GENETRACK Diagnostics

Progesterone

WHAT IS PROGESTERONE?
Progesterone (P4) is a female sex hormone that is primarily produced in the corpus luteum in normally menstruating women, with small amounts also produced in the adrenal cortex (1).

PURPOSE OF A PROGESTERONE TEST
Progesterone testing is beneficial for determining the cause of infertility and monitoring the success of medicines taken to treat fertility problems. It can also help assess the risk of miscarriage, help diagnose an ectopic pregnancy, and monitor the function of the ovaries and placenta during pregnancy. Progesterone testing may be used as an aid in the diagnosis of adrenal gland problems, a molar pregnancy (growth in the abdomen that causes symptoms of pregnancy), and some types of cancers (e.g., ovarian and adrenal cancer).

ROLES OF PROGESTERONE
Progesterone is essential for the preparation of the uterus for implantation by causing the uterine lining to thicken. During pregnancy, progesterone production continues to maintain the uterine lining, help nurture the developing fetus throughout the pregnancy, and to trigger the breasts to produce milk (2).

Progesterone also acts in non-reproductive tissues, often in partnership with estradiol. Examples include estradiol reduction of bone resorption and progesterone stimulation of bone formation, and coordinated increases in nitric oxide activity to improve blood flow (3).

PROGESTERONE LEVEL FLUCTUATIONS
Progesterone levels fluctuate during each menstrual cycle. They are low (< 0.5 ng/mL) during the follicular phase, with a rapid rise following the luteinizing hormone (LH) surge at ovulation to 3 – 25 ng/mL (4). If no conception occurs, progesterone levels decline and menstruation beings (5). If an egg is fertilized, the corpus luteum maintains progesterone levels until around week six. The placenta produces progesterone for the remainder of the pregnancy, with levels at 7.25 – 44 ng/mL in the first trimester, and 65 – 229 ng/mL by the third trimester (4).

ABNORMAL PROGESTERONE LEVELS
Abnormally low progesterone levels are observed in mid-luteal phase in females whom have disorders of ovulation. This luteal phase deficiency is associated with infertility and spontaneous abortion, and is estimated to occur in approximately 10% of infertile women (6). Low progesterone levels during the first 10 weeks of pregnancy are indicative of threatened abortion and ectopic pregnancy (7, 8).

PROGESTERONE CHANGES DURING PERIMENOPAUSE
Menopause is defined as the final menstrual period. The term perimenopause literally means “around menopause”, but often refers to the time prior to the final menstrual period. This is a time when hormonal changes can cause various physical signs of menopause (e.g. night sweats and mood changes), but menstruation remains like, or near, normal. Postmenopause is the remainder of a women’s life after menopause.

During the perimenopause phase, progesterone production decreases, but estrogen levels often remain higher (9). This results in an imbalance of estrogen and progesterone, contributing to the many symptoms that can occur in the months-to-years before menopause (3).

PROGESTERONE THERAPY
Oral progesterone can be prescribed to symptomatic women during perimenopause. It is effective for improving sleep, vasomotor symptoms, increasing bone formation, and has beneficial cardiovascular effects (3).

TEST PROCEDURE
Correct specimen collection and handling is required for optimal assay performance.

This test requires a blood sample from a finger prick. All supplies for sample collection are provided in this kit. First wash and dry hands. Warm hands aid in blood collection. Clean the finger prick site with the alcohol swab and allow to air dry. Use the provided lancet to puncture the skin in one quick, continuous and deliberate stroke. Wipe away the first drop of blood (as it may be contaminated with tissue fluid or skin debris). Massage finger to increase blood flow at the puncture site and hold in a position that gravity facilitates the collection of blood on the fingertip. Transfer the blood to the blood collection card or blood collection tube (microtainer).

Avoid squeezing or ‘milking’ the finger excessively. If blood flow stops, perform a second skin puncture on another finger if more blood is required.

Dispose of all sharps safely and return sample to the laboratory in the provided prepaid return shipping envelope.

Upon receipt at the laboratory, the blood sample is analyzed by the fully automated Alinity i Progesterone chemiluminescent microparticle immunoassay on the Alinity ci series analyzer. This assay measures progesterone levels by binding to monoclonal anti-progesterone coated microparticles. The amount of progesterone in the blood sample is measured in relative light units by a chemiluminescent reaction. This assay has a precision value of <6.5 %CV.

TEST INTERPRETATION
This assay will provide accurate progesterone values for the tested specimen. This value is to be used in conjunction with other clinical and laboratory information for analyses of women’s health and fertility.

DISCLAIMERS/LIMITATIONS
Certain medications (e.g., birth control pills and ampicillin), estrogen or progesterone supplements, and a recent test using a radioactive substance (e.g., bone scan) may affect progesterone test results. In addition, progesterone levels fluctuate throughout each menstrual cycle in reproductive age females, so the timing of sample collection may influence the interpretation of the progesterone level.

These results should be interpreted in conjunction with other laboratory and clinical information.

Assay interference may occur in specimens from individuals routinely exposed to animals or to animal serum products. Additional clinical or diagnostic information may be required for these specimens.

Additional testing is recommended if progesterone results are inconsistent with clinical evidence.

False results may occur in specimens from individuals that have received preparations of mouse monoclonal antibodies for diagnosis or therapy. Additional clinical or diagnostic information may be required for these specimens.

Correct specimen collection and handling is required for optimal assay performance. The assay is unaffected (≤10% interference) by hemoglobin (500 mg/dL), bilirubin (20 mg/dL), triglycerides (1000 mg/dL), and protein (12 g/dL).

REFERENCES

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