# SALIVA TEST SPECIFICATIONS

# Estradiol

## Clinical Information

Estradiol is the predominant, and the most potent, circulating estrogen. Estrogens are present in very minute quantities in saliva, at only 1—5% of the total amount, including protein-bound hormone, found in serum. The very low concentration of salivary estradiol, especially in populations such as postmenopausal women, necessitates extremely sensitive assay methods. ZRT is unique as the only commercial laboratory using extracted saliva testing for estrogens. Extraction removes contaminants that interfere with the assay and concentrates the sample, significantly improving assay sensitivity compared to "direct" assay methods available commercially.

In reproductive age women, an excess of estradiol relative to progesterone, known as "estrogen dominance", can explain many symptoms including endometrial hyperplasia, pre-menstrual syndrome, fibrocystic breasts, and uterine fibroids. Perimenopausal women can also experience symptoms of estrogen dominance, which include weight gain, fibrocystic and tender breasts, uterine fibroids, irritability, and water retention. With the onset of menopause, low estradiol levels lead to hot flashes, night sweats, vaginal dryness, sleep disturbances, foggy thinking, and bone loss. In men, too much estradiol, relative to testosterone, leads to feminizing effects such as breast enlargement and can result in a functional testosterone deficiency. The reference range for saliva estradiol is 1.3—3.3 pg/mL in premenopausal women during the luteal phase; 0.5—1.7 pg/mL in postmenopausal women; and 0.5—2.2 pg/mL in men.

**References:**


Newman MS, Stanczyk FZ, Zava DT. Extraction prior to enzyme immunoassay gives reliable salivary estradiol monitoring during estrogen therapy. Soc Gynecol Invest 55th Annual Scientific Meeting, San Diego, March 26-29, 2008.

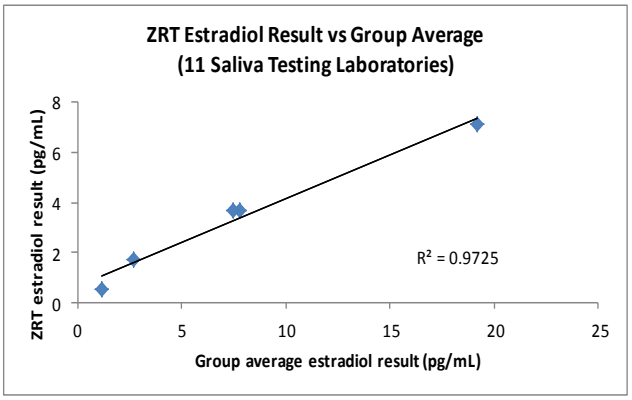
Worthman CM, Stallings JF, Hofman LF. Sensitive salivary estradiol assay for monitoring ovarian function. Clin Chem 1990;36:1769-73.

Wong YF, Mao K, Panesar NS, et al. Salivary estradiol and progesterone during the normal ovulatory menstrual cycle in Chinese women. Eur J Obstet Gynecol Reprod Biol 1990;34:129-35.


## 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 estradiol. As shown in the graph, ZRT results compare very favorably to the consensus of all 11 saliva testing laboratories for the estradiol assay.




### Precision/Reproducibility

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

| Mean Estradiol Concentration (pg/mL) | Coefficient of Variation (C.V. %) |
|---|---|
| 1.1 | 16.3 |
| 3.5 | 2.7 |
| 11.5 | 3.7 |

### Linearity

The ZRT saliva estradiol assay gives excellent linearity over the reportable range of 0.5—50 pg/mL. Samples giving values >50 pg/mL are diluted and re-assayed for accurate reporting. Values below 0.5 pg/mL are not sufficiently precise and are reported as <0.5 pg/mL.

### Sensitivity

The analytical limit of detection for estradiol is 0.35 pg/mL.

### Stability

Saliva samples are stable at room temperature for 30 days for estradiol 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.