

# Progesterone

## SUMMARY AND EXPLANATION OF TEST

Progesterone (pregn-4-ene-3, 20-dione) is a steroid hormone produced mainly by the ovary and adrenal cortex in females and, in lesser amounts, by the adrenal cortex in males <sup>(1,2)</sup>. Progesterone is secreted in small amounts by the ovaries during the follicular phase of the menstrual cycle and increases sharply following ovulation and corpus luteum development <sup>(3)</sup>. Unless pregnancy occurs, a steep decline to follicular levels occurs prior to the next menstrual cycle <sup>(4)</sup>. This pattern provides the rationale for the use of serum progesterone measurements as a reliable method for ovulation detection <sup>(5)</sup>.

Daily progesterone levels are considered the most accurate means for documenting luteal phase defect <sup>(6)</sup>. Measurements of serum progesterone can also be used to detect and evaluate patients at risk for abortion during the early weeks of gestation <sup>(7,8)</sup>.

## PRINCIPLE OF THE ASSAY

The ST AIA-PACK PROG is a competitive enzyme immunoassay, which is performed entirely within the AIA-PACK. Progesterone present in the test sample competes with enzyme-labeled progesterone for a limited number of binding sites on a progesterone-specific antibody immobilized on magnetic beads. The beads are washed to remove the unbound enzyme labeled progesterone and are then incubated with a fluorogenic substrate, 4-methyl-umbelliferyl phosphate (4MUP). The amount of enzyme labeled progesterone that binds to the beads is inversely proportional to the progesterone concentration in the test sample. A standard curve using a range of known standard concentrations is constructed and unknown progesterone concentrations are calculated using this curve.

## SPECIFICITY

The following substances were tested for cross-reactivity. Cross-reactivity (%) is the percent of the compound, which will be identified as progesterone. If these compounds are present in the specimen at the same concentration as progesterone, the final result will be increased by these percentages.

Compound	Cross-reactivity
Progesterone	100.0
17a-Hydroxyprogesterone	1.2
11-Deoxycorticosterone	3.5
Pregnelone	0.3
Corticosterone	1.79
5b-Pregnan-3,20-dione	6.3
Testosterone	0.03
Cortisol	ND
5a-Pregnan-3,20-dione	12.8

Incubation time:	10 minutes
Specimen volume:	75 µl
Specimen type:	Serum
Assay range:	up to 45 ng/ml
Calibration stability:	90 days
Sensitivity:	0.1 ng/ml

## Reference range

Male	< 0.5
Female	
Follicular phase	< 1.0
Luteal phase	0.37 ~ 18.4
Post menopausal	< 0.5

## PRECISION

Within run precision was determined using four controls in a total of 20 runs. Within each run, one set of duplicates per control was assayed. The mean of each duplicate was used to obtain the pooled standard deviation (SD), which was then used to calculate the coefficient of variation (CV).

<b>Sample</b>	<b>Mean (ng/mL)</b>	<b>Pooled SD (ng/mL)</b>	<b>CV (%)</b>
Control A	0.902	0.0962	10.7
Control B	2.48	0.158	6.4
Control C	8.65	0.437	5.1
Control D	17.73	0.577	3.3

Total precision was determined by the duplicate assay of four controls in 20 separate runs. The means of each run were used to calculate the standard deviation (SD) and coefficient of variation (CV).

<b>Sample</b>	<b>Mean (ng/mL)</b>	<b>SD (ng/mL)</b>	<b>CV (%)</b>
Control A	0.902	0.117	12.9
Control B	2.48	0.205	8.3
Control C	8.65	0.541	6.3
Control D	17.73	0.826	4.7

## SENSITIVITY

The minimal detectable concentration (MDC) of progesterone is estimated to be 0.1 ng/mL. The MDC is defined as that concentration of progesterone, which corresponds to the rate of fluorescence that is two standard deviations from the mean rate of fluorescence of 20 replicate determinations of a zero calibrator.

## INTERFERENCE

Interference is defined, for purposes of this study, to be recovery outside of 10% of the known specimen mean concentration.

- Haemoglobin (up to 412 mg/dL), free bilirubin (up to 15.5 mg/dL) and conjugated bilirubin (up to 1.8 mg/dL) do not interfere with the assay.
- Lipaemia, as indicated by triglyceride concentrations (up to 71 mg/dL) does not interfere with the assay.
- Protein, as indicated by added albumin (up to 0.5 g/dL), does not interfere with the assay.
- Ascorbic acid (up to 20 mg/dL) does not interfere with the assay.
- Conjugated bilirubin (more than 9.5 mg/mL) may interfere with the assay. Such specimens may show falsely elevated PROG concentration.

ST AIA-PACK PROG	025281
Calibrator Set	020381
Sample Diluting Solution	020581
Substrate Set II	020968
Wash Concentrate	020955
Diluent Concentrate	020956