



Patient: **FEMALE**
TEST



Menopause Check Plus - Salivary Profile

Therapeutic Cohort Results

Hormone	Result †	QUINTILE DISTRIBUTION					Therapeutic Range*
		1st	2nd	3rd	4th	5th	
Estradiol (E2)	5.0						2.9-13.7 pmol/L
Estrone (E1)	115.0						36.6-253.2 pmol/L
Estriol (E3)	<70						<=135 pmol/L
Testosterone	125						34-183 pmol/L
Progesterone	65						52-850 pmol/L

* The therapeutic ranges depicted are for informational purposes only, and were derived from a cohort of peri/menopausal women ranging in age from 37-62 years. All women were treated with bioidentical hormone therapy (HT) utilizing combinations of the following: Biest (transdermal); Progesterone (oral micronized); Testosterone (transdermal); and 7-keto-DHEA (oral).

† Patient results with Genova's standard reference ranges are reported on the following pages.



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Salivary Hormone Results

Estradiol ♦ pmol/L

5.0

	Reference Range
Follicular	2.8-8.8 pmol/L
Peak *	4.5-19.1 pmol/L
Luteal	2.8-8.2 pmol/L
Menopausal	3.7-9.4 pmol/L
Male	3.1-7.4 pmol/L
* Peak = Days 11 and 12	

Testosterone ♦ pmol/L

125

	Reference Range
Premenopausal	34-148 pmol/L
Menopausal	34-148 pmol/L
Male	110-513 pmol/L

Estrone pmol/L

115.0

	Reference Range
Menopausal	31.9-183.4 pmol/L

Progesterone ♦ pmol/L

65

	Reference Range
Follicular	17-321 pmol/L
Peak *	151-829 pmol/L
Luteal	33-452 pmol/L
Menopausal	45-370 pmol/L
Male	31-280 pmol/L
* Peak = Days 18 and 20	

Estriol ♦ pmol/L

<70

	Reference Range
Menopausal	<= 133 pmol/L

DHEA pg/mL

500

	Reference Range
DHEA 7am-9am	71-640 pg/mL

Comments

Please note the reference range for Estrone has been updated due to a change in methodology.

The performance characteristics of all assays have been verified by Genova Diagnostics, Inc. Unless otherwise noted with ♦, the assay has not been cleared by the U.S. Food and Drug Administration.

Methodology: LIA, EIA and RIA

Commentary is provided to the practitioner for educational purposes, and should not be interpreted as diagnostic or as treatment recommendations. Diagnosis and treatment decisions are the practitioner's responsibility.

Estrogens play a critical role in female sexual development, menstrual function, protein synthesis, cardiovascular

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function, bone formation and remodeling, cognitive function, emotional balance and other important health factors. The estrogenic potency of estradiol is 12 times that of estrone and 80 times that of estriol. Estradiol is the primary estrogen in premenopausal women. Estrone is the second most potent estrogen compared to estradiol. After menopause, estrone becomes the primary estrogen as the ovary loses its ability to manufacture estradiol, and it is synthesized in the adrenal glands and fat cells. Estriol is considered to be the mildest and briefest-acting of the three estrogens. Estrogen metabolism and synthesis in men appear to remain relatively stable across the life course.

- In women, lower levels of estrogens have been associated with a variety of clinical symptoms: peri/menopausal symptoms (vasomotor symptoms; mood and memory alterations; atrophic vaginitis, a condition associated with decreased vaginal lubrication and thinner vaginal epithelial; lining diminished skin tone); altered lipid metabolism; accelerated rate of bone loss. Excessive estrogen levels have been associated with increased risk of some hormone-dependent cancers.

- In men, low levels of estrogen may be associated with decreased bone density, cognitive decline and cardiovascular disease. Excessive estradiol levels have been associated with greater risk of stroke and cardiovascular disease, as well as BPH, gynecomastia, decreased sexual function and weight gain. A source of elevated estrogen in men may be associated with men who have a higher body fat percentage, as increased aromatization of testosterone to estradiol can occur in adipose tissue.

- In a large, population based study of salivary sex hormone levels in older adults researchers found: Older men and women had similar estradiol concentrations. Estradiol concentrations have been associated with cognition, mood, and memory in women and, in combination with testosterone and other factors, preservation of memory and cognitive function in men.

Progesterone is important for normal reproductive and menstrual function, and influences the health of bone, blood vessels, heart, brain, skin, and many other tissues and organs. As a precursor, progesterone is used by the body to make other steroid hormones, including DHEA, cortisol, estrogen and testosterone. In addition, progesterone plays an important role in mood, blood sugar balance, libido, and thyroid function, as well as adrenal gland health. Progesterone is primarily produced in the ovaries in premenopausal women and in the adrenal cortex in postmenopausal women. Although progesterone is found in both women and men, the physiologic role in men is poorly understood.

- In women, lower levels of progesterone have been associated with dysfunctional uterine bleeding, and may play a role in osteoporosis and impaired neurological function. Excessive amounts can result in problems such as dysglycemia, alopecia, acne and breast tenderness.

- The clinical significance of elevated or low levels in men is poorly understood. Low progesterone levels may be involved in male infertility. Increased levels of progesterone have been found in states of stress and anxiety in men and women: this may relate to its sedative or stress countering effects.

Testosterone is an androgenic sex steroid/hormone that helps maintain libido, influences muscle mass and weight loss, and plays a role in the production of several other hormones. During the aging process, testosterone levels gradually decline in both sexes, which can lead to loss of bone density. Testosterone concentrations tend to be higher in men versus women.

- In women, imbalances of testosterone have been associated with various forms of coronary heart disease and cardiovascular events, including myocardial infarction in postmenopausal women. Low salivary testosterone levels have also been shown in women with breast cancer compared to age-matched controls. Obese women exhibit higher levels of free salivary testosterone. Excessive amounts are associated with PCOS, acne, oily skin and hirsutism.

- In men, lower levels of testosterone are associated with aortic, peripheral vascular, and cardiovascular disease in middle-aged and older men. In some but not all studies, lower levels of testosterone predict increased incidence of cardiovascular events and mortality. Additionally, elevated testosterone can be associated with CVD risk. Men with excessive testosterone may exhibit aggressive behavior or increased irritability, and hair loss (scalp).

- In men and women, low levels of testosterone have been associated with lower coital frequency and loss of sexual desire in men and women. Low levels are also associated with reduced stamina and lean muscle mass, anxiety,

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depression and cognitive decline in both men and women.

Step 3:

Ship the saliva specimen to the lab

Specimen must be returned in the Genova Diagnostics kit box for correct delivery to the lab. Not following these instructions may result in a shipping charge.

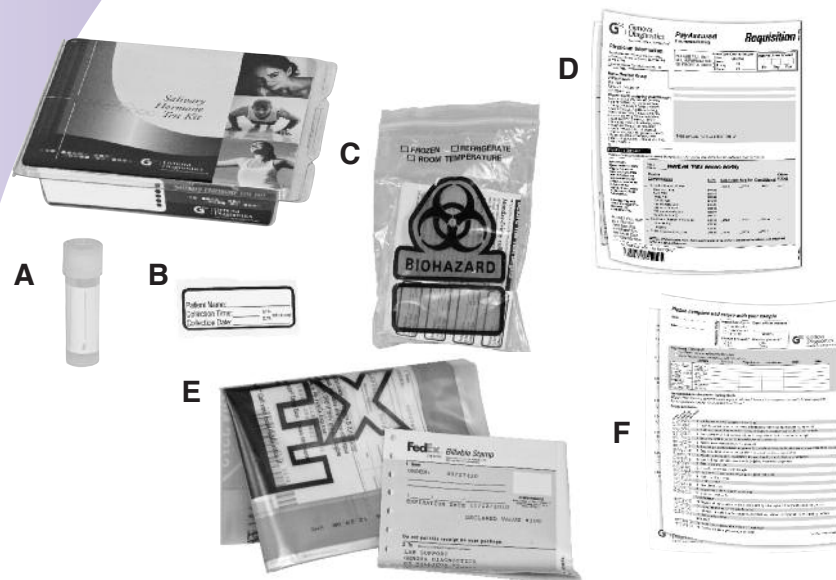
- Plan to ship the specimen **Monday – Friday overnight delivery only**.
- Call 1.800.GoFedEx (1.800.463.3339) to schedule shipping. When the automated system asks “How may I help you?” say “Return a Package.” Tell the FedEx representative “I am using a billable stamp” and they will walk you through the process and make it easy.
- **Seal the frozen saliva tube and the pad in the biohazard bag** and place it in the clear plastic box.
- Place your **completed and signed requisition form** on top of the biohazard bag and close plastic box. *Do NOT staple or tape box.*
- **Print your name and address** in the section marked “From” on the prepaid shipping envelope label. *DO NOT mark or write in any other sections.*
- Put the kit box into the prepaid mailing envelope and seal the envelope.
- Keep your shipment and tracking numbers for future reference and tracking purposes.



Menopause Check™ & Menopause Check Plus™

IS-1077

Patient Collection Instructions



Check Your Kit

- A - 1 Collection tube
- B - 1 Label
- C - 1 Biohazard bag with absorbent pad
- D - 1 Requisition (to be completed and signed)
- E - 1 Prepaid mailing envelope
- F - 1 Questionnaire (to be completed and returned)

- If any items are missing or expired, call Client Services at 800.522.4762, then press 1
- Keep the kit box for shipping your specimen to the lab.

Step 1:

Important things to know and consider

- **Transdermal (cream) and sublingual bio-identical hormones may produce artificially high levels in the saliva that do not correlate with blood levels. This increase from cream hormones may last for weeks to months after discontinuing use. If you are taking these substances – or have taken them within the last 12 months – please consult with your healthcare practitioner before taking this test.**
- The following **drugs, herbs and dietary supplements may influence levels of hormones reported** in this test: melatonin (at doses greater than 5 mg), ketoconazole, cimetidine (Tagamet), anastrozole (Arimidex), letrozole (Femara), exemestane (Aromasin), Chrysin, Apigenin, Tribulus terrestris, clomiphene, antiepileptics, digoxin, and oral steroids (e.g. Prednisone). *Let your physician know about these and any other medications, herbs, and supplements that you have used in the past 3 months.* Do not change use of supplements or medications unless instructed to do so by your healthcare provider.

Schedule and prepare for your saliva collection

- It is important that you **collect saliva during the specified time frame.** Collect saliva gradually over the 2-hour collection period. For example, spitting approximately every half hour until the collection tube is full.
- **If you have difficulty producing enough saliva for the tube,** press the tip of your tongue to the roof of your mouth against your teeth. Yawning can also generate saliva.
- **One hour prior to collection** do not eat, brush or floss your teeth, use mouthwash, chew gum or use any tobacco products. *You may drink ONLY water during this time.*
- **Contact FedEx and schedule to ship the specimen overnight delivery Monday - Friday. Sample MUST be stored frozen at least 2 hours before shipping.**
- **Complete the requisition form** with all patient and billing information. Be sure it is signed by the patient/responsible party and the healthcare provider.

Saliva Collection Schedule:

Gradually collect a total of one saliva sample between 7:00 AM and 9:00 AM.

Step 2:

Collecting your saliva specimens

Not following these instructions may affect your test results.



- 1 Write your full name, time, and date of collection** on the label using a ballpoint pen or pencil only. Attach the label to a collection tube.



- 2 When ready to collect the saliva, rinse your mouth with drinking water.** Spit out the water completely, and do not cough or clear your throat into the collection tube.



- 3 Fill the collection tube until liquid saliva level reaches the 3-ml mark.** To reduce a foamy saliva collection, tap the tube on a hard surface. Insufficient saliva samples cannot be processed.



- 4 Replace the cap tightly to avoid leakage. Place the filled tube into the biohazard bag and freeze immediately.** Sample must be frozen a minimum of 2 hours prior to shipping. Keep sample frozen until ready to ship.

Consult your healthcare provider if you have any questions at any time during this test.