits, which could create false test results, or if results are incorrectly interpreted, Monobind shall have no liability.
6. If a computer controlled data reduction is used to interpret the results of the test, it is imperative that the predicted values for the calibrators fall within 10% of the assigned concentrations.

13.0 EXPECTED RANGES OF VALUES

In agreement with established reference intervals for a "normal" adult population and females during gestation the expected ranges for the Progesterone AccuLite® CLIA Test System are detailed in Table 1. During pregnancy the progesterone serum levels rise rapidly till the end of trimester.

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<th>Sample</th>
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<td>Cal A</td>
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14.0 PERFORMANCE CHARACTERISTICS

14.1 Precision

The within and between assay precision of the Progesterone AccuLite® CLIA Test System is determined by analyses on three different levels of pool control sera. The number, mean values, standard deviation and coefficient of variation for each of these control sera are presented in Table 2 and Table 3.

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<td>Sample</td>
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<td>TABLE 3</td>
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14.4 Specificity

The % cross reactivity of the progesterone antibody 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 progesterone needed to displace the same amount of labeled analog.

<table>
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<th>Sample</th>
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<td>TABLE 4</td>
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15.0 REFERENCES


For Order and inquiries, please contact:

In Vitro - Based on Dose Requirement Specimen Handling Condition (2-8°C)

LOT Code

The text of this document is not available in natural language format.