

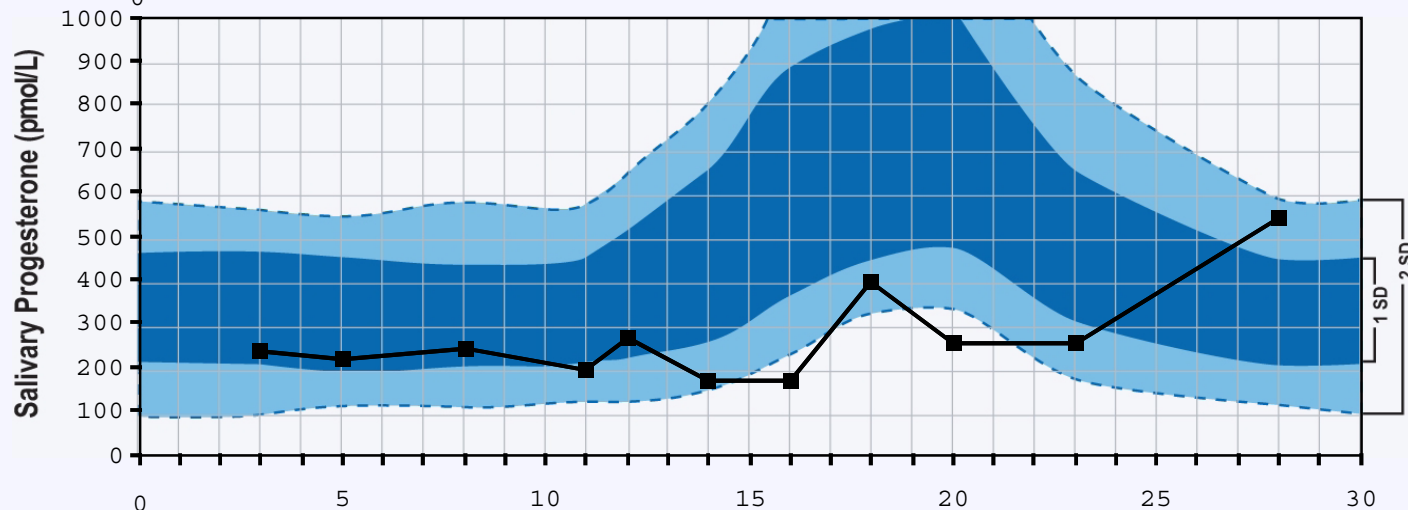
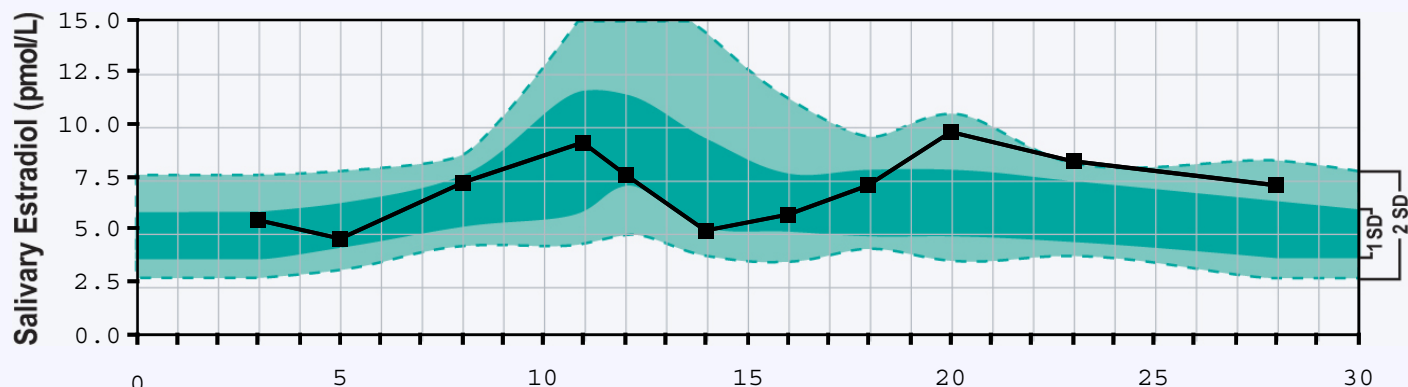
Patient: **SAMPLE
PATIENT**

Age:

Sex:

MRN:

Salivary Estradiol & Progesterone Activity plus Testosterone Level



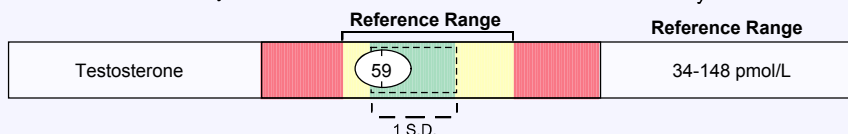
Day of Cycle	3	5	8	11	12	14	16	18	20	23	28	Avg.
Estradiol	5.4	4.5	7.2	9.1	7.6	4.9	5.6	7.1	9.6	8.2	7.1	6.9
Progesterone	236	214	239	190	265	166	168	395	256	251	540	265
P/E2 Ratio	44	48	33	21	35	34	30	56	27	31	76	40

Estradiol Ref 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

Progesterone Ref Range
 Follicular: 120 - 593 pmol/L
 Peak*: 328 - 1385 pmol/L
 Luteal: 145 - 797 pmol/L
 Menopausal: 163 - 669 pmol/L
 Male: 141 - 529 pmol/L
 * Peak = Days 18 and 20

P/E2 Ratio Ref Range
 Follicular: 23 - 159
 Luteal: 25 - 141
 Menopausal: 33 - 116

Testosterone Ref Range
 Premenopausal: 34 - 148 pmol/L
 Menopausal: 34 - 148 pmol/L
 Male: 110 - 513 pmol/L



Commentary

Reference ranges are based on morning collection.

The Reference Range for each day is a statistical interval representing 95% or 2 Standard Deviations (2 S.D.) of the reference population. One Standard Deviation (1 S.D.) is a statistical interval representing 68% of the reference population. Values between 1 and 2 S.D. are not necessarily abnormal. Clinical correlation is suggested.

The performance characteristics of all assays have been verified by Genova Diagnostics, Inc. Unless otherwise noted with ♦ as cleared by the U.S. Food and Drug Administration, assays are For Research Use Only.

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

The first half of the menstrual cycle (Follicular Phase) culminates in an Estradiol peak between Days 10-14 (in a 'perfect' 28 day cycle - counting from first day of last menses). The second half of a 28-day menstrual cycle (Luteal Phase) should demonstrate a Progesterone peak between Days 18-22, which coincides with a smaller Estradiol rise. Alterations in this normal hormonal cycling may be indicative of anovulation or luteal phase defects, which may be associated with menstrual bleeding problems. Finally, menstrual cycle lengths often vary from 24-35 days. While the follicular phase may vary in duration, the luteal phase is relatively fixed at 14 days.

Excess luteal estradiol: Higher than usual levels of estradiol show on one or more occasions in the luteal phase of the cycle. This may be due to decreased hepatic clearance of estrogen, high body mass index, hypothyroidism, or current or recent use of transdermal estradiol. High estradiol may contribute to disorders such as PMS, dysmenorrhea, certain types of seizure activity, or dysfunctional uterine bleeding.

Testosterone is within the expected range for this patient's age. Normal levels of this hormone are important for libido, maintaining lean body mass and bone density.

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 all filled saliva tubes and the pad in the biohazard bag,** and place it in the clear plastic box.
- Place your **completed and signed requisition form and questionnaire** 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.



Rhythm™

IS-583

Patient Instructions for Saliva Collection



Check Your Kit

- A - 11 Collection tubes
- B - 11 Labels, numbered 1-11 in red
- C - 1 Biohazard bag with absorbent pad
- D - 1 Requisition (to be completed and signed)
- E - 1 Questionnaire (to be completed and returned)
- F - 1 Prepaid mailing envelope

- 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), digoxin, antiepileptics, Chrysin, Apigenin, and Tribulus terrestris. *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

- Your **collection schedule is based on the first day of your menstrual cycle** (the day menstrual blood flow begins). If you are not experiencing periods, you may start on any day. You may find it helpful to **use a calendar** to remind you of collection dates.
- It is important that you **collect saliva during the specified time frame.**
- **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: Keep this nearby for the next 28 days!

Collect your saliva during the specified time frame each day:	DAY 1:	Count from this day (<i>the first day of your menstrual cycle</i>). Do not collect on this day.	
	DAY 2:	No collection on this day	
	DAYS 3, 5, 8, 11, 12, 14, 16, 18, 20, 23, 28:	7:00 AM to 9:00 AM	(Use labels #1, 2, 3, #4, 5, 6, 7, #8, 9, 10, 11)

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 label #1 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.** Samples must be frozen a minimum of 2 hours prior to shipping. Keep sample frozen until ready to ship.

- Repeat steps 1-4 for each collection, using the labels numbered 2 and 3, etc., in order.

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