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 frozen saliva tubes 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.





Comprehensive Melatonin Profile

IS-579

Patient Collection Instructions













Check Your Kit

- A 3 Collection tubes
- B 3 Labels, numbered 1-3 in red
- C 1 Biohazard bag with absorbent pad
- **D** 1 Requisition (to be completed and signed)
- E 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.



63 Zillicoa Street Asheville, NC 28801 800.522.4762 ©2011 Genova Diagnostics IS-579,e,pi,b-408-s,080811

800.522.4762 Fax: 828.252.9303 www.gdx.net

Step 1:

Important things to know and consider

Let your physician know about any medications, herbs, and other supplements 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.
- 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 day!

Collect your saliva during the specified time frame:

MORNING:	7:00 AM to 9:00 AM	(Use label #1)
AFTERNOON:	3:00 PM to 5:00 PM	(Use label #2)
EARLY NEXT MORNING:	2:30 AM to 3:30 AM	(Use label #3)

Tip: 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.

Step 2:

Collecting your saliva specimens

Not following these instructions may affect your test results.



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.



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.



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.





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 samples 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.





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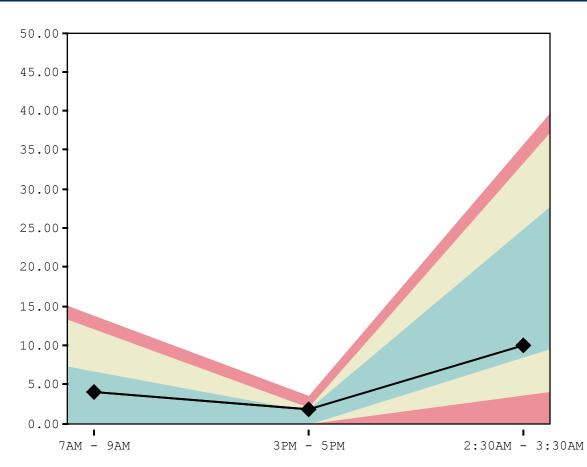


Patient: PATIENT TEST

4108 Comprehensive Melatonin Profile

Methodology: EIA

Salivary Melatonin



Results

Nesuits				
	7AM-9AM*	3PM-5PM*	2:30AM - 3:30AM*	
Patient Results (pg/mL) >>	4.00	1.80	10.00	
Reference Range (pg/mL) *Based on Collection Times	<=12.12	<=1.97	3.71-33.38	



Patient: PATIENT TEST Page 2

Commentary

Please note the reference range for melatonin 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 ullet , 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.

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.