SALIVA TEST SPECIFICATIONS

Progesterone

Clinical Information

Progesterone's primary function during the menstrual cycle is to induce a secretory endometrium ready for implantation of a fertilized egg. Levels therefore increase during the luteal phase of the cycle after ovulation. If no implantation occurs, progesterone returns to follicular phase levels. If a pregnancy results, progesterone continues to rise to very high levels and carries out a variety of functions necessary to sustain the pregnancy. In some patients with infertility, ovulation may occur but luteal phase levels of progesterone are inadequate. Luteal phase deficiency is a result of inadequate progesterone production by the corpus luteum. During menopause, ovarian progesterone production dwindles, resulting in postmenopausal levels similar to those seen in men. Progesterone has wide-ranging physiological effects, including neuroprotection, maintenance of skin elasticity, and development of bone tissue. Progesterone also counteracts the proliferative effects of estrogen on the endometrium. When samples are collected after transdermal application of progesterone, saliva progesterone levels are higher than serum, indicating distribution of progesterone to tissues. Reference range saliva progesterone levels in premenopausal women (luteal phase) are 75—250 pg/mL, and in postmenopausal women and men 12—100 pg/mL.

References:

Du JY, Sanchez P, Kim L, Azen CG, Zava DT, Stanczyk FZ. Percutaneous progesterone delivery via cream or gel application in postmenopausal women: a randomized cross-over study of progesterone levels in serum, whole blood, saliva, and capillary blood. Menopause. 2013;20:1169-75.

Petsos P, Ratcliffe WA, Heath DF, Anderson DC. Comparison of blood spot, salivary and serum progesterone assays in the normal menstrual cycle. Clin Endocrinol (Oxf). 1986;24:31-8.

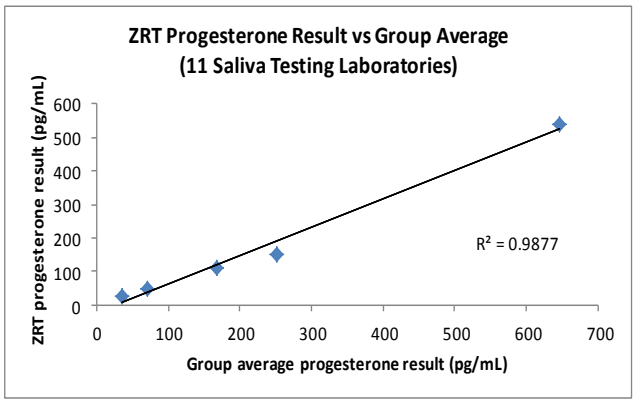
Meulenberg PM, Hofman JA. Salivary progesterone excellently reflects free and total progesterone in plasma during pregnancy. Clin Chem 1989;35:168-72.

Ishikawa M, Sengoku K, Tamate K, et al. The clinical usefulness of salivary progesterone measurement for the evaluation of the corpus luteum function. Gynecol Obstet Invest 2002;53:32-7.

Assay Method: ELISA

Accuracy

ZRT has established the first salivary proficiency testing program, which includes most of the major saliva testing laboratories in the US. Twice yearly, results from carefully selected pooled samples are compared to those from 10 other laboratories that test progesterone. As shown in the graph, ZRT results compare very favorably to the consensus of all 11 saliva testing laboratories for the progesterone assay.



Precision/Reproducibility

Inter-assay precision was determined by choosing pooled saliva samples spanning the reference range for progesterone, and analyzing them multiple times over a 30-60 day period. Results are shown below:

Mean Progesterone Concentration (pg/mL)	Coefficient of Variation (C.V. %)
25.8	10.6
164.2	6.4
11088	5.7

Linearity

The ZRT saliva progesterone assay gives excellent linearity over the reportable range of 5.0—33,333 pg/mL. Samples giving values >33,333 pg/mL are diluted and re-assayed for accurate reporting. Values below 5 pg/mL are not sufficiently precise and are reported as <5 pg/mL.

Sensitivity

The analytical limit of detection for progesterone is 1.17 pg/mL.

Stability

Saliva samples are stable at room temperature for 30 days for progesterone determination, but customers are advised to mail samples as soon as possible after collection. Samples are rejected for analysis if they were not received within 30 days of collection and were not refrigerated or frozen.

Accreditation

ZRT Laboratory is a CLIA and New York State certified testing laboratory.