GENOVA DIAGNOSTICS
63 Zillicoa Street
Asheville, NC 28801

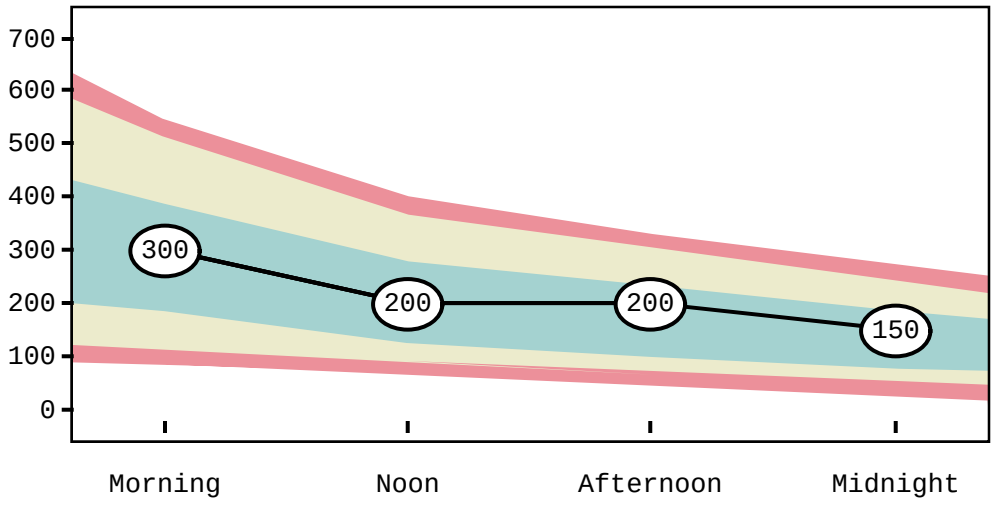
Male Hormones Plus™

Patient: **SAMPLE PATIENT**
DOB:
Sex:

4105 Male Hormones Plus - Saliva

Methodology: LIA

Testosterone



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 1and 2 S.D. are not necessarily abnormal. Clinical Correlation is suggested.
Please note: Conversion calculation pg/ml=pMol/L / 3.47

Results

	Morning*	Noon*	Afternoon*	Midnight*
Patient Result (pmol/L) >>	**300**	**200**	**200**	**150**
Reference Range (pmol/L) *Based on Collection Times	110-513	89-362	66-304	52-239

Commentary

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.

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.

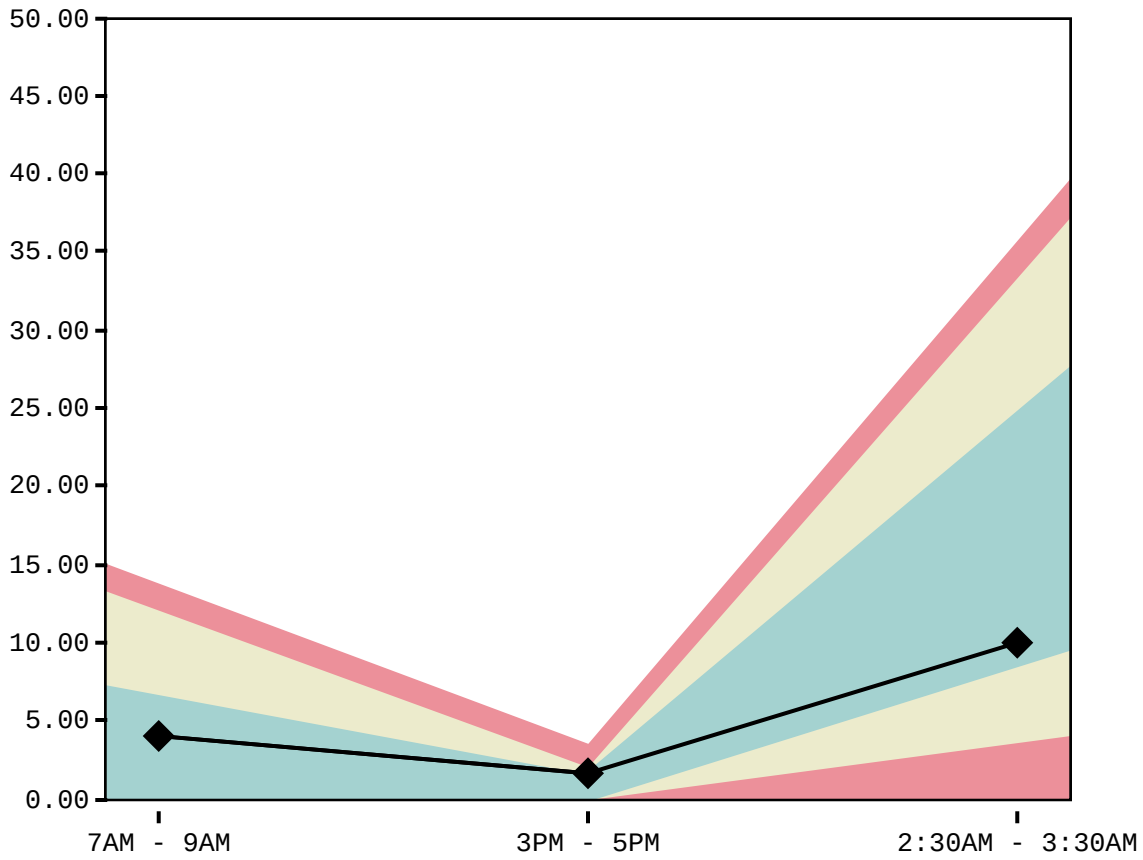
In the adult male, testosterone maintains the structure and function of the prostate, testes, seminal vesicles, and external male genitalia. In addition, testosterone affects lean body mass, bone density, hematopoiesis, libido and mood.

Testosterone levels are within reference range for all samples.

Comprehensive Melatonin Profile

Methodology: EIA

Salivary Melatonin



Results

	7AM-9AM*	3PM-5PM*	2:30AM - 3:30AM*
Patient Results (pg/mL) >>	**4.00**	**1.70**	**10.00**
Reference Range (pg/mL) *Based on Collection Times	<=12.12	<=1.97	3.71-33.38

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Melatonin activity is normal throughout the sample period revealing a normal melatonin circadian rhythm.

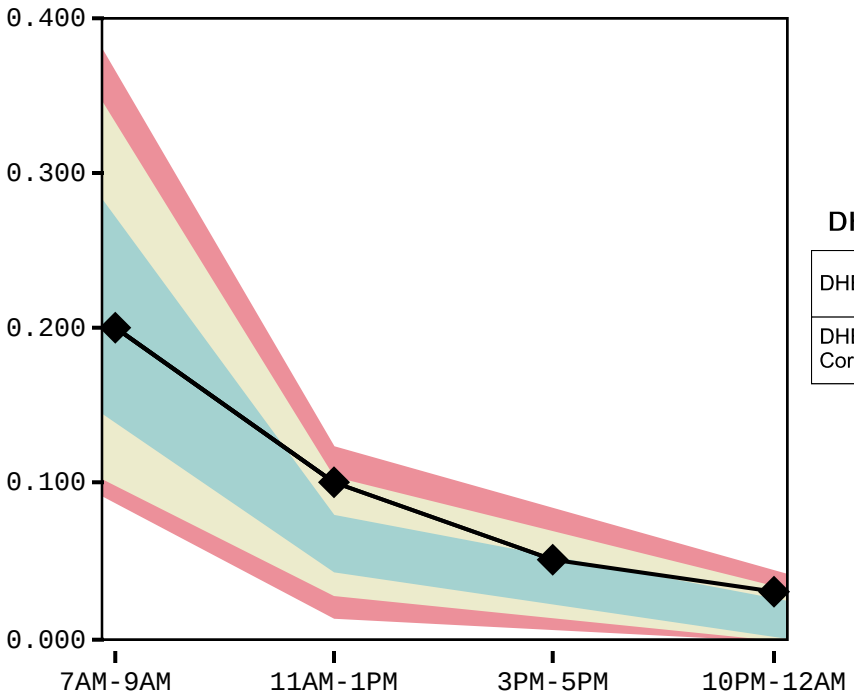
As well as playing a crucial role in sleep-wake cycles, melatonin influences other vital functions, including cardiovascular and antioxidant protection, endocrine function, immune regulation and body temperature.

Adrenocortex Stress Profile

Methodology: EIA

Salivary Cortisol and DHEA

Salivary Cortisol



DHEA

		Reference Range
DHEA 7AM - 9AM♦	100	71-640 pg/mL
DHEA: Cortisol Ratio/10,000♦	500	358-2,538

Results

	7AM-9AM*	11AM-1PM*	3PM-5PM*	10PM-12AM*
Patient Result (mcg/dL) >>	**0.200**	**0.101**	**0.050**	**0.030**
Reference Range (mcg/dL) *Based on Collection Times	0.097-0.337	0.027-0.106	0.013-0.068	<=0.034
Actual Collection Time	7:00AM	11:05AM	3:00PM	10:03PM

Commentary

Cortisol reference ranges are for patients 18-65 years old.

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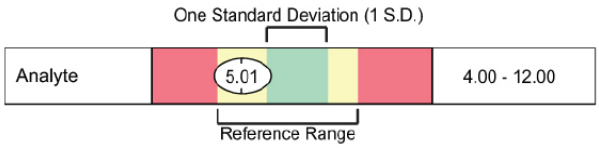
The **Reference Range** is a statistical interval representing 95% or 2 Standard Deviations (2 S.D.) of the reference population.

Commentary

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. (See example below)



Diurnal Cortisol Rhythm/Slope

The natural cortisol diurnal rhythm shows a peak within the first hour after awakening, a rapid decline over the morning hours, and then a tapering through the rest of the day before reaching a nighttime nadir.

A flat slope is characterized by low morning levels, blunted afternoon response and/or evening drop in cortisol levels. Flattened slopes are:

- Associated with a chronic stress burden, poor psychosocial functions, lack of HPA axis resiliency and lower perceived control over stress.
- Predictive of health outcomes, such as increased breast cancer mortality, increased coronary calcifications, and increased body mass index.
- Seen in Post-Traumatic Stress Disorder (PTSD), persistent fatigue, anxiety, depression, and Addison's Disease.

A "high flat" slope is characterized by high morning levels that fail to show a diurnal decrease.

- They can be a normal/appropriate response to a major stressor.
- High flat slopes might also suggest a challenge that seems insurmountable.

Timed Cortisol Measurements

Specific cortisol elevations throughout a diurnal rhythm may be caused by any number of acute mental, emotional and physical daily stressors, blood sugar dysregulation, exercise or pain. Abnormal results should be correlated with each patient's clinical presentation and specific daily routine.

Morning (7:00 AM – 9:00 AM) cortisol measurement reflects peak ACTH-mediated adrenal gland response.

- Exaggerated levels can be seen with exercise, blood sugar dysregulation, daily stressors, pain, and underlying adrenal hyperplasia or Cushing's syndrome.
- Low levels may reflect an inability to mount a peak response as is seen in adrenal dysfunction and/or down regulation from chronic stressors.

Mid-morning (11:00 AM – 1:00 PM) cortisol levels reflect an adaptive function of the HPA axis to daily routine.

- Elevated levels should be correlated with daily stressors, such as exercise, blood sugar dysregulation, perceived and actual lifestyle stressors and pain.
- Lower levels can reflect HPA axis dysfunction.

Afternoon (3:00 PM – 5:00 PM) cortisol is often reflective of glycemic control due to the post-prandial timing of collection.

Commentary

- Elevated levels can reflect any number of daily stressors as previously outlined.
- Low levels can reflect underlying HPA axis dysfunction.

Evening (10:00 PM – 12:00 AM) cortisol levels are a good indication of baseline HPA axis function since they represent the lowest level during the circadian rhythm.

- Elevated levels may be due to stress, exercise, alcohol, and specific lifestyle stressors.
- Elevated evening salivary cortisol is linked to insomnia
- High evening cortisol levels are also associated with various diseases such as diabetes, cardiovascular disease, hormonally driven cancers, and osteoporosis.

Treatment of elevated cortisol should be directed at the root cause of the stressor. Lifestyle modification with relaxation methods, dietary changes, pain management, and overall HPA axis support with nutrition and/or adaptogens can be helpful. Glandulars may be added if additional support is necessary.

References:

1. Clow A, Thorn L, Evans P. Hucklebridge F. The awakening cortisol response: methodological issues and significance. *Stress.* 2004;7(1):29-37.
2. Stalder T, Kirschbaum C, Kudielka BM, et al. Assessment of the cortisol awakening response: Expert consensus guidelines. *Psychoneuroendocrino.* 2016;63:414-432.
3. Wust S, Wolf J, Hellhammer DH, Federenko I, Schommer N, Kirschbaum C. The cortisol awakening response-normal values and confounds. *Noise health.* 2000;2(7):79.
4. Fries E, Dettenborn L, Kirschbaum C. The cortisol awakening response (CAR): facts and future directions. *IntJPsychophysiol.* 2009;72(1):67-73.
5. Saxbe DE. A field (researcher's) guide to cortisol: tracking HPA axis functioning in everyday life. *Health Psychol Rev.* 2008;2(2):163-190.

CHECKLIST (PRIOR TO SHIPPING)

1. All Tubes

- ❑ **Patient's First and Last Name, Date of Birth, and Collection Start Time and Stop Time** written on all tube labels
- ❑ The specimen **reaches** the FILL LINES in all tubes
  - **3 ml** – White-top tubes
  - **1 ml** – Blue-top tubes
- ❑ All the tubes are **tightly closed**

2. Tubes

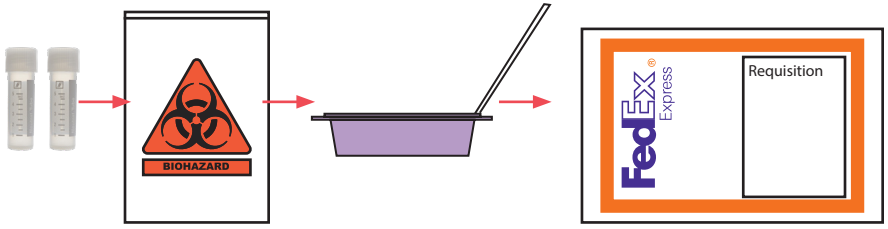
- ❑ All Tubes - frozen

3. Test Requisition Form with Payment

- ❑ Test Requisition Form is complete – **Test is marked, patient's first and last name, date of birth, gender,** and **time collection ended** are recorded
- ❑ **Payment** is included or pay online at **www.gdx.net/prc**

4. Return to the Laboratory

- ❑ Please place samples in biohazard bag, then place biohazard bag in clamshell container. Place container in mailing envelope with requisition. No need to send plastic tray.



SHIP THE SPECIMEN(S) TO THE LAB

Please refer to the shipping instruction insert found in your kit box.

GENOVA DIAGNOSTICS

Call **800.522.4762** or visit our website at **www.gdx.net**

MALE HORMONES PLUS PROFILE

PATIENT SALIVA COLLECTION INSTRUCTIONS

Male Hormones Plus™

The following test(s) can be collected using these instructions:

Male Hormone Plus™*	**#4006**
Add-on Cortisol Awakening Response (CAR)*	**#4309**

** Not available in New York*

Test may not be processed without this information:

Test Requisition Form

Please Provide:
- ❑ **Patient's First/last Name**
- ❑ **Date of Birth**
- ❑ **Gender**
- ❑ **Date of Collection**

All Tubes

Please Label:
- ❑ **Patient's first/last name**
- ❑ **Patient's date of birth**
- ❑ **Collection date**
- ❑ **Collection start/stop time**

Please read and follow instructions completely to ensure accurate results.

Specimen

Saliva

Additional Materials

- Biohazard bag with absorbent material
- Test Requisition Form
- Collection labels
- Prepaid mailing envelope

Collection Materials for Saliva

2 Blue-top Collection tubes

5 White-top Collection tubes

IMPORTANT PREP PRIOR TO TESTING

IMPORTANT:

- ❑ It is important that you collect saliva according to the Collection Schedule below. All samples must be collected within one day.
- ❑ Consider waking at **6am** on day of collection.
- ❑ 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.
- ❑ **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:** ketoconazole, cimetidine (Tagamet), anastrozole (Arimidex), letrozole (Femara), exemestane (Aromasin), Chrysin, Apigenin, Tribulus terrestris, clomiphene, antiepileptics, digoxin, oral steroids (e.g. Prednisone), cortisone cream, and any steroid-based nasal sprays, inhalers, or eye drops. 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.

IMPORTANT:

NIGHT BEFORE COLLECTION:

- ❑ Before you go to sleep on Collection Day, place your collection tube (with a completed label) at your bedside, along with a glass of water and a low level light. Do not turn on a bright light, it will cause your melatonin level to drop.

ONE HOUR BEFORE COLLECTION:

- ❑ 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.

For full details refer to: www.gdx.net/tests/prep

COLLECTION

IMPORTANT: To ensure accurate test results you MUST provide the requested information.

Please refer to your requisition for the testing option ordered by your clinician. Pay close attention to the collection times and amount of saliva required. Failure to do so may cause samples to be rejected or alter results.

Male Hormones Plus **Labels 1, 2, 3, 4, 5**

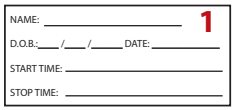
with Cortisol Awakening Response**:** **Labels 1, 2, 3, 4, 5, 6**

1. **Write patient's first and last name, date of birth, gender, and dates of collection** on the Test Requisition Form.

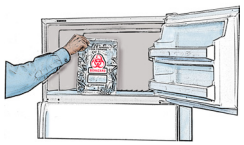
Collecting Your Saliva Samples:

2. **Fill** tube with saliva to designated level, without bubbles or mucus, within 5 minutes. **Replace** the cap tightly to avoid leakage.

3. Please **write** the **patient's first and last name, date of birth, and the start and stop collection times on the label. Attach** the label to the collection tube.



4. **Freeze** tube immediately. Samples must be frozen a minimum of 2 hours prior to shipping. Keep samples frozen until ready to ship.



5. **Repeat** these steps for each sample according to the Specimen Collection Chart.

SPECIMEN COLLECTION CHART

SPECIMEN INTERVALS	MH+	with CAR
WAKING Collect immediately upon waking		1 ml
30 MINUTES Collect 30 minutes from end of waking collection		1 ml
Collect Between **7:00AM – 9:00AM**	3 ml	3 ml
Collect Between **11:00AM – 1:00PM**	3 ml	3 ml
Collect Between **3:00PM – 5:00PM**	3 ml	3 ml
Collect Between **10:00PM – 12:00AM**	3 ml	3 ml
Collect between **2:30AM - 3:30AM**	3 ml	3 ml