

Check Your Kit

- 1 Collection tube
- 1 Biohazard bag with absorbent pad
- 1 Requisition (to be completed and signed)
- 1 Gel Freezer Pak
- 1 Flexfoil pack

◆ If you are missing any of these items, please call Genova on 020 8336 7750.

Before the Test Begins

Ship Monday-Thursday only

◆ The specimen must be shipped Monday through Thursday only. Arrange shipping prior to testing. Specimen must be stored frozen prior to shipping.

◆ The following drugs and herbs 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, 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 Physician or Therapist.

◆ The "normal" range for hormone levels reported on this test was determined with individuals who were not taking hormone supplements (including pills, patches, and creams). Transdermal (cream) hormones will generally produce artificially high levels in the saliva that do not correlate with blood levels. This increase may last for weeks to months after discontinuing use. If you are taking these substances, or have recently, consult your Physician or Therapist before taking this test.

At least 4 hours prior to collection

◆ Freezer Pak must be frozen a minimum of 4 hours before shipping.

During the 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.

Before beginning each collection

◆ WASH HANDS thoroughly with soap and water.

FYI

- ◆ The specimen must be shipped Monday through Thursday only. Arrange shipping prior to testing. Specimen must be stored frozen prior to shipping.
- ◆ Can I reuse a tube if I have problems with the collection? No. Call Genova on 020 8336 7750 for assistance.
- ◆ Hormone replacement therapy (especially skin creams) is likely to significantly affect test results, causing them to be outside the normal range. Oral contraceptives are likely to significantly decrease test results below the normal range. If you are taking these substances, or have recently, consult your Physician or Therapist before taking this test.
- ◆ The minimum volume of saliva required for testing is 2ml.

Consult your Physician or Therapist if you have any questions at any time during this test.

Saliva Collection Schedule

Are you Pre Menopausal? Yes ___ No ___ If yes please follow schedule A

Are you Post Menopausal? Yes ___ No ___ If yes please follow schedule B

Have you had a Hysterectomy? _____ Were ovaries removed? _____ If yes follow schedule B

SCHEDULE A - FOR PRE MENOPAUSAL WOMEN:

- 1 sample to be taken 21 days after the start of last period.
- Date at start of period ___/___/_____ Saliva collection date ___/___/_____
- Are you currently taking or have recently stopped (within the last 6 months) taking hormones? Including natural progesterone creams Yes ___ No ___ If YES, please complete the hormone information.

SCHEDULE B - FOR POST MENOPAUSAL WOMEN:

- 1 Sample to be taken on any day.
- Are you currently taking or have recently stopped (within the last 6 months) taking hormones? Including natural progesterone creams Yes ___ No ___ If YES, please complete the hormone information.

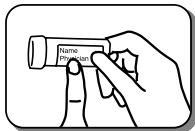
Hormone Type _____ Brand Name _____

Last Time Taken _____ Last Dose _____

When do you use the hormones ? _____ For How long? Months _____ Years _____

Collection

Not following these instructions may affect your test results.



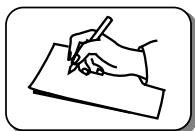
- 1 Using a ballpoint pen or pencil only, write your name and the time and date of collection on the label with the red #1 on it. Attach the label to a collection tube.



- 2 To collect the sample, rinse your mouth with drinking water before collection. Spit out water completely. During collection, do not cough or clear your throat into the collection tube.



- 3 Fill the collection tube until the liquid saliva level reaches the 2-ml mark. To reduce a foamy saliva collection, tap the tube on a hard surface. **Insufficient saliva samples cannot be processed.**



- 4 Make sure collection time and date are written on the tube and the cap is replaced 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.
- 5 **Required:** Complete all patient information on the Requisition. Enter date in box labeled "Date Final Sample Collected" before returning the specimens. Sign the form and place it back inside the return envelope.

Shipping

- Biohazard bag containing the filled tube
- Frozen Gel Freezer Pak
- ◆ Check that you have placed the following items in the shipment:
 - Flexfoil Pak, containing the Biohazard bag (with specimens) and the frozen Gel Freezer Pak
 - **Requisition, completed and signed & this instruction sheet with completed patient information.**
- ◆ Return the sample using the return mailing envelope to Genova by special delivery.

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Check Your Kit

- 4 Saliva collection tubes
- 4 Labels, numbered 1-4
- 1 Biohazard bag
- 1 Requisition (to be completed and signed)
- 1 Gel Freezer Pack
- 1 Flexfoil Pack

◆ If you are missing any of these items please call **Genova on 020 8336 7750**

Before the Test Begins

◆ The following drugs and herbs may influence levels of hormones reported in this test: ketoconazole, clomiphene, phenytoin, oral steroids (e.g. Prednisone), cortisone cream or patches, 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 Physician or Therapist.

◆ The "normal" range for hormone levels reported on this test was determined with individuals who were not taking DHEA or cortisol supplements (including pills, patches, and creams). Cortisol and DHEA skin creams, in particular, are likely to significantly increase test results above the normal range. This increase may last for weeks to months after discontinuing use.

◆ For other test profiles that include measurements of Testosterone and / or Melatonin, supplementation will result in a similar increase in test results (including pills, patches, and creams). If you are taking these substances, or have recently, consult your Physician or Therapist before taking these tests.

At least 4 hours prior to collection

◆ Gel Freezer Pack must be frozen a minimum of 4 hours before shipping.

During the 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.

Before beginning each collection

◆ **WASH HANDS** thoroughly with soap and water.

FYI

- ◆ Can I reuse a tube if I have problems with the collection? No. Call IVDL Genova for assistance.
- ◆ DHEA and cortisol supplements (especially skin creams) are likely to significantly increase test results above the normal range. If you are taking these substances, or have recently, consult your Physician or Therapist before taking this test.
- ◆ Testosterone and Melatonin supplements are likely to significantly increase test results above the normal range. If you are taking these substances, or have recently, consult your Physician or Therapist before taking this test.

Consult your Physician or Therapist if you have any questions at any time during this test.

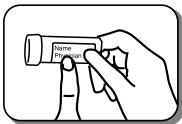
Saliva Collection Schedule

- ◆ On the day you collect specimens for this profile, plan to awaken and rise between 6:00AM and 9:00AM.
- ◆ Collect a total of 4 saliva samples, one sample at each of the following intervals:

| | |
|-------------------|---|
| Morning | 1 hour after rising for the day (Use label #1.) |
| Midday | 4 to 5 hours after last sample (Use label #2.) |
| Afternoon | 4 to 5 hours after last sample (Use label #3.) |
| Late Night | Prior to sleep (Use label #4.) |

Collection

Not following these instructions may affect your test results.



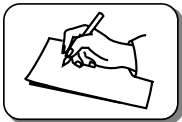
- 1 Using a ballpoint pen or pencil only, write your name and the time and date of collection on the label with the #1 on it. Attach the label to a collection tube if not already labelled.



- 2 To collect the sample, rinse your mouth with drinking water before collection. Spit out water completely. During collection, do not cough or clear your throat into the collection tube.

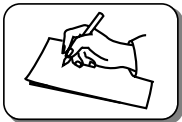


- 3 Fill the collection tube until the liquid saliva level reaches the 2-ml mark. To reduce a foamy saliva collection, tap the tube on a hard surface. **Insufficient saliva samples cannot be processed.**



- 4 Make sure collection time and date are written on the tube and the cap is replaced 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.

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



- 6 When ready to ship, place the 4 samples into the **Biohazard bag and seal.** Place the Biohazard bag **along with the frozen Gel Pack in the Flexfoil pack.**

- 7 Fill out the Requisition Form, including the date of collection and sign.

Shipping

- ◆ Check that you have placed the following items in the Flexfoil Pack:
 - 4 filled and labelled collection tubes
 - Frozen Gel Freezer Pak
- ◆ Check that you have placed the following items in the return padded mailer for shipment.
 - Flexfoil Pack containing the **Biohazard bag** (with specimens) and the frozen Gel Pack.
 - Requisition, completed and signed.
- ◆ Return the sample using the return mailing envelope to Genova for processing.

Consult your Physician or Therapist if you have any questions at any time during this test.

Check Your Kit

- 1 Urine collection cup
- 2 Tubes*
- 1 Pipette
- 1 Glove
- 1 Biohazard bag and absorbent pad
- 1 Flexfoil pack
- 1 Gel Freezer Pack
- 1 Requisition (to be completed and signed)

◆ If you are missing any of these items contact Genova on 020 8336 7750.

Before the Test Begins

- ◆ If your physician/therapist has also ordered the Bone Resorption Assessment, the specimen must be received by the laboratory within 2 weeks of collection.
- ◆ In order for the test results to be representative, the patient's kidney function must be normal. Unusual fluid intakes or use of diuretics may influence test results. This test should not be performed on individuals with kidney disorders.
- ◆ If you are experiencing a urinary tract infection, delay collection of specimens until after completing treatment.

Collection schedule criteria

- ◆ For premenopausal women, specimens must be collected between days 19 and 25 of the menstrual cycle (luteal phase). Day 1 is the day menstrual flow begins. Do not collect specimen if you are experiencing break-through bleeding.
- ◆ For menopausal women, specimens may be collected on any day.
- ◆ For women on hormone replacement therapies or hormonal contraceptives, we recommend that the specimen should be obtained approximately 8-10 hours AFTER the last dose of oral, transdermal, or vaginal hormone-containing medication. Consult your physician/ therapist before changing your hormone replacement regimen.
- ◆ For optimal follow-up testing, it is essential to collect the specimens at the same day of cycle or phase of hormone therapy as the previous sample.

Ship Monday-Thursday only

- ◆ The specimens must be shipped overnight delivery Monday through Thursday only. Arrange shipping prior to testing (see Shipping section on other page). Sample **MUST** be stored frozen prior to shipping.

At least 4 hours prior to collection

- ◆ Gel Freezer Pack must be frozen a minimum of 4 hours before shipping.

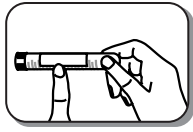
FYI

- ◆ *If I have to get up during the night to urinate, is this my first urine of the day?* No. Your first urine is the urination upon awakening after a night's sleep (approximately six to eight hours).
- ◆ Hormone-modifying substances such as Tamoxifen, contraceptives, antibiotics, hormone replacement therapies, and herbal and nutritional supplements may modify results, as can severe illness. These circumstances will not impair the laboratory test procedure, but are likely to shift some of the results and may be used as clinical guidelines to customise therapy.
- ◆ If you have a kidney disorder, consult your healthcare provider about having this test performed using a blood sample.

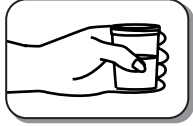
Consult your Physician or Therapist if you have any questions at any time during this test.

Collection

Not following these instructions may affect your test results.

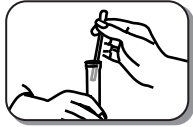


① Using a ballpoint pen or pencil only, write your name and the time and date of collection on each tube*.

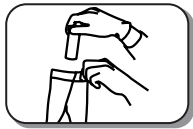


② After awakening for the day, collect your first urine in the collection cup provided in your kit.

③ Open the tubes*. Use the pipette to transfer urine from the collection cup into the tubes. Fill each tube to the 5-ml mark. Screw the top on the tubes tightly to avoid leakage and shake to mix thoroughly.



④ Discard the remaining urine, the collection cup, the pipette, and the glove.



⑤ Place the filled tubes into the biohazard bag and close the bag securely. Then put the biohazard bag in a freezer for a minimum of 2 hours. If unable to ship on the day of collection, continue freezing specimens until ready to ship.

⑥ Complete the Requisition, including required signatures, date of collection, and date of birth. Return the requisition form along with the samples, using the return mailing envelope.

⑦ When ready to ship, make sure the tubes in the Biohazard bag are tightly closed and are labeled. Place the Biohazard bag into the Flexfoil pack, along with the frozen Gel Freezer Pak, and seal using the adhesive strip. Place the Flexfoil pack into the return mailing envelope. Follow the shipping instructions.

***CAUTIONS: A very small amount of Ascorbic Acid is contained in one of the tubes as a preservative. ¥Do not discard tube fluid. ¥Avoid contact of the eyes or skin with the fluid in the tube. For contact with eyes, wash thoroughly for 15 minutes. For skin contact, wash thoroughly with soap and water. ¥Do not inhale or ingest liquid.**

Shipping

- ◆ Verify that the following items are shipped:
 - Biohazard bag containing the 2 filled tubes
 - Frozen Gel Freezer Pak
- ◆ Check that you have placed the following items in the shipment:
 - Flexfoil Pak, containing the Biohazard bag (with specimens) and the frozen Gel Freezer Pak
 - Requisition, completed and signed.
- ◆ Return the sample using the return mailing envelope to Genova by special delivery.

Consult your Physician or Therapist if you have any questions at any time during this test.